ETIOLOGY, MORPHOLOGY, TREATMENT MODALITIES AND EARLY OUTCOMES OF FEMORAL SHAFT FRACTURES IN ADULT PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET

BY

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A THES IS SUBMITTED TO MOI UNIVERSITYAS PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE (ORTHOPEDIC SURGERY) AT MOI UNIVERSITY

DECLARATION

Declaration by Candidate

This research thesis is the personal work of the author and has not been submitted for an award of academic credit in any other university or research institution.

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DEDICATION

This work is dedicated to all those who have committed their effort, time and resources in provision and improvement of orthopedic healthcare services in Kenya and beyond.

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DISCLOSURE

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

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ABBREVIATIONS AND ACRONYMS

AO Is an initialism for the German words "Arbeitsgemeinschaftfür Osteosynthesefragen," the predecessor of the AO Foundation.

FSF Femoral Shaft Fractures

IQR Inter Quartile Range

MTRH Moi Teaching and Referral Hospital

OTA Orthopedic Trauma Association

RTAs Road traffic Accidents

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OPERATIONAL DEFINITIONS OF VARIABLES AND KEY CONCEPTS

Early outcomes: outcomes occurring after three months of treatment.

Femur: Thigh bone, it is both the longest and the strongest bone in the human body, extending from the hip to the knee.

Femoral shaft fracture: A fracture of the middle straight part of a long bone occurring between 5 cm distal to the lesser trochanter and 5 cm proximal to the adductor tubercle.

Fracture pattern/morphology: Physical and radiological characteristic of a fracture that may define its treatment modalities**.**

Intramedullary nail: is a metal rod forced into the medullary cavity of a long bone for the purpose of fixing a fracture.

Treatment modalities: Treatment options available to make a fracture heal.

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ABSTRACT

Background: The femur is the longest, strongest weightbearing bone in the lower limb. Femur shaft fractures (FSF) arise from variable causes of trauma and assume variable morphology. They are managed through different treatment modalities and their early outcomes also differ. There is paucity of published research information regarding the FSF in terms of the etiology, morphology, treatment modalities and early outcomes at Moi Teaching and Referral Hospital (MTRH), Eldoret.

Objective: To determine the etiology, morphology, treatment modalities and early outcomes of FSF in adult patients seeking treatment at MTRH.

Methods: This was prospective descriptive study involving adult patients with FSF carried out at MTRH orthopedics wards and outpatient fracture clinic. Informed consent was obtained before enrollment. Consecutive sampling was used. Data collection was via a researcher-administered questionnaire and radiological and clinical examination of the patients. Patients were followed up for three months and the outcomes assessed using the American Academy of Orthopedic Surgeons Lower Limb Questionnaire. Data was analyzed using standard software for statistical analysis system software (Version 9.1). Associations were assessed using Chi- Square and Fischer's exact tests. A total of 137 patients with 149 FSF was recruited into the study.

Results: Median age was 36 (IQR: 28, 53) years with a minimum and maximum of 18 and 81 years respectively. Recruited were 72 males and 65 females. Most of the FSF (64%) were due to Road Traffic Accidents (RTAs); falls 20 (15.0%); assault 16(12%); Sports 12 (9%). Up to 47% of the fractures were open type while 53% were closed. Middle 1/3 femur shaft was the commonest level of fracture at 53%. Intramedullary nailing was the commonest treatment modality at 79%. Outcomes were Good to Excellent at 92.7%, with a complication rate of 15.3% of which infection was the commonest at 28.6%.

Conclusion: RTAs were the major cause of FSF. Most FSFs were closed with type AO 32 A being the commonest. Intramedullary nailing was the preferred treatment modality. Outcomes were predominantly Good to Excellent with a fairly low complication rate.

Recommendations: The use of intramedullary nailing should be encouraged and upheld for FSF.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The femur is the longest, strongest, and heaviest tubular bone in the human body and one of the principal load bearing bones in the lower extremity (Moore, 2009).

Femoral shaft fractures are fractures involving the shaft of the femur which is the section between the proximal and distal metaphysis. The annual incidence of FSFs is approximately 37.1 per 100,000 person-years (Enninghorst, et al., 2013; Hedlund, 1986). The incidence peaks among the young, decreasing after age 20, and then again in the elderly (Hedlund R, 1986) with a marked increase occurring in those over age 75 years (Baron, et al., 1996).

Fractures of the femoral shaft often result from either high energy forces such as motor vehicle collisions (Bucholz, 1991) or low energy forces as in patients with osteoporosis and the elderly (Dencker, 1969).

There are diverse fracture characteristics that result from the various etiologies that could demand different treatment modalities. FSF can be describe as either involving proximal, middle or distal one third by roughly dividing the shaft into three apparent segments. The majority of FSF are closed and involve the middle third (Anyaehie, et al., 2015). These fractures can be morphologically classified in different ways (Bucholz, 1991) and this can be used for determining the modality of treatment to be employed (Neumann, et al., 2015).

Operative treatment is the standard of management of FSF with use of an Intramedullary Nail being the Gold standard (Ricci, et al., 2009). Plate osteosynthesis and External fixation can be utilized under certain circumstances with favorable outcomes (Loomer, et al., 1980;Testa, et al., 2017).

1.2 Problem Statement

FSF are a major cause of morbidity and mortality, with massive socioeconomic impact at the national, community, family and individual level in this country. FSF account for 17% of musculoskeletal injuries (Bach, 2004). There has been a rising trend in the number of hospital admissions for FSF at MTRH causing increasing financial burden to the families and the country as shown in the table below:

Table 1: Rising trend in the number of hospital admissions at MTRH

Year	FSF
2010	89
2011	123
2013	129
2017	207

FSF have been managed at MTRH over the years with an ever-increasing burden. Since FSFs have a massive socioeconomic impact at the individual, family, community and national level, it is imperative that this research be conducted to give highlights on the issues stated in the objectives of the study. These musculoskeletal injuries are often associated with a disability, high morbidity and mortality with a huge socioeconomic burden (Siqueira, et al., 2005). In Kenya over 12,000 cases do occur annually (Muchene, 2015). Approximately 26,000 vehicle crashes are reported causing over 3,000 fatalities and 9,000 serious injuries such as FSFs.

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1.3 Justification

There is paucity of data in the etiology, morphology, treatment modalities and early outcomes of these fractures. This study therefore sought to establish the etiology, morphology, treatment modalities employed and the early clinical outcomes of FSF as managed at MTRH.

I. Well-defined etiology and corresponding morphology of fractures will help highlight possible areas of primary prevention and the need to strengthen existing mechanism to prevent FSF.

The treatment modalities and the early clinical outcomes of this treatment will help provide data to doctors and other healthcare personnel on the variable outcomes of FSF management and eventually improve patient care at MTRH. The paucity of knowledge in this area shall be addressed to a certain degree and data from this study will also be compared with that from other studies and other countries. Future studies on FSF can also be based on the data realized from this study.

1.4 Research Question

What is the etiology, morphology, treatment modalities and early outcomes of Femoral Shaft Fractures in adult patients seeking treatment at MTRH?

1.5 Research Objectives

1.5.1 Broad objective

To determine the etiology, morphology, treatment modalities and early outcomes of Femoral Shaft Fractures in adult patients seeking treatment at MTRH.

1.5.2 Specific objectives

1. To describe the etiology of FSF in adult patients presenting at MTRH.
2. To outline the morphology of FSF in adult patients presenting at MTRH.
3. To describe the treatment modalities of FSF in adult patients at MTRH.
4. To outline the early outcomes of FSF presenting to MTRH.

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CHAPTER TWO

2.0 REVIEW OF LITERATURE

2.1 Introduction

2.1.1Definition of Femoral Shaft

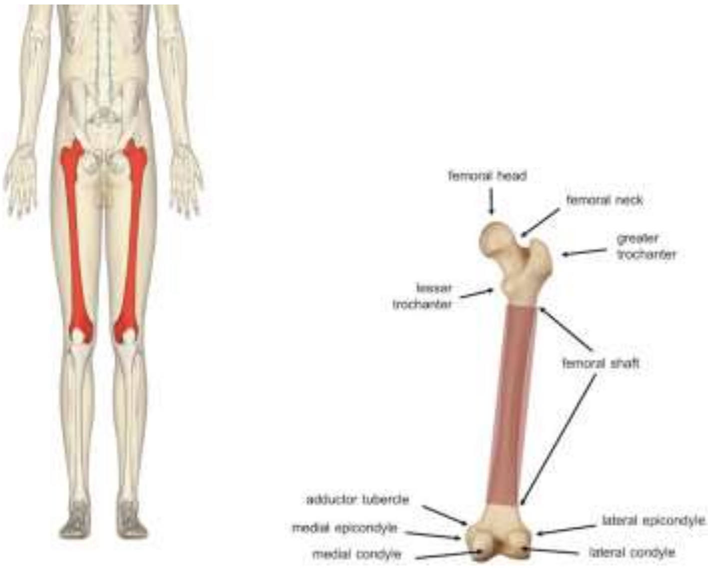

Figure 1: Femur

The length of a tubular human femur is about one fourth of the height of a person (Moore, 2009). The skeletal maturity of the adult type of femoral diaphysis can be judged by the age of the patient, which usually has been 17years or older in studies concerning femoral shaft fractures in adults (Kootstra, 1973), but more definitely by the closed (mature) growth plates (Hedlund & Lindgren, 1986).

