SHORT-TERM OUTCOMES OF OPERATIVE SURGICAL TREATMENT OF FEMUR DIAPHYSEAL FRACTURES IN CHILDREN AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE (ORTHOPEDICS SURGERY) OF MOI UNIVERSITY

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DECLARATION

Declaration by Researcher

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DISCLOSURE

The researcher did not receive any external funding or grants in support for this study. Neither the researcher nor the immediate family members received payments or other benefits or commitment or agreement to provide such benefits from a commercial entity.

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ABBREVIATIONS AND ACRONYMS

AO	Arbeitsgemeinschaft fur Osteosythesefragen
DCP	Dynamic Compression Plate
EXOFIX	External fixator
IREC	Institutional Research and Ethics Committee
MTRH	Moi Teaching and Referral Hospital
TENS	Titanium Elastic Nails

DEFINITION OF TERMS

AO classification – This is a comprehensive fracture classification system of bones.

Child – This refers to individual who was less than 14 years of age at the time of recruitment into the study. Patients less than 14 years of age in this study are referred to as children.

Flynn Criteria – This is an outcome criteria based on the work of Flynn et al., (2001) who used Titanium Elastic Nails and then stratified outcome into three groups: excellent, satisfactory and poor, based on the worst complication, has been useful in the objective analysis of the outcome of function following management o the paediatric femur fractures according to Kumar and Chandrasekhar, 2014; and Tochie et.al., 2017. Kumar and Chandrasekhar, (2014) used both Titanium Elastic Nails and DCP operative techniques in their patients, and used the Flynn criteria.

Surgical Treatment – categorized into operative and nonoperative. Each has various techniques. Operative surgical treatment is part and parcel of surgical management. This study will focus mainly on the operative surgical treatment.

ABSTRACT

Background: In the past three years at Moi Teaching and Referral Hospital (MTRH) an observation has been made that less patients with paediatric femur diaphyseal fractures are treated nonoperatively. The change from nonoperative to operative surgical treatment was seen in Europe and United States of America three decades ago. This study served to evaluate the operative surgical treatment outcomes of femur diaphyseal fracture in children.

Objective: This study set out to characterize femur diaphyseal fractures in children operated at Moi Teaching and Referral Hospital, determine the operative surgical treatment techniques used and assess their short term outcomes.

Methods: This was a cross sectional study, conducted at the paediatric orthopaedics clinic of MTRH after ethical clearance was obtained from IREC. Forty-three patients were identified and recruited 12 weeks after operative surgical management for their femur diaphyseal fractures and discharged from orthopaedics ward. Demographics of the patient, mechanism of injury and type of fracture, days to admission and days to surgery, operative surgical techniques, and the clinical outcomes including complications (knee stiffness, length discrepancy, and infection), the time to walk on crutches, and time to walk without support were recorded in a structured data collection form. Union was determined using clinical and radiological means. The Flynn criterion grading was determined for each patient at the same time. Data was entered into SPSS® version 23 for analysis and results presented in graphs, tables and figures.

Results: There were forty-three patients seen at the clinic on the 12th week after their operative surgery and discharged from orthopaedics ward. Male to female ratio was 2.23:1. At the time of injury the mean age was 9 years (SD 2.9). Majority of the fractures were caused by a fall from height (46.5%) followed by road traffic accidents (32.5%). The fractures were simple (32- D/4.1) for majority of the patients (65.1%). Patients were admitted at a mean of 3.3 (SD 6.6) days after injury and had surgery done at a mean of 7.4 days (SD 4.9) after injury. However it took a mean of 10.7 (SD 7.6) days from injury to surgery. Dynamic compression plate (DCP) was used to treat 86% of the fractures. At 12 weeks knee stiffness was present in 8 (18.6%) of the patients, shortening of the femur in two. Deep infection occurred in one patient. Union and alignment were good at twelve weeks. However, two patients required reoperation due to loss of reduction before their twelfth week clinic checkup. Patients who scored satisfactory to excellent on Flynn criteria grading were 41 out of 43.Patients who scored poorly on the Flynn criteria grading were those who had open fractures and required external fixators and had deep infection at twelve weeks, 74% of patients were able to walk on crutches within 3 days after surgery and at 12 weeks 9 patients were still ambulating with crutches.

Conclusions: Majority of the patients requiring surgery presented with type 32-D/4.1. The DCP was the main technique of fixation offered to the children, with surgery for femur fractures done within 8 days of their injury. At twelve weeks the majority of patients were able to ambulate without support but knee stiffness was encountered in some patients. The Flynn criteria grading were satisfactory to excellent for most of the patients at twelve weeks.

Recommendations: Creating awareness on injury prevention should be encouraged. Use of DCP for simple femur fractures in children should be encouraged. Knee stiffness is a complication that surgeons should deliberately look for in the post-operative period following femur plating and take appropriate action, so as to improve the clinical short- term outcomes and Flynn criteria grading.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background to the study

Throughout childhood, changes in physical and social maturation place children at varying risk for femoral shaft fractures due to different mechanisms. These include risky behaviour e.g. climbing of obstacles like trees, walls for boys, while girls on the other hand will get injured while playing sports or in traffic accidents.

Femoral shaft fractures are typically caused by blunt trauma, are the most common major paediatric injuries treated by the orthopaedic surgeon. About 70% of femoral fractures involve the shaft (Flynn & Schwend, 2004), accounting from 1.4 % (Kocher et al., 2009) to 1.7% (Landin, 1983; McCartney, Hinton, & Heinrich, 1994) of all paediatric fractures and about 33.7% of the long bone fractures (Nwadinigwe, Ihezie, & Iyidiobi, 2006). Studies in the developed world have estimated the incidence of femoral fractures at approximately 1% for children under the age of 12 years. It is amongst the commonest reason for admission in the United States with an estimated annual incidence of 19.5 per 100 000children (Hinton, Lincoln, Crockett, Sponseller, & Smith, 1999; Hosalkar et al., 2011).

In the past operative surgical treatment was discouraged, in part because no technique yielded consistently better results than casting (Anglenn & Choi, 2005), but over the past 15 years there has been a change in trend away from nonoperative treatment such as traction and prolonged spica casting and one toward operative surgical stabilization (Kocher et al.,2009).

In the developed countries different operative surgical stabilization techniques have been researched and developed. This is evident by the availability of such techniques as elastic nails, rigid nails, and minimally invasive plating (Kocher et al., 2009), but there is still controversy on whether operative is better than nonoperative surgical treatment or vice versa.

In Africa there is paucity of published data on operative surgical management for these fractures. A study in Nigeria, observed the outcome of femur diaphyseal fracture in children using a retrospective study design. The treatment in their setup is nonoperative in contrast to the operative surgical treatment used in the developed countries. This was due to lack of the necessary equipment and supplies for operative surgical treatment (Akinyoola, Odunsi, Taiwo, & Orekha, 2011).

In Kenya there is paucity of published information on the surgical treatment of femur diaphyseal fracture in children, but these injuries are not uncommon and are mainly treated by nonoperative surgical techniques in the public hospitals where the bulk of the population get medical attention. The paucity of published data makes it difficult to determine the burden of this injury and the outcomes of local management protocols.

Treatment of a fractured femur in a child or adolescent presents special challenges to the orthopaedist. In addition to small size, the presence of open physes and immature vascular patterns must be considered. Although the potential for rapid healing and remodeling during growth are helpful, the potential of interference with that growth introduces special hazards. Psychological and social effects play a role in selecting optimal treatments. Both the injury and treatment affect the family unit as a whole in ways that an adult femur fracture may not (Anglen & Choi, 2005). The mean cost of treatment in US is $ 51.2, though looks very low, is quite a significant cost in an environment with low per capita income.

The nonoperative surgical treatment options require that the children remain immobilized and results in loss of about a third of the school year period for the affected children (Akinyoola et al., 2011).

1.2 Problem statement

Limited published data is available on this injury at Moi Teaching and Referral Hospital; there have been changes in the management of paediatric femur diaphyseal shaft fractures over the past two decades when developed countries have advanced their treatment techniques, from nonoperative to operative, in part due to need to shorten the immobilization period associated with nonoperative treatment which was responsible for loss of school days by children and loss of work by guardians and parents who required to be home to take care of the children, and medico-legal reasons. MTRH is at the transitory period, moving towards the operative surgical treatment.

1.3 Justification of study

Femoral diaphyseal shaft fractures in children provide a challenge to the surgeon during management. The management strategies have evolved with time. The last three decades has seen the introduction of operative surgical management of these paediatric injuries.

The developing countries are still at this crossroad. With various management strategies aimed at different age groups and fracture patterns the surgeon needs to be equipped with knowledge on the choices available for the best outcomes.

There has been no evaluation of the treatment strategies available at MTRH and their outcomes. This research is thus intended to provide useful information about the characteristics of femur fractures in children, operative surgical techniques available and short-term outcomes (at three months’ post operation) as well as determining the outcomes based on the Flynn criteria grading for operative surgical treatment techniques of femur diaphyseal fractures in children at MTRH. The information will be useful to the orthopaedic surgeons, the hospital management and the stakeholders, as it will help in formulating policies necessary in the care of paediatric patients with femur diaphyseal fractures at MTRH.

1.4 Research question

How are the short- term outcomes of operative surgical treatment of femur diaphyseal fractures in children at MTRH?

1.5 Objectives

1.5.1 Broad objective

To determine the short- term outcomes of operative surgical treatment of femur diaphyseal fractures in children at MTRH.

