



**University of Nairobi**

**EARLY OUTCOME OF LOCKED INTRAMEDULLARY  
NAILING OF DIAPHYSEAL FEMORAL FRACTURES AT  
KENYATTA NATIONAL HOSPITAL.**

A dissertation submitted in part of fulfilment for the requirements of the degree of  
Master of Medicine (M.MED) in Orthopaedic Surgery

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I, Dr. Laichena Jeremiah declare that this dissertation is my original work and has not been submitted in whole or part in any institution of learning for award of a degree

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## **DEDICATION**

I dedicate this book to my greatest friend Lois, Mum Agnes, Dad Laichena Justus and to my siblings. They have continuously supported me, encouraged me and loved me, without them this journey wouldn't have been possible

## **ACKNOWLEDGEMENT**

My heartfelt appreciation to my family and friends, all the support I got was overwhelming all the encouragement throughout this study was more than enough. Thank you

To my supervisor's Dr Ombachi and Dr Mogire Tom, thank you for the guidance and the valuable critique.

My appreciation of the staff in the Orthopaedic wards, KNH, and staff at Orthopaedic clinic no.5 for facilitating my data collection

Thank you all

# CONTENTS

DECLARATION .....	ii
Declaration of Originality Form .....	iv
DECLARATION .....	v
DEDICATION .....	vi
ACKNOWLEDGEMENT .....	vii
CONTENTS .....	viii
LIST OF TABLES .....	xi
LIST OF FIGURES .....	xii
LIST OF ABBREVIATIONS .....	xiii
ABSTRACT .....	14
1.0 INTRODUCTION. ....	16
2.0 LITERATURE REVIEW. ....	18
2.1.1 History and use of intramedullary nailing.....	18
2.1.2 Outcomes after diaphyseal femoral intramedullary nailing.....	19
2.1.3 Effects of outcomes after intramedullary nailing of femur.....	22
2.1.4 Assessment of outcomes .....	22
2.1.5 Quality assurance procedures.....	25
3.0 RESEARCH QUESTION.....	26
4.0 STUDY JUSTIFICATION .....	26
5.0 STUDY OBJECTIVES.....	27
5.1.1 Main objective.....	27
5.1.2 Specific objectives. ....	27
6.0 METHODOLOGY.....	27
6.1 STUDY DESIGN.....	27
6.2 STUDY SETTING.....	27
6.3 STUDY POPULATION .....	27
6.4 SAMPLE SIZE .....	28
6.5 STUDY PERIOD .....	28
6.6 ELIGIBILITY CRITERIA.....	28
6.7 EXCLUSION CRITERIA.....	29



6.8 STUDY PROCEDURES .....	29
6.9 DATA COLLECTION PROCEDURES .....	29
6.9.1 Materials.....	30
6.9.2 Data collection instruments.....	30
6.9.3 Data handling.....	30
6.10 ETHICAL CONSIDERATIONS .....	31
6.10.1 Confidentiality of participants .....	31
6.10.2 Confidentiality of data obtained.....	31
6.10.3 Beneficence/maleficence .....	31
6.11 DATA MANAGEMENT AND STATISTICAL ANALYSIS PLANS .....	32
6.11.1 Data management.....	32
6.11.2 Data analysis .....	32
6.12 OUTCOME INTERPRETATION .....	32
6.13 STUDY LIMITATIONS.....	32
7.0 RESULTS .....	33
8.0 DISCUSSION .....	49
9.0 CONCLUSION.....	52
10.0 RECOMENDATIONS.....	52
11.0 REFERENCES.....	53
12.0 APPENDIX.....	59
DATA COLLECTION SHEET.....	59
A) PATIENT DATA.....	59
B) FRACTURE DATA.....	59
CONSENT FORM.....	62
PATIENT CONSENT FORM FOR PARTICIPATION IN THE STUDY .....	62
INVESTIGATOR’S STATEMENT .....	62
STUDY BACKGROUND .....	63
VOLUNTARINESS OF PARTICIPATION .....	63
CONFIDENTIALITY.....	63
BENEFITS OF PARTICIPATION.....	64
RISKS OF PARTICIPATION .....	64

RIGHT OF WITHDRAWAL .....	64
CONSENT CERTIFICATE:.....	65
STATEMENT BY THE RESEARCHER.....	65
IN CASE OF ANY QUERRIES: WHO TO CONTACT .....	66
STAKABADHI YA IDHINI .....	68
KNH STUDY REGISTRATION.....	72
KNH – UON ERC CERTIFICATE .....	73

## LIST OF TABLES

Table 1: Winqvist and Hansen classification .....	24
Table 2: Thoresen Criteria .....	25
Table 3: Summary of the parameters .....	33
Table 7: Mechanism of injury .....	37
Table 8: Fracture location .....	38
Table 9: Winqvist Hansen classification in the study .....	39
Table 10: Angular Malalignment .....	40
Table 11: Thoresen criteria .....	41
Table 12: Rotational deformity and Winqvist-Hansen classification .....	41
Table 13: Rotational Malalignment (Thoresen) .....	42
Table 14: Limb length and Winqvist-Hansen grade .....	43
Table 15: Limb length discrepancy .....	43
Table 16: knee range of movement at 3 months .....	45
Table 17: Hip range of movement after 3 months .....	46
Table 19: Callus at 12 weeks .....	47
Table 20: Adverse effects .....	48

## LIST OF FIGURES

Figure 3: Frequency of age group .....	36
Figure 4: Mechanisms of injury in the study population .....	37
Figure 5: Fracture location .....	38
Figure 6: Chart Winqvist and Hansen classification.....	39
Figure 7: Limb length discrepancy .....	44
Figure 8: grouped Winqvist-Hansen on LLD .....	44
Figure 9: Grouped knee flexion .....	45
Figure 10: callus at 12 weeks .....	47
Figure 11: Adverse effects .....	48

## **LIST OF ABBREVIATIONS**

AP=Anteroposterior

ILN= Intramedullary locking nail

TMM= Tape Measure Measurement

IMN= Intramedullary nail

WOMAC = Western Ontario & McMaster Universities Arthritis Index

LLD= Limb Length Discrepancy

ERC= Ethics and Research Committee

KNH= Kenyatta National Hospital

UON= University of Nairobi

SPSS= Statistical Package for the Social Sciences

ROC Curve= Receiver Operating Characteristic

PPV= Positive Predictive Value

NPV= Negative Predictive Value

AO= Arbeitsgemeinschaft fur Osteosynthesefragen (German for Association for the Study of Internal Fixation)

## ABSTRACT

### Background

Diaphyseal femoral fractures are common injuries seen at Kenyatta National Hospital with an average of 508 fractures being admitted annually. Locked Intramedullary nailing is now the gold standard for the treatment of diaphyseal femoral fractures and functional outcomes are good. Locked nailing is done either closed with an image intensifier or open with a proximal and distal locking jig. The locked nails used are from different manufactures and have different manufacture's preferred specifications on the fixation.

At KNH both methods are used, and the surgeries are carried out by Orthopaedic surgeons and residents at different levels of training.

Major complications of intramedullary nailing are low internationally, at around 5%. Some of them are angular and rotational malalignment, limb length discrepancy, decreased knee and hip range of motion. At KNH, the only study on ILN is on complications of diaphyseal fractures has been on the infection rates.

This study examined a group of patients treated at Kenyatta National Hospital which is a trauma Centre serving a big population of over 4.5 million in Nairobi and its environs. The outcomes examined were angular and rotational malalignment, limb length discrepancy, range of motion of the hip and knee joints and presence of callus at 12 weeks after the surgery. The above parameters have not been studied before in our setting.

**Objective:** To determine the early outcomes of diaphyseal femoral fractures treated by locked intramedullary nail at KNH

**Design:** A prospective observational study.

**Setting:** Orthopaedic wards and orthopaedic outpatient clinics at Kenyatta National Hospital (KNH).

**Study population:** Patients admitted to KNH with diaphyseal femoral fractures and underwent fixation with locked intramedullary nails

**Study period:** The study period was twelve weeks

**Patient and methods:** The study involved patients aged 18 years and above with diaphyseal femoral fractures treated by ILN. The patients who were selected to undergo locked intramedullary nailing and consented to the study were recruited. Their demographics, mechanisms of injury, fracture pattern and timing of surgery were recorded and then followed up for various outcomes

The patients recruited were assessed preoperatively, immediately after surgery and at 12 weeks' post-operative. Rotational and axial alignment, LLD, range of motion of the hip and knee joints and radiologic appearance of callus at 12 weeks was assessed and recorded.