The proximal end of the femur consists of the head, the neck, the greater trochanter, and the lesser trochanter. The distal end of the femur has medial and lateral condyles. The proximal and distal parts widen into metaphyseal sub trochanteric and supracondylar regions(Bucholz & Jones, 1991; Healey, 1969; Moore 2009;Platzer, 2003). The designation femoral shaft fracture denotes that the fracture situates entirely on the femoral diaphysis.

The definition of the diaphysis measured from the anteroposterior (AP) radiographs has varied (Dencker, 1963; Kootstra, 1973;Leighton & Trask, 2009).

The femoral shaft is;

1. The portion of the bone between the proximal boundary of 4 inches (10.16 cm) from the tip of the greater trochanter and the distal boundary of 4 inches (10.16 cm) from the end of the femoral medial condyle (Salminen, et al., 2000);
2. The distance between 5 cm distal to the lesser trochanter and 6 cm proximal to the most distal point of the medial femoral condyle (Dencker, 1963)
3. The diaphyseal section between the boundaries of the lower edge of the lesser trochanter and of a line which parallels the joint space of the knee at a distance equal to the width of the condyles (Kootstra, 1973);
4. The part of the femur between 10 cm distal to the lesser trochanter and 15 cm proximal to the knee joint line (Hedlund, 1986);
5. The portion of bone between a point 5 cm distal to the lesser trochanter and 8 cm proximal to the adductor tubercle (Salminen, et al., 2000).

2.1.2 Anatomy of Femoral shaft

The femoral shaft has a physiologic anterior curve (Dencker, 1963); Kootstra, 1973; Thorek, 1962), which can increase in certain pathologic conditions, such as fibrous dysplasia or Paget’s disease (Bucholz & Jones, 1991; Whittle, 2003)

The external circumference of the femur is triangular exhibiting three surfaces: anterior, lateral, and medial surfaces (Healey, 1969; Kootstra, 1973; Platzer, 2003; Thorek, 1962).

The femur has an anterior curve making the anterior cortex the tension side and the posterior cortex the compression side. The cortex posterior is also thicker while that posterior is thicker. This affects the mechanics of intramedullary nails as they have a wider radius of curvature than the femur. It may also lead to anterior thigh pain as has been documented. Posteriorly, where the fascia inserts to the linea aspera, a two-lipped roughened line (Bucholz & Jones, 1991;Healey, 1969). The medial and lateral lips of the linea aspera diverge proximally and distally, the lateral lip becoming continuous proximally with the gluteal tuberosity (Platzer, 2003;Thorek, 1962). The medial lip extends up to the undersurface of the femoral neck (Platzer, 2003).Lateral to this lip is a ridge, the pectineal line, descending from the lesser trochanter. Both proximally and distally the femoral shaft loses its triangular form and becomes four-sided (Platzer, 2003). The medullary cavity varies in diameter and shape (Healey, 1969; Kootstra, 1973; Moore, 2009). Slightly proximal to the midshaft is the isthmus, where the circular medullary cavity is its narrowest with a diameter of 8 mm to 16 mm compared with the otherwise more oval medullary canal (Dencker, 1963). This may lead to fractures at the sub trochanteric level when the retrograde nail used does not cross this section.

The thigh extends superficially from the inguinal ligament anteriorly and the gluteal skin fold posteriorly to the knee level (Healey, 1969; Thorek, 1962). Superficial fascia contains cutaneous nerve branches from the lumbar plexus (the lateral femoral cutaneous nerve), the femoral nerve (the anterior and medial femoral cutaneous nerves), the obturator nerve (medial aspect of the thigh), and the genitofemoral nerve (the lumbo-inguinal branch). The included arteries are the superficial circumflex iliac, the superficial inferior epigastric, and the superficial external pudendal arteries branching from the common femoral artery. The great saphenous vein has the ramifications of the superficial circumflex iliac, the superficial inferior epigastric, and the superficial external pudendal veins at the region (Healey, 1969). On the posterior side of the femoral diaphysis attach the pectineus, adductor brevis, adductor magnus, adductor longus, and gluteus maximus muscles. From the femoral shaft originate muscle vastus lateralis (upper half of the intertrochanteric line), vastus medialis muscle (medial lip of linea aspera and spiral line of femur), vastus intermedius muscle (anterior and lateral aspect of upper two thirds of femoral shaft), the short head of biceps femoris muscle (linea aspera and lateral supracondylar line of femur), and articularis genus muscle(Healey, 1969; Kootstra, 1973; Thorek, 1962). The muscles of the thigh are encased by dense fibrous tissue (Healey, 1969; Kootstra, 1973;Moore, 2009).The fascia lata reinforces the lateral aspect to form distally the iliotibial tract (Kootstra, 1973; Platzer, 2003;Thorek, 1962), which on the lateral side extends to the Gerdy's tubercle of the tibia (Platzer, 2003).

The thigh contains three distinct fascial compartments. The anterior compartment encases the knee extensor muscles (quadriceps femoris including rectus femoris, vastus intermedius, vastus medialis, and vastus lateralis; and Sartorius) innervated by the femoral nerve from the lumbar plexus L 2-4 for the quadriceps femoris and L 2-3 for the Sartorius (Healey, 1969; Kootstra, 1973;Moore, 2009; Platzer, 2003). The rectus femoris muscle is also a weak flexor of the hip (Marongiu, et al., 2020; Platzer, 2003). The Sartorius flexes, abducts, and medially rotates the thigh (Healey, 1969; Kootstra, 1973;Moore 2009;Thorek, 1962).

The anterior compartment also includes the tensor fascia lata, the iliacus and psoas major muscles, and the femoral artery and vein, femoral nerve, and lateral femoral cutaneous nerve (Moore, 2009).The medial compartment contains the adductor muscles (gracilis, adductor longus, adductor brevis, adductor magnus, pectineus) and the obturator externus muscle, which are supplied by the obturator nerve(Healey, 1969;Kootstra, 1973; Moore, 2009; Platzer, 2003;Thorek, 1962).The pectineus and

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the adductor magnus muscle receive dual innervation: the former from the femoral nerve and the latter from the sciatic nerve (Kootstra, 1973;Platzer, 2003). The medial compartment also includes the deep femoral artery, obturator artery and vein, and obturator nerve.

The posterior compartment includes the flexor muscles (biceps femoris, semitendinosus, and semimembranosus), which extend the hip, and a portion of the adductor magnus muscles, as well as branches of the deep femoral artery, sciatic nerve, and posterior femoral cutaneous nerve. The posterior knee flexor group is innervated by the sciatic nerve (Healey, 1969;Thorek, 1962). The biceps femoris extends, adducts and laterally rotates the thigh, as well as flexes the lower leg (Healey, 1969; Platzer, 2003;Thorek, 1962). The long head of the biceps femoris is innervated by the tibial nerve (L5-S2), and the short head receives innervation from the common peroneal division (S1-2) (Platzer, 2003). The semimembranosus and semitendinosus muscles also act as medial rotators of the thigh (Healey, 1969;Thorek, 1962), and are innervated from the tibial nerve (L5-S2) (Platzer, 2003). The intermuscular septum between the anterior and posterior compartments is thicker than the septa between the medial and anterior compartments (Bucholz, 2010;Platzer, 2003). Because of the high volume of these three compartments, compartment syndrome of the thigh is much less common than that of the lower leg (Bucholz, 2010).The arterial supply of the femur is mainly derived from the deep femoral artery (profundal femoris artery) (Bucholz R & Bucholz, 2010) Healey, 1969;Thorek, 1962).

From its branches, the lateral circumflex femoral artery, among others, supplies blood to the extensor muscles, while other proximal branches provide vascular supply to the adductor muscles, and more distally, three perforating arteries supply the flexor muscles (Kootstra, 1973). The muscular branch of the superficial femoral artery supplies blood to the vastus medialis muscle (Kootstra, 1973).