1.5.2 Specific Objectives

1. To describe the characteristics of children with femur diaphyseal fractures treated at MTRH.
2. To determine the operative surgical treatment techniques for children with femur diaphyseal fractures at MTRH.
3. To assess the short- term clinical outcomes of operative surgical treatment of femur diaphyseal fractures in children at MTRH.
4. To determine the functional outcomes based on Flynn criteria grading for operative surgical treatment techniques of femur diaphyseal fractures in children at MTRH

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

2.1.1 Anatomic considerations

The femur is the longest, heaviest and strongest bone in the human body; it connects the hip to knee joint. The proximal and distal ends are made up of irregular projections, head and neck proximally and condyles distally, while the intervening segment is made up of a relatively regular cylindrical portion known as the diaphysis (Chang & Hubbard, 2018).

The femur diaphysis undergoes changes in size, shape and bone structure during childhood. There is a change in the biomechanical properties, with bone strength increasing with age; earlier in life the cross section of bone is rounded and thin compared to the asymmetrical shape and increased cortical thickness in the adult.

2.1.2 Functions of femur

The main function of the femur is weight bearing and gait stability. It also contributes 26.2% of the final height of the individual (Chang & Hubbard, 2018).

2.2 Femur diaphyseal fractures in children

Trauma is the leading cause of death of children in the United States, and major sociodemographic variations in the rates of fatal injury in this population have been reported. However, there have been fewer studies of more common, nonfatal injuries in children (Hinton et al., 1999). Trauma apart from causing death is associated with morbidity and disability.

Diaphyseal femoral fracture is one of the commonest injuries in childhood. During this time the changes in physical and social maturation place children at varying risk for femoral diaphyseal fractures due to different mechanisms (Hinton et al., 1999).

2.2.1 Epidemiology of paediatric femur diaphyseal fractures

The injury is as a result of high impact trauma the commonest causes being fall from height or sports, vehicle pedestrian accidents, vehicle passenger accidents and abuse. The primary mechanism of injury has been found to be age dependent with children less than 6 years of age due to falls, 6-9 years mainly due to pedestrian accidents, teenagers due to passenger accidents and children not yet walking due to abuse (Canale & Beaty, 2012).

This injury has been found to be more prevalent among the male with researchers finding a male to female ratio as high as 2.6:1(Hoffmann, Traldi, & Posser, 2012) in a European setting, a ratio of 2.21:1 from a South African setting (Mughal, Dix-Peek, & Hoffman, 2013) and an almost equal ratio of 1.6:1 in a Cameroonian hospital (Tochie, Guifo,Yamben, Moulion, & Farikou, 2017).

Besides the usual mechanisms of injury, femoral fractures can occur at birth, can be caused by child abuse, or can be pathological. In children younger than 1 year of age, 70% of femoral fractures are abuse related. Abuse should be suspected if any of the following are present: (1) unreasonable history, (2) inappropriate delay in coming to the hospital, (3)previous history of abuse, (4) evidence of other fractures in various stages of healing, (5)multiple acute fractures, and (6) characteristic fracture patterns (Canale & Beaty, 2012).

Higher energy injuries e.g. those caused by motor vehicle accidents have been associated with injuries to other body parts and also responsible for open femur fractures in the paediatric femur (Ramseier, Bhaskar, Cole, & Howard, 2007).

2.2.2 Classification of femur fractures in children

The diaphysis is the section of the femur between the greater trochanter proximal and the distal metaphyseal area. This region is composed of cortical bone and is the structural pillar of the limb.

Historically the long bones classification system used anatomic classification whereby the shaft is divided into three portions i.e., the proximal, middle and distal third. A descriptive classification divides the fracture based on the pattern of the fracture on radiographs into spiral, comminuted and transverse as well as whether it is an open or closed fracture.

Open femoral diaphysis fractures are rare in children accounting for 4% of all femoral diaphyseal fractures; they are usually due to high energy mechanisms (Hutchins, Sponseller, Sturm, & Mosquero, 2000). The presence of associated injuries and complications are proportional to the severity of the trauma (Allison, Dahan-Oliel, Jando, Yang, & Hamdy, 2011; Hutchins et al., 2000).

The current AO comprehensive classification takes into account new scientific knowledge of fracture types and difficulties in management. The classification seeks to classify fractures in a consistent and uniform manner to allow for standardization of research and communication. Since 1996 when the AO classification was introduced, it has been used by several Orthopaedic societies and in the publications of journals. The system has developed wide acceptance and has dramatically improved the way information on fractures are communicated and stored (Marsh et al., 2007).

In contrast to the adult fractures, the paediatric fracture classification system must do justice to the phenomenon of injury pattern and growth (Slongo, Audige, & Group, 2007).

There are well known fracture classifications of paediatric fractures: Salter-Harris for epiphyseal injuries, Baumann, Gartland and LV Laer for supracondylar fractures. None of these have been scientifically validated (Audige, Bhandari, & Kellam, 2004). Before 2007 there was no classification system available for paediatric diaphyseal fractures. The need for clinical relevance dictates that a system different from the adult system is required and pre-existing classifications must be considered.

The AO paediatric classification categorizes the fractures into 4 main groups as shown in figure 2.2.2.1. The simple fractures, 32-D/4.1 and 32-D/5.1 are considered length stable fractures and the 32-D/4.2 and 32-D/5.2 are the length unstable fractures. The length unstable fractures are at risk of length discrepancies at the time of reduction.

Diaphyseal fractures femur (32-D)

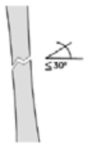
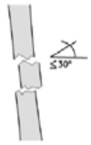
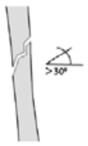
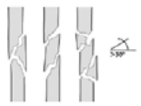
Simple fractures			Wedge/multifragmentary fractures		
Code	Figure	Description	Code	Figure	Description
32 – D/4.1		Simple complete transverse (≤30°)	32 –D/4.2		Multifragmentary transverse (≤30°)
32 – D/5.1		Simple complete oblique or spiral (>30°)	32 – D/5.2		Multifragmentary oblique or spiral (>30°)

Figure 2.2.2.1: Classification of paediatric femur diaphyseal fractures (Marsh et al., 2007)

In this study the AO paediatric classification will be used to distinguish the different patterns of fractures.

2.3 Surgical treatment of femur diaphyseal fractures in children

The goal of management of this fracture is to restore anatomical length and rotation, maintain alignment to facilitate return of normal function and preserve the proximal normal growth potential in the skeletally immature.

Despite all the challenges children have a remarkably high rate of remodeling and consistent healing with good outcomes has been observed as almost all unite rapidly regardless of the fracture type, location or treatment. It had been believed that neither nonoperative nor operative surgical management offers better results (Anglen & Choi, 2005; Lebel, Karasik, Fisher, & Itzchaki, 2006; Sanders et al., 2001). The choice of treatment is influenced by age and size of the patient, site of fracture, associated injuries, family social issues and the cost of management.

Several nonoperative surgical treatment techniques are available for the treatment of femur fractures in children: pelvic harness, traction, spica cast, as well as operative surgical treatment techniques with elastic nails, plating, rigid nail, external fixators (Jain, Aggarwal, Gulati, & Singh, 2014; Kuremsky & Frick, 2007; Lee, Mahar, & Newton, 2001; Stannard, Christensen, & Wilkins, 1995; Stans, Morrissy, & Renwick, 1999).

Nonoperative surgical treatment technique has been used for these fractures in children with immediate spica casting or traction followed by casting (Flynn et al., 2001), but for the last four decades there has been a change towards the use of operative surgical stabilization. Spica casting has remained the main nonoperative treatment technique for infants and toddlers less than 5 years of age (Flynn & Schwend, 2004). Older children are now more commonly treated with operative surgical techniques with better outcomes and quick reintegration of the child back into society (Khoriati, Jones, Gelfer, & Trompeter, 2016; Kumar & Chandrarashekar, 2014; Kuremsky & Frick, 2007; Sela, Hershkovich, Sher-Lurie, Schindler, & Givon, 2013; Wright et al., 2005).

The treatment of children aged 8-12 years has been most controversial, with good results obtained with traction followed by spica casting, flexible intramedullary nailing, plating and external fixation (Beebe, M. Kelly, Warner, & Sawyer, 2009; Kosuge & Barry,2015; Kregor et al., 1993; Kumar & Chandrarashekar, 2014; Wright et al., 2005). The difficulty with nonoperative surgical treatment in the older child includes the increased muscle mass which results in greater deforming forces and an increased healing time. This method requires frequent radiographs, adjustment and prolonged hospitalization (Kosuge & Barry, 2015; Wright et al., 2005).

Primary indications for operative surgical treatment have included severe head trauma and open fractures. Open femoral fractures are uncommon and occur in the presence of other injuries.

The wound care principles are well established, with early debridement and initiation of antibiotics. The treatment of such open fractures will be made easier by external fixation (Mooney, 2012; Ramseier et al., 2007).

The intramedullary nailing is the gold standard for adult femoral shaft fractures and can be used for the treatment of selected children. There are two main types of intramedullary devices, the flexible and rigid nails. The flexible nails are inserted into the metaphysis thus avoiding the epiphysis. They are less stable and do not allow locking. The titanium elastic nail and ender nail are flexible intramedullary devices available for use in the younger child who still has growth potential (Anglen & Choi, 2005; Flynn & Schwend, 2004; Khoriati, Jones, Gelfer, & Trompeter, 2016). The flexible nails provide some of the advantages of external fixation – rapid fracture stabilization, early patient mobilization and potential anatomic fracture union – without the major disadvantage of stress shielding, delayed healing and pin tract infection (Fein, Pankovich, Spero, & Baruch, 1989). The flexible nails are introduced percutaneously thus have minimal interference to the biology at the fracture site and results in minimal bleeding. The titanium elastic nails have been commonly used in the

European countries for more than three decades now, but only got wide spread acceptance in the USA about fifteen years ago (Moroz et al., 2006).

