A FIVE YEAR REVIEW OF THE OUTCOMES OF INTRAMEDULLARY NAILING OF DIAPHYSEAL FEMUR FRACTURES IN LUSAKA.

By

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I, GODFREY PHIRI, hereby declare that this dissertation is a product of my own work and has never been submitted, in part or in full, for a diploma or a degree in any other university.

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I have read this dissertation and approved it for examination.

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CERTIFICATE OF COMPLETION OF THE DISSERTATION

I, GODFREY PHIRI, hereby certify that this dissertation is a product of my own work and that it has never been submitted in part or whole to any other university.

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APPROVAL

This dissertation by **Godfrey Phiri** is approved as partial fulfillment of the requirement for the award of the Master of Medicine (Orthopaedics) degree of the University of Zambia.

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ABSTRACT

Introduction

Trauma is increasing in Zambia and currently ranks 4th in causing morbidity and mortality (WHO, 2008). Head Injury (HI) and fractures of long bones are the leading cause of hospital admissions among trauma cases. Like most third world countries, Zambia is struggling to offer medical services that would result in timely operative management of fractures (Mock, 1997). Thus, majority of patients wait for long durations for surgery. This has a potential to complicate outcomes such as infection, nonunion, shortening, stiff joints (Nowatarski, 2000). This study reviewed the outcomes of diaphyseal femur fractures managed operatively using Intramedullary Nails (IMNs) in Lusaka from 2009 to 2013.

Objectives

To review the outcomes of diaphyseal femur fractures managed operatively with IMNs in Lusaka from 2009 to 2013.

Methodology

This was a retrospective observational study at the University Teaching Hospital (UTH) and Zambia Italian Orthopaedic Hospital (ZIOH). A review of theater registers for patients with femur daiphyseal fractures that were operated on with IMNs during the review period was done. Patients' file numbers were used to retrieve medical records. 115 records were retrieved and analysed. The burden of patients, clinical & radiological outcomes after surgery and factors associated with nonunion were analysed using frequency tables and graphs. Associations were analysed using appropriate tests.

Results

There was on average 100.5% increase in the burden of patients with diaphyseal femur fractures managed operatively using IMNs from the year 2010 to 2013. Road traffic accidents accounted for 83% of patients and the majority were males at 83.5% with an average age of 33 years. The average waiting time for surgery was 35.2 days at UTH and 6.2 days at ZIOH which is statistically significantly different. T-tests showed no association between 'duration from injury to surgery' and union rates & infection rates. However, the need for bone excision (surgical limb shortening) to achieve reduction was directly related to the 'duration from injury to surgery' at UTH, especially if exceeded 29.05 days. Subsequent postoperative Limb Length Discrepancy (LLD) was at 35.3 % and 16.0 % at UTH & ZIOH respectively. The union rates were 82.4% and 86.4% respectively. Age and gender did not influence union of the fractures.

Conclusion

The burden of patients with diaphyseal femur fractures managed operatively using IMNs doubled from the year 2010 to 2013. UTH is overwhelmed with this burden resulting in long waiting time for surgery, averaging 35.2 days. The longer the waiting time for surgery, the more likely the need for bone excision leading to limb shortening. The outcomes of surgery in Lusaka are comparable with other centers across the world except for high incidence of postoperative LLD.

DEDICATION

To my wife Miyanda; thank you very much for your support and understanding my often times demanding schedule. Truly, without your patience and support this would have been difficult and so I dedicate this work to you love.

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ABBREVIATIONS AND ACRONYMS

ARDS	:	Acute Respiratory Distress Syndrome
ATLS	:	Advanced Trauma Life Support
EF	:	External Fixator
ETC	:	Early Total Care
DCOS	:	Damage Control Orthopaedic Surgery
FFH	:	Fall from Height
FWB	:	Full Weight Bearing
Hb	:	Haemoglobin
HI	:	Head Injury
HIV	:	Human Immunodeficiency Virus
IMN	:	Intramedullary Nail
K-Nail	:	Kuntscher Nail
NR	:	Non Reactive
NSAIDs	:	Non Steroidal Anti-Inflammatory Drugs
NWB	:	Non Weight Bearing
ORIF	:	Open Reduction and Internal Fixation

POP	:	Plaster of Paris
PWB	:	Partial Weight Bearing
R	:	Reactive
RTA	:	Road Traffic Accident
SIGN	:	Surgical Implant Generation Network
UNZABREC	:	University of Zambia Biomedical Research Ethical Committee
UTH	:	University Teaching Hospital
Vs	:	Versus
WHO	:	World Health Organisation
ZIOH	:	Zambia Italian Orthopaedic Hospital

DEFINITIONS

Diaphyseal femur fracture is defined as a fracture occurring more than 5cm below the subtrochanter and more than 5 cm above the distal femoral metaphyseal flare.

Operative management of diaphyseal femur fracture is defined as Open Reduction and Internal Fixation (ORIF) using IMN, either K- Nail or Interlocking Nail.

Complications include infections, malunion, nonunion, shortening, stiff knee & hip joints and implant migration or failure.

Nonunion: refers to fractures that failed to unite by 6 months and secondary surgical procedures had to be performed. Radiological features of nonunion include persistent fracture line, lack of bridging trabeculae or cortical continuity on more than one cortex.

Implant failure: This includes implant migration and implant breakage leading to a nonunion or malunion necessitating subsequent secondary surgical procedures. Asymptomatic implant breakage or loosening that did not lead to a secondary surgical procedure was excluded from this definition.

Superficial infection: Infection at the incision site that was cleared by use of antibiotics without need for surgical debridement.

Deep infection: The deep infection includes all infections except superficial ones and needed surgical debridement or sloughectomy.

Secondary surgical procedures: This refers procedures done to reduce or replace the initial fixation device that may have loosened, migrated or broken.

CHAPTER ONE

1.1 INTRODUCTION/ BACKGROUND

Trauma is on the increase in Zambia. Currently, it ranks fourth in causing morbidity and mortality (WHO, 2008). Head Injury (HI) and fractures of long bones are the leading cause of hospital admissions among trauma cases (UTH data, 2006-2007). These patients need properly trained medical staff so that they do not only survive the traumatic ordeal but also return to full functional status within a shortest possible time. However, like most third world countries, Zambia has a long way to attaining the kind of medical services that would result in timely operative management of fractures (Mock, 1997). This is evidenced by lack of trauma centers in the country. Thus, the majority of trauma patients needing operative management of fractures end up at the University Teaching Hospital (UTH), creating long waiting lists for operations.

The long duration from trauma to surgery has the potential to complicate the outcomes of operative management of long bone fractures. This includes infection, malunion, nonunion, shortening, stiff joints, disuse osteoporosis and muscle atrophy (Nowatarski, 2000). On the contrary, timely operative management has been shown to have fewer complications (Bhandari, 2005). There has never been a study on the outcomes of operative management of femur fractures in Zambia, resulting in lack of data.

This study brought to light the outcomes of operative management of diaphyseal femur fractures in Lusaka. Participants were recruited from a public hospital (UTH) with a long waiting list and a private hospital (Zambia Italian Orthopaedic Hospital) with a relatively shorter waiting list. The effects of delayed surgery were showcased, and it's on that premise that advocacy for improved orthopaedic services in public institutions can be generated.

1.2 LITERATURE REVIEW

1.2.1 Cause of injury

Studies have shown that pedestrians and passengers of public service vehicles account for between 41% and 75% of all RTA victims in developing countries (Odero, 1997). The problem posed by Road Traffic Accidents is increasing at a fast rate in these countries due to rapid motorisation with second hand cars which may not be roadworthy. Public health policy responses to this epidemic are inadequate (Khayesi, 2005). It is either still being formulated, or in countries where it exists, implementation still remains a challenge (Khayesi, 2005). Road Traffic Accidents give rise to a wide spectrum of injuries; diaphyseal femur fracture is the focus for this literature review. Femoral fractures account for 9% of the non-fatal musculoskeletal injuries resulting from Road Traffic Accidents (WHO, 2008).

1.2.2 Epidemiology

Diaphyseal fractures of the femur have a bimodal distribution; young men with a peak at 25 years and elderly women peaking at 65 year (Bazebeh, 2010). These are caused by high energy and low energy forces respectively. High energy causes includes Road Traffic Accidents or a fall from a height while low energy fractures result from trivial falls (Bazebeh 2010, Egol, 2010). For the later, the bone integrity is mainly compromised by postmenopausal osteoporosis (Egol, 2010). Other conditions that compromise bone integrity at any age include infection(s), malignancies and irradiation. In such cases, the fracture is classified as pathological (Bazebeh 2010, Egol, 2010). The average global incidence is 10/100,000 population per year (Bazebeh, 2010).

1.2.3 Anatomical consideration

The femur is the largest bone in the human body and is surrounded by large mass of muscle which creates deforming forces when it fractures (Egol, 2010). The femoral diaphysis has an anterior bow and the medial cortex is under compression whereas the lateral cortex is under tension (Egol, 2010). The isthmus of the femur is the narrowest intramedullary diameter and dictates the size of the intramedullary nail (IMN) that can be used (Egol, 2010). The vascular supply to the femoral diaphysis is provided chiefly by the profunda femoris artery and both the nutrient artery and

periosteal vessels enter the bone along the linea aspera (Egol, 2010). The nutrient artery forms the endosteal vessels and supplies the inner two-thirds of the cortex while the periosteal supplies the outer one-third of the cortex (Egol, 2010). Following diaphyseal femur fracture, the endosteal blood supply is frequently disrupted and the periosteal vessels proliferate to act as the primary source of blood for healing (Egol, 2010). Reaming during IMN insertion damages endosteal blood supply which is only restored after 3-4 weeks (Egol, 2010).