**Methods of data analysis:** Data was analysed by use of SPSS version 22 and has been presented as tables, bar graphs and pie charts. Analysis of the demographic data was conducted using descriptive statistics

**Results:** Most patients were male (77.6%), RTA's were the leading cause of the injuries with motor vehicle accidents(driver/passenger) being commonest (39.7%). Antegrade nailing 56(98.2%) was performed in most of the patients with use of a distal locking jig. The patterns were Winkquist-Hansen grade 0 (22.4%), grade I (27.6%), grade II (25.9%), grade III (12.1%) and IV (12.1%). 88% of the patients scored excellent with Varus and Valgus below 5 degrees using Thoresen criteria. Varus deformity above 10 degrees was 3.5% and 5.2% in the valgus group which scored poor according to Thoresen criteria. 91.4% of patients had good to excellent outcome of angular alignment according to Thoresen criteria. External rotation deformity of 20 degrees and above was seen in 13.8% of patients. More than 15 degrees of internal rotation deformity occurred in 1.7%. In Thoresen criteria 81.1% of patients had good to excellent limb rotational alignment outcome. Limb length discrepancy of 2 to 3cm occurred in 3.5% of patients and another 3.5% had LLD of more than 3cm. Using Thoresen criteria, 92.9 % of patients had excellent to good limb length outcome.

Overall knee flexion of below 90 degrees was recorded in 12.1% of patients. Most patients maintained a normal hip range of movement. 39.7% patients had visible callus 12 weeks' postoperative while the rest 60.3% did not show any callus bridging the fracture site

## **1.0 INTRODUCTION.**

The treatment of femoral diaphyseal fractures has seen a change from the historical non-operative management to the most recent methods of fixation with intramedullary nailing. ILN have greatly expanded the indications for intramedullary fixation of diaphyseal femoral fractures (1). One of the advantages of intramedullary nailing following fractures of the femoral diaphysis has is early mobilization (2,3)

The treatment goals in patients with femoral diaphyseal fracture includes, restoration of alignment, rotation and length, preservation of the blood supply to aid union and early mobilization of the patient.

Intramedullary nailing of femoral shaft fractures can be performed with the patient in either the supine or lateral position on the fracture table (4,5,6). Lateral position allows an easier entrance portal, but disadvantaged as it presents problems in rotatory malalignment (7)

Use of interlocking nails as Intramedullary devices on diaphyseal femur fractures provides a stable fixation. This method yields high union rates and low complication rates when vigilance is maintained with good preoperative planning, the surgical procedure, and the postoperative care (8)

Interlocking nails have an advantage in maintaining the restored anatomy and permit early weight bearing (7)

Femoral diaphyseal fractures can be surgically managed by either open or closed nailing. In open nailing, the fracture is exposed, and reduction done under direct visualization whereas in closed nailing the intramedullary device is inserted under fluoroscopic control (9)

The nails can be inserted either antegrade or retrograde approach, this is influenced by the location of the fracture. Retrograde nailing has been advocated in cases of polytrauma, ipsilateral pelvic fractures, obese and pregnant patients (10). Among outcomes of locked ILN of diaphyseal femoral fractures are, angular deformity, rotational malalignment, LLD and range of motion of the knee and hip

An angular deformity of the femur in either coronal or sagittal planes is defined as angulation of greater than 5 degrees (11,12). The incidence of malalignment has been reported to range between 4.4% to 9% for the entire cohort of patients with diaphyseal femoral fractures that were



treated with intramedullary nailing. This has an impact on ipsilateral joint mechanics and therefore associated more with fracture patterns that are unstable as compared to stable fracture patterns (13).

Studies have shown that after IM nailing up to 28% of patients have rotational deformities of 15 degrees or more (14). With the amount of the rotation of the femur that can be tolerated well by the patient is not known, though more than 15 degrees has shown to have significant symptoms and often needs operative correction (15). These patients present with functional limitations and have difficulties with demanding activities (16). It is reported that more functional problems are associated with external rotation as compared with those patients with an internal rotational abnormality (17)

Limb length discrepancy of more than 2.5cm (18) has associated increase in functional energy demands following IM nailing of diaphyseal femoral fractures. LLD has effects on structure and has been associated with low back pain (19)

Knee stiffness has been observed after a fractured femoral diaphysis, and some of the factors associated with this is the type of treatment, location of the fracture and other associated injuries. Some studies have shown the hip and knee joints range of motion is comparable between the injured and uninjured leg, notwithstanding the nailing technique used (20)

Appearance of the callus is determined when there is callus on the postoperative radiographs, and fracture healing when the bridging callus completely connects the adjacent proximal and distal fragments at least in three cortices. There is a wide range of how long or how much callus is present on radiographs at 12 weeks, with ranges of 20% to 35% callus formation by 12th week post-surgery (21,22)

This study aim was to determine early outcomes of intramedullary nailing of diaphyseal femur fractures at Kenyatta National Hospital

## **2.0 LITERATURE REVIEW.**

### **2.1.1 History and use of intramedullary nailing**

An interlocking nail is defined as an intramedullary pin used in long bones with proximal and distal transfixing screws and provides torsional stability and axial bending.

The first account of use of intramedullary devices was first recorded by an anthropologist Bernardino de Sagagun in the 16<sup>th</sup> century. He witnessed Aztec physicians in South America use wooden sticks in patients with long bones non-union (23). A physician by the name Gluck in 1890 used the first interlocking nail made of ivory with holes on the ends where ivory interlocking pegs were passed through (23)

With more knowledge on the biomechanics of the intramedullary nails, and a basic principle of dynamic osteosynthesis, newer advances and use of intramedullary nailing of diaphyseal femur fractures has increased significantly. Kutcher used tight fitting nails that were associated with additional fractures, and the development of locked intramedullary nails with a lesser diameter than the canal allowed easier placement and use of locking screws to provide stable fixation (24) Biomechanically, after nail insertion, longitudinal, transverse and rotational forces act, of which their magnitude strongly depend on the point of entry and proper position of the nail. Biomechanical characteristics of the contemporary nails allow good bone healing and early mobilization (24)

The surgical procedure involves advancing a guide wire through the proximal and into the distal main fragment to a level 5 mm above the intercondylar notch for the reamed nails.

The length of the ILN can be determined using a second guide wire to the one that has been inserted or use of a radiographic ruler. Its recommended to ream beginning with a 9mm medullary reamer over the guide wire and adequate reaming must be performed to allow for smooth nail insertion. Normally a size below the reamed diameter is used.

In open nailing, direct reaming is done adequately on the proximal and distal segment

A nail insertion handle is used to manually advance the nail. Distal locking and proximal locking is done and then closure of the fascia and the skin as separate layers. The procedure ends with physical examination to assess limb length and rotation.

At our setting, most nailing is done open due challenges with availability of image intensifier and late access to theatre. Therefore, distal locking of the nail is also done with a distal locking jig

### **2.1.2 Outcomes after diaphyseal femoral intramedullary nailing**

Various outcomes after locked intramedullary nails have been reported. The incidence of angular malalignment varies from study to study. It was reported by Ricci WM et al (12) to be up to 9% in the entire group nailed and depending on the portion of the diaphysis, the highest malalignment when the fracture involved the proximal third, thirty percent and least when the middle third is involved two percent however Borel JC et al (26) found the incidence going up to 11.7% when he looked at 5 degrees to 15 degrees on both Varus and valgus planes

The factors that were conclusively considered not to be associated with increase in fracture angulation were the nail diameter used, the antegrade or retrograde method of treatment, fractures of the middle third and those that were stable simple pattern. Intraoperatively, the rotation was assessed using linea aspera (23).

Clinical measurement of rotational malalignment of the femoral diaphysis is expressed as a difference in femoral anteversion between the injured and the normal limb (26-30) and by radiography (32-34) ultra-sound (35-38) and computed tomography (39-42) with computer tomography giving most accurate results

Low incidence has been described by Kempf et al (30) and Johnson et al (31) who found no rotation and on the other hand Wiss et al (27) noted seven percent with more than ten degrees and Alho et al (28) reported only 0.8% in a series of 123 with a malalignment of greater than 20 degrees. In all the above studies, closed nailing was used, and fracture patterns varied from simple to Winquist-Hansen IV.

Contrasting opinions by other authors has been greatly reported with Mrita et al (21) in his follow up of 85 patients reporting external rotation malalignment of >20 degrees in 6.3% and internal rotation malalignment of >15 degrees in 8.9% of these patients.

There are two studies that have had a similar opinion, that of Sennerich et al who found more than 10 degrees of 40% and more than 20 degrees of 16% and Bråten et al (15) of more than 10 degrees of 43% and more than 15 degrees of 19% in his series of 110 patients. Fracture comminution also influences the malrotation.