The rigid intramedullary nails provide secure fracture fixation and rapid mobilization of the patient with minimal risk of malunion, nonunion or refracture. This technique is limited to older children due to the size of the femoral canal and due to the risk of causing avascular necrosis of the femoral head (Sanders et al., 2001). The rigid intramedullary nail is inserted in an antegrade fashion; it is thought that the blood supply to the femoral head, medial femoral circumflex artery, is damaged during the piriformis entry. A more lateral approach at the greater trochanter will avoid the retinacular supply to the femoral head (Momberger et al., 2000). Most of the greater trochanter growth is appositional after 8years and growth arrest of the trochanteric physis after this age should not result insignificant slowing of the trochanteric growth (Gage & Cary, 1980). Thus a rigid nail can be used for the older child.

Plate fixation of femoral shaft fractures provides excellent stability, anatomic reduction and allows for better nursing care and early mobilization. This involves placing a rigid flat metal and securing it to the bone with screws. The plate can be introduced through a large incision on the skin via the traditional plating technique or through a small incision via a less invasive submuscular technique.

The traditional compression plate technique offers direct visualization of the fracture and allows anatomic reduction. It however involves a large skin incision followed by disruption of the biology around the fracture site. Due to this it was feared that it would lead to infection and had been labeled a mistake and should not be offered as a technique for femoral fracture treatment (Ziv & Rang, 1983). This fear has been dispelled as the technique has offered excellent results and healing in children managed by this technique (Fyodorov, Sturm, & Robertson, 1999; Kregor et al., 1993;

Kumar & Chandrarashekar, 2014; Ward, Levy, & Kaye, 1992). The compression plate technique was earlier on used for the treatment of femoral fractures in multiply injured patients to facilitate nursing care and rehabilitation (Kregor et al., 1993; Ziv & Rang, 1983).Plating for isolated femoral fractures has been shown to be successful (Fyodorov et al., 1999).

Traditional plating has the disadvantages of thigh scar, longer surgical exposure with resultant soft tissue injury and periosteal stripping, need for secondary procedure to remove implant, blood loss, risk of infection, and risk of refractures after plate removal (Caird, Mueller, Puryear, & Farley, 2003).

Less invasive techniques of plate placement have found important role in traumatology. These techniques involve the utilization of small incisions and percutaneous insertion of plates with locking screws. This provides the benefits of plate fixation minus the scarring, large exposure and blood loss experienced with the traditional plating.

The external fixation is a minimally invasive technique of stabilizing the femur fracture. In this technique the surgeon introduces percutaneous pins that are secured onto a bar above the skin surface. This is a procedure that has minimal blood loss and allows access to wounds; it is quickly applied as damage control to provide immediate stabilization of the fracture and for early mobilization and ease of management of associated injuries (Allisonet al., 2011). It is commonly advocated for femur fracture associated with soft-tissue disruption, head or multisystem injuries (Anglen & Choi, 2005). The use has been expanded to include isolated femur fracture (Kong & Sabharwal, 2014) with good results without malunion, nonunion or significant length discrepancies (Aronson & Tursky, 1992; Blasier, Aronson, & Tursky, 1997).

Traditionally, femur fractures in children of all ages had been treated by an initial period of traction, often until the appearance of callus on the radiograph, followed by a spica cast until solid union is achieved.

Infants up to 18 months of age can be treated well in a Pavlik harness, which is well tolerated, easy to adjust, holds the femur in the correct position of reduction, and avoids the risk of skin complications from casting (Anglen & Choi, 2005; Podeszwa, Mooney, Cramer, & Mendelow, 2004).

Spica casting is simple, safe, and effective. It avoids the risks of operative surgical treatment and requires no specialized tools or implants. The success of this technique is facilitated by the fact that infants and children have a tremendous ability to remodel the deformities that remain after closed treatment (Anglen & Choi, 2005; Shapiro, 1981; Viljanto, Kiviluoto, & Paananen, 1975).

Casting after a period of traction is used for older children (8-10yrs) and yields good results that are comparable to immediate spica cast, however this age group tolerate casting and hospitalization poorly and have diminished growth potential so that residual defects in angulation and shortening may persist.

Nonoperative surgical treatment of femur diaphysis fracture in children requires prolonged immobilization which stresses the child and the family with missed school, lost work for the primary care giver of the child and has deleterious psychological effects.

The nonoperative surgical techniques have good results but have been associated with some poor outcomes such as nonunion, delayed union, length discrepancies, angular and torsional deformities, neurovascular injuries and stiffness of hip, knee, back and ankle.

The nonoperative surgical treatment of these fractures was the most frequent and expensive malpractice claim against Orthopaedic surgeons (Kuremsky & Frick, 2007), together with the need for rapid mobilization, shorter inpatient hospitalization and quicker integration of patient into social activities have contributed to the gradual evolution in the past decade towards operative surgical treatment.

Operative surgical treatment techniques offer quick stabilization of the fracture and allow early ambulation and shorter hospital stay and avoid detrimental psychological and social effects often associated with prolonged nonoperative surgical treatment techniques (Beaty, 2005).

The treatment guidelines are based on the patient's age, size, fracture pattern, associated injuries and social circumstances. The increasing costs of healthcare and the impetus to shorten the hospitalization time have influenced the treatment of these fractures (Flynn & Schwend, 2004; Fyodorov et al., 1999).

There are several operative surgical treatment techniques available to choose from. The treatment of these fractures is age dependant, with the bone age, bone canal size and the size of the child influencing the treatment type. The surgical expertise and local trends in practice also play a major role in the choice of operative surgical treatment technique offered (Anglen & Choi, 2005; Khoriati et al., 2016).

The ideal treatment is one that controls alignment and length and is compatible for the child and convenient for the family causing the least negative psychological impact possible and the least complications.

2.4 Clinical outcomes of operative surgical treatment of femur diaphyseal fractures in children

The bone of the child is at a rapid growing phase. This allows for rapid callus formation; radiological union is reported to be evident after fractures at 6-8 weeks in plate fixation. Hence allows the child to be non-weight bearing by the 8^{th}week (Fyodorov et al., 1999).

Complications that occur following the treatment of femur fractures have been classified as major and minor. Major complications are those that will need unplanned operative surgical treatment while those that do not need operative surgical treatment are classified under minor complications (Flynn et al., 2001; May et al., 2013).

Major complication includes loss of reduction, deep infection and plate breakage, while the minor complications are the ones that resolve on their own without the need for operative surgical treatment, such as knee stiffness, pin tract infection, and superficial surgical site infection.

2.5 Functional outcomes of operative surgical treatment of femur diaphyseal fractures in children

This is an outcome score based on the work of Flynn et al., (2001) who stratified the outcome as shown in table 2.5.1 below into three groups, excellent, satisfactory and poor. The patient is scored based on the worst complication found and assigned to the corresponding group. It can be noted that there is also an anatomical element as limb length discrepancy and sequence disorder (malalignment) are addressed in the table; the same concept advocated by Fein et al, 1989.

Table 2.5.1: Flynn criteria grading

	Excellent	Successful	Poor
Limb length discrepancy	<1.0 cm	<2.0 cm	>2.0 cm
Sequence disorder	5°	10°	>10°
Pain	Absent	Absent	Present
Complication	Absent	Mild	Major complication and/or extended period for resolvable morbidity

This scoring system has been useful in the objective analysis of the outcome of function following management of the paediatric femur fractures (Kumar & Chandrarashekar, 2014; Tochie et al., 2017).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study site

This study was conducted at the Moi Teaching and Referral Hospital (MTRH) in Eldoret, on Nandi Road, Uasin Gishu County, in Kenya. MTRH is the second largest referral centre in the country and home of the second largest medical school, Moi University medical school, in the country. It is about 320 km northwest of Nairobi, within longitude 34° 50’ and 35° 37’ east and latitude 0° 03’ and 0° 55’ North. Its bed capacity is 1000 and approximately 500 clients seek services at the institution daily, with a catchment area of 20 million people. The main focus of the study was at paediatric orthopaedics clinic. The patients had been attended to at the hospital by nurses, clinical officers, plaster technicians, medical officers, orthopaedic registrars and orthopaedic surgeons.

3.2 Study design

This study used a cross- sectional descriptive study design. Data was collected using interviewer administered questionnaire, clinical evaluation and extraction of secondary data from patients’ medical records.

3.3 Study population

Patients aged 14 years and below who presented at paediatric orthopaedics clinic of MTRH with femur diaphyseal fractures, at 12 weeks for follow- up following discharge from orthopaedics ward after operative surgical treatment; subjected to the eligibility criteria as outlined below:

3.4 Eligibility criteria

3.4.1 Inclusion criteria

- Patients aged 14 years and younger with femur diaphyseal fracture admitted and received operative surgical treatment at MTRH.

3.4.2 Exclusion criteria

- Pathologic femur diaphyseal fracture e.g. secondary to bone tumours, osteomyelitis, metabolic bone disease, and bone cyst.
- Patient who did not receive operative surgical treatment at MTRH.
- Patients (minors) who declined to assent, guardians and parents who declined to give consent yet operative surgical treatment was offered at MTRH.

3.5 Sampling

3.5.1 Sample size determination

To have a 95% confidence that the proportion of patients who develop complications after a short term follow-up was within plus or minus 5% the population prevalence of 13% (May et al., 2013).The following formula by Daniel and Cross (2018) was used to estimate the minimum number of patients.

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-p)}$$

Where

n' = sample size with finite population correction,

N = Population size (estimated to be 54 patients in a year),

Z = Z statistics for a level of confidence (1.96 for 95% level of confidence)

P = expected proportion (in proportion of one) (13% complication rate) and

d = precision (in proportion of one) (using a 0.05 level of precision).