1.2.4 Making a diagnosis

A diagnosis of diaphyseal femur fracture is usually obvious: patient presenting non ambulatory with thigh pain, variable gross deformity, swelling and shortening of the affected extremity (Egol, 2010). The fracture pattern varies and as a means of classification, the descriptive criteria is used: *open versus closed; location-proximal, middle or distal one-third: pattern-spiral, oblique or transverse; comminution, segmental or butterfly fragment: angulation or rotational deformity; and displacement-shortening or translation* (Egol, 2010).

1.2.5 Initial management

The initial treatment of patients who have just sustained femur fracture is the Advanced Trauma Life Support (ATLS) protocol (Fulkerson, 2009 and Ali, 1993). The patients' Airway and cervical spine is the first thing to assess and manage. Breathing, Circulation, Disability and Exposure follow in that order and problems are managed as they are identified (Ali, 1993). A secondary survey quickly follows and aims at identifying injuries that could have been missed during the primary survey (Ali, 1993). The ATLS protocol classifies long bone fracture as an emergency and recommends that it should be stabilised early (at least 8 hours) either by internal fixation or by external fixation (Fulkerson, 2009 and Ali, 1993). In Zambia, initial stabilization is by use of 'splints and non-operative treatment regime which involves use of skeletal or skin traction, daily limb length measuring and Perkins exercises. The non-operative regime is employed in the patients on the waiting list for surgery. Failure of non-operative regime is due to inadequate traction and lack of Perkins exercises. Inadequate traction is detected by daily limb measuring and resolved by addition of weight until limb length equalization. Perkins

Exercises prevents joint stiffness and muscle wasting and promotes callus formations at the fracture site. It is the difficulties in following strictly the non-operative regime that leads to treatment failure in patient on the waiting list for the preferred operative management.

The role of an orthopaedic surgeon in the acute setting is to determine the nature of the bony injury and the subsequent urgency of care in the setting of concomitant injuries (Fulkerson, 2009). The extent of associated soft tissue injury, vascular injury, neurologic deficits and overt compartment syndrome have to be assessed and managed appropriately (Fulkerson, 2009 and Rüedi, 2007). Principles of Damage Control Orthopaedic Surgery (DCOS) come into play in cases where the patient is severely injured and physiologically unstable (Fulkerson, 2009 and Rüedi, 2007).

1.2.6. Definitive management

The main goals of definitive operative management of diaphyseal femur fracture are as follows: (Brumback, 1988).

1. Maintenance of normal length and axis of the lower extremity
2. Attainment of complete union
3. Early mobilisation and
4. Maintenance of normal range of motion in knee and hip joints.

To attain these, the operative management has to be done optimally (Dabezies et al, 1984). The definition of 'optimal timing' is a subject of much debate among orthopaedic surgeons (Rüedi, 2007; Fulkerson 2009 and Leunig, 2000).

1.2.7 Timing of definitive management

Three different time periods have been proposed:

1. Early Total Care (ETC): advocates for the definitive treatment of the femoral diaphyseal fracture within the first 24 hours of injury with the aim of attaining rapid mobilisation and restoration of function (Rüedi, 2007).

However, this may be dangerous in severely injured patients and can precipitate further physiologic derangement (Rüedi, 2007).

2. Intermediate period (INT): recommends that femoral diaphyseal fracture in patients with multiple injuries at risk of post traumatic complications be stabilised early within 24 hours either temporarily or definitively depending on the patients' condition. This concept favours early temporary fixation over definitive stabilisation (Rüedi, 2007).

3. Damage Control Orthopaedic Surgery (DCOS): advocate for quick temporal stabilisation using external fixation. Definitive IMN is only considered once the patient has been fully resuscitated and is physiologically stable (Rüedi, 2007; Leunig, 2009; Kehlet, 1999 and Kempf, 1984). This concept seeks to minimise the 'second hit' inflicted by prolonged operative treatment and allows for rapid transfer of the patient to the intensive care unit for supportive care (Kehlet, 1999 and Kempf, 1984). Adequate resuscitation before definitive operative management has been defined as: serum lactate less than 2.5 mmol/L and base deficit of -2 to +2 mmol/L and adequate urine output of at least 0.5ml/kg/min. Reversal of coagulopathy and correction of core body temperature is mandatory and has been shown to influence positively the outcome of definitive surgery (Rüedi, 2000 and Waydhas, 1990).

Bhandari et al found low infection rates if Intramedullary Nailing (IMN) of the femur is done within 28 days of injury (Bhandari, 2005). It has also been shown that high rates of fracture union and low rates of infections are achieved if surgery is done within 2 to 4 weeks from injury (Bhandari, 2005). It must however be noted that timing for operative management for femur fractures is frequently confounded by the presence of injuries to other organ systems, the presence of open wounds, and hemodynamic status which takes priority in terms of management (Fulkerson, 2009).

1.2.8 Internal fixation devices

Whichever time frame selected to operate on diaphyseal femur fractures, the technique employs biologic fixation (Egol, 2010 and Leunig, 2000). Devices used are grouped as external fixators (EF), plate-screw system and IMNs (Leunig, 2000). The IMNs are the devices of choice and can either be interlocking or non-locking (Egol, 2010). Example for the former is a Surgical Implant Generational Network (SIGN) nail and for the later Kuntscher nail (K-Nail) (Egol, 2010). At the introduction of IMNs, the K-Nail was mainly reserved for transverse fractures (Egol, 2010). The shortcoming of this nail is lack of rotational stability and maintenance of axial length when it comes to fixation of comminuted fractures (Leunig, 2000). The advent of interlocking nails however, has taken care of the shortcoming and has widened the spectrum of femoral diaphyseal fractures that can be fixed with IMNs. This is because Interlocking devices ensure cortical contact which is usually difficult to achieve and maintain in segmental and comminuted fractures, thereby reducing the risk of losing alignment, shortening, angulation and rotation (Winquist,2001). Brumback et al reported a 10.5% rate of loss of reduction after using interlocking nails (Brumback, 1988). He found that loss of reduction usually occurs within the first weeks postoperative and that correction of the angulation and shortness is relatively easy if done early; otherwise, more complex revision surgery will have to be undertaken (Brumback, 1988). In another study, Winquist et al found shortening of more than 2 cm with locking IMNs at 2% (Winquist, 2001). He went on to postulate that if the contact area between the fracture parts is more than 50%, shortening is unlikely and dynamic locking will be adequate(Winquist,2001).

Locked IMNs are the first choice device for diaphyseal femur fractures and are the most widely used in the western world (Egol, 2010). Generally, use of IMNs for diaphyseal femur fractures has been shown to give union rates up to 85% to 100% with a chance of nonunions up to 25% (Brumback, 1988). In a more recent study, rate of nonunion after all kinds of intramedullary nailing was reported at 8.5% (Zaka, 2011).

Comparing IMNs and plate & screws system, the former is more mechanically stable and allows the patient to bear weight soon after surgery (Egol, 2010). Furthermore, plate and screws fixation involves stripping of larger portions of soft tissue including

the periosteum (Egol, 2010 and Chilengwe, 2000). This disturbs the biology of fracture healing (Egol, 2010). Thus, most authorities prefer the IMN to plate &screw system (Egol, 2010). The type of fracture healing with these devices is secondary and primary bone healing respectively (Chilengwe, 2000).

At UHT most diaphyseal femur fractures are fixed with a Kuntscher intramedullary nail. In cases where rotational stability is difficult to attain because of its non-locking nature, a de-rotator Plaster of Paris (POP) boot with a horizontal stabilising bar is applied to the patient's foot. The disadvantage is that it hinders early mobilisation as the patient has to be bed bound for at least four weeks to allow for adequate callus formation which will add to stabilisation of the fracture. Suffice to mention that K-Nail is a cheaper device than Interlocking Nails.

1.2.9 Reaming Vs unreamed technique

Generally, IMNs can either be used reamed or unreamed depending on the indication and the philosophical school of the surgeon (Ürgüden et al, 2001). Controversy exists regarding this topic (Ürgüden, 2001). Some authors have argued that reaming causes both local and systemic negative effects (Ürgüden, 2001). Among the local effects, reaming has been blamed for disrupting the endosteal blood flow, thermal necrosis of the inner cortical bone and can potentially cause marrow embolisation, which may trigger Acute Respiratory Distress Syndrome (ARDS) (Ürgüden, 2001).

Further studies have shown that because unreamed IMNs spare both endosteal and periosteal circulation, it gives high union rates, good functional outcomes and low infection rates (Ozdemir, 2012). On the molecular level, Smith et al (2000) reported immunologic alterations after femoral nailing and measured the systemic interleukin-10 release and the class II human leukocyte antigen-DR expression on peripheral blood mononuclear cells. According to their findings, reamed femoral IMNs were associated with greater impairment of immune reactivity than the unreamed technique (Smith, 2000). Yet other clinical investigations revealed a significant increase of elastase levels in central venous blood in patients with reamed compared with unreamed femoral nailing (Pape, 1993).

Although reamed IMNs have potential risks and complications and past studies have favoured unreamed IMNs, the latter are not totally innocent (Duan, 2011). The

biggest disadvantage reported is that of relatively higher rates of delayed union, non union and implant failure (Duan, 2011). These complications often require revision surgeries (Duan, 2011). The same study further reported that there was no significant difference between the two techniques with respect to mortality rate and risk for ARDS (Duan, 2011). Time for union with reamed & unreamed IMNs has been reported in the literature as between 4.4 & 4.8 and 6.2 & 7 months respectively (Star, 2006). Therefore, the decision as to whether to use reamed or unreamed technique is still debatable and surgeons' preference comes into play. Preliminary data at the UTH shows that reaming is preferred. Perhaps what is more paramount for the surgeon is to consider the personality of a fracture in addition to the selection of device and technique (Duan, 2011).