The femoral shaft has periosteal and endosteal bloods supply(Gebhard & Huber-Lang, 2008). The endosteal circulation of the femoral diaphysis is predominantly derived from a nutrient artery that branches from the first perforating branch of the deep femoral artery (Brookes, 1971; Gebhard & Huber-Lang, 2008), enters the bone proximally and posteriorly through a nutrient foramen in the middle of the diaphysis near the linea aspera, and arborizes proximally and distally (Bucholz, 2010;Gebhard & Huber-Lang, 2008). Very seldom, a second nutrient artery exists distally, but no major artery enters the lower third of the shaft (Gebhard& Huber-Lang, 2008). Under normal physiologic conditions, the circulation is endosteal to the inner two thirds to three quarters of the cortex (Rhinelander, 1998), and periosteal to the outer one quarter of the cortex (Bucholz, 2010). Endosteal circulation anastomoses with the numerous small periosteal vessels that are derived from the adjacent soft-tissues (Kootstra, 1973). The periosteum is protected from complete vascular disruption by an extensive collateral circulation and perpendicularly orientated vessels, which seldom undergo major stripping with the exception of severe open injuries or perioperative injuries that can possibly result in delayed fracture healing (Bucholz, 2010; Kootstra, 1973).

The normal blood flow is centrifugal (Brookes, 1971), although some blood returns to the large venous sinusoids of the medullary canal. After diaphyseal fractures, the circulatory pattern is altered (Trueta, 1955). In a non-displaced fracture of the shaft, the endosteal supply can be relatively undisturbed and remains dominant, whereas displacement results in a complete disruption of the medullary vessels. Proliferation of the periosteal vessels is the paramount vascular response to a fracture, and the rapidly enhanced periosteal circulation is the primary source of cells and growth factors for healing. The medullary blood supply is eventually restored during the healing process (Bucholz, 2010; Trueta, 1955). Preservation of the muscle envelope around the fracture enhances revascularization of the injured bone and promotes periosteal callus formation.

2.2 Social demographic characteristics

The annual incidence of Femoral shaft fractures is approximately 37.1 per 100,000 person-years (Enninghorst, et al., 2013). The incidence peaks among the young, decreasing after age 20, and then again in the elderly (Hedlund & Lindgren, 1986). A marked increase occurs in those over 75 years of age. The mean age is 31.5years (Kamau, 2014; Opondo, et al., 2013), and this is the young and aggressive population. Males are usually more affected than females and this has been demonstrated in other studies such as Anyaehie, et al., 2015 at 63.7% and Opondo, et al., 2013 at 77.7% . Majority of the Kenyan population (80%) are in the informal employment as seen by the Institute of Economic Affairs in Kenya while a paltry 20% are formally employed(*Institute of Economic Affairs*, 2016)

2.3 Etiology of Femoral Shaft Fractures

The causative violence of FSF can be divided into high energy injuries: motor vehicle accidents, auto-pedestrian accidents, motorcycle accidents, falls from a height and gunshot wounds as well as low energy injuries: slipping or stumbling at ground level, falls from the height of less than one meter, and most sports injuries. FSF, like other long bones of the body, occur as a result of direct or indirect violence (Hedlund & Lindgren, 1986) or muscular action (Bucholz R & Bucholz, 2010)

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Road Traffic accidents are responsible for 57-74% of all femoral shaft fractures (Dencker, 1963; Kootstra, 1973), while the remaining fractures consist of occupational injuries and domestic accidents. The latter have mostly involved elderly patients with 65% of patients aged 70 years or older who got injured at home (Kootstra, 1973). It could also be attributed to undiagnosed conditions such as tumors that could lead to pathological fractures (Arneson, et al., 1988).

In the Kootsra study carried out in Sweden (n=329) the results were as follows:

Table 2: Distribution of injury mechanisms causing FSF in Adults

Injury type		**No. of Fractures**	**%**
	Details	242	73.6
Traffic	On foot	28	8.5
	On two wheels	130	39.5
	In car	84	25.6
Occupational		32	9.7
	Direct	16	4.9
	Indirect	14	4.2
	Sports	2	0.6
Domestic(stumbling)		46	14
Unclassified		9	2.7
Total		329	100

In the same study there is a gender-specific distribution of femoral shaft fractures and has significantly varied according to the accident type: 82% of men sustained a femoral shaft fracture in a traffic accident, 13% at work, and only 5% at home, whereas, of women, none was injured at work, 53% in a traffic accident, and 47% at home (Kootstra, 1973).

A study done in Nigeria (Anyaehie, et al., 2015) found that the commonest etiological factor was Road Traffic Accidents and this is similar to another study done in Kenya (Njoroge, et al., 2013). Among the road traffic accidents , motorcycles are one of the leading causes as seen in another study in Kenya (Bundi, et al., 2015). This is due to the rise in use of motorcycles as means of public transport in the developing world

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(Khanbhai & Lutomia, 2012). It could also partly be attributed to poor adherence to road traffic rules and regulations and even reckless riding (Matheka, et al., 2015). The motorcycle- related road traffic crashes in Kenya in terms of facts, figures and even prevention have been documented by the WHO and Ministry of Health, 2019.

2.4 Fracture Morphology

Numerous fracture classifications have been proposed over the past decades. Most tend to be descriptive in nature and are based on the following criteria:

i. Open versus closed injury;
ii. Involvement of the proximal, middle, or distal thirds;
iii. The fractures can be simple, wedger or Complex;
iv. The number and position of fragments, such as comminution or butterfly fragments;
v. Varus, valgus, anterior, or posterior angulation;
vi. Displacement of the fracture;
vii. Rotation;
viii. Laterality of the fracture and
ix. Associated injuries.

The right limb is usually more affected than the left as seen in a study in India (Deepak, et al., 2012) and another in Kenya (Njoroge, et al., 2013).

The most commonly used classification of FSF is the Orthopedic Trauma Association (OTA) classification initially described by the AO group (Müller, et al., 1990). This is a classification based on radiographs in anterolateral and lateral views (*see Appendix 7*). Type A fractures are the majority at 77% of all FSF (Salminen, et al., 2000).The most commonest level affected is the mid third of the shaft (Deepak, et al., 2012)

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A separate study done in Nigeria found that the most occurring pattern in high energy trauma is comminuted fractures(AO 32-C) in the midshaft of the femur (Anyaehie, et al., 2015).

Generally, there are more Closed fractures than Open fractures and both are classified (Yongu et al., 2012) differently.

Open fractures are most commonly classified according to Gustilo-Anderson classification proposed in 1976 (Kim & Leopold, 2012) and modified in 1984 (Gustilo, et al., 1984) subdivides open wounds into three main categories: (*see Appendix 8*).

This system captures the size of the wound (1cm, 1-10cm,>10cm), the level of energy involved (low energy, high energy), the amount of soft tissue coverage (adequate or requires flaps) and the level of wound contamination (clean, contaminated, clean contaminated and dirty). Gustilo I fractures have far better outcomes than the more severe fractures (Salminen, et al., 2000).

Closed fractures can be classified according to Tscherne and Oestern Classification (Ibrahim, et al., 2017) that was introduced in 1982 in Germany (*See Appendix 9)*. This is usually pegged on the extent of soft tissue abrasions and contusions, the radiologic features of the fracture, the presence of closed degloving injuries, the rupture of major blood vessels, and the presence of a compartment syndrome. Closed fractures occur more frequently than open fractures in most studies and could be as high as 80% (Moraes, et al., 2009). Closed FSF also have acceptable low infection rates following intramedullary nailing (Galvin, et al., 2015).

2.5 Treatment Modalities

Generally, two modalities of treatment for a femoral fracture are in use. These modalities are either non-operative or operative. Fracture stabilization is applied after the patient stabilization following the Acute Trauma Lifesaving Protocols (James Dennis & Pennardt, 2020).

Non-operative treatment of femur fractures is no longer the preferred method of treatment but may be used in certain circumstances. This may include use of traction (skeletal of skin traction); This methods could be used as a temporary measure before operative definitive fixation or could be used as definitive treatment (James Deeptiman, 2015).

Currently, operative treatment is indicated for most femur fractures because of the high rate of union, low rate of complications, and the advantage of early fracture stabilization, which decreases morbidity and mortality in patients (especially polytrauma patients) with these fractures (Berezka, et al., 1991;Tscherne, et al., 1998).

Intramedullary nailing is the criterion standard for treating FSF. Antegrade reamed intramedullary nail is the gold standard (Ricci, et al., 2009; Wolinsky, et al., 1999). Reamed intramedullary nailing of femoral shaft fractures results in a low rate of nonunion, malunion, infection, and hardware failure. It is ideal for fracture stabilization (Winquist, 1993). The exposure is small and soft tissue damage is limited. Retrograde intramedullary nailing can be used as an alternative to Antegrade intramedullary nailing (Gogna & Singla, 2013;Watson & Moed, 2002).

Plating remains a viable surgical option for femoral shaft fractures and can be employed for selected fractures such as cases of atrophic non-union (Lai, et al., 2019).

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Itis also applicable in situations where intramedullary nailing is not feasible e.g., in patients with very narrow canals or those with associated distal femur fractures.