Using the above formula, the sample calculated was **42** patients.

3.5.2 Sampling techniques

A non-probability sampling method was employed with all paediatric patients presenting at study site 12 weeks after operative surgical treatment for femur diaphyseal fractures and had been discharge from orthopaedics ward for follow- up at orthopaedics clinic of MTRH were given equal opportunity to be enrolled in the study. Therefore, all patients seen at the study site and had been admitted to the ward for operative surgical treatment of femur diaphyseal fracture were eligible for enrolment.

3.6 Data collection techniques

All patients presenting to the study site for follow- up at week 12 after operative surgical treatment for fracture involving the femoral diaphysis based on radiograph finding and were being followed up were eligible for recruitment into the study. The study period was from 23rd January, 2017 to 22nd January, 2018.

Patients of consenting guardians and parents were awarded study number after assenting. The data in their files were retrieved by Principal Investigator with the help of trained research assistant, and the questionnaires were filled based on the findings by the clinician.

The patients had received operative surgical treatment based on the current protocol available at the facility.

Study variables:

- Demographic data – age, case identity, sex, weight, and residence
- Time from injury to presentation

- Mechanism of injury
- Time from admission to operative surgical treatment
- Time from injury to operative surgical treatment
- Diagnosis – Based on radiological findings
- Operative surgical treatment technique
- Length of hospital admission

Variables collected at follow- up clinic:

1) Clinical outcomes:
    - Limb Length discrepancy
    - Range of motion at Knee
    - Time to ambulation
    - Time to full weight bearing
    - Rotation
2) Complications:
    a) Major
        - Unplanned reoperation
        - Limb length discrepancies requiring surgical intervention e.g. epiphyseodesis or osteotomies
        - Deep infection
    b) Minor
        - Malunion
        - Nonunion, delayed union
        - Limb length discrepancies: Shortening or lengthening
        - Angulation
        - Joint stiffness; knee, hip, back, ankle

- Superficial infections

3) Malunion was defined as:

1. Angular deformity greater than ≥10˚on AP x-ray film or ≥15˚on lateral x-ray film
2. Rotational deformity ≥ 15˚
3. Limb length discrepancy: accepted 1.5 – 2cm of shortening and 0.6 – 1.1 cm of lengthening

3) Nonunion – defined as no callus at the fracture site after 6 weeks.

The time of the study for each patient was at 12th week following operative surgical treatment for femur diaphyseal fractures, and discharged for follow- up.

3.7 Data management

The collected data was analysed using SPSS® version 23. Fracture patterns were determined and the association between operative surgical treatment techniques and outcomes analysed. Findings were presented in frequency distribution tables, graphs and charts and in narrative form as well.

3.8 Ethical considerations

The study was undertaken after approval by the IREC (Ref. IREC/2012/182). An informed assent and consent were sought from patient, and the guardian and parent of patient respectively before enrolment. No harm was imposed on the patient who was also free to withdraw from the study at any time.

Confidentiality of the patients (with that of their guardians and parents) was assured as no identifiable information was recorded on the data collection tool; all patients were given study numbers. The information collected was stored under lock and key and accessible to the Principal investigator only.

After successful completion of the study, the information contained in the thesis will be available at the Moi university library and at the Department of Orthopaedics and Rehabilitation for reading and referencing. Dissemination may also be achieved through presentation at Scientific Kenya Orthopaedics Association Conference and publication in East African Orthopaedics Journal.

3.9 Study limitations

The time available for the study was limited by the duration of the course; a longer follow- up period would yield better comparison of the outcomes of the operative surgical treatment techniques.

CHAPTER FOUR

4.0 RESULTS

4.1 Characteristics of children with femur diaphyseal fractures treated at MTRH

Table 4.1.1: Distribution of patients by sex

Sex	Frequency	Percent
Male	30	69.77
Female	13	30.23
Total	43	100

Over two thirds (69.77%) of the patients were male, with Male: Female ratio of 2.31:1.

Table 4.1.2: Summary of respondents' age and chronology of management

Variable (n=43)	Mean	SD	Minimum	Maximum
Age (years)	9.0	2.9	3	14
Injury to admission (days)	3.3	6.6	0	35
Injury to surgery (days)	10.7	7.6	1	42
Admission to surgery (days)	7.4	4.9	1	19

Table 4.1.2 presents a summary of patients' age (years), days from injury to admission, and to surgery, and days from admission to surgery. There were a total of 43 patients sampled for the study. The mean age of patients was 9 (SD 2.9) years. The eldest one was 14 years while the youngest was 3 years.

It took a mean of 3.3(SD 6.6) days for a patient to be admitted after having an injury. The shortest time was within few hours of injury while the longest took 35 days. The mean time from injury to surgery was 10.7 (SD 7.6) days, with the least reported being 1 day and the highest 42 days. From admission to surgery, it took the patients an average of 7.4 (SD 4.9) days; the minimum reported being 1 day and the maximum 19 days.

Aetiology of femur diaphyseal fractures in children at MTRH

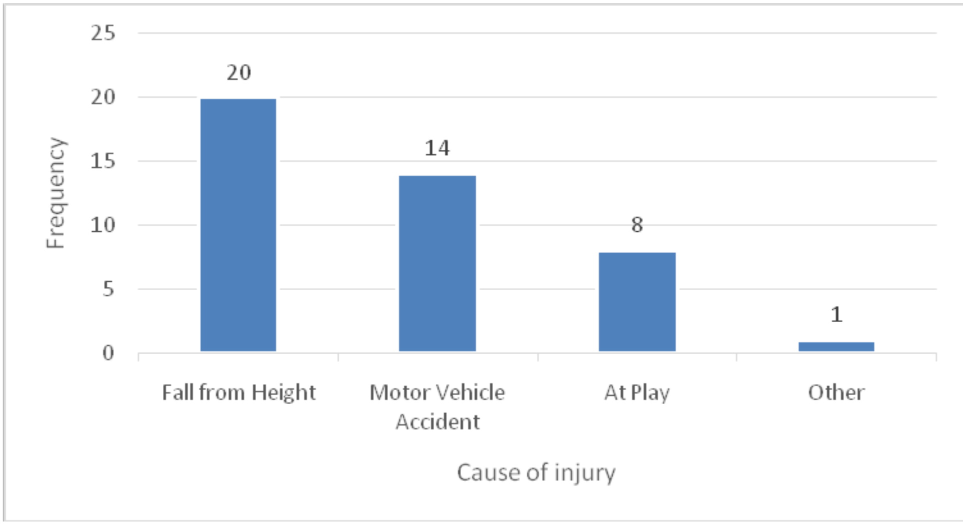


Figure 4.1.1: Aetiology of femur diaphyseal fractures in children at MTRH

The most common mechanism of injury was a fall from height 20(46.5%) followed by motor vehicle accident at 32.6%.

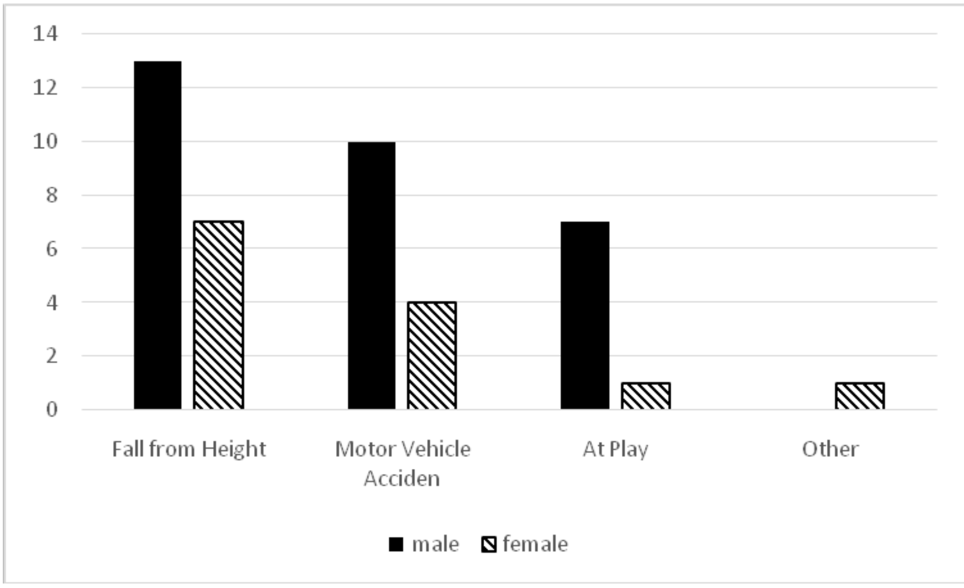


Figure 4.1.2: Mechanism of injury by sex

Figure 4.1.2 illustrates the mechanism of injury by sex. More than half of the females (53.8%) reported a fall from height compared to 43.3% in males. Of those who were injured at play, males' proportion was higher 87.5% (7/8) than that of females' 12.5% (1/8).

Types of femur diaphyseal fracture in children at MTRH

Table 4.1.3: Soft tissue integrity and associated injury

Variable	Category	Frequency (n)	Percent (%)
Soft tissue integrity	Open	4	9.3
	Closed	39	90.7
	Total	43	100
Associated injury	None	32	74.4
	Present	11	25.6
	Total	43	100

Table 4.1.3 illustrates the soft tissue integrity and presence of associated injury in sampled patients. Most of the fractures (90.7%) were closed injury with 74.4% of the fractures having no associated injuries.