The limb length discrepancy outcomes on comminuted femoral shaft fracture treated by interlocking IM nail has been reported by numerous authors with shortening of the nailed limb being more common. According to Winqvist et al (7) limb shortening more than 2 cm was seen in 2.0% and in 4.5% of patients by Arpacioğlu et al (43). However White et al studied 92 comminuted femoral shaft fractures revealed that 3.3% had shortening between 1 to 2 cm (44) and in contrast Sjøbjerg et al in his study on comminuted femoral fracture treated with closed interlocking nail found shortening of 1 to 2 cm in 7.5% of patients and 5% of patients lengthening of about 1 cm (45).

Many other authors have had contrasting opinions with the like of Zukerman et al showing from his study that 3.2% of patients had shortening or lengthening of more than 1 cm by use of tape measure method (46) and Tüzüner et al (47) from his study on comminuted femoral shaft fractures that limb LLD of more than 1cm occurred in 14.3%, and 2.3% of patients had shortening of more than 2.5cm. In Zukerman's study, 81.3% had static nailing while the rest were dynamized plus 26% patients had open fractures. In Tuzuner's study, patients included in the study were followed up for an average of 26 weeks which could have resulted to the differences. The presence of a limp after IM nailing of femur diaphyseal fractures was more associated with measured leg length discrepancy of more than 1 cm (48)

The passive hip and knee range of movement have been correlated with the method of treatment used with authors having varied opinions on the effect of antegrade and retrograde nailing. Injuries to the quadriceps muscles by the fracture or after open reduction causes scarring and there of affection knee flexion, on the patients reported to have knee stiffness that needed quadricepsplasty, they had high energy injuries and severely comminuted and associated patella fractures (49)

Antegrade and retrograde nailing has been reported not to have an influence on the knee range of motion by Bitta et al from his study in Tanzania, and similarly Moumni M. et al (20) and Sahmir Sadic et al (36) reported the range of motion of the two joints being comparable between the injured and the normal leg, irrespective of the antegrade or retrograde nailing, retrograde nailing was performed for fractures on the distal third of the diaphysis. Lelei et al (50) concluded that knee stiffness was higher in retrograde group than in Antegrade in his 2 years follow up of 124 patients, the retrograde nailing was done for lower third in 60% and middle third in 40% and

antegrade only in 2% of the distal and 65% on the mid third. Surgery was done by open method and it was postulated that knee pain and lack of rehabilitation protocol after retrograde nailing could have resulted to the above results.

Kibira G M et al reported lower range of movement on the knees in retrograde nailing in comparison to antegrade. This was affected by time to surgery and time of start of physiotherapy with patients who were operated earlier and started physiotherapy earlier showing better results (51)

Knee stiffness has been reported to improve in the first 6 to 12 weeks after surgical stabilization of a femoral diaphyseal fracture (50) The return of full range of movements varies from patient to patient and the patients who showed earlier ability of flexion of more than 90 degrees within 2 weeks also managed full range of motion within 2 months' post operatively (52). In another study, flexion of the knee was more than 120 degrees in 95.23% after a mean follow up of up to 14.4 months (47)

Appearance of the callus is when the callus is seen on the postoperative radiographs, and fracture healing is defined when the callus completely connects the proximal and distal fragments in at least 3 cortices in 2 views.

The mean duration of callus formation varies from study to study, Mrita et al (21) reported  $10.9 \pm 5.3$  weeks with thirty-five percent of patients having callus formation by 12th week post-surgery with no effective change with the number of locking screws used, patients underwent open nailing and direct visual fracture reduction and ranged from simple to comminuted fractures. Christopher et al (53) reported that at 12 weeks after injury, minimal callus for bone healing was present in 20% after nailing. Callus formation was measured on lateral and anteroposterior radiographs using a validated software that extracted the size of the peripheral callus on the digital radiographs therefore measuring callus area per location. According to Yamaji et al (54) study on femoral diaphysis type A fractures in AO classification, the callus appeared at an average of 3.9 weeks post-surgery after locked intramedullary nail. Yamaji et al compared closed interlocking and Ender nailing and they calculated the cross-sectional area of callus on the AP and lateral plain radiographs, it was reported that fixation obtained with Ender nailing promoted callus formation due to the elasticity.

Other authors like Edwin and Ugbeye et al (22) estimated the time of disappearance of fracture site tenderness was at  $9.13 \pm 1.4$  weeks with Initial radiologic callus activity at  $9.25 \pm 1.6$  weeks postoperatively.

### **2.1.3 Effects of outcomes after intramedullary nailing of femur**

Rotational deformities have been shown to cause problems of clinical significance (27,55-58) as reported by Jaarsma et al (13) who showed difficulties with demanding activities like climbing stairs and had hip and knee pain with reduced range of movement that has been associated with the change of biomechanics. This was for the patients with above 15 degrees of rotational deformity in comparison to the normal side. In agreement with his findings, Christie and Ehrenstein T et al reported less complains in patients with less than 15 degrees (37,57,59). Patients with internal rotation have better outcomes in comparison to those with external rotations and studies using the Knee Society scores have proved that (6). Similarly, Johnson and Greenberg (31) reported that patients could compensate well for internal rotational malalignment. Also, an additional complication of rotational malalignment is the degenerative arthritis of the hip and knee (60)

Among reported effects of LLD is pelvic torsion in the frontal or sagittal planes and LLD of 10 – 20 mm have clinical significance, although there is minimal evidence outside of severe, abrupt loading (61,62) to cater for unequal limb lengths. Compensatory gait abnormalities may resort to degenerative arthritis in the lower extremity and lumbar spine (63,64)

### **2.1.4 Assessment of outcomes**

To measure sagittal and coronal angulations, anteroposterior and lateral plain radiography is taken for the femur in each patient. On the radiographs measurement of the residual angle at the fracture site in the 2 planes (coronal and sagittal) is measured to give the angular alignment using the anatomical axis (25,28)

The degree of limb rotation is clinically measured with the patient lying supine and the hip in neutral by using a goniometer and the angle between an imaginary line along medial border of the foot and vertical axis is measured (4,69). A comparison of the obtained angles between the injured and the uninjured limb is measured (27,65). It is assumed that the contralateral limb has

the same physiological rotation, and the measurements proves a challenge when there is a foot deformity Various authors have reported on the use of tape measurements, Jamaluddin et al (66) reported on excellent agreement between the surgeons using a tape measure, 2 radiologists with CT sonogram, and between the tape measure and CT measurements.

True limb length measured from ASIS to the medial malleolus using a tape measure is a validated tool (58)

Knee range of movement is measured by a goniometer placed laterally on flexed knee to measure the degree of knee flexion and extension and then a comparison of the two sides is done (11,56) agreement between visual estimates and the use of goniometer indicates good agreement in a study on reliability of a goniometer and visual estimates of hip range of motion by Inger Holm et al (69) and Watkins MR (58)

Studies by Winqvist and Hansen on fractures of femur diaphysis resulted to coining a classification that was shown to have an on the outcome of a nailed femoral diaphyseal fracture with grade I and grade II being stable as compared to grade III and IV which are have a higher risk of malrotation and shortening. AO rating and Winqvist have a high rate of agreement between observers for diaphyseal femoral fractures in adults (63).

**Table 1: Winqvist and Hansen classification**

<b>Grade</b>	<b>Level of comminution</b>
<b>Grade 0</b>	Minimal or no comminution
<b>Grade 1</b>	Butterfly fragment (<25%) or minimal comminuted segment with at least 75% cortical contact between the proximal and distal segments
<b>Grade II</b>	Butterfly fragment or comminuted segment with (approximately 25–50%) with at least 50% cortical contact between the proximal and distal segments
<b>Grade III</b>	Butterfly fragment or comminuted segment (approximately 50–75%) with minimal cortical contact between the proximal and distal segments
<b>Grade IV</b>	Complete cortical comminution with no cortical contact between the segments. Segmentally comminuted

Thoresen et al (16) in their study of intramedullary nails classified outcomes and developed Thoresen scoring systems that has been used to classify malalignment and the range of knee motion with their degree outcome score range from excellent to poor considering the criterion of lesser performance.



**Table 2: Thoresen Criteria**

<b>Criteria</b>	<b>Excellent</b>	<b>Good</b>	<b>Fair</b>	<b>Poor</b>
Malalignment of femur(degrees)				
Varus/valgus	5	5	10	>10
Internal rotation	5	10	15	>15
External rotation	10	10	20	>20
Limb length discrepancy(cm)	1	2	3	>3
Knee motion(degrees)				
Flexion	>120	120	90	<90
Extension deficit	5	10	15	>15

### **2.1.5 Quality assurance procedures**

Recommended views of the femur postoperatively are AP and lateral views of entire femur, determination of angular malalignment using the anatomical axis on the femurs (25,28)

Use of goniometric measurement is a validated tool in measurement of limb rotation (2,10,68) and range of motion of the hip and knee (56,58). Tape measure measurements for LLD (23,26) and the recorded measurements together with the information obtained by clinical examination was presented for evaluation and interpretation

Therefore, it is noted that different authors in their studies have had various outcomes reported with incidences varying from study to study. The angular malalignment varies from 4.4% to 9% but with an agreement that stable fractures and fractures in the diaphyseal mid third have the least angulation. Rotational malalignment has the biggest variability among the studies but with the agreement that the patients with external rotational have poorer outcomes. Limb length difference influence gait and widely reported about back pain that could be associated with the discrepancy.