External fixation is a common method of treating some types of femoral shaft fractures. It is especially useful in polytrauma patients for definitive fracture stabilization with minimal additional operative treatment balanced with acceptable complication rates (Testa, et al., 2017). The timing of definitive fixation for major fractures in patients with polytrauma is controversial. One school of thought advocates for early total care whereas another advocates of initial damage control orthopedics followed by definitive fixation after the patients is more stable for surgery. Damage control orthopedics in polytrauma patients is one area where External Fixators are utilized before final conversion to definitive management (Mathieu et al., 2011; Pape, et al., 2007).

External fixation is the treatment of choice for patients with Gustilo IIIB or IIIC open fractures in which vascular surgery is needed (Saitta, et al., 2019). In the patients who are unstable and surgery cannot be performed immediately, the external fixator can be used akin to damage control orthopedics (Mathieu, et al., 2011). External fixators are also ideal during mass casualties as seen in Major road/rail accidents and during wars (Mohr, et al., 1995).

2.6 Early outcomes

The outcomes following treatment are largely dependent on the degree of injury, time to definitive treatment, associated injuries, patient co-morbidities and treatment modalities. The outcomes of Femur shaft fractures have been seen to be generally good to excellent. A study in India found favorable outcomes in patients treated with intramedullary nailing with union rates as high as 96.6% (Deepak, et al., 2012). This was also seen in a Kenyan study that showed good to excellent outcomes at 95.2% with Intramedullary nailing that was done with either antegrade or retrograde nailing. It however found that there was significantly higher rates of knee pain associated with retrograde (37.5%) as opposed to antegrade (10%) intramedullary nailing (Njoroge, et al., 2013).

Outcomes with plate osteosynthesis using AO compression plates has also been seen to give good results. A study by Loomer *et al* in Vancouver showed good results in 88% of all patients and 100% in patients who did not have complications. The complication rates was at 24% and was due to failure of plates and screws, refracture after plate removal, periprosthetic fracture and infection (Loomer, et al., 1980).

The most common complication across the studies is Infection. This is more so in open fractures (especially Gustilo III fractures). Systematic review of 17 studies found that infection was the commonest at 11.6% (deep infection at 6% and superficial infection at 5.6%) and were more prominently seen in Gustilo type III fractures. Other complications were delayed union(3%) and malunion(8.4%) (Saleeb, et al., 2019). A local study at MTRH on outcomes of open Gustilo I and II injuries of both the femur and tibia shaft fractures after intramedullary fixation with Sign Nails showed an infection rate of 6.9% topping the complications (Lelei, et al., 2010). This was followed by broken nails (1.2%) and failed distal locking (0.6%).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study setting

The study site was Moi Teaching and Referral Hospital, Eldoret, Uasin Gishu County. This is a national teaching and referral hospital and the largest hospital in Western Kenya.

Moi Teaching and Referral Hospital offers a wide range of health services in its Out-Patient and In-Patient sections. The hospital has a bed capacity of 1000. The facility boasts of highly trained and specialised medical staff from both the hospital and its associated training institution, College of Health Sciences, Moi University. The hospital's catchment regions include North Rift Region, Western Kenya, parts of Eastern Uganda and Southern Sudan with a population of at least 20 million people. The hospital also hosts students from Moi University, Kenya Medical Training College (KMTC), University of East Africa, Baraton, and the Moi Teaching and Referral Hospital Training Center. It also boasts of an exchange program for both visiting lecturers and students from the USA.

The hospital has a very busy department of surgery with the orthopedic department being one of the busiest of the surgical departments with dedicated 24-hour Trauma theaters and several other elective theaters. There are at least 15 operating Orthopedic surgeons and 30 trainee orthopedic surgeons(Moi Teaching and Referral Hospital, 2013).

3.2 Study design

This was a hospital-based prospective study carried out between March 2018 and March 2019.

3.3 Study population

All the adult patients with FSF seeking treatment at MTRH.

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3.4 Eligibility

3.4.1 Inclusion criteria

Adult Patients diagnosed with isolated femoral shaft fractures seeking treatment at MTRH

3.4.1 Exclusion Criteria

Patients with serious life-threatening comorbidities and those whose definitive treatment was done elsewhere were excluded from the study.

3.5 Sample Size determination

The Cochrane formula(Cochran, 1977) for getting a sample size was used . The prevalence of FSF in this setup is not established and therefore a proportion of 50% was used to calculate the sample as follows:

- Sample size:
  - Cochran Formula (Cochran, 1977): $\mathbf{n_0 = Z^2pq / e^2}$
    - p taken as 0.5
    - $n_0 = ((1.96)^2\ (0.5)\ (0.1)) / (0.05)^2 =$ **385.**
  - Modification for small study population (<10,000): $\mathbf{n = n_0 / (1 + ((n_0 - 1) / N))}$
    - Approximate no. of patients presenting with FSF at MTRH = 207/year (2017 data)
    - n = 385 / (1 + (385/207)) = 135.
    - Adjustment for potential loss to follow-up: 110% of 135 = 149
  - Sample size of **149** used

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3.6 Data collection tools

The study tool was an interviewer administered questionnaire which was designed by the researcher. The questionnaire had questions on patient's socio-demographic factors, etiology of injury, fracture morphology and treatment modalities. Morphological classification of the fracture was also documented as discerned from the radiological investigation and clinical evaluation. At the end of three months the AAOS Lower Limb questionnaire (see Appendix4) was administered and standardized scores assigned.

3.8 Quality Control

Development of questionnaire and pre-testing of the questionnaire was carried out. Review of data after collection to check for missing data and unclear parts, cleaning of data and counter checks on data entry was done.

3.9 Research Procedure

Respondents who met the selection criteria were identified in the orthopedic wards and enrolled into the study. Informed consent was obtained and a structured questionnaire was administered by a trained research assistant. Clinical and radiological assessment was done before surgery and another one immediately following definitive treatment. Patients were reviewed at three months and lower limb function was assessed using the AAOS Lower Limb Score.

3.8 Data analysis and presentation

Data analysis was done using Statistics and data software program (Statistical Analysis System version 9.1). Categorical variables were summarized as frequencies and the corresponding percentages while continuous variables that assume Gaussian distribution were summarized as mean and the corresponding standard deviation

(SD). Continuous variables that violated the Gaussian assumptions were summarized as median and the corresponding inter quartile range (IQR). Association between categorical variables was assessed using Pearson's Chi Square test and Fisher's exact test. Results were summarized as tables, graphs, charts and figures.

3.10 Ethical considerations

To carry out the study, permission was sought and granted from the Institutional Research and Ethics Committee (IREC) and Hospital Administration evidenced by the attached Approval letters in the Appendices Section. Informed consent was sought from all eligible patients in a language that they fully understood and his/her written consent sought. Any risks or benefits accrued to the research were explained to each patient. This was voluntary participation and no patient was denied treatment whether she/he gave consent or not. Utmost confidentiality with regards to the patients was assured. The patients had the leeway to withdraw from the study at any stage even after consenting and this did not affect their medical care. The research finding was compiled into a thesis which has been submitted in partial fulfilment of the requirements for award of Master of Medicine in Orthopedic Surgery Program.

3.11Potential risks

The likelihood of leakage of patient information was mitigated by de-identification of the patients.

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CHAPTER FOUR

4.0 RESULTS

4.1 Sociodemographic Characteristics

A total of 137 patients with 149 FSF were recruited into the study with 12 having been lost to follow-up.

Table 3: Demographic characteristics (overall n=137)

Variable	Category	Frequency	Percentage
Age	Median (IQR)	36 (28, 53)	
Sex	Male	72	**52.55**
	Female	65	47.45
Occupation	Informal	108	**78.83**
	Unemployed	21	15.33
	Formal	8	5.84
Education level	None	4	2.92
	Primary	17	12.41
	Secondary	71	**51.82**
	College	45	32.85

The table above shows the demographic characteristics of the study population. The median age was 36 (IQR: 28, 53) years with a range of 18 to 86 with 52.5% being male. Majority (78.8%) were informally employed while most had attained secondary level education at 51.82%.