Table 4.1.4: Association between soft tissue integrity and having associated injury

Soft tissue integrity	Associated injury		Total, n(%)
	None, n(%)	Present, n(%)	
Open	2(50)	2(50%)	4(100%)
Closed	30(76.9%)	9(23.1%)	39(100%)
Total	32(74.4%)	11(25.6%)	43(100%)
Fisher's exact = 0.267			

Half of those who had open injury had no associated injury while more than two thirds (76.9%) of those who had closed injury had no associated injury. The association between the nature of injury and having associated injury was not statistically significant (p=0.267).

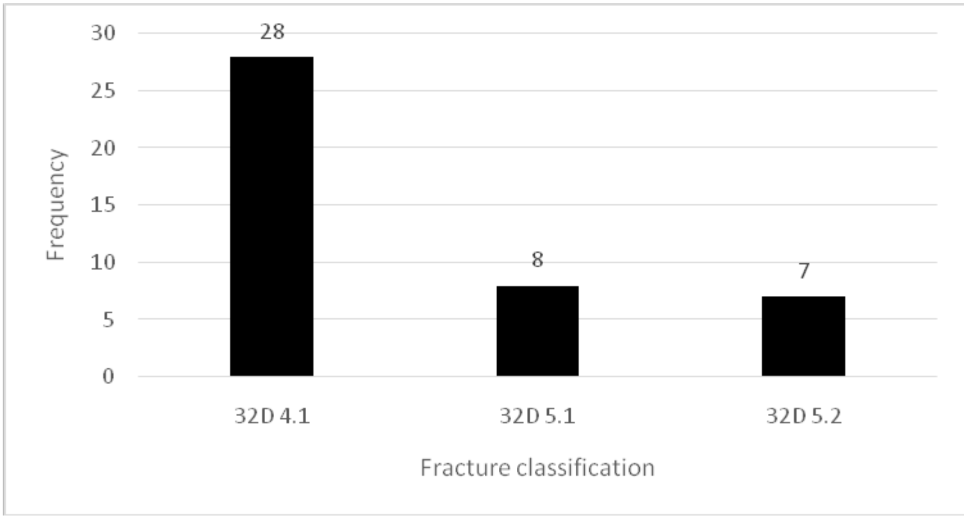


Figure 4.1.3: Classification of injuries

Figure 4.1.3 presents classification of injuries of patients. Almost two-thirds (65.1%) of the injuries were classified as 32- D/ 4.1 with the least reported being 32- D/ 5.2 (16.3%).

4.2 Operative surgical treatment techniques for femur diaphyseal fracture in children at MTRH

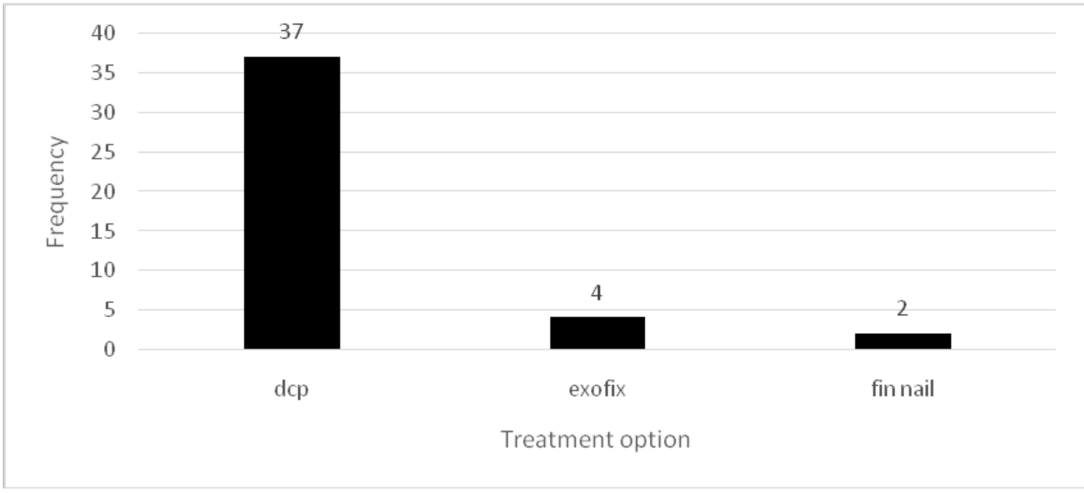


Figure 4.2.1: Operative surgical treatment techniques for femur diaphyseal fracture in children

Majority of the patients were treated using DCP 37 (86.0%), followed by those who were treated by external fixator 4 (9.3%), while 2 patients received fin nail as treatment.

Table 4.2.1: Operative surgical treatment techniques available by nature of injury

Type of treatment given	Nature of injury		Total, n(%)
	Open, n(%)	Closed, n(%)	
DCP	1(25)	36(92.3)	37(27.9)
External fixator	3(75)	1(2.6)	4(9.3)
Fin nail	0(0)	2(5.1)	2(4.7)
Total	4(100)	39(100)	43(100)

A majority (92.3%) of those with closed injury were treated with DCP while none of those with open injury received Fin Nail. Three quarters 3(75%) of those who had open injury received external fixator as treatment while only 9.3% of those with closed injury did.

4.3 Clinical short- term outcomes of treatment of femur diaphyseal fractures in children at MTRH

Table 4.3.1: Summary of the clinical and radiological outcomes

Outcome	Variant	Frequency
Knee range of motion	Normal	35
	Stiff	8
Limb Length Discrepancy	Equal	41
	Shortening	2
Infection	Superficial	1
	Deep	1
Radiological	Good Alignment	43
	Union	42

Table 4.3.1 shows that there was good radiological alignment at 12 weeks and there was radiological union features present. Knee stiffness was reported in 8 patients. Two patients had recorded limb shortening in comparison to the uninjured leg. This shortening was less than 2 cm in both patients. One patient had deep infection while only one showed features of superficial infection.

Complications

Table 4.3.2: Complications

Complication		Frequency
Major	Hardware Failure	2
	Deep Infection	1
Minor	Knee Stiffness	8
	Shortening	2
	Pin Site Infection	1
	Surgical Site Infection	1
	Total	15

There were 15 reported complications. Major complications were three: with two hardware failures requiring stabilisation of fracture and one deep infection that required debridement in theatre. The major complications were 6.9% (3) of the treated while minor complications were 27.9% (12). Knee stiffness was the commonest complication reported during the study.

Time to ambulation

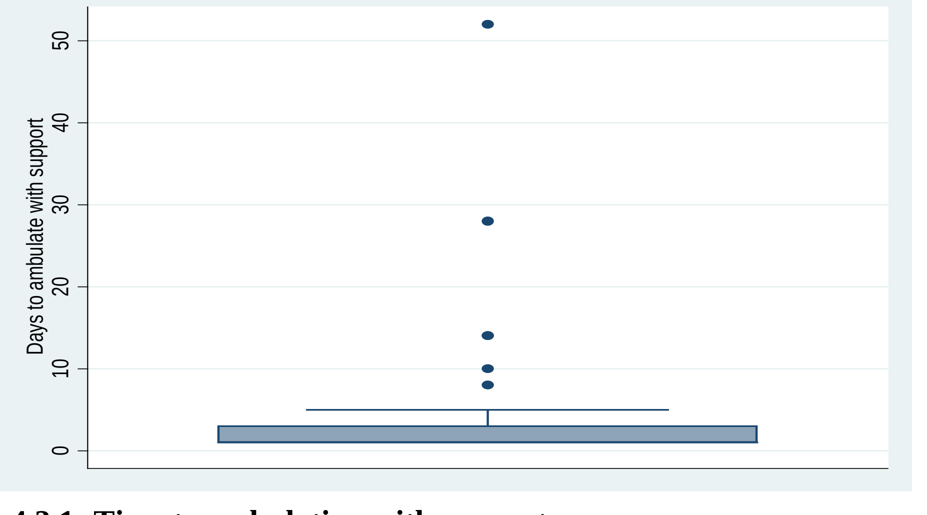


Figure 4.3.1: Time to ambulation with support

About 50% of the patients started ambulation with support on the 1st day after treatment and 75% ambulated with support by the 3rd day. However, 4 patients had not started ambulation with support by 60th day.

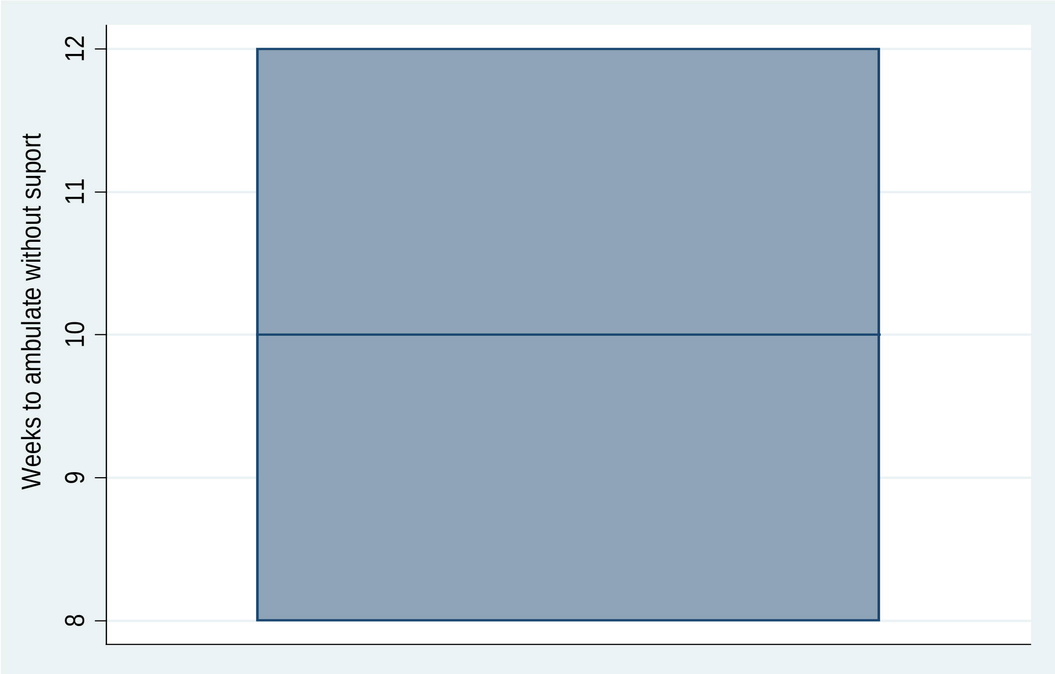


Figure 4.3.2: Time to ambulation without support

From the secondary date (medical records), there were 12 patients (27.9%)who were ambulating without support at week 8, while by week 12 almost all (79%) were able to ambulate without support. Nine patients were not able to ambulate without support by day 60^{th}.