Another dimension to consider for IMNs devices is the contact between the fracture segments. Drosos et al (2006) and Yuvarajan (2009) reported that there is a high risk of nonunion if the gap between the fracture edges is 3 mm or more.

1.2.10 Factors influencing fracture healing

Other identified risk factors for femoral nonunion after IMN include the use of Non-Steroidal Anti Inflammatory Drugs (NSAIDs) and smoking (Taitsman, 2009). NSAIDs inhibit cyclooxygenase 2 (COX-2), an enzyme needed during enchondral ossification of fracture healing (Miller, 2012). Nicotine kills osteoblasts, thereby prolonging time needed for the fracture to heal (Miller, 2012). Even the strength of callus is diminished and therefore the risk for nonunion is increased (Miller, 2012). Although it remains unknown if modifying tobacco use after injury has an impact on fracture healing, many authors still advocate for tobacco cessation before embarking on operative management of a fracture (Taitsman, 2009). The technique of surgery also had a bearing on the outcome of the operation. For instance, excessive soft tissue stripping during surgery increases risk for nonunion and it follows therefore that percutaneous procedures give better union rates (Egol, 2010). Lastly, protein malnutrition interferes with collagen 1 synthesis needed for fracture healing and therefore is also associated with increased risk for nonunion (Yuvarajan, 2009).

On the contrary, some conditions have been shown to accelerate fracture healing. HI and paraplegic patients have been observed to have their fractures heal faster (Miller,

2012). The exact mechanism is not known, but a factor 'X' is said be produced by injured neurons and is responsible for this accelerated fracture healing seen (Taitsman, 2009).

Demographic indices like patients' age and gender, fracture classification type, and nail insertion direction have been shown not to significantly influence the outcome of surgical management of diaphyseal femur fractures (Taitsman, 2009). With extreme of age however, long-term outcome appears to favour younger patients than elderly patients with osteoporosis related concerns (Yuvarajan, 2009).

Good postoperative follow-up of the patients with emphasis on early rehabilitation, mobilisation and cautious weight bearing contribute to a good functional outcome (Dabezies, 1984 and Star, 2006). Early mobilisation of the hip and knee joints as soon as the patient can tolerate and toe touching partial weight bearing graduating to guarded partial weight bearing is the recommended protocol (Dabezies, 1984). Interlocking nail is superior over the K-Nail in facilitating early mobilisation without risking loss of reduction (Dabezies, 1984 and Star, 2006).

1.2.11 Non-operative management

This literature review will not be complete without mentioning that a good number of patients in developing countries are still being managed nonoperatively, largely due to resource constraints for operative management (Gosselin, 2007). The Perkins traction has remained the gold standard for non-operative management since its introduction in 1953 (Gosselin, 2007). It is based on the principle that alignment of a long bone fracture can be achieved and maintained by continuously pulling (isotonic traction) on the soft tissue envelope along its longitudinal axis and early active range of motion for the knees (Gosselin, 2007). If these principles are followed correctly, good results can be achieved (Opondo et al, 2013). For instance, a study in Kenya documented an average of 60 days to achieve union (Opondo et al, 2013). Bezabeh and colleagues in a prospective study at Addis Ababa University Hospital in Ethiopia reported an average of 45 days (Bazebeh, 2010) while Gosselin in a retrospective study involving 53 adult patients in Sierra Leone reported a mean duration of hospital stay in patients managed by Perkins traction as 52 days (Gosselin, 2007). A local study at the UTH found an average 59.5 days. Additionally 50% infection rates of pin sites; limb shortening of more than 2 cm in 42% and residue knee stiffness in

32% patients were reported (Chilengwe, 2000). The additional results probably demonstrate the complications and therefore the disadvantages of nonoperative management. The number one undesirable thing about Perkins traction is the long hospital stay and delayed return to function (Winquist, 2001).

Compared to operative management, relatively poor functional and clinical outcomes have been documented with non-operative management (Gosselin, 2007). Furthermore, Medico-legal problems have also been reported following undesirable outcomes of non-operative management such as reduced range of motion in knee and hip joints, malunion, and nonunion (Whittle, 2003). However, some studies including that by Gosselin and Lovary reported no significant difference in fracture union rates after management by surgery or Perkins traction (Gosselin, 2007).

1.3 STATEMENT OF THE PROBLEM

There are a few hospitals in Zambia offering orthopaedic services. The resultant long waiting lists of patients needing operative management of diaphyseal femur fracture at the few hospitals offering the service imply that surgery is usually delayed. This has the potential to complicate the outcomes.

1.4 STUDY JUSTIFICATION

The outcome of operative management of diaphyseal femur fractures depends on so many factors. Among these include patient, hospital facilities, surgical expertise and postoperative rehabilitation factors. In order to achieve optimal functional outcome, these factors must be favourable and the patient has to present to the hospital on time so that they can be operated on as soon as possible.

There had never been a study on the outcomes after operative management of diaphyseal femur fractures in Zambia. An information gap existed and implied that policy makers might have not appreciated the extent of the problem and therefore made it difficult to put in place measures that would minimize this problem. This study showcased the outcomes and it is on this premise that advocacy can now be generated.

1.5 RESEARCH QUESTIONS

What are the outcomes after operative management of diaphyseal femur fractures in Lusaka?

CHAPTER TWO

2.0 OBJECTIVES

2.1 MAIN OBJECTIVES

To review the outcomes of diaphyseal femur fractures managed operatively in Lusaka over a five year period.

2.2 SPECIFIC OBJECTIVES:

1. To establish the burden of patients with diaphyseal femur fractures managed operatively.
2. To determine the clinical and radiological outcomes of IMN of diaphyseal femur fractures.
3. To determine the medical, social and demographic factors associated with nonunion after IMN of diaphyseal femur fractures.

CHAPTER THREE

3.1 RESEARCH METHODS

This was a retrospective study. A pilot study had shown that data was available and credible. The reason for choosing retrospective over prospective was twofold; firstly, there were few ORIF cases for diaphyseal femur fractures that were being done at UTH because the operating theatre wasn't functioning at full capacity due to understaffing and poor supply of implants. Secondly, it takes a long time (up to a year) to follow up a patient post ORIF to talk about union or failure thereof.

Site: University Teaching Hospital and Zambian Italian Orthopaedic Hospital based in Lusaka. The mentioned hospitals handle the bulk of patients seeking orthopedic services among the public and private hospitals respectively. Thus, data from the two hospitals was a good reflection of Lusaka city.

Duration: 1st January, 2009 to 31st December, 2013. A five year period was chosen to ensure the sample size was met as there were a few ORIF cases for diaphyseal femur fractures that were being done at UTH because the operating theatre wasn't functioning at full capacity due to understaffing and poor supply of implants. Secondly, the cut off was placed on 31st December, 2013 to facilitate at least a year of postoperative follow up.

3.2 INCLUSION CRITERIA

Both male and female patients aged between 18-50 years (skeletally mature and non-osteoporotic) with diaphyseal femur fractures managed with IMN from 1st January, 2009 to 31st December, 2013 at UTH and ZIOH.

3.3 EXCLUSION CRITERIA

- Pathological fractures
- Open fractures
- Non diaphyseal fractures
- Age outside the range of 18-50 years
- Fractures treated non-operatively and
- Incomplete medical records with missing demographic, diagnosis, treatment modality and follow up information.

3.4 SAMPLE SIZE CALCULATION

All cases that were operated on during the period under review were to be captured because of the limited operative capacity as highlighted above. A minimum according to the calculation below had to be reviewed to attain statistical significance.

Sample Size

The sample size was calculated based on the formula below:

$$N = \frac{Z^2 \times P(1-P)}{(E)^2}$$

N = Sample required

Z = Z statistic for a given level of confidence = 1.96 when using a 95% CI

P = the expected prevalence of the condition in the population being studied; if unsure, then use 0.5 to give the most conservative sample size

E = confidence interval, usually 0.05= this refers to the accuracy range (+/- 5%)

N.B: Literature reported prevalence of Union after IMN of diaphyseal femur fractures between 85-100 percent, with a mean of 92.5%.

Thus:

$$N = \frac{1.96^2 \times 0.925(1-0.925)}{(0.05)^2}$$

N= 107 cases

Therefore based on the expected average prevalence of union of 92.5% after operative management of diaphyseal femur fractures, a minimum of 107 participants were needed to be enrolled into the study in order to identify the true prevalence of union with precision of +/- 5 % and 95% confidence interval.

3.5 DATA COLLECTION AND MANAGEMENT

The data collection process started by reviewing the theatre registers at both UTH and ZIOH. I took note of patients' file numbers and not their names (to conceal identity) that were operated upon during the period of the study. The file numbers were then used to retrieve the files and radiological films from the respective registries. The inclusion and exclusion criteria were applied to select the eligible participants retrospectively. Serial numbers were assigned and using the annexed data collection sheet, the files and radiological films of the selected participants were reviewed to ensure credibility & uniformity of the data. The codes on the data collection sheet were used for data collection. Data collected was stored in different box files for each hospital.

Data was entered in to a computer statistical software, Statistical Package for Social Sciences (SPSS 16.0).