Hip and knee range of movements have been reported widely also, with no agreement as to which method of fixation between antegrade and retrograde has an effect, with most studies reporting reduced range of movement of the knees with the retrograde group. Radiologic presence of callus in the lateral and antero-posterior views is a marker of fracture healing and it has also been reported above and varies from study to study, with differences in the open fracture fixation and closed fracture fixation

Conclusively, there is a variability on the early outcome of diaphyseal femoral fractures fixed with ILN. Tools of measurements of angular and rotational alignment have been used including computer tomography. In most of the studies, plain radiography and direct measurements with a goniometer was used. Cost and availability are the major considerations. Plain radiography and goniometer are readily available and cheaper. Limb length and range of movements was measured using a tape measure and goniometer respectively. A study in our set up is therefore necessary to determine these outcomes and compare with the studies in other centres.

### **3.0 RESEARCH QUESTION**

What is the early outcome of the use of locked intramedullary nails in femur diaphyseal fractures at Kenyatta National Hospital?

### **4.0 STUDY JUSTIFICATION**

Lower limbs fractures are among the commonest admissions to the orthopaedic wards in Kenyatta National Hospital. An average of 508 diaphyseal femoral fractures and 30.7% being nailed with an ILN in KNH annually.

The only studies done locally on outcome after locked nailing has been on infection rates. There was a need therefore to do this study at our set up. The aim of the study was focus on the early outcome after the use of locked intramedullary nails in diaphyseal femoral fractures

## **5.0 STUDY OBJECTIVES**

### **5.1.1 Main objective**

To determine the early outcomes of patients treated with locked intramedullary nails on diaphyseal femur fractures at Kenyatta national hospital

### **5.1.2 Specific objectives.**

- i) To determine rotational malalignment of the femur after ILN of diaphyseal femoral fractures
- ii) To determine angular malalignment of the femur after ILN of diaphyseal femoral fractures
- iii) To determine the range of motion of the knee after ILN of diaphyseal femoral fractures
- iv) To determine the range of motion of the and hip after ILN of diaphyseal femoral fractures
- v) To determine limb length discrepancy after ILN of diaphyseal femoral fractures
- vi) To determine the radiologic presence of callus at 12 weeks after ILN of diaphyseal femoral fractures

## **6.0 METHODOLOGY**

### **6.1 STUDY DESIGN.**

A hospital based prospective observational study with follow up to 12 weeks after the surgery

### **6.2 STUDY SETTING**

The study was undertaken at the KNH orthopaedic wards and clinics

### **6.3 STUDY POPULATION**

Patients admitted to KNH with diaphyseal femoral fractures and undergo fixation with locked intramedullary nails

## 6.4 SAMPLE SIZE

$$N = \frac{z^2 pq}{d^2}$$

Where: N represents the sample size z is the standard normal variant corresponding to the 95% confidence interval, and which is 1.96

p= the expected prevalence of patients who undergo femoral shaft intramedullary locked nailing admitted to the Kenyatta National Hospital. q=1-p

d=the required precision of estimate (0.05)

Prevalence of diaphyseal femur fractures is 12.7% (70) and of those that underwent intramedullary nailing in KNH from April 2015 to March 2016 were 30.7%. That gives 3.9% total of nailed femur fractures

N = 57

+ 10% possible drop out (6)

TOTAL=63 PATIENTS

## 6.5 STUDY PERIOD

The study period was six months

## 6.6 ELIGIBILITY CRITERIA.

Patients 18 years and above with diaphyseal femoral fractures who underwent locked intramedullary nailing during the period of the study and gave an informed consent to participate in the study

## **6.7 EXCLUSION CRITERIA**

- i) Patients with intra-articular extension of the fracture
- ii) Patients with previous surgery of the ipsilateral femur
- iii) Patients with other limb deformities
- iv) Patients with bilateral femur fractures and associated pelvic fractures
- v) Patients with contractures of the knees or hips preoperatively
- vi) Patients with open fractures
- vii) Patients with pathological fractures
- viii) Patients with hip and knee joint limited range of motion preoperatively due to osteoarthritis or any other condition
- ix) Patients with head injury and neurological deficits

## **6.8 STUDY PROCEDURES**

All patients who qualified for the study and agreed to participate in the study were recruited into the study. A brief clinical history was taken, and the patient examined

A consent form was filled by all the participants.

## **6.9 DATA COLLECTION PROCEDURES**

Mode of injury, age, sex, lateralization, location, fracture pattern description for each patient was noted preoperatively.

Number of days to surgery and information on operative procedure was recorded after surgery

Post-operative radiological and clinical findings and 12 weeks' post-operative clinical and radiological findings were recorded

Findings from each exam was captured in a data collection form

### **6.9.1 Materials**

All the patients who qualified for the study and gave an informed consent were assessed by the principal investigator or trained colleagues who conducted the examination to the patients and filled the data collection forms. The data collection form addressed the following areas;

- i) Age
- ii) Sex
- iii) Mechanism of injury
- iv) Side of the fracture
- v) Site of the fracture on the diaphysis: proximal, mid-, or distal third of the diaphysis
- vi) Pattern of fracture (Winqvist and Hansen classification) using the plain radiographs
- vii) Timing of surgery
- viii) Patient positioning during surgery
- ix) Closed or open fracture nailing
- x) Antegrade or retrograde nailing
  
- xi) Limb length discrepancy
- xii) Rotational malalignment
  
- xiii) Angular malalignment on postoperative plain radiographs
  
- xiv) Knee range of motion and Hip range of motion
  
- xv) Radiological presence of callus on the radiographs at 12 weeks

### **6.9.2 Data collection instruments**

Data was collected by the principal investigator and research assistants who were working amongst the health workers working in KNH.

### **6.9.3 Data handling**

The questionnaires were sorted at Kenyatta National hospital. The filled questionnaires have been stored and moved for safekeeping at an offsite location. Data was entered in a password protected Microsoft access database. Once entry was completed, the principal investigator

compared contents of the database with the hard copy results to identify and correct any data entry errors.

## **6.10 ETHICAL CONSIDERATIONS**

1. Written consent was sought from the patients participating in the study with the risks and benefits of participation explained to them. The consent form included the rights of the participants
2. Ethical clearance. The research team obtained ethical clearance to conduct this study from the KNH/UON Ethics and Scientific Review Committee.
3. Institutional permission was sought from both KNH and university of Nairobi and granted 4. Confidentiality was maintained always during the study

### **6.10.1 Confidentiality of participants**

The principal investigator ensured that there were no identifiers that may link the research data to study patients.

Each study patient was allocated a unique numeric identifier that was used in the data abstraction tool and database.

### **6.10.2 Confidentiality of data obtained**

Access to the participant data was restricted. No unauthorized persons will be allowed any access to participant records. These records are stored in a locked cabinet. All electronic databases are password protected to control access.

### **6.10.3 Beneficence/maleficence**

The results of the study will be useful in improving patient management by the participants and will be published to benefit other clinicians

All participants are protected from any health, physical, social or economic harm. The principal investigator ensured that no information that is obtained from the participant was used anywhere else

## **6.11 DATA MANAGEMENT AND STATISTICAL ANALYSIS PLANS**

### **6.11.1 Data management**

All data abstraction tools and electronic databases (MS Excel) utilized in this study are protected by procedures which are consistent with applicable laws, policies, regulations and standards in Kenya. Data will be entered in computers and will be password protected. These electronic databases are password protected.

Any hard copies have been kept under lock and key.

### **6.11.2 Data analysis**

Data has been analysed and presented in form of tables, bar graphs and pie charts.

Analysis of clinicians' demographic data has been conducted using descriptive statistics and chi-square testing at 95% confidence intervals.

At the end of the study data has been analysed and reported on the early outcome after intramedullary nailing of femur fractures and it includes angular and rotational malalignment, limb length discrepancy and presence of callus at 12 weeks

## **6.12 OUTCOME INTERPRETATION**

The angular and rotational malalignment, LLD and knee range of motions have been interpreted using modified Thoresen et al criteria (23) with their degree outcome score range from excellent to poor considering the criterion of lesser performance and the presence of callus separately

## **6.13 STUDY LIMITATIONS**

- i) Unavailability of locking nails in the hospital and therefore patients had to source from outside, this delayed time to surgery
- ii) Patients opting out of the study – patients were educated well on enrolment to the study.
- iii) Seven discharged patients were lost to follow up.