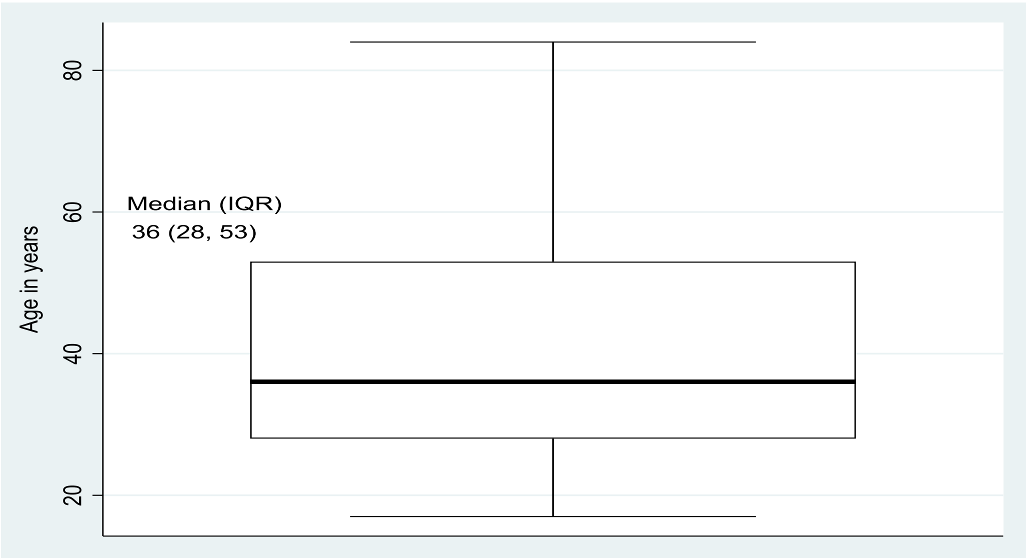

Figure 2: Age distribution (n=137)

4.2 Etiology

Table 4: Etiology of fractures n=137

Cause	Circumstance	Frequency	Percentage
Motor vehicle accident	Passenger	39	88.64
	Driver	3	6.82
	Pedestrian	2	4.55
	TOTAL	**44**	**32%**
Motorcycle accident	Passenger	21	47.73
	Rider	18	40.91
	Pedestrian	5	11.36
	TOTAL	**44**	**32%**
Fall	Trivial fall	9	45.00
	Down Gradient	7	35.00
	From height	4	20.00
	TOTAL	**20**	**15%**
Assault	Direct blows	10	62.50
	Gunshot	6	37.50
	TOTAL	**16**	**12%**
Sports		12	**9%**
Bicycle	Pedestrian	1	**<1%**

The table above shows the etiology of the FSF as shown in the study. There were 88 (64%) FSF caused by Road Traffic Accidents both motor vehicle and motorcycle. A further 20(15%) FSF were caused by falls while another 16(12%) were due to assault. Of those assaulted 6(37.5%) were due to gunshots.

4.3 Fracture morphology

Table 5: Fracture morphology n=149

Variable	Category	Frequency	Percentage
Fracture characteristic	Closed	79	53.02
	Open	70	46.98
Fracture laterality	Right	89	64.96
	Left	36	26.28
	Bilateral	12	8.76

The table above shows various fracture characteristics. Closed fractures were 79(53%) while 70(47%) were Open. Right sided FSF were the majority at 89(65%) while left sided were at 36(26%). There were 12(9%) bilateral FSF.

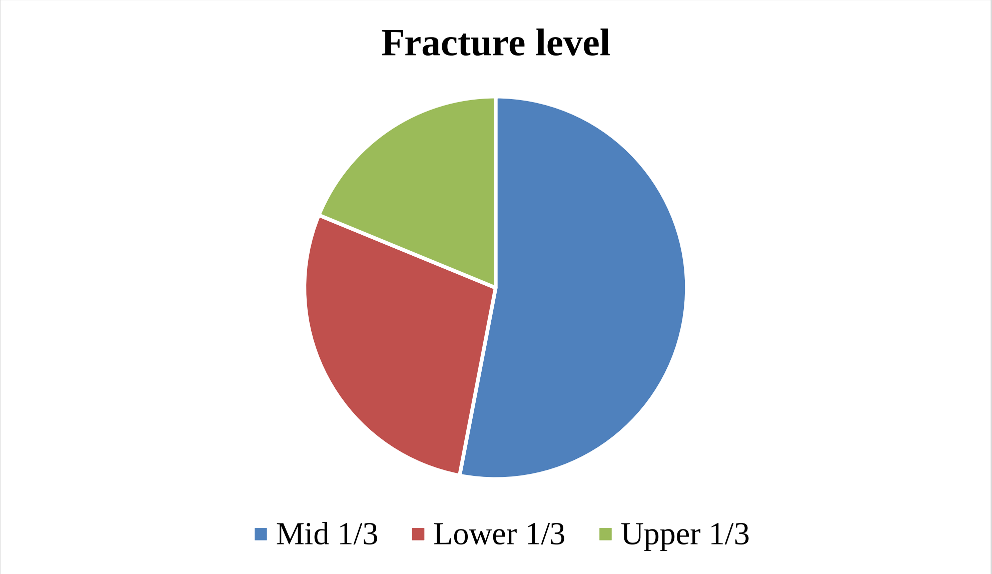

Figure 3: Level of fracture along the shaft

The figure above shows that a majority of the fractures, 79(53%) were at the Mid-shaft level whereas the Upper 1/3 was least affected at 28(18.8%).

Table 6: Fracture classification

Classification		**Frequency**	**Percentage**
AO/OTA Classification	Spiral	20	26.32
AO32 A: Simple (n=76)	Oblique	32	42.11
	Transverse	24	31.58
AO32B: Wedge (n=56)	Bending	29	51.79
	Spiral	15	26.79
	Fragmented	12	21.43
AO32C: Complex (n=17)	Spiral	5	29.41
	Segmented	12	70.59
Gustilo Classification	I	21	30
(Open fractures): n=70	II	38	54.29
	IIIA	11	15.71
Tscherne Classification	Grade 0	35	44.3
(Closed fractures): n=79	Grade 1	41	51.9
	Grade 2	3	3.8

Table above shows the different classifications used to characterize the fractures. In the AO/OTA classification for diaphyseal fractures, simple fractures were 76(51%) while Complex fractures were the least at 17(11%). The open fractures were mostly Gustilo II at 38(54%) with Gustilo III being the least at 11(16%). Closed fractures (Tscherne Classification) were most commonly classified as Grade 1 at 41(52%) and least classified as Grade 2 which were 3(<1%).

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4.4Treatment Modalities

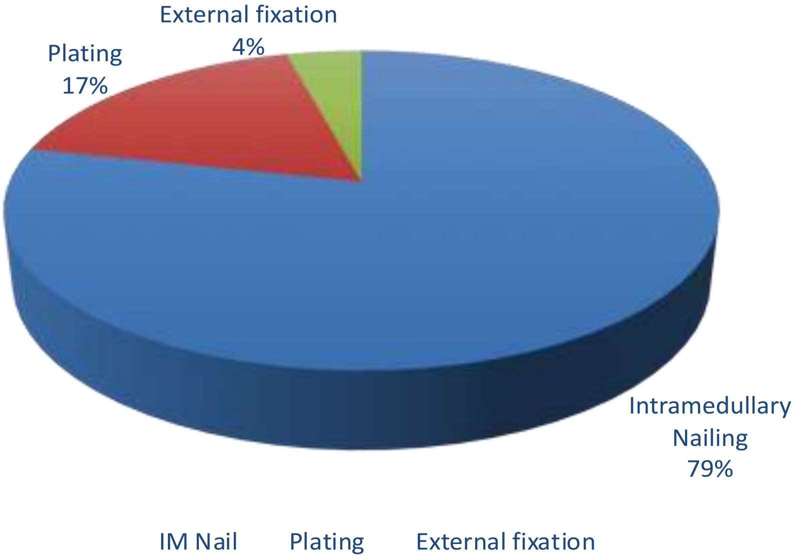

Figure 4: Treatment modalities

As seen in the chart above, most FSF (79%) were treated with intramedullary nails (all intramedullary nails were considered) followed by Plating at 17% and external fixation at 4%.

4.5 Early Outcomes

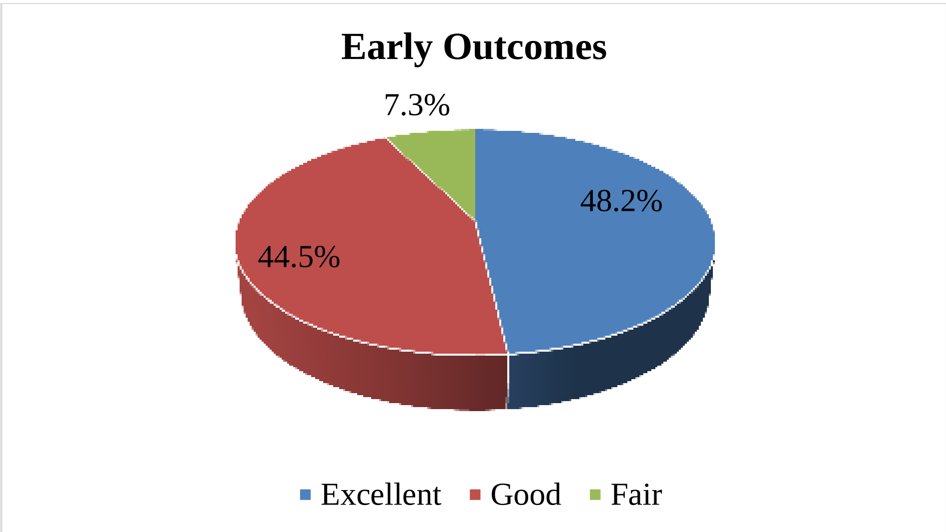

Figure 5: Early outcomes of FSF

As shown above, excellent outcomes were seen in 66(48.2%) of the patients followed by 61(44.5%) with Good Outcomes and 10(7.3%) with Fair outcomes. No patients had Poor outcomes.