3.6 STATISTICAL ANALYSIS

SPSS 16.0 was used for data analysis. Frequency tables and graphs were used to describe the socio-demographic characteristics, the burden of patients, cause of injury, other injuries sustained and treatment modalities, mode of admission, non-operatively treatment prior to operative, operative management and postoperative outcomes. Computing of proportions and percentages was done. Fisher test, Mann

Whitney U test were used to test for associations for categorical variables while Independent Samples t tests was used for continuous variables with p value of < 0.05 was considered statistically significant at confidence level of 95%.

3.7 ETHICAL CONSIDERATION

Ethical clearance was obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC). No informed consent was used as this was a retrospective study. The medical records were handled with utmost care and confidentiality. Permission to conduct the study at the aforementioned hospitals was sought from hospital heads respectively.

Identity of participants was concealed by initially using file numbers to retrieve files from the registry and later serial codes on data collecting sheets. The data entry sheets were secured in a lockable cabinet and all electronic entries were password protected on the researcher's computer.

CHAPTER FOUR

4.0 RESULTS AND DATA ANALYSIS

4.1 DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS

Tables 1 and 2 present the demographic characteristics of the patients involved in the study. There were a hundred and fifteen patients involved in the study. Thirty-four (29.6%) patients were from the University Teaching Hospital (UTH) and eighty one (70.4%) patients were from the Zambia Italian Orthopaedic Hospital (ZIOH).

Table 1 show presents the demographic characteristics of patients from UTH. Thirty-two (94.1%) patients were males while only two (5.9%) were females. All the participants from UTH were Africans. The youngest participant from UTH was aged 18 years whilst the oldest was aged 50 years, giving an average age of 31.45 years.

Table 1: Demographic characteristics of the patients at UTH

Variables	Values	Frequency (n=34)	Percentage
Gender	Male	32	94.1
	Female	2	5.9
Race	African	34	100.0
Smoking	Yes	2	5.9
	No	6	17.6
	Unknown	26	76.5
HIV status	NR	7	20.6
	Unknown	27	79.4

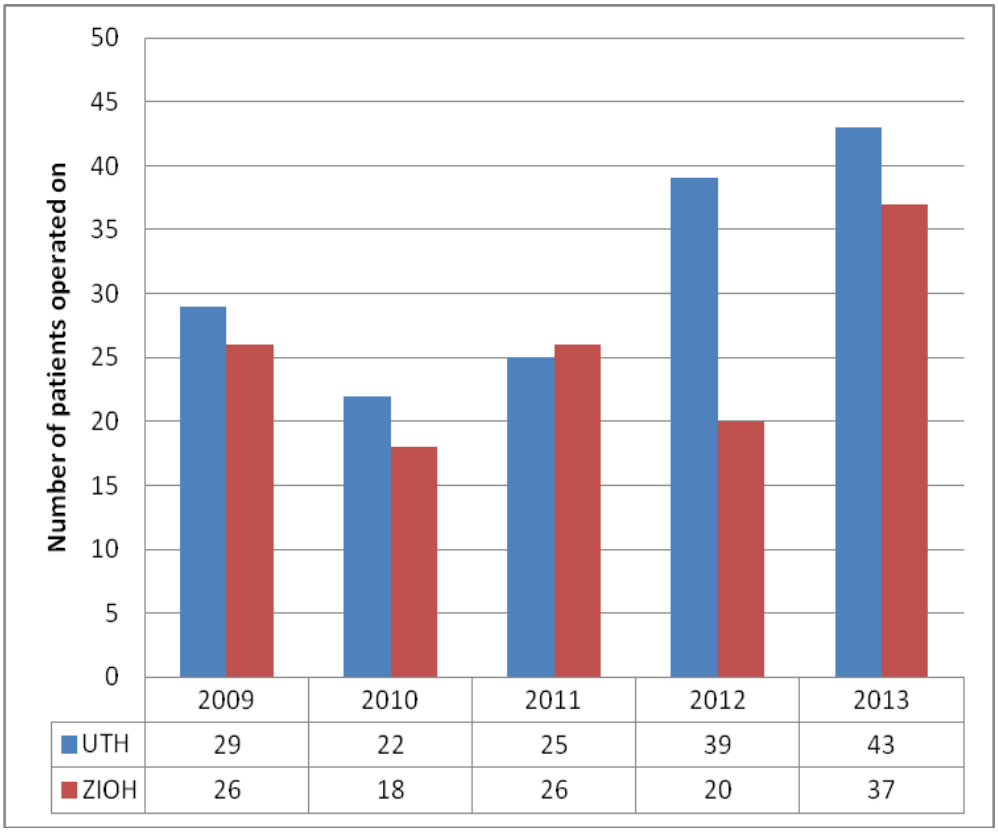
Table 2 presents the demographic characteristics of participants from ZIOH. Sixty-four (79.0%) participants were males while only 17 (21.0%) were females. Seventy-three (90.1%) of the participants from ZIOH were African, three (3.7%) were Caucasian, and five (6.2%) were Asian. The HIV status of all the participants at ZIOH was unknown. The youngest participant from ZIOH was aged 19 years whilst the oldest was aged 50 years, giving an average age of 34.35 years.

Table 2: Demographic characteristics of the patients at ZIOH

Variables	Values	Frequency (n=34)	Percentage
Gender	Male	64	94.1
	Female	17	5.9
Race	African	73	90.1
	Caucasian	3	3.7
	Asian	5	6.2
Smoking	Yes	1	1.2
	Not stated	80	98.8
HIV status	Unknown	81	100.0

4.2 BURDEN OF PATIENTS WITH DIAPHYSEAL FEMUR FRACTURES MANAGED OPERATIVELY

Figure 1 shows the burden of patients with diaphyseal femur fractures managed operatively from 1st January, 2009 to 31st December, 2013 at both UTH and ZIOH. UTH handled at total burden of 158 while ZIOH handled a total burden of 127 patients. It's been noted that there is a general increasing trend of the number of patients operated on at UTH while at ZIOH the number of patients operated on fluctuates from year to year.



	2009	2010	2011	2012	2013
UTH	29	22	25	39	43
ZIOH	26	18	26	20	37

Figure 1: Burden of patients operated on with diaphyseal femur fractures at UTH & ZIOH

4.3 CAUSE OF INJURY, MODE OF ADMISSION, OTHER INJURIES & TREATMENT

58.8% and 4.9% of patients were admitted directly to UTH & ZIOH respectively. The rest of the patients were referrals (Table 3). Forty-eight (41.74%) patients had other injuries (Table 4). These injuries were head injuries (22.9%), upper limb fractures (20.8%), ipsilateral tibia fractures (14.6%), bilateral femur fractures (10.4%), contralateral tibia fractures (6.3%), ipsilateral foot injuries (4.2%), spinal injuries (2.1%), chest injuries (2.1%), and other unspecified injuries (16.7%).

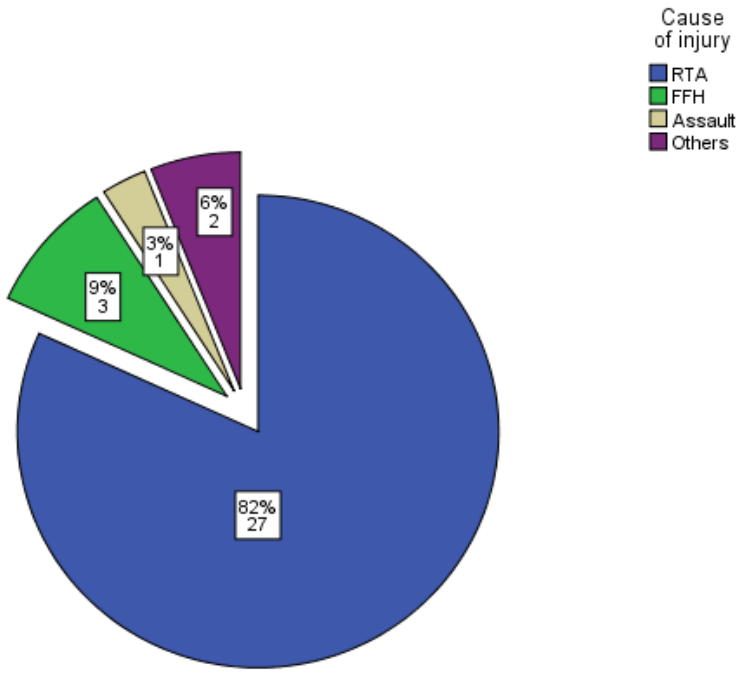


Figure 2: Cause of Diaphyseal Femur Fractures at UTH

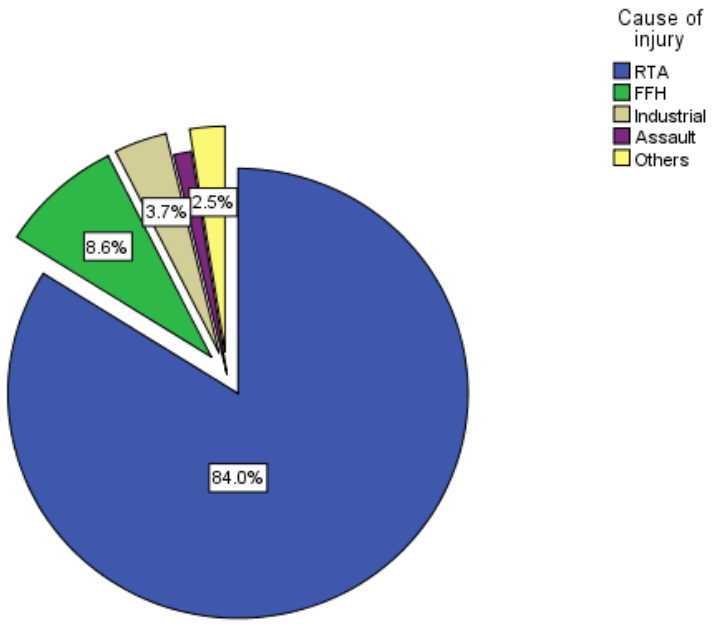


Figure 3: Causes of Diaphyseal Femur Fractures at ZIOH

Table 3: Mode of admission to the hospitals

Mode of Admission	Hospital	
	UTH	ZIOH
Direct admission	20	4
	58.8%	4.9%
Referral	14	77
	41.2%	95.1%
Total	34	81
	100%	100%