## 7.0 RESULTS

**Table 3: Summary of the parameters**

Parameters	Results
Total number of fractures	58
Age range of patients	18-66 Years
Mean of age in years	32.6
Femoral diaphysis fracture	
Proximal third shaft	12
Middle third shaft	37
Distal third shaft	9
Side of the fracture	
Right side	30
Left side	28
Male to female ratio	3.46:1
Most common type of fracture as per Winqvist Hansen classification	Grade 1

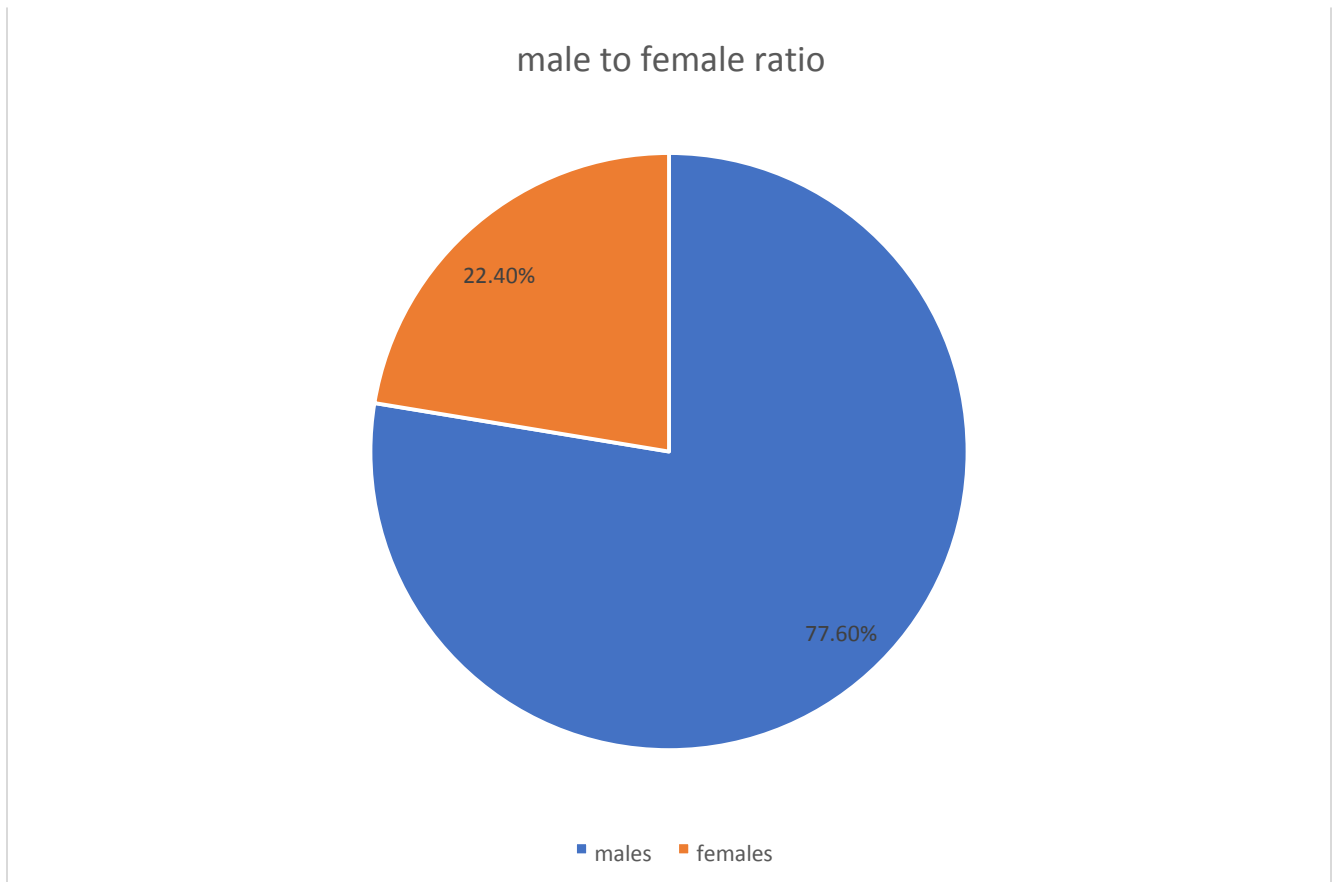
A total of 65 study participants were recruited and included in the analysis. 7 patients were lost to follow up. The age range was 18 to 66 years with a mean of 32.6 years and a standard deviation of 10.9 with an average of 29 days from injury to surgery which ranged from 2 to 107 days (SD 24)

There were total of 45(77.6%) males and 13(22.4%) females giving a ratio of 3.46:1

**Table 4: Male Female to distribution**

Gender	Number	Percent
Male	45	77.6
Female	13	22.4
Total	58	100

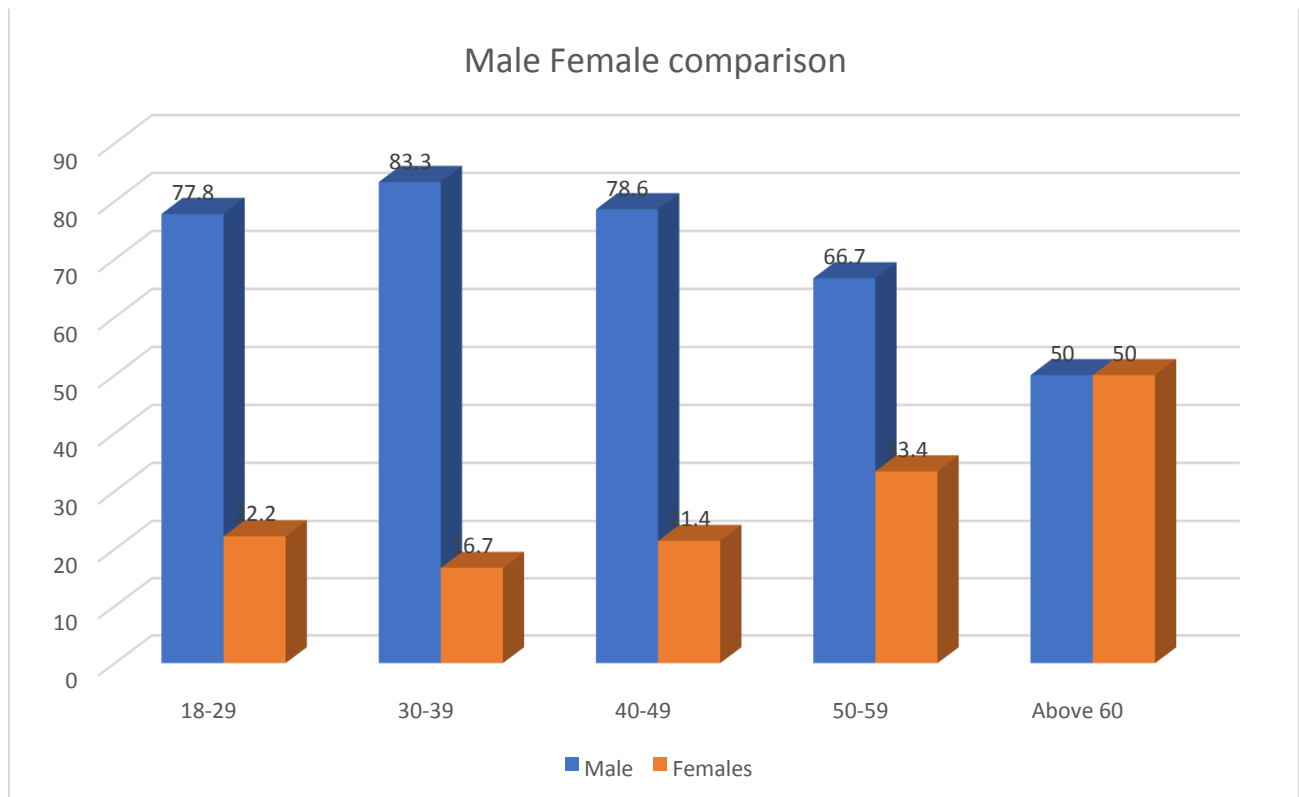
**Figure 1. Pie chart depicting gender**



**Table 5: Comparison male to female**

		Sex			
		Male		Female	
		N	%	n	%
Age group	18-29 years	21	77.8	6	22.2
	30-39 years	10	83.3	2	16.7
	40-49 years	11	78.6	3	21.4
	50-59 years	2	66.7	1	33.4
	60 years and above	1	50	1	50