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Table 7: Association between the AAOS score and other variables
Level of significance is a ***p***-value of <0.05

Variable	**Category**	**Fair**	**Good**	**Excellent**	***p*-value**
Gender	Male	5 (6.8%)	40 (54.8%)	28 (38.4%)	**0.027**[f]
	Female	5 (7.8%)	21 (32.8%)	38 (59.4%)	
Treatment modality	Plating	5 (20.8%)	13 (54.2%)	6 (25.0%)	<**0.001**[f]
	IM nail	2 (1.9%)	47 (43.5%)	59 (54.6%)	
	Exofix	3 (60.0%)	1 (20.0%)	1 (20.0%)	
Morphology	Wedge	5 (9.4%)	21 (39.6%)	27 (50.9%)	0.364[f]
	Simple	4 (5.8%)	30 (43.5%)	35 (50.7%)	
	Complex	1 (6.7%)	10 (66.7%)	4 (26.7%)	
Fracture characteristic	Closed	6 (8.3%)	34 (47.2%)	32 (44.4%)	0.666[f]
	Open	4 (6.2%)	27 (41.5%)	34 (52.3%)	
Gustilo Classification	I	1 (5.3%)	5 (26.3%)	13 (68.4%)	**0.013[f]**
	II	1 (2.8%)	15 (41.7%)	20 (55.6%)	
	III	2 (20.0%)	7 (70.0%)	1 (10.0%)	
Tscherne Classification	Grade 0	1 (3.1%)	14 (43.7%)	17 (53.1%)	0.477[f]
	Grade 1	5 (13.5%)	18 (48.6%)	14 (37.8%)	
	Grade 2	0 (0.0%)	2 (66.7%)	1 (33.3%)	

[f] Fisher's Exact Test; [c] Chi Square Test; Wilcoxon rank sum Test

The table above seeks to establish the association between Outcome scores as per the AAOS Lower Limb score and that of various other variables. The study found a statistically significant association between the sex of patients with females having more numbers with a Good and Excellent outcome as opposed to males. Trivial falls leading to FSF were more common with the female gender giving higher AAOS score. The treatment modality also showed significant correlation. The use of IM Nails preferentially conferred higher scores (Good to Excellent) compared to other modalities. The study found that the lower the Gustilo grade the higher the AAOS scores, thus better scores with smaller wounds. This concurs with another study (Salminen et al., 2000) that found similar outcomes. There was no statistically significant association when compared to the other variables i.e. Tscherne Classification, open versus closed fractures and morphology.

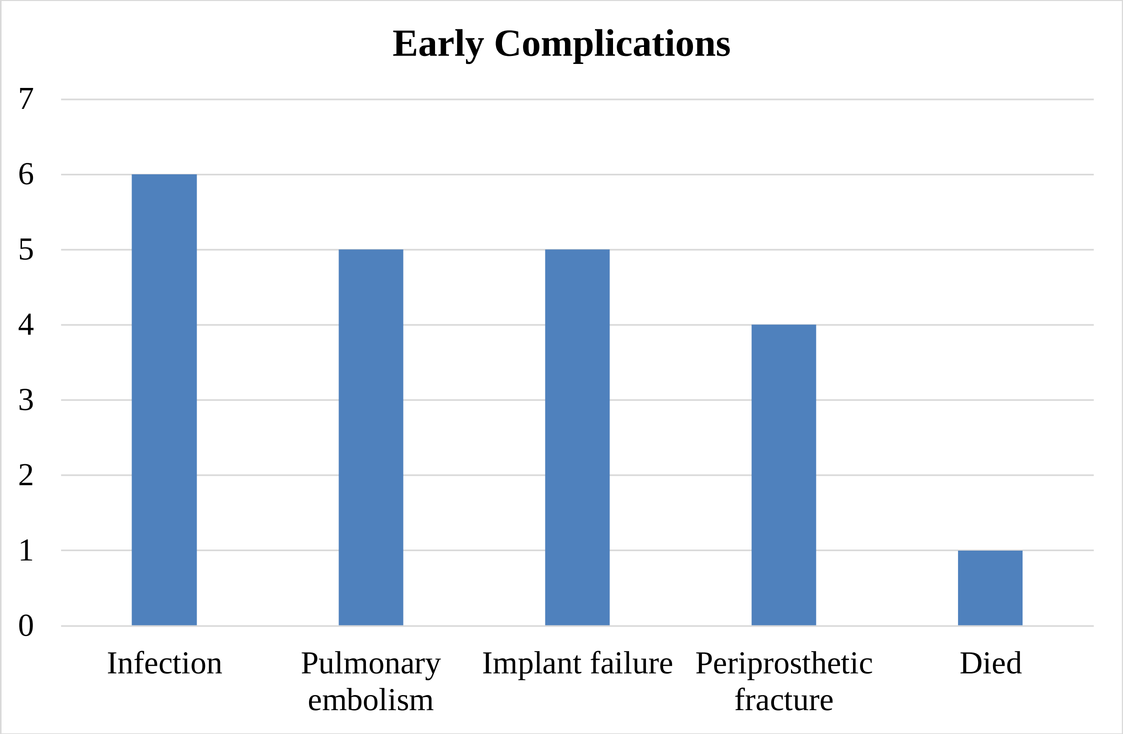

Figure 6: Early complications

The complication rate was at 15.1% (n=137). Infection was highest at 6 (29%) followed by Pulmonary embolism at and implant failure each with 5 cases (24%) while there was only one death (5%).

Table 8: Association between Early Complications and other variables

Variable	Category	No complications	With complications	p-value
Age	Median (IQR)	35.5 (28, 49.5	38 (33, 54)	0.201[w]
Gender	Male	60(82.2%)	13(17.8%)	0.390[c]
	Female	56(87.5%)	8(12.5%)	
Education level	None/Primary	20(95.2%)	1(4.8%)	0.200[f]
	Secondary	68(87.2%)	10(12.8%)	
	College	28(73.7%)	10(26.3%)	
Etiology	RTA	21(70.0%)	9(30.0%)	-
	Fall	20(100%)	0	
	Assault	2(33.3%)	4(67.7%)	
	Sports	12(100%)	0	
Fracture characteristic	Closed	59(81.9%)	13(18.1%)	0.351[c]
	Open	57(87.7%)	8(12.3%)	
Morphology	Wedge	49(92.5%)	4(7.5%)	**0.002**[f]
	Simple	59(85.5%)	10(14.5%)	
	Complex	8(53.3%)	7(46.7%)	

[f] Fisher's Exact Test; [c] Chi Square Test; [w] Wilcoxon rank sum Test

As shown in the table above, there is a statistically significant association between the fracture morphology and complications. The simple fractures were shown to have a lower rate of complications followed by wedge fractures while complex fractures had a higher complication rate. There is no clinically significant correlation that could be drawn from other variables notably: age, sex, education level, Open versus closed fractures and etiology of fracture.

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CHAPTER FIVE

5.0 DISCUSSION

5.1 Sociodemographic characteristics

In this study, majority of the participants were young with a mean age of 36 (IQR: 28, 53) years. This is in agreement with other studies: In Nigeria, a study found the mean age at 27.2 (IQR:12,68) years (Anyaehie, et al., 2015) and a Kenyan study at 31.5 (IQR: 18,50) years (Kamau, 2014). This could be attributed to the fact that majority of the fractures are due to Road traffic accidents; half of which are due to motorcycles. Majority of the riders are also young males as this is their form of transport and in other cases also form of employment. Young males are generally more aggressive; they are the breadwinners in their families; there are more aggressive and more likely to take part in contact sports.

There were more males (52%) than females (48%). This is in agreement with other studies where 63.7% were male (Anyaehie, et al., 2015) and a male to female ratio of 3.3:1 (Njoroge, et al., 2013). Male dominance may be reflective of a society where the male is largely the provider to the family thus takes more risks in his economic quest. Majority of riders are also seen to be males and this contributes a lot to the Road traffic accidents (Khanbhai & Lutomia, 2012). Those in formal employment are the minority at less than 6% while those unemployed are 15%. This is in agreement with the Kenyan statistics as seen in economic surveys where the majority are in the informal sector(*Institute of Economic Affairs*, 2016).