Table 4: Other injuries

Other injuries	Hospital					
	UTH		ZIOH		Total	
	Count	Table Valid N %	Count	Table Valid N %	Count	Table Valid N %
HI	8	16.7%	3	6.2%	11	22.9%
Spinal Injury	0	0.0%	1	2.1%	1	2.1%
Chest Injury	0	0.0%	1	2.1%	1	2.1%
Abdominal Injury	0	0.0%	0	0.0%	0	0.0%
Upper Limb Fracture	1	2.1%	9	18.8%	10	20.8%
Bilateral Femur Fractures	2	4.2%	3	6.2%	5	10.4%
Ipsilateral Tibia Fracture	1	2.1%	6	12.5%	7	14.6%
Contralateral Tibia Fracture	2	4.2%	1	2.1%	3	6.2%
Ipsilateral Foot Injury	0	0.0%	2	4.2%	2	4.2%
Contralateral Foot Injury	0	0.0%	0	0.0%	0	0.0%
Others	3	6.2%	5	10.4%	8	16.7%
Total	17	35.4%	31	64.6%	48	100.0%

Table 5: Treatment modality of other injuries

Treatment Modality	Hospital					
	UTH		ZIOH		Total	
	Count	Table Valid N %	Count	Table Valid N %	Count	Table Valid N %
Non Operative	11	64.7	3	10.0	14	29.8%
Operative	6	35.3	27	90.0	33	70.2%
Total	17	100.0	30	100.0	47	100.0%

4.4 NON-OPERATIVE MANAGEMENT PRIOR TO OPERATIVE MANAGEMENT

Table 6 presents findings on non-operative management of fractures prior to operative management at UTH. Thirty (82.2%) participants at UTH were on traction. Types of traction done were skeletal (93.3%) and skin (6.7%). The duration of the traction ranged from 1-14 weeks, with an average of 5.52 weeks. Removal of traction was mainly due to infected pin site (16.7%), non-healing fracture (36.7%), and patient was due for operation (46.6%).

Further findings revealed that only 8 (23.5%) patients had done Perkins exercises at UTH. The duration of the Perkins exercises ranged from 2-14 weeks; with an average of 5.4 weeks.

Table 6: Non-operative management prior to operative management at UTH

Variable	Values	Frequency (n=34)	Percentage
Was traction done?	Yes	30	88.2
	No	4	11.8
Type of traction done	Skeletal	28	93.3
	Skin	2	6.7
Why traction removed	Infected Pin Site	5	16.7
	Non Healing Fracture	11	36.7
	Due for Operation	14	46.6

Table 7 presents findings on non-operative management of fractures prior to operative management at ZIOH. Twenty-five (30.9%) participants at ZIOH were on traction. Types of traction done were skeletal (68.0%) and skin (32.0%). The duration of the traction ranged from 1-12 weeks, with an average of 2.23 weeks. Removal of the traction was mainly due to patient being due for operation (88.0%). Further findings revealed that only one (1.2%) patient had done Perkins exercises. The duration of the Perkins exercises was six weeks.

Table 7: Non-operative management prior to operative management at ZIOH

Variable	Values	Frequency (n=81)	Percentage
Was traction done?	Yes	25	30.9
	No	55	67.9
	Not stated	1	1.2
Type of traction	Skeletal	17	68.0
	Skin	8	32.0
Type of traction done	Non Healing Fracture	3	12.0
	Due for Operation	22	88.0

4.5 OPERATIVE MANAGEMENT

Figure 4 presents the findings on preoperative Hb (in g/dl) of the patients at UTH. Eighty two percent had Hb more than 12g/dl and 15.2% had 9-12g/dl. K-Nail was used on all the 34 patients at UTH. The length of the nails ranged from 30-44 cm; with an average of 38.16 cm. The diameter of the nails ranged from 7.0-14.0 mm with an average of 10.92 mm. Reaming was done on 28 (82.4%) patients. The sizes of the reamers ranged from 9.0-14.0 mm; with an average of 11.80 mm. Bone excision was done on 12 (35.3%) patients only. The sizes of the osteotomised bone ranged from 1-10 cm; with an average of 3.0 cm.

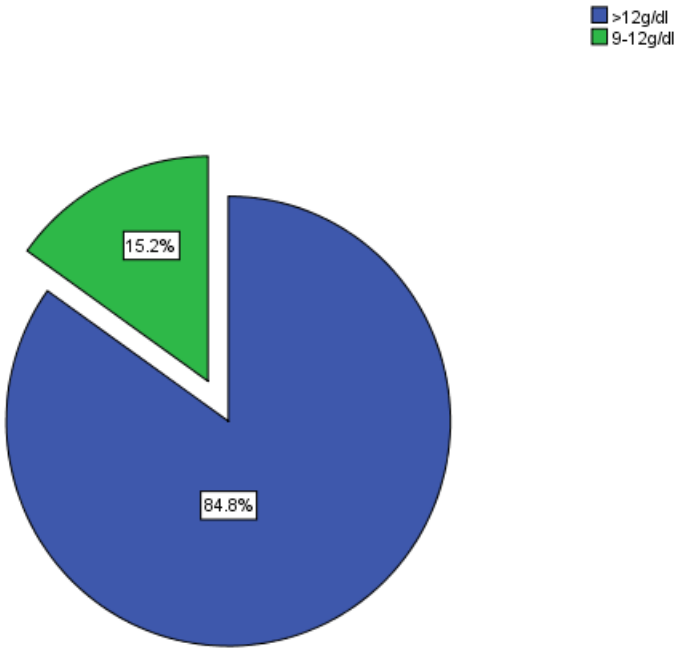


Figure 4: Preoperative Hb of the patients at UTH

Figure 5 presents the findings on pre-operative Hb (in g/dl) of the patients at ZIOH. Fifty-two (64.2%) patients had more than 12g/dl, 20 (24.7%) patients had 9-12g/dl, 8 (9.9%) patients had 6-9g/dl, and one patient had less than 6g/dl.

The types of nails used at ZIOH were as follows: K-Nail was used on 27 (33.3%) patients; Interlocking nail was used on 53 (64.4%) patients; and SIGN nail was used only on one patient. The length of the nails ranged from 32-48 cm; with an average of 39.81cm. The diameter of the nails ranged from 7.0-14.0mm with an average of 10.704 mm. Reaming was done on 74 (91.4%) patients. The sizes of the reamers ranged from 9.0-14.0 mm; with an average of 11.55 mm. Bone excision was done on 9 (11.1%) patients only. The sizes of the osteotomised bone ranged from 1-3 cm; with an average of 1.71 cm.

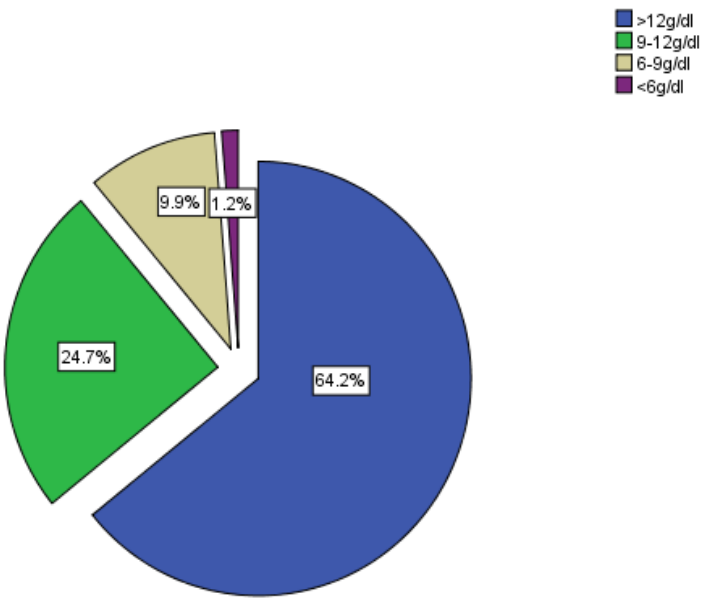


Figure 5: Preoperative Hb of the patients at ZIOH

Table 8 below presents postoperative outcomes findings at the UTH; twenty-eight (82.4%) patients had postoperative Hb greater than 12g/dl; five (14.7%) patients had postoperative Hb ranging from 9-12g/dl; and one (2.9%) patient had postoperative Hb ranging from 6-9g/dl. Only four (11.8%) patients had postoperative infection. Postoperative infection was treated using antibiotics only on two (50 %) patients, and removal of implants on another two (50 %) patients.