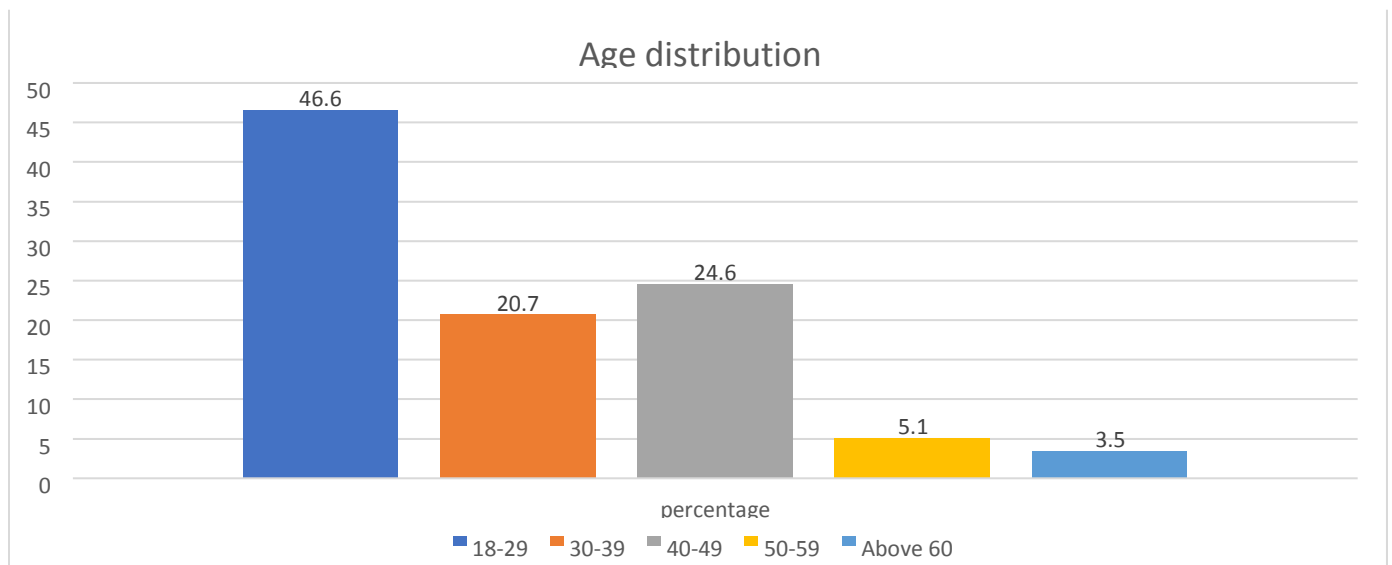
**Figure 2: Comparison of Male Female distribution**



Patients between ages 18 to 29 were more (46.6%) and over 60 years old the least (3.45) Table 6: Age distribution

Age in years	Total	Percentages
18 - 29	27	46.6
30 - 39	12	20.7
40 - 49	14	24.6
50 - 59	3	5.1
>60	2	3.45

Figure 3: Frequency of age group



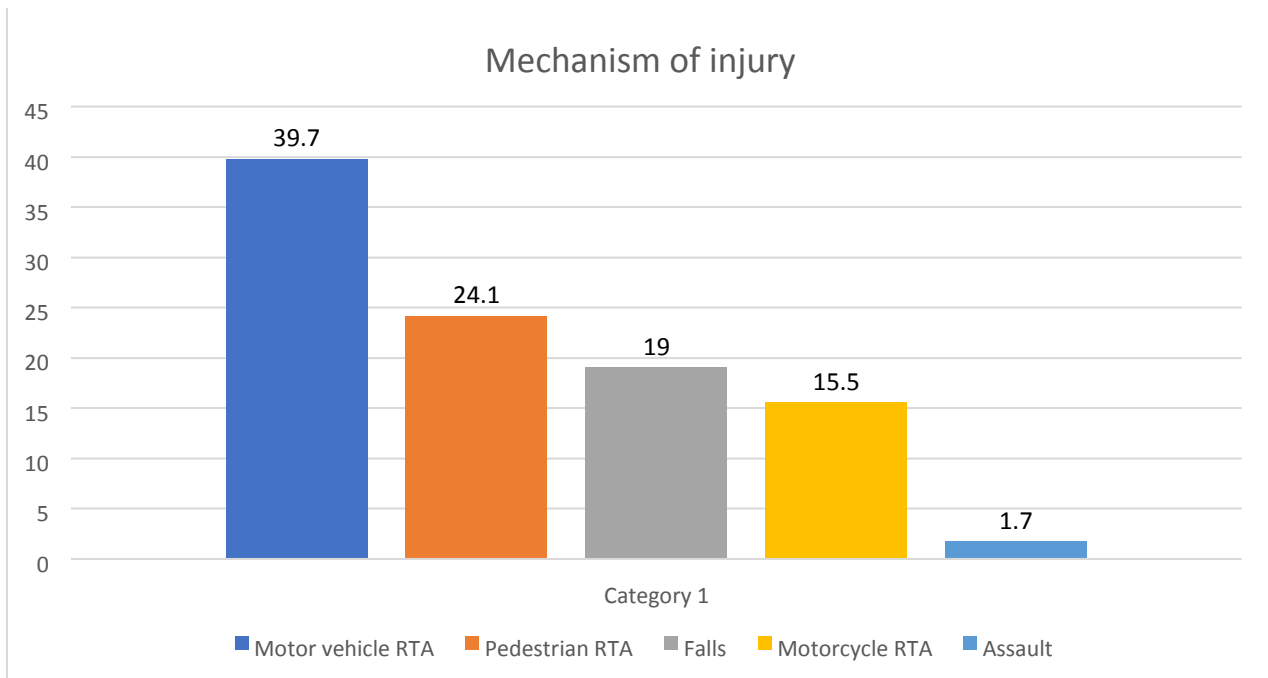
### Mechanism of injury

RTA's were the leading cause of the injuries with motor vehicle accidents(driver/passenger) 39.7% followed by pedestrian (hit by motor vehicle/motor bike) 24.1%, falls (19.0%) then motorcycle accidents(driver/passenger) 15.5% and assault (1.7%) last

**Table 7: Mechanism of injury**

Mechanism of injury	Count	Percentage
RTA-Vehicle	23	39.7
RTA-Motorbike	9	15.5
Pedestrian	14	24.1
Fall	11	19.0
Assault	1	1.7

**Figure 4: Mechanisms of injury in the study population**



There was no statistically significant difference on the side of the limb involved with the left involved in 51.7% and right 48.3% of the totals. Intraoperatively, Method of IM nailing was either lateral positioning 32(55.2%) or supine 26(44.8%)

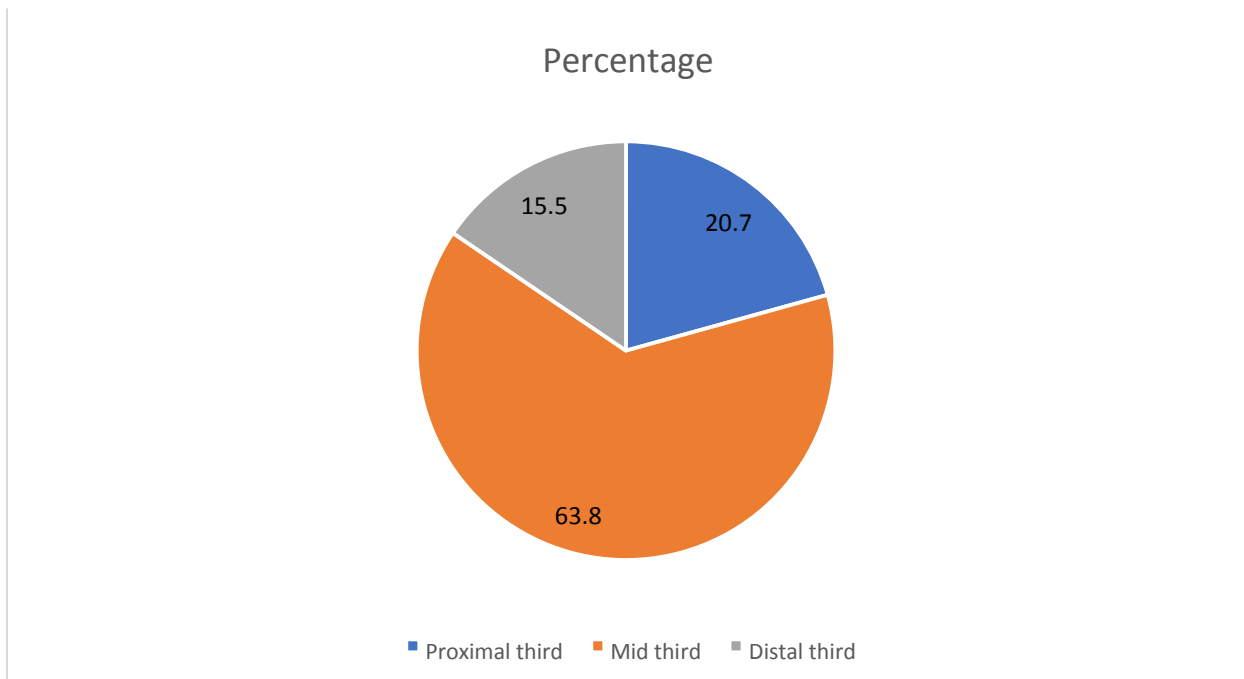
Antegrade nailing 56(98.2%) was performed in most of the patients and only 2 underwent retrograde nailing 2(1.8%). These two patients had distal third fractures. The commonest method of nailing was open nailing 57(98.3%) and only one patient underwent Closed nailing 1(1.8%) due to unavailability of the image intensifier.