5.2 Etiology of Fracture

The commonest etiology for FSF was Road Traffic Accidents at 64%. Half of which were due to motorcycle associated injuries and the other half was due to motor vehicle related injuries. This is in agreement with several studies including Anyaehie, et al.,

(2015) at 62.8% and Salminen, et al., (2000) at 68%; being due to an increased use of motorized transportation and especially motorcycles (WHO and Ministry of Health, 2019) and even possibly recklessness and poor road safety practices (Matheka, et al., 2015).

Falls, either from a height or trivial falls, were the second most common etiology at 15% while assault came third at 12%.Trivial fall FSF could be associated with undiagnosed bone pathology among the patients (Arneson, et al., 1988).

5.3 Fracture morphology

The right limb was disproportionately more affected than the left with a ratio of 5:2 whereas there were 12 cases (9%) with bilateral fractures. Similar studies have reported such bias in laterality (Dencker, 1969)which showed statistical significance. Other studies however showed no significance at all (Testa, et al., 2019). This study did not analyze the dominant limb although this bias in laterality could be attributed to the fact that most individuals in the general population had the right side being the dominant side.

Most of the fractures were closed (53%) while 47% were open. A similar study in Nigeria (Yongu et al., 2012) found the difference to be higher at 72.7% for closed FSF and 27.3% for open FSF. The study however did not explain this. This study however, established a statistically significant association between less severe open fractures (Gustilo I) with better functional outcomes. A concurrence with another study such as that done by Salminen, et al., 2000. Among the open fractures, majority (54%) were Gustilo II while minority were Gustilo IIIA. The Closed fractures, under the Tscherne classification, were mostly Grade 0 (44%) while a few were Grade 3 (4%) which is the most severe form. There was no statistical significance between the

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Tscherne classification and any other variable in this study. The majority (53%) of the fractures were found at the middle 1/3 level of the shaft while lower 1/3 was 20.1% and upper 1/3 at 18.8%. This concurs with a study by Salminen, et al., (2000) that found this to be as high as 79%. This could be because the midshaft is the most vulnerable region of the femur after the neck of femur. This midshaft fractures favor the use of intramedullary nails as opposed to use of plates as this is the gold standard.

The fracture morphology that was commonest is the simple fractures (51%) and the least were the complex fractures (11%). The simple Oblique (AO 32 A2) fractures were the biggest proportion. This could be attributed to the to the etiology of simple fractures being both high and low energy as seen in this study

5.4 Treatment modalities

The most commonly used modality was the use of Intramedullary nailing (79%). The one used in the course of this study was the SIGN nail which is a locking solid intramedullary nail. This is the Gold standard for FSF (Winquist, et al., 1984). This has been replicated in similar studies including that by Lelei, et al., 2010.This study found out that the use of reamed intramedullary nail has good union rates and low complications. The use of Plate osteosynthesis is also recommended under certain scenarios and has demonstrated excellent outcomes (Loomer, et al., 1980). In the *Loomer et al* study, it found Excellent outcomes in 88% of the patients and 100% in the patients without complications. This drew the conclusion that plate osteosynthesis can be used in patient who is not amenable to intramedullary nailing. In this study, plate osteosynthesis was applied in 18% of the patients. This was in patients who could not use IM nails due to having narrow canals, lack of appropriately sized nails, patients with associated distal femur fractures or those with pre-existing implants in situ. External fixators as a definitive treatment modality was applied in 6 (4%) of the patients. The use of external fixators has been advocated under special circumstances. It can be used in patients with polytrauma (Pape, et al., 2007). In the study by Testa,et al., (2017), 83 patients with 87 FSF were treated with monoaxial external fixators; all the 87 fractures united at an average period of 23.6 weeks with minimal complications. The study therefore drew the conclusion that External fixation of femoral shaft fractures in polytrauma is an ideal method for definitive fracture stabilization, with minimal additional operative trauma and an acceptable complication rate.

5.5 Early outcomes

The outcomes in this study were assessed using the validated American Academy of Orthopedic surgeons Lower Limb Score and the standardized findings were mostly Good to Excellent at 92%. This concurs with a study done in India where Excellent to Good results were seen in 86.6% of FSF as per modified Klaus and Klemm criteria (Deepak, et al., 2012). The study targeted FSF managed by closed intramedullary interlocking nails. A similar study on FSF analyzed functional knee outcomes following antegrade and retrograde intramedullary nailing and found Good to Excellent outcomes in 95.2% (Njoroge, et al., 2013). In this study, there was a statistically significant correlation between use of intramedullary nails and Good to Excellent outcomes. The favorable outcomes reinforce the superiority of intramedullary nailing for FSF. Plate osteosynthesis was applied to 17% of the patients with FSF and showed Good to Excellent results in 79.2%. This is in agreement with the *Loomer et al* study done in Canada which found Good to Excellent outcomes in 88% of all plated FSF and 100% in those who had no complications (Loomer, et al., 1980). Thus, plating is an acceptable alternative in FSF not amenable to intramedullary nailing.

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There was the use of Exofix in 4% of the FSF and the study showed a statistically significant poorer score compared to the other modalities. The study showed that 60% of FSF fixed with External fixation had a Fair score.

There was a 15.3% complication rate with infection being the leading complication at 28.6%. This was seen in a separate study by Lelei, et al., (2010) where the infection was the leading cause at 7%. This study also found a statistically significant association between fracture morphology and presence of complication whereby, the more complex a fracture was the higher the chances of having complications. Gustilo III fractures also had a higher rate of complications. This concurs with a study in which deep infection, union and non-union following intramedullary nailing, and that infections were more prominent with Gustilo III fractures (Saleeb, et al., 2019). This is to be expected as open complex fractures have higher levels of contamination and consequently a higher risk of infection.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1CONCLUSION

The commonest etiology for FSF at MTRH was found to be Road Traffic Accidents caused by motorcycles or motor vehicles.

Simple Midshaft FSF (AO 32 A) was most common morphological characteristic encountered.

Intramedullary nailing was the preferred treatment modality for FSF.

Predominantly Good to Excellent outcomes were seen in majority of FSF. In general, Good to Excellent outcomes was seen in majority of the cases with a low complication rate of 15.3%.

There was significant association between female sex, Intramedullary nailing and Gustilo I fractures with higher Good to Excellent AAOS lower limb questionnaire scores.

6.2 RECOMMENDATIONS

There should be public sensitization of the youthful population on Road Safety measures coupled with enforcement of traffic rules and regulations to reduce the number of road traffic accidents.

Intramedullary nailing of FSF should be upheld as the standard of care for FSF.

Every effort should be put in place to uphold or even improve on outcomes of treatment of FSFs.

Further studies with longer duration of follow-up for these patients are highly recommended.

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APPENDICES

Appendix 1: Hospital Approval (MTRH)

IRE / 2017/207

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone:(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

8th March, 2018

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

APPROVAL TO CONDUCT RESEARCH AT MTRH

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

"Etiology Morphology and Treatment Modalities of Femoral Shaft Fractures in Adult Patients at Moi Teaching and Referral Hospital".

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

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPROVED
08 MAR 2018
SIGN.........
P.O. Box 3 - 30100, ELDORET

08/03/2018

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - DCEO, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM

All correspondence should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
A WORLD CLASS TEACHING AND REFERRAL HOSPITAL

Appendix 2: Institutional Research and Ethics Committee Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

1st March, 2018

Reference: IREC/2017/207
Approval Number: 0002067

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
01 MAR 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

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

Dear Dr. Maritim,

RE: FORMAL APPROVAL

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

"Etiology, Morphology and Treatment Modalities of Femoral Shaft Fractures in Adult Patients at MTRH".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 2067*** on 1st March, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 28th February, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

Appendix 3: Research Questionnaire

A: Demographic Data

Case identity…………….

Age……………………….

Gender ☐Male ☐Female

Occupation- Dependent☐ Self-employed☐ Informal/Casual☐ Formal ☐

Unemployed☐ Others ☐

Level of education

No formal education A☐ Primary: B☐ Secondary: C ☐ College: D☐ Others

B: Etiology of injury:

MVAs ☐ Motorcycle ☐ Gunshot ☐ Falls ☐ Sports ☐ Direct blows/Assault ☐

Others☐………………………

MVAs (Motor vehicle occupants)

Driver ☐ Passenger ☐ Pedestrian ☐

Seat Belt ☐ No Seat Belt ☐

Motorcycle:

Rider☐ Passenger☐ Pedestrian ☐

Bicycle

Cyclist ☐ Passenger☐ Pedestrian ☐

Gunshot injuries

Incidence: ……………………………………………………………

Sports

Type of Sport …………………………………………

Nature of sport: Contact ☐ Non-contact ☐

Falls

Nature: Simple ☐Down a Gradient ☐ From Height ☐

Direct blows/Assaults

Incidence: ……………………………………………….