4.4: Functional outcomes of femur diaphyseal fractures in children treated at MTRH

Table 4.4.1: Flynn Criteria Grading

Factor	Factor level	Frequency	Percent
Flynn criteria	Excellent	28	65.12
	Satisfactory	12	27.91
	Poor	3	6.98
	Total	43	100

Based on Flynn criteria grading, 28(65.12%) patients had excellent outcomes while 27.91% and 6.98% had satisfactory and poor outcomes respectively.

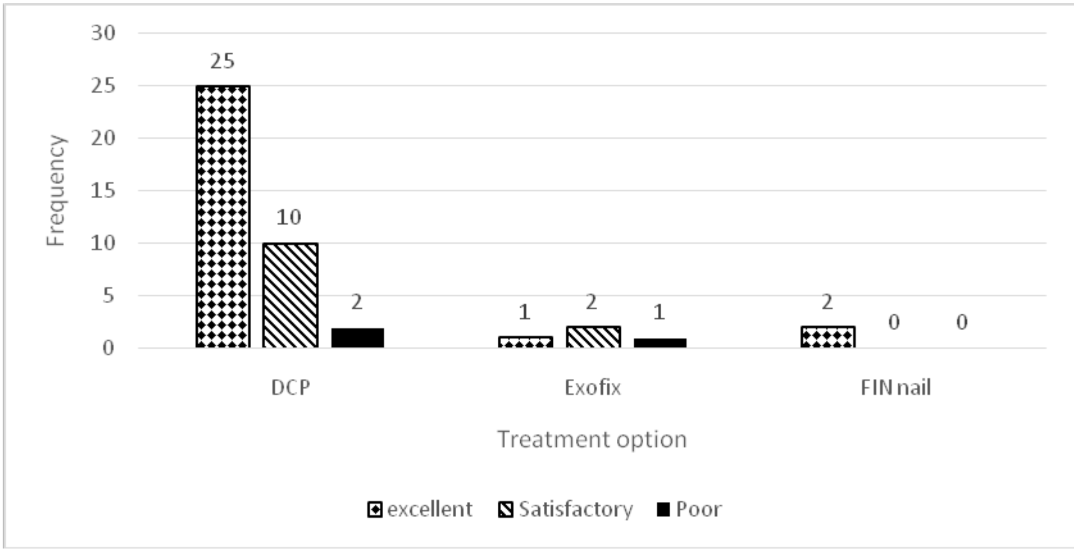


Figure 4.4.1: Outcome Flynn criteria for operative surgical treatment techniques

From figure 4.4.1, it is clear that the dominant outcome across treatment techniques was excellent (with the exception of external fixator). More than half 25(67.6%) of those under DCP treatment had an excellent outcome and all patients who were treated with fin nail had excellent outcomes.

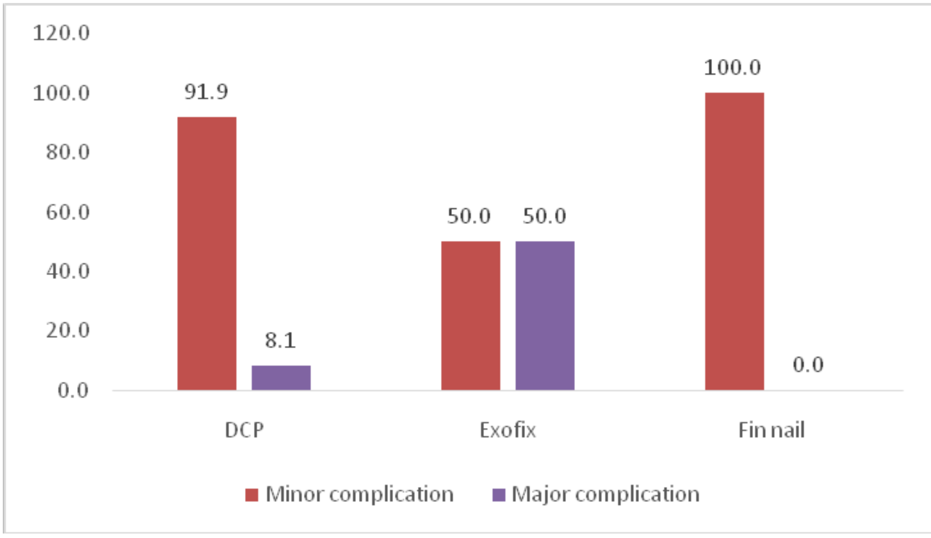


Figure 4.4.2: Operative surgical treatment techniques against complication class

Figure 4.4.2 is a bar chart displaying classes of complication during treatment across the available treatment techniques. Overall, the proportion of minor complications was higher across treatments (except external fixator). Majority

(91.9%) of those who received DCP and fin nail (100%) treatments had minor and no injuries respectively. Only half of those treated with external fixator had minor complications.

Table 4.4.2: Cross-tabulation of Flynn criteria and potential associated factors

Factor	Factor level	Flynn criteria			Total
		Excellent	Satisfactory	Poor	
Sex	Male	19	9	2	30
	Female	9	3	1	13
Bones affected	Unilateral	28	11	3	42
	Bilateral	0	1	0	1
Nature of injury	Open	0	3	1	4
	Closed	28	9	2	39
Mechanism of injury	Fall from height	14	3	3	20
	MVA	7	7	0	14
	At play	6	2	0	8
	Others	1	0	0	1
Associated injury	None	21	8	3	32
	Present	7	4	0	11

MVA =Motor vehicle accident

Table 4.4.2 is an illustration of association between potential associated factors and the outcome. There was no statistical significance (p>0.05).

Table 4.4.3: Cross-tabulation of outcome and treatment techniques

Treatment mode	Outcome		Total
	No Complications	Complications	
DCP	25	12	37
External fixator	1	3	4
Fin nail	2	0	2
Total	28	15	43

Table 4.4.3 is an illustration of association between outcome and treatment techniques. There was no statistical significance (p>0.05).

CHAPTER FIVE

5.0 DISCUSSION

5.1 Characteristics of children with femur diaphyseal fractures treated at MTRH

Femur diaphyseal fractures in children are not uncommon. However, local and national incidences of paediatric femur diaphyseal fractures in Kenya are undocumented. In this study, the age of the patients ranged from 3 to 14 years with a mean of 9 (SD 2.9) years. This concurs with finding by Hinton et al., (1999)who documented that the overall rate of paediatric femur diaphyseal fractures was found to peak at between 10 and 13 years. A study by McCartney et al., (1994) in America show that the femur diaphyseal factures are rare accounting for 2% of paediatric and adolescent fractures. There is a bimodal age distribution in this fracture with the first occurring between ages 2-4 years and the later one occurring at adolescence.

The male to female ratio 2.31:1 shows more males were attended to during the study period, and this concurs with a South African study by Mughal et al., (2013) who found male to female ratio at 2.21:1. However, a study by Tochie et al., (2017)is contrasting as they found an higher male to female ratio in a Cameroonian hospital at 1.6:1. In the developed countries the range has varied but the males are usually more afflicted than the females. It is still not clear why the male child is more prone to this fracture but it has been postulated that the male child is more aggressive in taking risk e.g. climbing of trees or obstacles.

The mechanism of injury in children treated at MTRH was mainly due to fall from a height (included fall from trees, walls, and even a car) leading, followed by motor vehicle accidents, and fall at organised games. This contrasts findings by Mughal et al., (2013) and Hinton et al., (1999) who found motor vehicle accident to be the main causes of these injuries. This can be speculated to be due to differences in the setup.

The higher MVA incidences imply that the latter two groups of researchers conducted their epidemiological studies in the more developed society than Kenya.

In this study a number of patients- 11 (25.6%) had associated injuries, while 4 (9.3%) had open fractures. This implies high energy was involved in the mechanisms of injury, though there was no statistical significance for associated injuries and whether the fracture was open or closed (p= 0.267). The presence of associated injuries and open femur diaphyseal fractures in this study concurs with findings by Hutchins et al., 2000; and Ramseier, et al., 2007.

The period from injury to reporting to the hospital and subsequent operative treatments in this study shows interesting trend. When the child sustains the injury, a lot of time may be wasted seeking “over the counter” drugs for self- treatment, or seeking services of herbalists and traditional bone setters, and only when the situation cannot be contained is when alternative of bringing child to hospital is sought, thus delay in reporting to hospital for treatment. For peripheral health institutions, referral to MTRH is made. At the Hospital set up, it may take time to work- up and stabilize the patient for operative surgical treatments. To make the situation worse, the parents or guardians may not have ready finance to purchase whatever implants that may be required. The cost of treatment and family social issues among others in this local setting are responsible for delays encountered are in agreement with those by Anglen and Choi, 2005; Lebel, et al., 2006; and Sanders et al., 2001.