Most fractures involved the middle third (63.8%) followed by proximal third (20.7%) and lastly distal third (15.5%)

**Table 8: Fracture location**

	Proximal third	12	20.7%
Site of fracture	Mid third	37	63.8%
	Distal third	9	15.5%

**Figure 5: Fracture location**

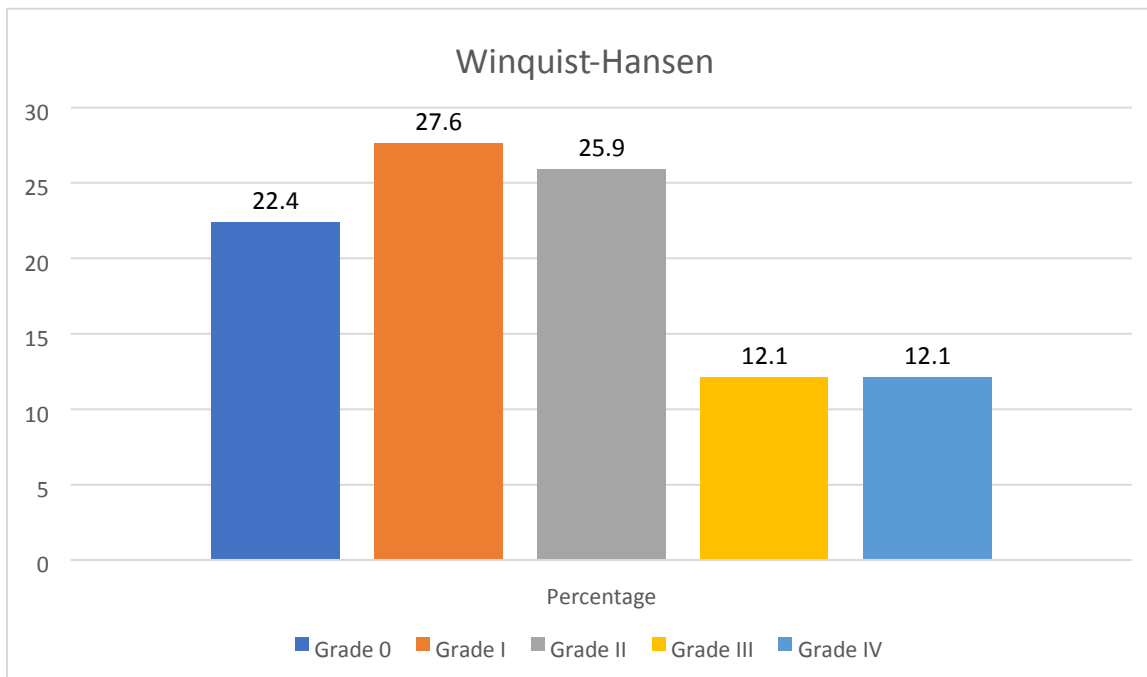


Most fractures were Winquist Hansen grade 1(27.6%) and the least was grade III (12.1%)and IV (12.1%)

**Table 9: Winqvist Hansen classification in the study**

Winqvist-Hansen grade	Count	Percentage
Grade 0	13	22.4%
Grade I	16	27.6%
Grade II	15	25.9%
Grade III	7	12.1%
Grade IV	7	12.1%

**Figure 6: Chart Winqvist and Hansen classification**



### Angular malalignment

Most patients scored excellent with Varus and Valgus below 5 degrees (88%). Varus above 10 degrees was 3.5% and 5.2% in the valgus group which scored poor according to Thoresen. There was no statistical significance on the effect of comminution on the angular malalignment

**Table 10: Angular Malalignment**

		Winquist-Hansen grade										p-value
		Grade 0		Grade I		Grade II		Grade III		Grade IV		
		n	%	N	%	n	%	n	%	n	%	
Grouped Varus	0-5	8	13.8	6	10.3	8	13.8	0	0	2	3.4	0.234
	6-9	0	.0	0	.0	1	1.7	0	.0	0	.0	
	10 and above	0	.0	2	3.4	0	.0	0	.0	0	.0	
Grouped Valgus	0-5	8	13.8	8	13.8	8	13.8	2	3.5	1	3.4	0.368
	6-9	1	1.7	0	.0	0	.0	0	.0	0	.0	
	10 and above	0	0	0	0	1	1,7	2	3.5	0	0	



**Table 11: Thoresen criteria**

Status	Frequency	Percentage	Thoresen score
Varus			
0-5	24	41.4	Excellent
6-9	1	1.7	Good
Above 10	2	3.5	Poor
Valgus			
0-5	27	46.6	Excellent
5-9	1	1.7	Good
Above 10	3	5.2	Poor

**Rotational deformity**

Most patients (72.4%) had normal alignment. External rotation malalignment of more than 20 degrees was seen in 13.8% of patients. Internal rotation malalignment of more than 15 degrees occurred in 1.7%. In Thoresen criteria 81.1% of patients had excellent limb alignment outcome. There was no statistical significance of the level of comminution on rotational malalignment

**Table 12: Rotational deformity and Winquist-Hansen classification**

		Winquist-Hansen grade										p-value
		Grade 0		Grade I		Grade II		Grade III		Grade IV		
		n	%	N	%	n	%	n	%	n	%	
Group external rotation	11-15	0	.0	1	1.7	1	1.7	0	.0	0	.0	0.248
	16-20	1	1.7	0	.0	0	.0	1	1.7	0	.0	
	Above 20	2	3.5	1	1.7	0	.0	2	3.5	3	5.2	
Group internal rotation	5-9	0	.0	1	1.7	2	3.5	0	.0	0	.0	0.505
	10-14	0	.0	0	.0	0	.0	0	.0	0	.0	
	Above 15	0	.0	0	.0	1	1.7	0	.0	0	.0	

**Table 13: Rotational Malalignment (Thoresen)**

Status	frequency	percentage	Thoresen score
Normal alignment	42	72.4	Excellent
External rotation deformity			
11-15	2	3.45	Good
16-20	2	3.45	Fair
Above 20	8	13.8	Poor
Internal rotation			
5-9	3	5.2	Good
10-14	0	0	Fair
Above 15	1	1.7	Poor

### Limb length discrepancy

Limb length discrepancy of 2 to 3cm occurred in 3.5% of patients and another 3.5% had LLD of more than 3cm. Interpretation using Thoresen criteria 92.9 % of patients had excellent to good limb length outcome. Most shortening was in fractures grouped grade III and IV (Winqvist and Hansen) which was significant (p value 0.017) showing the effect of comminution on LLD