Nature: Accidental ☐ Intentional ☐

Object: Blunt ☐ Sharp ☐

Others ...…………………………………………….

`

D: Fracture characteristics

1. Open ☐ Closed ☐
2. Laterality of the fracture: Left ☐ Right ☐ Bilateral ☐
3. Levels: Upper 1/3☐ Mid 1/3☐ Lower 1/3 ☐
4. Morphology

SIMPLE Spiral ☐ Oblique ☐ Transverse☐

WEDGE Spiral☐ Bending☐ Fragmented☐

COMPLEX Spiral Segmented Irregular

5. Gustilo Classification (Open fractures)

Class: I ☐ II ☐ IIIA ☐

III B ☐ IIIC ☐

6. AO/OTA Class……………………………………………

5. Tscherne Classification; (Closed fractures with soft tissue injury)

Grade O☐ Grade 1☐ Grade 2☐ Grade 3☐

E: Treatment modality

Non-Operative: External Casting ☐ Functional Bracing ☐

Operative: Amputation ☐ Debridement ☐

External Fixator ☐ Plating ☐ IM Nail ☐

Soft tissue coverage for Open fractures:

STSG ☐ Muscle flaps ☐

G: Early complications (within one month)

Infection ☐ Periprosthetic fracture ☐

Pulmonary embolism ☐ Implant/explant failure ☐

Others ☐

`

Appendix4: AAOS Lower Limb Score

Lower Limb Questionnaire

Instructions

Please answer the following questions for the lower limb being treated or followed up. If it is BOTH lower limbs, please answer the questions for your **worse** side. All questions are about how you have felt, on average, during the **past week.** If you are being treated for an injury that happened less than one week ago, please answer for the period since your injury.

1. During the **past week**, how **stiff** was your lower limb? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

2. During the **past week**, how **swollen** was your lower limb? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

During the **past week**, please tell us about how painful your lower limb was during the following activities. (Circle ONE response on each line that best describes your average ability.)

	Not painful	Mildly painful	Moderately painful	Very painful	Extremely painful	Could not do because of lower limb pain	Could not do for other reasons
3. Walking on **flat** surfaces?	1	2	3	4	5	6	7
4. Going up or down stairs?	1	2	3	4	5	6	7
5. Lying in bed at night?	1	2	3	4	5	6	7

6. Which of the following statements **best** describes your ability to get around most of the time during the **past week**? (Circle one response.)

1 I did not need support or assistance at all.
2 I mostly walked without support or assistance.
3 I mostly used one cane or crutch to help me get around
4 I mostly used two canes, two crutches or a walker to help me get around.
5 I used a wheelchair.
6 I mostly used other supports or someone else had to help me get around.
7 I was unable to get around at all.

7. How difficult was it for you to put on or take off socks/stockings during the **past week**? (Circle one response.)

1 Not at all difficult 2 A little bit difficult 3 Moderately difficult 4 Very difficult 5 Extremely difficult 6 Cannot do it at all

`

Appendix 5: Consent Form: English version

ETIOLOGY, MORPHOLOGY AND TREATMENT MODALITIESOF FEMORAL SHAFT FRACTURES IN ADULTS PATIENTS AT MOI TEACHING & REFERRAL HOSPITAL

INVESTIGATOR – DR. MARITIM BENARD OF P.O BOX 4606, ELDORET, KENYA

I……………………………………of P.O Box…………………………….

Tel……………………………. hereby give informed consent to participate in this study in MTRH. The study has been explained to me clearly by DR. MARITIM BENARD (or his appointed assistants) of P.O. Box 4606 ELDORET.

I have understood that to participate in this study, I shall volunteer information regarding nature and cause of my injury and undergo medical examination. I am aware that I can withdraw from this study at any time without prejudice to my right of treatment at MTRH now or in the future. I have been assured that no injury shall be inflicted on me from my participation in this study. I have also been assured that all information shall be treated and managed in confidence. I have not been induced or coerced by the investigator (or his appointed assistant) to append my signature in this form and by extension participate in this study.

Initials of participant…………………………. Signature…………………………….

Date………………………………………………………………………………

Name of Witness…………………………………Signature………………………

Date………………………………………………………………………………

`

Appendix 6: Consent Form: Swahili Version

MajinayanguniMaritimBenard.Miminidaktarinaliyehitimunakusajiliwanabodiyamadaktariwa Kenya nambari A8129. Kwa wakati huu ninasomea shahada ya juu ya upasuaji katika choukikuu cha Moi.

Ninafanyautafitiunaohusukuvunjikakwamfupawapajahaswasehemuyakatiyamfupahuo.Maelezohayayanawezakutumiwakuimarishamatibabunakuangaziajinsiyakuimarishautendakazikatikahospitalizetu.

Ujumbe utakao jumuishwa ni kama: maelezo kuhusu waathiriwa,ainatofauti za njia ambazomtuawezakuvunjamifupayapaja,matibabualiyopatanajinsiambavyomhathiriwa alivyowezakuimarikakiafyabaadayakupatamatibabu.Utapatamatibabuyaugonjwawako kamainavyohitajikakatikahosipitaliya MTRH naukiamuakutojijumuishaaukujiondoakatikautafitihuumatibabuyakohayataathirika. Maelezo utakayotoa yatahifadhi wavyema.

Hakunam anufaayakibinafsikamamalipo Kwa kujumuishwakatikautafitihuuwalahakunamadharakwa wale watakaohusishwa.Iwapoutakuwanamaswalikuhusuutafitihuu,unawezakuwasilianana,

Mwenyekiti

Institutional Research and Ethics Committee,

Moi University/Moi Teaching and Referral Hospital

P.O. Box 3-30100

Eldoret.

Telephone number: 053-2033471/2/3 Extension 3008.

SEHEMU B: KIBALI CHA UTAFITI NA MHUSIKA

Miminiliyetiasahihihapochini,nimekubalikwahiariyangukujumuishwakatikautafitihuu. Nimeelezwa kuhusu huu utafitinamtafiti, Dr. MaritimBenard

Ninaelewakuwaninawezakujiondoakutokautafitihuuwakatiwowotenikibadiliniayangu nakuwaujumbenitakaotoautahifadhiwavyemanakutumiwakatikautafitihuupekeyake.

Jina---

Sahihi ------------------------------------- Tarehe-------------------------

Ninahakikishakuwanimetoamaelezoyanayohitajikakwamhusikahuyunaanawezakuwas ilianananamikwanambariyasimuiwapoanaswali au tashwishi.

Sahihi---------------------------------------Tarehe-------------------------

`

Appendix 7:AO/OTA Classification of Femur Shaft Fractures

The Femur bone assigned bone number 3, diaphyseal region number 2

A: Simple Fracture

32-A1 Spiral

32-A2 Oblique ($<30^0$)

32-A3 Transverse ($>30^0$)

B: Wedge Fractures

32-B1 Spiral Wedge

32-B2 Bending wedge

32- B3 Fragmented Wedge

C: Complex Fractures

32-C1 Complex Spiral

32-C2 Complex Segmental

32-C3 Complex Irregular

Appendix 8: Gustilo-Anderson classification of Open Fractures

Grade I

- The skin opening is 1 cm or less.
- This injury is most likely due to an inside-out mechanism.
- Muscle contusion is minimal.
- The fracture pattern is transverse or short oblique.

Grade II

- The skin laceration is greater than 1 cm, with extensive soft-tissue damage, flaps, or avulsion.
- A minimal to moderate crushing component may be noted.
- The fracture pattern is simple transverse or short oblique, with minimal comminution**.**

Grade III

- Extensive soft-tissue damage includes the muscle, skin, and neurovascular structures.
- This is a high-velocity injury with a severe crushing component.
    - **Grade IIIA**: Involves extensive soft-tissue laceration (10 cm) but adequate bone coverage and includes segmental fractures and gunshot wounds.
    - **Grade IIIB:** Consists of extensive soft-tissue injury with periosteal stripping and bone exposure. This grade is typically associated with massive contamination and inadequate bone coverage. The treatment requires flap advancement or a free flap.
    - **Grade IIIC:** Is a vascular injury requiring repair.

`

Appendix 9: Tscherne Classification of Closed Fractures

Grade 0

- Soft-tissue damage is absent or negligible. The fracture is a result of indirect forces with a simple fracture pattern.

Grade 1

- Superficial abrasion or contusion is caused by fragment pressure from within. The fracture configuration is more severe than that of grade 0.

Grade 2

- Deep, contaminated abrasion is associated with localized skin or muscle contusion from direct trauma. Impending compartment syndrome is part of this grade of injury, which is usually the result of direct violence.

Grade 3

- This injury is characterized by extensively crushed, contused skin and severe muscle damage. Other criteria are subcutaneous avulsions, decompensated compartment syndrome, and rupture of a major blood vessel. Usually, patients have a severe, complex fracture pattern.

`