5.2 Operative surgical treatment techniques for children with femur diaphyseal fractures at MTRH

Operative surgical treatment techniques available at MTRH for paediatric femur diaphyseal fractures are the dynamic compression plate; external fixator and the fin nail (a rigid intramedullary nail). The DCP has been used for the treatment of femur fractures at MTRH, its use concurs with that by Fyodorov et al., (1999); Kumar and Chandrarashekar, (2014); and May et al., (2013) who reported on plating of the femoral diaphyseal fractures as being age appropriate for the patients. This is a contrast to other researchers such as Ziv and Rang, (1983) who had condemned the use of plate for femur diaphyseal fracture treatment after 4 of 5 patients they were treating with plating of femur developed infection. In this study however, there was no statistical significance ($p>0.05$) between the outcome versus the operative treatment technique used. Therefore the management of this injury has been a challenge for the Orthopaedic Surgeon.

Two patients at MTRH who were older were operated and fin nails used for fracture fixation. The majority of patients 37 (86%) at MTRH had their fractures fixed using the dynamic compression plate. The principle of using fin nail for the older children concurs with what is in the current guidelines as proposed by Khoriati et al., (2016) and Sela et al., (2013) that Orthopaedic Surgeon should utilise the age of the patient to determine the surgical implant for use in the operative surgical management of this injury. The older children are closer to the adult femur physiologically and are thus not at risk of deleterious effects on the growth plate which is expected to be at the end of growth period.

In this study, there were four patients with open femur diaphyseal fractures. One patient benefitted from operative treatment technique using DCP, while three patients benefitted from operative treatment techniques using external fixators. Since open fractures are at risk of infection, thorough initial surgical debridements were carried out, then stabilization achieved by use of the external fixators which provided good choices as they did not interfere with the fracture site as would a plate or intramedullary device. Use of external fixator concept in operative treatment of paediatric femur diaphyseal fractures concurs with that by Kong and Sabharwal, (20014) who recommended that the external fixator can be used for the treatment of length unstable femur diaphyseal fractures in children albeit the risk of refracture after fixator removal. The indication of the external fixator goes beyond the open fracture, and is valuable for very proximal and distal fractures where options for nailing or plating are limited.

5.3 Short- term clinical outcomes of operative surgical treatment techniques of femur diaphyseal fractures in children at MTRH

As for the clinical outcomes (short- term), majority had good range of motion while a few had knee stiffness, limb length discrepancy in few while infections (superficial and deep) quite few. In support for the clinical outcomes, the radiographs taken showed that all the patients had good bone alignment with 42 showing anatomical fracture union signs. Paediatric femur diaphyseal fractures in these patients therefore healed well despite the complications encountered. These findings are in agreement with those by Anglen and Choi, 2005; Fein et al., 1989; Label, Karasik, Fisher and Itzchaki, 2006; and Sanders, et al., 2001. Complications have been found to occur in the operative surgical management of femur diaphyseal fractures in children. These range from major complications which require reoperation to minor which can be managed without operation as documented by Flynn et al., (2001); and May et al., 2013.

The major complications occurred in 3 (6.9%) patients. In two of these patients one had hardware failure characterised as loss of reduction in a length stable fracture before the twelfth week clinic visit, while the other had a length unstable fracture. They both had reoperation, reduction and stabilization maintained; they went on to have a well aligned fracture. The third patient was a recorded case of deep infection. This patient had an open femur diaphyseal fracture following a fall from a height. There was delay of 35 days from the time of injury to arrival at the hospital. Early debridement and start of antibiotics would have averted the occurrence of infection; in contrast the other three children were admitted 2 days after sustaining the fractures.

Minor complications were seen in twelve patients: eight had a stiff knee, one had a superficial infection, and one had pin site infection while two had limb shortening. Fortunate enough they did not require operative treatment.

Regarding the complications, a total of 15 were recorded: twelve and three following DCP and external fixators operative techniques respectively. Out of the 37 patients who benefitted from operative treatment techniques using DCP, 12 had complications, giving a rate of 27.9%, while out of the 4 who benefitted from external fixation, 3 had complications, giving a rate of 7.0%.The short- term outcome complications can therefore be rated at a total of 34.9%. The complication rate of 27.9% following use of DCP at MTRH however cannot be compared with that by May et al., (2013)who investigated the presence of complications in the treatment of femur diaphyseal fractures using DCP and found an overall complication rate of 13% over a two year follow-up period, which is considered long term. The short- term follow up period at MTRH nevertheless gives us valuable information on what to look out for as the children heal from these fractures. Knee stiffness is a problem that needs to be tackled early and aggressively in order to prevent it.

5.4 Functional outcomes based on Flynn criteria grading for operative surgical treatment techniques of femur diaphyseal fractures in children at MTRH

There is no published data on the short- term outcomes of diaphyseal femur fractures in children. This period is vital in the management of the child with a femur diaphyseal fracture. The placement of a plate to fix fracture after reduction is a race against time for the bone to heal before the plate undergoes failure. This is not the case with the intramedullary devices which share the load with the bone. This time period is important as it signifies a major milestone in the operative surgical treatment of the child with a fractured femur.

In this study, a factor level of satisfactory (12) and excellent (28) out of 43 patients was realized based on the Flynn criteria grading. This however may not be comparable to other studies elsewhere as it was only for short- term outcome. Other investigators working in resource limited centres found impressive long term outcome results. Kumar and Chandrarashekar (2014) followed 30 patients over a longer period of time and made comparisons using Flynn criteria grading while using Titanium elastic nails and DCP operative treatment techniques for femur diaphyseal fracture and they found 95% satisfactory to excellent scores.

In this study, calculation of the measures of association between potential associated factors and outcome, and between outcome and operative treatment techniques by using cross- tabulations to get more information regarding statistical significance was done and found to have no statistical significance in each situation ($p > 0.05$).

CHAPTER SIX

6.0 CONCLUSION AND RECOMMNEDATION

6.1 Conclusions

The mean age of patients was 9 (SD 2.9) years, majority were males, most presented to hospital late, falls from height and RTAs caused most injuries, most of femur diaphyseal fractures were closed, with majority being of AO 32-D/4.1 with associated injuries.

The DCP was mostly used and offered rapid fixation and stabilisation of the fracture, allowing early ambulation on crutches; few major complications needing operative surgical intervention were encountered; majority of complications were minor and did not require operations.

The clinical short- term outcomes were good despite the complications.

The functional outcomes based on Flynn criteria grading was satisfactory to excellent in the majority of the patients.

6.2 Recommendations

Creating and intensifying awareness on the risks of falls from height and RTAs can help reduce the cases of femur diaphyseal fractures; should injury occur, presentation to hospital should be immediate.

Use of DCP in children should be encouraged as it is age appropriate providing favourable outcomes.

The clinical short- term outcomes may be further improved by prompt and appropriate care of the children with femur diaphyseal fractures.

Functional outcomes based on Flynn criteria grading may be further improved by prompt and appropriate operative surgical treatment techniques when the patient is admitted, and instituting prompt corrective measures against the complications that may be encountered.

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APPENDICES

Appendix1: Information Sheet and Consent Form

SHORT- TERM OUTCOMES OF OPERATIVE SURGICAL TREATMENT OF FEMUR DIAPHYSEAL FRACTURES IN CHILDREN AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

INVESTIGATOR–DR.OKOTHNICHOLASOCHIENGP.OBOX4 6 0 6

ELDORET, KENYA.TELEPHONE No. 0721596034

Informed assent for children who present at MTRH for treatment of femur diaphyseal fracture and consent for their guardians or parents who accompanied them.

This informed consent has two parts

- Information sheet (to share information about the study with you)
- Certificate of consent (for signatures if you choose to participate)

Part I: INFORMATION SHEET

The patients in this study are the children who are under age and in the custody of guardians and parents. The children have to be informed on what the study is about. They will be required to assent to be recruited into the study. As the guardian or a parent, you are being asked to participate in the study. This information is provided to tell you about the study. Please read this form carefully. You will be given chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your record.

Taking part in this research study is voluntary. You may choose not to take part in the study. You will still receive treatment. Declining to participate will not affect your rights to health care or services. You are also free to withdraw from this study at anytime. If after data collection you choose to quit, you can request that information provided by you be destroyed under supervision and thus not used in the study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study or not.

The purpose of the study is to identify the causes of the femoral diaphyseal fractures in children, describe the operative surgical treatment techniques used at MTRH, and problems that might occur as a result of the treatment. The study will continue following the routine treatment. A questionnaire will be used to collect data, clinical findings and radiological findings will be collected into a data collection tool.

The child will be received at the orthopaedics clinic and undergo preliminary survey to determine the extent of injury. A radiograph will be used to determine the diagnosis. Following the diagnosis, the attending clinician had made and the decision to reduce the fracture. The reduction of the fracture being temporary as child is prepared for operative surgical treatment.

Your child has been identified because he/she had came for operative surgical treatment of a femur diaphyseal fracture, based on the current techniques available and later discharged for follow- up in orthopaedics clinic, and being reviewed at 12^{th} week.

The study will involve the initial meeting with the clinician who will check the healing process, as well as extracting secondary data from patient's medical records.

There will be no direct side effects from this study, the treatment results and any associated complications such as nonunion, delayed union, length discrepancies, angular and torsional deformities; neurovascular injuries and stiffness of hip, knee, back and ankle among others will be documented.

The benefits of taking part in this study will be for the betterment of approach in the handling of the femur diaphyseal fractures in children and there will be no financial benefits for being part of this study.