Table 8: Postoperative Hb, postoperative infection & treatment at UTH

Variable	Values	Frequency	Percentage
Post op Hb	>12g/dl	28	82.4
	9-12g/dl	5	14.7
	6-9g/dl	1	2.9
Post op infection	Yes	4	11.8
	No	30	88.2
Treatment of infection	Antibiotics only	2	50.0
	Removal of implant	2	50.0

Table 9 below presents postoperative outcomes findings at the ZIOH; forty-eight (59.3%) patients had postoperative Hb greater than 12g/dl; 26 (32.1%) patients had postoperative Hb ranging from 9-12g/dl; and 7 (8.6%) patients had postoperative Hb ranging from 6-9g/dl. Only six (7.4%) patients had postoperative infection at ZIOH. Postoperative infection was treated using antibiotics only on 66.6% of the patients, antibiotics/debridement/sloughectomy on 16.7% patients, and removal of implants on 16.7% of the patients.

Table 9: Postoperative Hb, postoperative infection & treatment at ZIOH

Variable	Values	Frequency	Percentage
Post op Hb	>12g/dl	48	59.3
	9-12g/dl	26	32.1
	6-9g/dl	7	8.6
Post op infection	Yes	6	7.4
	No	74	91.4
	Unknown	1	1.2
Treatment of infection	Antibiotics only	4	66.6
	Antibiotics, debridement & sloughectomy	1	16.7
	Removal of implant	1	16.7

4.7 CLINICAL AND RADIOLOGICAL OUTCOMES

4.7.1 UTH

Findings regarding union at 6 months and 1 year postoperative were the same (Table 10); i.e. 6 (17.6%) were delayed union, 0 (0%) were nonunion and 28 (82.4%) were united fractures. Twelve (35.3%) patients had postoperative shortening. The length of shortening ranged from 1.0 cm to 10.0 cm; with an average of 3.167 cm (SD=2.8231 cm). Furthermore, only 2 (5.9%) patients had experienced implant migration. One patient had his/her implant migration treated non-operatively while the other patient had his/her implant migration treated operatively. No patient had suffered an implant break.

Table 10: Clinical and Radiological Outcomes at UTH

Variable	Values	Frequency	Percentage
Union at 6 months	Delayed	6	17.6
	Nonunion	0	0.0
	United	28	82.4
Union at 12 months	Delayed	6	17.6
	Nonunion	0	0.0
	United	28	82.4
Post op shortening	Yes	12	35.3
	No	22	64.7
Implant Migration	Yes	2	5.9
	No	32	94.1
Implant migration treatment	Nonoperative	1	50.0
	Operative	1	50.0
Implant Break	No	34	100.0

4.7.2 ZIOH

Findings regarding union at 6 months and 1 year postoperative were the same (Table 11); i.e. 9 (11.1%) were delayed union, 2 (2.5%) were nonunion and 70 (86.4%) were united fractures. Thirteen (16.0%) patients had postoperative shortening. The length of shortening ranged from 1.0 cm to 4.0 cm; with an average of 1.714 cm (SD=0.975 cm). Furthermore, only three (3.7%) patients had experienced implant migration. 33.3% patients had his/her implant migration treated nonoperatively while the other remaining (67.3%) patients had their implant migration treated operatively. No patient had suffered an implant break.

Table 11: Clinical and Radiological Outcomes at ZIOH

Variable	Values	Frequency	Percentage
Union at 6 months	Delayed	9	11.1
	Nonunion	2	2.5
	United	70	86.4
Union at 12 months	Delayed	9	11.1
	Nonunion	2	2.5
	United	70	86.4
Post op shortening	Yes	13	16.0
	No	68	84.0
Implant Migration	Yes	3	3.7
	No	78	96.3
Implant migration treatment	Nonoperative	1	33.3
	Operative	2	66.7
Implant Break	No	81	100.0

4.8 ASSOCIATIONS

4.8.1 Association between Preoperative Hb and Postoperative Infection

Fishers' Exact Test was conducted to establish whether there was any association between Preoperative Hb and Postoperative Infection. The findings seem to suggest that there is an association between Preoperative Hb and Postoperative infection. *The findings at UTH (p=0.031, <0.05) and ZIOH (χ^2=8.620; df=1; p=0.031, <0.05) were significant. Out of the six patients who had Postoperative infection at ZIOH, 64.2% patients had Preoperative Hb greater than 12g/dl, 24.7% had Hb 9-12g/dl, 8.0% had 6-9g/dl, and 1.2% less than 6g/dl.*

4.8.2 Association between infection rate and duration from injury to surgery

Further analysis was conducted to establish whether there was an association between infection rate and duration from injury to surgery by running a Mann Whitney U test at a significance level of 0.05. *The findings suggest that there was no association between infection rate and duration from injury to surgery at both UTH (Mann Whitney U = 59.000; p=.957) and ZIOH (Mann Whitney U = 214.000; p=.882).*

4.8.3 Union rates and selected factors

Independent Samples t-tests were conducted to establish whether there was an association between union rates and age, duration from injury to surgery. Tables 12 and 13 summarize the results from UTH and ZIOH respectively. *The results show that there was no association between union rate and age (p>0.636; p>0.298) and duration from injury to surgery (p>0.803; p>0.685).*

Table 12: Union rates Vs age and duration from injury to surgery at UTH

Independent variable	Significance level (alpha=0.05)
Age	0.636
Duration from injury to surgery	0.803

Table 13: Union rates Vs age and duration from injury to surgery at ZIOH

Independent variable	Significance level (alpha=0.05)
Age	0.298
Duration from injury to surgery	0.685

Fishers' Exact tests were conducted to establish whether there was an association between fracture union and gender, reaming, Perkins exercises, traction, head injuries, type of nails used, , the level of preoperative and postoperative Hb. Table 14 summarizes the results at both hospitals. *The results show that there was no association between fracture union and gender (p>1.000; p>0.691), reaming (p>1.000; p>0.240), Perkins exercises (p>0.298; p>1.000), traction done (p>0.559; p>1.000), head/spinal injuries (p>0.082; p>1.000),level of preoperative Hb (p>0.216; p>0.805), and level of postoperative Hb (p>0.354; p>0.612).*

Table 14: Union rates Vs gender, reaming, Perkins exercises, HI injuries, Preoperative Hb and Postoperative Hb at UTH & ZIOH

Independent variable	Significance level (alpha=0.05)	
	UTH	**ZIOH**
Gender	1.000	0.691
Reaming	1.000	0.240
Perkins Exercises	0.298	1.000
HI/spinal injuries	0.082	1.000
Preoperative Hb	0.216	0.805
Postoperative Hb	0.354	0.612

4.8.4 Average duration from 'patient first seen at hospital to surgery'.

The average duration from "patient first seen at hospital to surgery" for UTH (n=34) was 35.21 days (SD=12.737). The minimum duration was 1 day; the maximum was duration was 74 days.

The average duration from "patient first seen at hospital to surgery" for ZIOH (n=81) was 6.16 days (SD=12.928). The minimum duration was 0 day; the maximum was duration was 99 days.

A t test was conducted to establish if there any difference in the average duration from 'patient first seen at hospital to surgery' between the two hospitals; at a significant level of 0.05. The results (t=7.251; df=35.412; p=0.001) indicated that there was a significant difference. The duration from 'patient first seen at hospital to surgery' was much longer at UTH than at ZIOH.

4.8.5 Need for bone excision on a patient Vs '1st seen at hospital to surgery duration'

A t test was conducted to establish whether there was any association between need for bone excision and '1st seen at hospital to surgery duration'. The test was conducted at a significance level of 0.05.

At UTH eight patients needed bone excision. The average duration from "patient first seen at hospital to surgery" for patients who needed bone excision at UTH was 50.63 days while the average for patients who did not need bone excision was 29.05 days. The results (t=2.959; df=26; p=0.006) indicate that there was a significant difference in the duration of categories of patients. At UTH patients who needed bone excision had a longer duration from 'patient first seen to surgery' than those who did not need bone excision.

At ZIOH nine patients needed bone excision. The average duration from "patient first seen at hospital to surgery" for patients who needed bone excision at ZIOH was 6.89 days (SD=7.507) while the average duration from "patient first seen at hospital to surgery" for patients who did not need bone excision was 6.07 days (SD=13.494). The results (t=0.178; df=78; p=0.859) indicate that, at ZIOH there was no significant difference in the duration between patients who needed bone excision and those who did not need it.

4.8.6 Need for bone excision Vs traction done on a patient or not

A Fishers' Exact test was conducted to establish whether there was any association between need for bone excision & traction on patients. The test was conducted at a

significance level of 0.05.

The findings ($\chi 2=1.407$; df=1; p=1.000, >0.05) for UTH indicated there was no significant association between need for bone excision and traction done on a patient or not. Similarly, the findings ($\chi 2=4.702$; df=1; p=0.051, >0.05) for ZIOH indicated there was no significant association between need for bone excision and traction done on a patient or not.

4.8.7 Percentages of reamed and those unreamed IMNs

Table15. Number of reamed and unreamed IMN technique at UTH

Reamed	Frequency	Percent
Yes	23	82.1
No	4	14.3
Total	27	96.4
Missing (not stated)	1	3.6
Total	28	100.0

Table16. Number of reamed and unreamed IMN technique at ZIOH

Reamed	Frequency	Percent
Yes	73	91.3
No	7	8.8
Total	80	100.0

4.8.8 Association between unreamed and

a. Delayed union
b. Non union
c. Implant migration

A Fishers' Exact test was conducted to establish whether there was any association between unreamed technique and delayed union, non-union, and implant migration. The test was conducted at a significance level of 0.05.

At UTH, the findings indicated there was no significant association between unreamed and implant migration ($\chi 2$=.181; df=1; p=1.000, >0.05); and between unreamed and nonunion of fractures.

Similarly, the findings at ZIOH ($\chi 2$=1.421; df=1; p=0.245, >0.05) indicated that there was no association between unreamed and nonunion of fractures. However, the results at ZIOH showed that there was a significant association between unreamed and implant migration ($\chi 2$=13.094; df=1; p=0.019, <0.05). Patients who had unreamed IMNs were more likely to suffer an implant migration.

4.8.9 Nail type Vs Implant migration at ZIOH (had both interlocking & K-nails)

A Fishers' Exact test was conducted to establish whether there was any association between nail type and implant migration. The test was conducted at a significance level of 0.05.

At ZIOH, the findings indicated there was a significant association between nail type and implant migration ($\chi 2$=11.014; df=2; p=0.004, <0.05). Patients with K-Nail were more likely to suffer an implant migration.

CHAPTER FIVE

5.0 DISCUSSION

5.1 THE BURDEN AND DEMOGRAPHIC PROFILE

Trauma is increasing globally and Zambia hasn't been spared (WHO, 2008). This is evidenced by the trends observed in this study in which there was a 95.5% and 105.5% increase in the burden of patients with diaphyseal femur fractures managed operatively from the year 2010 to 2013 at UTH and ZIOH respectively. Road traffic accidents account for the majority of these injures; 82% at UTH and 84% at ZIOH. Khayesi et al hypothesized that the increase in trauma as a result of RTA in third world countries could be due to rapid motorisation with second hand cars which may not be road worthy shortly after acquisition and lack of adequate Public Health Policy responses to this epidemic (Khayesi, 2005). This hypothesis needs to be tested in Zambia. The majority of the patients at both hospitals were males, at 83.5%. The average age was 31.5 and 34.4 years at UTH and ZIOH respectively. This is consistent with Egol who noted that diaphyseal femur fractures occur most frequently in young men following high-energy trauma (Egol, 2010). The bulk of these patients, 79.1%, were referrals. This showcases the lack of Trauma & Orthopaedic Surgeons and hospital infrastructure to handle such injuries across the country.

A significant proportion of the patients sustained other injuries as well; 50% at UTH and 38.3% at ZIOH. Head injury, upper limb fractures, ipsilateral tibia fractures and bilateral femur fractures were the commonest. Most of these injuries also required operative management. However, due to limited operative capacity at UTH, only 35.3% were treated operatively. The case was pretty much the opposite at ZIOH, with 90% treated operatively. Again, this showcases the need to expand the human resource pool of Orthopaedic Surgeons and hospital infrastructure across the country to handle this increasing burden of patients with fractures.

5.2 LIMITED OPERATIVE CAPACITY AND IMPLICATION

Unlike the doubling in the burden over the years, the infrastructure at the hospitals has relatively remained the same. This is particularly true in public institutions like UTH. Mock et al in 1997 pointed out that most third world countries have a long way to attain the kind of medical services that would entail timely operative management of fractures (Mock, 1997) and Zambia unfortunately falls in this blanket too. The resultant huge backlog of patients waiting for surgery ensures longer durations from injury to surgery. This has a potential to complicate the outcomes of operative management of femur fractures as was observed by Nowatarski et al who highlighted complications such as infection, malunion, nonunion, shortening resulting from delayed surgery (Nowatarski, 2000). Another study in 2005 by Bhandari reinforced this assertion by further showing that high rates of fracture union are achieved if surgery is done within 2 to 4 weeks from injury (Bhandari, 2005). In this study, the average waiting time for surgery was 35.2 days at UTH and 6.2 days at ZIOH. This is statistically significantly different. T-tests were conducted to establish whether there was an association between union rates, infection and duration from injury to surgery and the results show that there was no association at both hospitals. However, the need for bone excision that results in postoperative limb length discrepancy was directly related to the duration from injury to surgery at UTH. On the other hand, there was no such association at ZIOH because of the lesser waiting time. It therefore follows that if more trauma and orthopaedic surgeons are trained and hospital infrastructure improved across the country, the complication rate would reduce.

5.3 CLINICAL AND RADIOLOGICAL OUTCOMES

The union rates found in this study are comparable to literature. UTH recorded an average of 82.4% and ZIOH of 86.4%. Literature reports union rates of 85% to 100% (Brumback, 1988). In another recent study, rate of nonunion after all kinds of intramedullary nailing was reported at 8.5% (Zaka, 2011). In this study, ZIOH had nonunion rate of 2.4% while UTH none. Going by these figures, union rates at the

two hospitals are comparable to other centers across the world despite the long waiting time for surgery especially at UTH.

Post injury shortening results from two things; sequel of initial bone loss at the time of the injury and secondary to osteotomized bone during surgery. The former is difficult to mitigate while the latter is necessitated by the degree of overlap between the fracture fragments that hinders reduction during surgery. The longer the patient waits for surgery the more chances of overlap between the fracture fragments especially if the patient was not on traction or if traction was poorly managed. The longer waiting time at UTH than ZIOH as seen above explains partly why the former recorded more patients with postoperative LLD, at 35.3% than the later at 16.0%. Further analysis indicated that patients who waited for more than 29.05 days were at an increased risk of having bone excision during their surgeries and therefore were at an increased risk having a shorter limb postoperatively.

Another equally important dimension of outcomes to consider would have been the functional outcome. Klemm and Borner classification is widely used in this regard. However, this was difficult to evaluate for this study. Firstly, there was generally poor records' keeping especially at UTH. Secondly, there was lack of a uniform format with respect to postoperatively assessment of patients. For instance, not all surgeons were keen to record range of motion of ipsilateral hip and knee joints as the patients were followed up post operatively. This made it difficult to fully evaluate the clinical outcomes of operative management of diaphyseal femur fractures in this study.

5.4 INTERLOCKING VS NON LOCKABLE IMN AND LOSS OF FRACTURE REDUCTION

In this study, Fisher test demonstrated that K-nail system is more likely to migrate than interlocking nail system with subsequent loss of reduction. This is in keeping with a study by Winquist et al in 2001 who noted that interlocking devices ensure cortical contact which is usually difficult to achieve and maintain in segmental and comminuted fractures, thereby reducing the risk of losing alignment, shortening, angulation and rotation (Winquist, 2001). It is for this reason that interlocking IMNs

are the implants of choice for diaphyseal femur fractures and are the most widely used in the western world (Egol, 2010).

5.5 REAMED Vs UNREAMED NAILING TECHNIQUES & IMPLICATIONS

Reaming was done on 82.1% and 91.3% patients at UTH and ZIOH respectively. Analysis showed that unreamed technique was not associated with delayed union or development of nonunion at both hospitals. This is consistent with Giannoudis but contrary to the findings by two separate studies by Selvakumar in 2001 and Duan in 2011 (Giannoudis 1997, Selvakumar 2001 and Duan, 2011). On the other hand, unreamed technique was significantly associated with implant migration and subsequent loss of reduction and is in keeping with findings by Duan, 2011. As to whether reaming should be done during intramedullary nailing or not, still remains controversial (Ürgüden 2001, Orler 2002, el Moumni 2009 and Farshid 2013).Thus, the decision on this aspect has to be based on individual patient with respect to the personality of the fracture.

5.6 POSTOPERATIVE INFECTION RATES

Postoperative infection rate was observed in 11.8% patients at UTH and in 7.4% patients at ZIOH. Bhandari et al found low infection rates if intramedullary nailing (IMN) of the femur fractures was done within 28 days of injury (Bhandari, 2005). UTH had more waiting time averaging 35.2 days than ZIOH at 6.2 days. Therefore, Bhandari's theory holds true for the observation made in this study too. Once more, it therefore follows that if more trauma and orthopaedic surgeons are trained and hospital infrastructure improved across the country, the complication rate would reduce.

5.7 DEMOGRAPHIC, SOCIAL & MEDICAL FACTORS Vs UNION RATES

Demographic factors such as age and gender did not influence union rates in this study. T-test and fisher tests were used and gave p>0.636 at UTH & >0.298 at ZIOH and p>1.000 at UTH & p>0.691 at ZIOH respectively. These findings are in keeping with Taitsman, 2009. Effects of smoking and Human Immunodeficiency Virus (HIV) on fracture healing were not analysed as the data was missing in most files reviewed. This made it difficult to fully understand and interpret the clinical outcomes of operative management of diaphyseal femur fractures in this study since these potential confounding factors could not be ruled out.

5.8 NON-OPERATIVE MANAGEMENT PRIOR TO OPERATIVE MANAGEMENT

Both hospitals under review employ non-operative management prior to operative management of diaphyseal femur fractures. The UTH had 82.2 % of the patient load put on traction while ZIOH with 67.9%. UTH recorded 17.9 % while ZIOH didn't record any pin site infection. Comparing to an earlier study by Chilengwe in 2000 at UTH, the pin site infection rate dropped 2.8 fold (50% to 17.9%). One would expect an increase in pin site infection rate because of the increased patient burden and consequent ward congestion.

Furthermore, it was interesting to note that Perkins exercises were only done on 28.6% of patients on traction at UTH and on 5.8 % of patients at ZIOH. In as much as non-operative management of diaphyseal femur fractures is no longer the preferred method of management across the world, it should still be taken seriously and possibly done on all eligible patients especially in resource constrained settings like UTH (Kopits, 2005). This is because fracture union can still be achieved with non-operative management as the patients waits for surgery. For instance, a study in Kenya documented an average of 60 days to achieve union (Opondo et al, 2013) while Bezabeh at Addis Ababa University Hospital in Ethiopia reported an average of 45 days (Bazebeh, 2010). A local study at the UTH 15 years ago found an average of 59.5 days to achieve fracture union with non-operative management (Chilengwe,

2000). Otherwise all the patients will have to wait for operative management of diaphyseal femur fractures, thereby not helping in reducing the burden on the limited operative capacity. Furthermore, the need for bone excision can be reduced if the benefits of non-operative management are maximized prior to operative management.