If you have any questions about this study please feel free to contact Dr. Okoth Nicholas Ochieng via Telephone Number 0721596034. Questions about your rights as a human subject can be directed to the Institutional Research and Ethics Committee (IREC).

The information provided will be kept private and confidential. By signing this consent document you have given permission for the use and disclosure of information about the study. As part of the study, Dr. Okoth Nicholas Ochieng may shares the results of your clinical and radiological findings.

Your child's treatment, payment and enrolment in any health institution will not be affected if you decide not to participate. You will receive a copy of this form after it is signed

PART II: CONSENT TO PARTICIPATE IN THE STUDY

I________________of P.O Box_____Tel______________________________

Hereby give informed consent to participate in this study a t MTRH. The study has been explained to me clearly by Dr. OKOTH NICHOLAS OCHIENG.

I have understood that to participate in this study, I shall volunteer information regarding the medical condition, and undergo medical examination. I am aware that I can withdraw from this study 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.

Name of participant____

Signature_________Date_____________________________________

Name of witness___________________________ Signature__________

Date____

Appendix 2: Data Collection Tool

MTRH Clinic:____ Date:____________

Patient's Initials____

OP/IP NO._________________________________

Address__________ Phone no.________

Date of injury___________

Date of admission_______________

Date of surgery ________________

Age_____________ Sex: Male ☐ Female ☐ Weight______kg

School___________

Mechanism of injury

Fall from height

Motor Vehicle accident (Pedestrian)

Motor vehicle accident (Passenger)

Child Abuse

Others (Specify)___

Diagnosis based on radiographs____________________________

AO Classification_____________________________________

Associated injuries (specify)____

Operative surgical treatment technique (Specify)________________________________

Time taken to Ambulate with support ______________

Time taken to Ambulate without support_____________

Complication_____

Malunion

Delayed Union

Length discrepancy: Shortening__Lengthening____

Nonunion ______

Stiffness

Others

- Hip
- Knee
- Ankle
- Back
- Compartment syndrome
- Allergy (Plaster cast)
- Infection

Flynn Criteria Grading (TICK Appropriate box)

- Excellent ☐
- Satisfactory ☐
- Poor ☐

Appendix 3: IREC Formal Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2012/182
Approval Number: 000897

21st September, 2012

Dr. Okoth Nicholas Ochieng,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Okoth,

RE: FORMAL APPROVAL

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

"Outcome of Non-Operative Treatment of Closed Diaphyseal Fracture Femur in Children at Moi Teaching and Referral Hospital, Eldoret, Kenya."

Your proposal has been granted a Formal Approval Number: **FAN: IREC 000897** on 21st September, 2012. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 20th September, 2013. 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.

Yours Sincerely,

For

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
APPROVED
21 SEP 2012
P.O. Box 4606 ELDORET

cc:			
	Director	-	MTRH
	Principal	-	CHS
	Dean	-	SOM
	Dean	-	SPH
	Dean	-	SON
	Dean	-	SOD

Appendix 4: MTRH Approval

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke

P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

21st September, 2012

Dr. Okoth Nicholas Ochieng,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

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

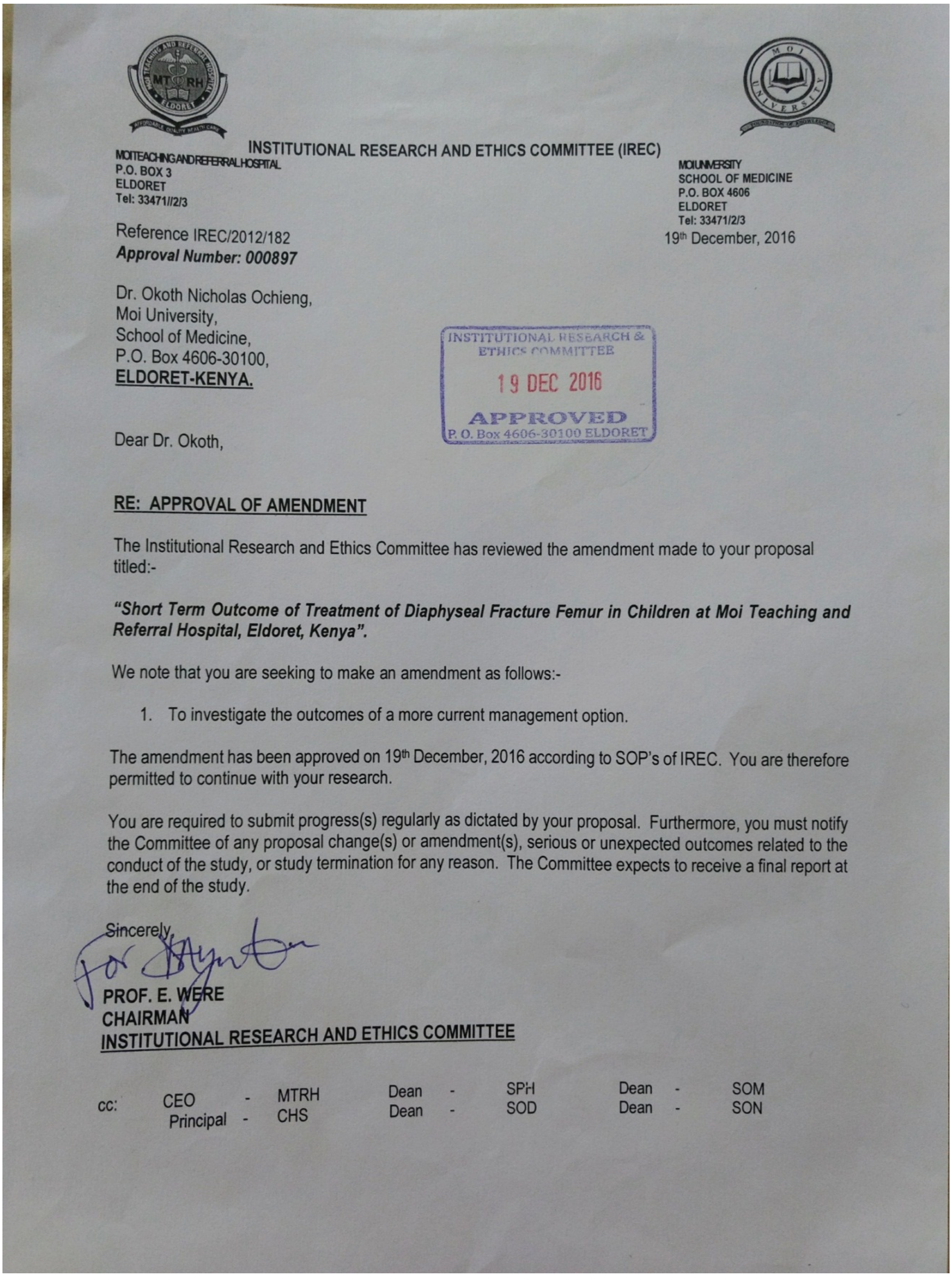
"Outcome of Non-Operative Treatment of Closed Diaphyseal Fracture Femur in Children at Moi Teaching and Referral Hospital, Eldoret, Kenya."

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

DR. J. KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Appendix 5: Approval of Amendment



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/1/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2012/182
Approval Number: 000897

19th December, 2016

Dr. Okoth Nicholas Ochieng,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
19 DEC 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Okoth,

RE: APPROVAL OF AMENDMENT

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

"Short Term Outcome of Treatment of Diaphyseal Fracture Femur in Children at Moi Teaching and Referral Hospital, Eldoret, Kenya".

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

1. To investigate the outcomes of a more current management option.

The amendment has been approved on 19th December, 2016 according to SOP's of IREC. You are therefore permitted to continue with your research.

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SPH	Dean	-	SOM
	Principal	-	CHS	Dean	-	SOD	Dean	-	SON

Appendix 6: Continuing Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

23rd January, 2017

Reference: IREC/2012/182
Approval Number: 000897

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
23 JAN 2017
APPROVED
P.O. Box 4606-30100 ELDORET

Dr. Okoth Nicholas Ochieng,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Okoth,

RE: CONTINUING APPROVAL

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

"Short Term Outcomes of Treatment of Diaphyseal Fracture Femur in Children at Moi Teaching and Referral Hospital, Eldoret, Kenya.

Your proposal has been granted a Continuing Approval with effect from 23rd January, 2017. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 22nd January, 2018. 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	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

Appendix 7: Budget for the study

Eight reams of plain paper	1 @ 500 each	4,000
Pens, pencils, rubber, folder		
	10 pens @ 50/ pen	500
	10 pencils@ 20/pencil	200
	10 rubbers @ 30/rubber	300
	10 folders @ 200/folder	200
Computer Flash discs	2 @ 1200 each	2,400
Print and bind Proposal 4 copies	1 @ 200	800
Printing draft thesis, 6 copies	1 @ 2500	15,000
Binding draft thesis, 6 copies	1 @ 1000	6,000
I.R.E.C. fee		1,000
Data handling (one-time fee)		15,000
Final Thesis Printing 8 copies	1 @ 2500	20,000
Final Thesis Binding 8 copies	1 @ 300	2,400
		67,800

Appendix 8: Work plan (Time line) for the study

Selection of topic	May, 2012- June, 2012
Literature review	June, 2012
Writing proposal	June - July 2012
Submission to IREC	August, 2012
Approval by IREC	September, 2012
Amendment approval by IREC	December, 2016
Continuing approval by IREC	January, 2017
Data collection and analysis	January 2017–May, 2017
Writing the thesis report	June, 2017 – September, 2017
Submission of thesis	December 2017
Marking of thesis	January 2018-February, 2018
Oral defense	August, 2018
Finalizing and submitting thesis for remarking	December, 2018
Submitting bound copies of Thesis	January, 2019