CHAPTER SIX

6.1 CONCLUSION

1. This study showcased an increase of 100.5% in the burden of patients with diaphyseal femur fractures managed operatively using IMNs from the year 2010 to 2013. RTA accounted for 83% of these injuries with males being more affected. The average age was 33 years. The increase in burden resulted in statistically significantly longer waiting time for surgery at UTH than ZIOH.

2. Clinical and radiological outcomes of diaphyseal femur fractures managed using IMNs are comparable with other centers across the world except for **high incidence of LLD** which is a result of delayed surgery, especially if exceeds 29.05 days. Furthermore, K-nails were found to be more likely to migrate than interlocking nails.

3. The patients' age, gender and reaming technique does not influence the development of nonunion.

6.2 LIMITATIONS

1. Missing medical records of some patients who were operated on during the period of the research question.

2. Poor record keeping giving incomplete medical records resulting in exclusion of many files.

3. Incomplete evaluation of patients, with demographic information (e.g. smoking and HIV status) missing. This made it impossible to analyse the effect of smoking and HIV on fracture healing.

4. Postoperative assessment of patients was not uniform with most surgeons not assessing ipsilateral hip and knee joints' range of motion. This made it difficult to fully assess the functional outcome.

6.3 RECOMMENDATIONS

1. To Road Transport and Safety Agency

   To mitigate the increasing number of road traffic accidents which are the commonest cause of fractures.

2. To the Ministry of health

   To Set up Trauma Centers across the country that will ensure timely

   operative management of fractures.

3. To the University Teaching Hospital and Department of Surgery

   To consider Interlocking IMN system as opposed to K-Nails as the former has less complications and expands the spectrum of fractures that can be fixed.

4. To Fellow Orthopaedic Registrars

   a. To standardise comprehensive evaluation of patients as this will help understand and interpret fully the outcomes of our interventions.

   b. To adopt the Klemm and Borner classification as a tool to guide postoperative assessment which is more informative regarding functional outcome.

   c. To maximise the benefits of non-operative treatment. This will help in reducing the burden of patients waiting for surgery as others will have

their fracture unite. Secondly, Perkins exercises will reduce potential complications including stiff joints, muscle atrophy, the need for bone excision and subsequent shortening.

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APPENDICES

Appendix A. : Data Collection Sheet

Demographics

1. Serial number:
2. Date of admission:
3. Age in years at last birthday:
4. Gender: 1) M 2) F
5. Race: 1) African 2) Caucasian 3) Asian 4) Mixed
6. Smoker: 1) Yes 2) No
7. HIV Status: 1) NR 2) R 3) Unknown

Injury

8. Date of fracture:
9. Cause of injury: 1) RTA 2) FFH 3) Industrial 4) Assault 5) Others……..
10. Admitted straight to UTH or ZIOH: 1)Yes 2)No
11. Other injuries sustained: 1) HI 2) Spinal injury 3) Chest injury 4) Abdominal trauma 5) Upper limb fracture 6) Bilateral femur fracture 7) Ipsilateral tibia fracture 8) Contralateral fem
12. ur fracture 9) Ipsilateral foot injury 10) Contralateral foot injury 11) Other……
13. Treatment of other injuries: 1) Non operative 2) Operative

Non-operative management prior to operative management

14. Was the patient on traction: 1) Yes 2) No
15. Type of traction: 1) Skeletal 2) Skin
16. Duration of traction in Weeks:
17. Reason traction removed: 1) Infected pin sites 2) Non healing fracture 3) Due for operation
18. Was Perkins exercises done: 1) Yes 2) No
19. Duration of Perkins exercises:

Operative Management

20. Date of surgery:
21. Pre op HB in mg/dl: 1) >12, 2)9-12, 3) 6-9, 4)<6
22. Type of nail: 1) K-Nail 2) Interlocking Nail
23. Size of nail:
24. Was reaming done: 1) Yes 2) No
25. Biggest reamer used:
26. Was bone excision done: 1) Yes 2) No
27. Length of bone osteotomised in cm:
28. Duration of surgery:

Post Operative

29. Post op HB in mg/dl: 1) >12, 2)9-12, 3) 6-9, 4)<6
30. Post operative infection: 1) Yes 2) No

31. How was infection treated: 1) Antibiotics only 2) Antibiotics & Debridement/sloughectomy 3) Removal of implants
32. Date of mobilization:
33. Type of mobilization: 1) NWB 2) PWB 3) FWB
34. Duration of hospital stay post surgery:
35. State of union at 6 months post operation: 1) Delayed union 2) Non union 3) United 4) Mal united.
36. State of union at 1 year post operation: 1) Delayed union 2) Non union 3) United 4) Mal united.
37. Date of clinical union:
38. Comment on the post operative X-ray at 6 months: 1) Adequate callus 2) Poor Callus 3) No Callus
39. Any shortening noted: 1) Yes 2) No
40. Length of shortening:
41. Did the implant migrate: 1) Yes 2) No
42. How was implant migration treated: 1) Non Operative 2) Operative
43. Did the implant break: 1) Yes 2) No
44. How was this treated: 1) Non operative 2) Implant removal without replacement 3) Implant removal and replacement
45. Date of discharge from the clinic:

Name of researcher:……, Signature:……., Date:…….

Appendix B:

Klemm & Borner classification

Grade	Description
Excellent	– Full hip and knee motion – No muscle atrophy – Normal radiological consolidation
Good	– Minimal loss of hip and knee motion – Less than 2cm of muscle atrophy – Less than 5 degrees axial deviation
Poor	– Moderate(25%) loss of hip and knee motion – More than 2cm muscle atrophy – Axial deviation of 5-40 degrees

Appendix C: UNZABREC Study Approval Letter

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm

Ridgeway Campus
P. O. Box 50110
Lusaka, Zambia

Assurance No. FW A00000338
IRB00001131 of IORG0000774

16th May, 2014.

Our Ref: 004-03-14.

Dr. Godfrey Phiri,
University Teaching Hospital,
Department of Surgery,
P/Bag RW IX
Lusaka.

Dear Dr. Phiri,

RE: RESUBMITTED RESEARCH PROPOSAL: "A RETROSPECTIVE STUDY TO DETERMINE THE RATE OF UNION AFTER OPEN REDUCTION AND INTERNAL FIXATION OF DIAPHYSEAL FRACTURES OF THE FEMUR AT THE UNIVERSITY TEACHING HOSPITALANDZAMBIAITALIAN ORTHOPAEDIC HOSPITAL, LUSAKA-ZAMBIA" (REF. NO. 004-03-14)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committeeon 14th May, 2014. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology; you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. J.C. Munthali
CHAIRPERSON

Date of approval: 16th May, 2014 **Date of expiry:** 15th May, 2015.

Appendix D: Clearance letter from UTH management to carry out the study

The University of Zambia
School of Medicine
Department of Surgery
P.O Box 50110
Lusaka.

20th February, 2014.

The Head, Clinical Care
University Teaching
Hospital
P/Bag RW 1X

Lusaka.

Dear Sir,

Ref: Permission to carry out a study **titled "A Retrospective Study to determine the Rate of Union after Open Reduction & Internal Fixation of Diaphyseal Fractures of the Femur at the University Teaching Hospital and Zambia Italian Orthopaedic Hospital, Lusaka-Zambia"**

I am a third year postgraduate student in Trauma and Orthopaedic Surgery at the University of Zambia, School of Medicine.

As part of the University requirements for a Master of Medicine Degree, a student has to carry out a research under supervision and use the findings to write up a thesis. It's on this premise that I write to you, requesting for permission to carry out part of the aforementioned study at your institution under the supervision of Professor Yakub Mulla, a Senior Lecturer and Consultant Orthopaedic Surgeon at the University and Hospital respectively.

The patients' medical records will be handled with uttermost confidentiality and care.

Attached hereto is my full research proposal.

Your favorable consideration shall be greatly appreciated.

Yours faithfully,

Dr. Godfrey Phiri.
Mobile: +260 977 659 166
Email: godfreynyanda@gmail.com

Appendix E: Clearance letter from ZIOH management to carry out the study

Cheshire Homes Society of Zambia

Zambian-Italian Orthopaedic Hospital

Creating opportunities with disabled people

MEMBER OF THE LEONARD CHESHIRE FOUNDATION INTERNATIONAL

February 20, 201 4.

Dr. Godfrey Phiri
University Teaching hospital
School of Medicine
Department of Surgery
P.O. Box 50110
Lusaka.

Dear Sir,

Re: PERMISSION TO CARRY OUT A STUDY TITLED "A RETROSPECTIVE STUDY TO DETERMINE THE RATE OF UNION AFTER OPEN REDUCTION & INTERNAL FIXATION OF DIAPHYSEAL FRACTURES OF THE FEMUR AT UNIVERSITY TEACHING HOSPITAL AND ZAMBIAN-ITALIAN ORTHOPAEDIC HOSPITAL, LUSAKA - ZAMBIA"

Referring to the mentioned subject, we confirm receipt of your letter dated 17th February, 2014. The hospital management has approved your request, to determine the rate of union after Open Reduction and Internal Fixation of Diaphyseal fractures of the femur at the University Teaching Hospital and Zambian-Italian Orthopaedic Hospital, under the supervision of Professor Yakub Mulla.

We hope you will acquire valuable data and needed knowledge for your research project.

God bless.

Yours sincerely,

ZAMBIAN - ITALIAN ORTHOPAEDIC HOSPITAL

Sr. Margaret Mweshi PT, PhD
Hospital Administrator.