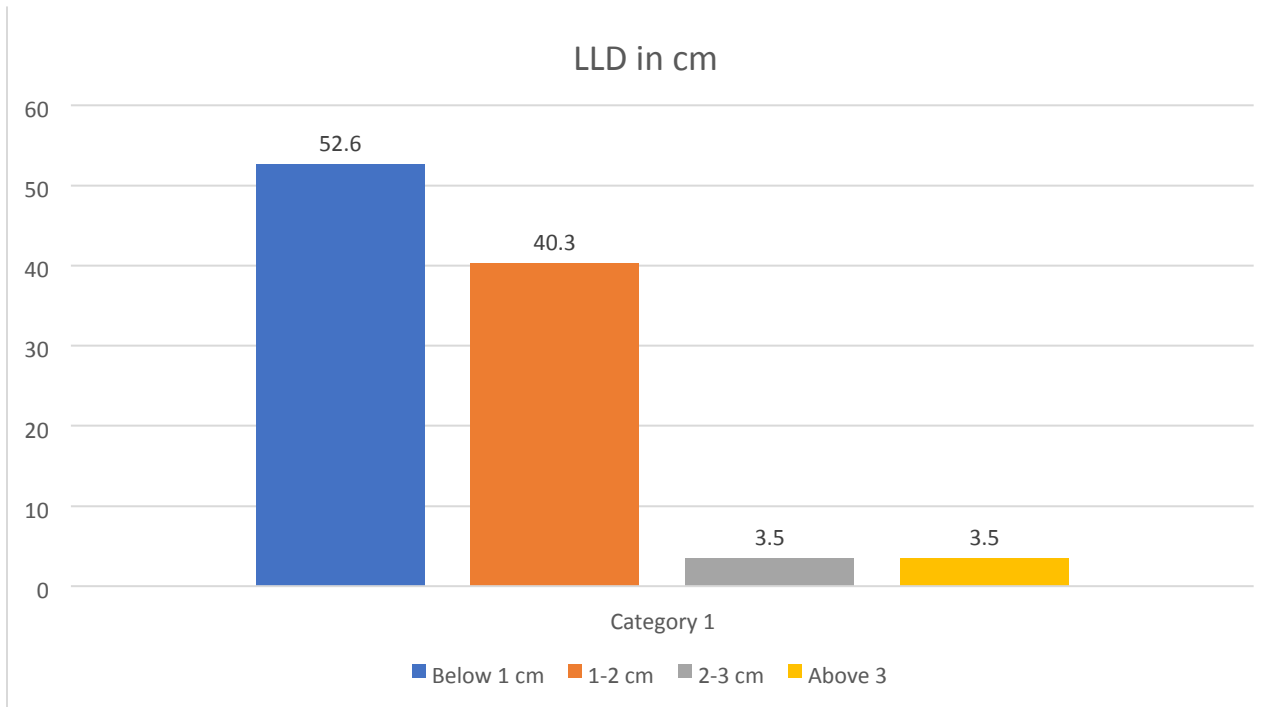
**Table 14: Limb length and Winqvist-Hansen grade**

		Winqvist-Hansen grade										p-value
		Grade 0		Grade I		Grade II		Grade III		Grade IV		
		n	%	N	%	n	%	n	%	n	%	
Group limb length	<1 cm	7	12.1	11	19.0	7	12.1	2	3.4	1	1.7	0.016
	1-2 cm	5	8.6	3	5.2	6	10.3	5	8.6	2	3.4	
	2-3 cm	0	.0	0	.0	0	.0	0	.0	1	1.7	
	Above 3 cm	0	.0	0	.0	0	.0	0	.0	1	1.7	

**Table 15: Limb length discrepancy**

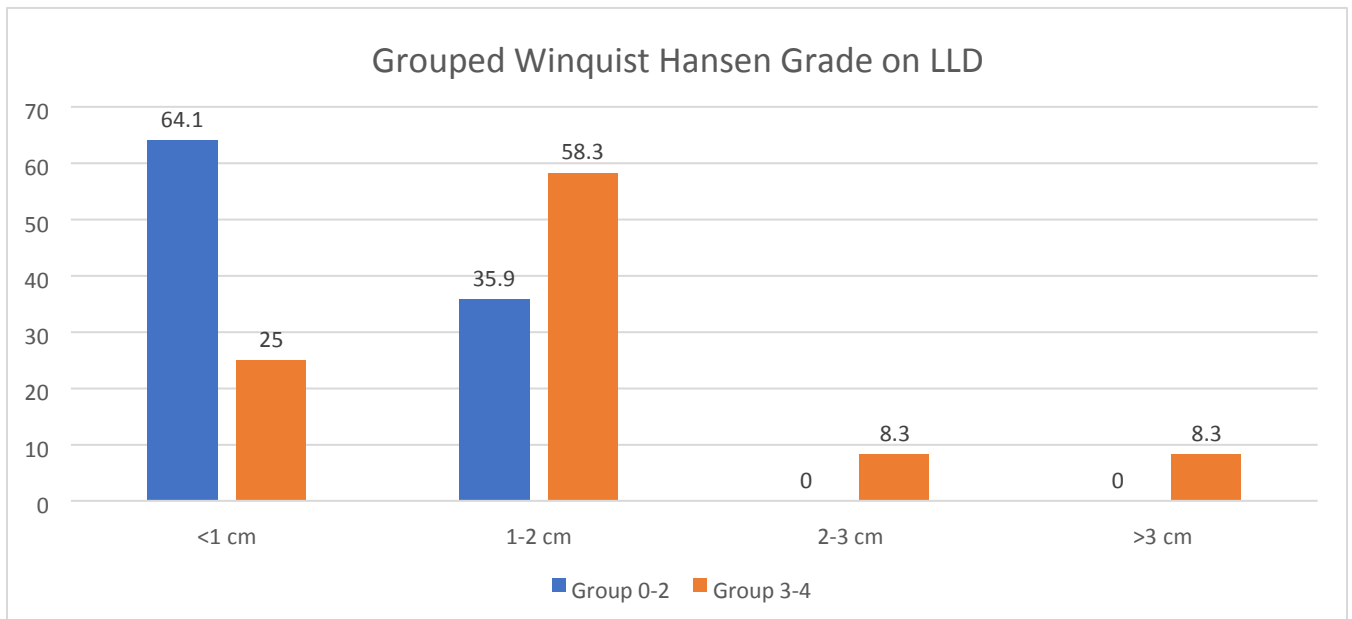
LLD	Below 1	1-2cm	2-3 cm	Above 3 cm
N=	30	23	2	2
%=	52.6	40.3	3.5	3.5
Thoresen	Excellent	Good	Fair	Poor

**Figure 7: Limb length discrepancy**



Most shortening was in fractures grouped grade III and IV (Winqvist and Hansen) which was significant (p value 0.017) showing the effect of comminution on LLD

**Figure 8: grouped Winqvist-Hansen on LLD**



### Knees range of movement after 3 months

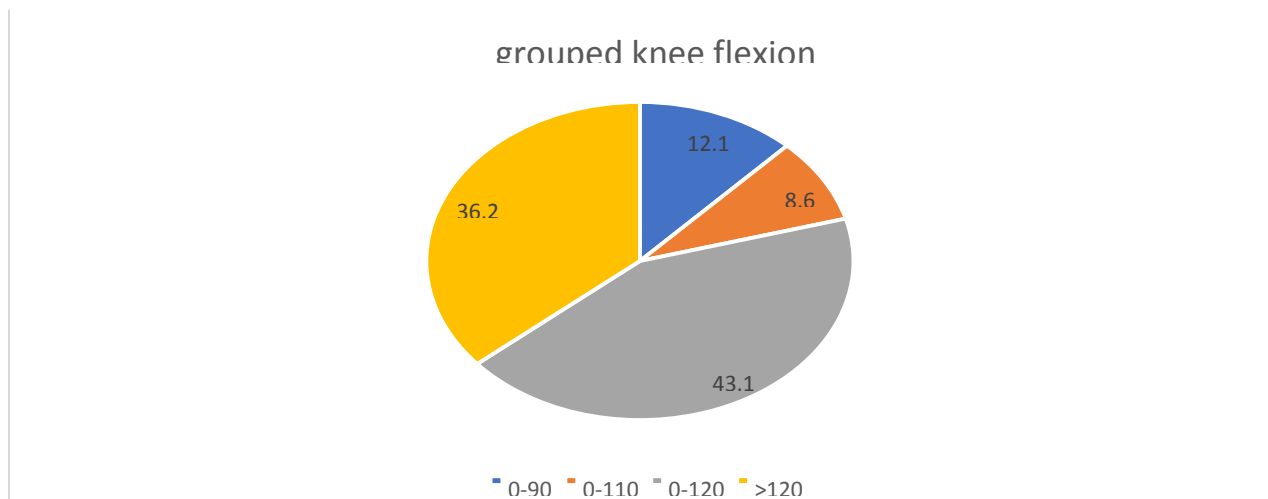
Range of movement of knee joint overall knee flexion of <90 degree was encountered in 12.1% of patients. One patient had a knee extension of 15 degrees

The difference was statistically difficult to compare between the antegrade and retrograde group due to the low number of retrograde group. By Thoresen criteria excellent to good knee flexion was encountered in 79.3% of patients.

**Table 16: knee range of movement at 3 months**

Grouped Knee flexion	n	%
0-90	7	12.1%
0-110	5	8.6%
0-120	25	43.1%
121 and above	21	36.2%

**Figure 9: Grouped knee flexion**



### Hip range of movement after 3 months

Most patients maintained normal range of movement

**Table 17: Hip range of movement after 3 months**

<b>Motion range</b>	<b>N</b>	<b>Mean (angles)</b>
Hip flexion	58	112.7
Hip extension	58	10.5
Hip adduction	58	26.6
Hip abduction	58	31.8
Hip internal rotation	58	28.9
Hip external rotation	58	36.2

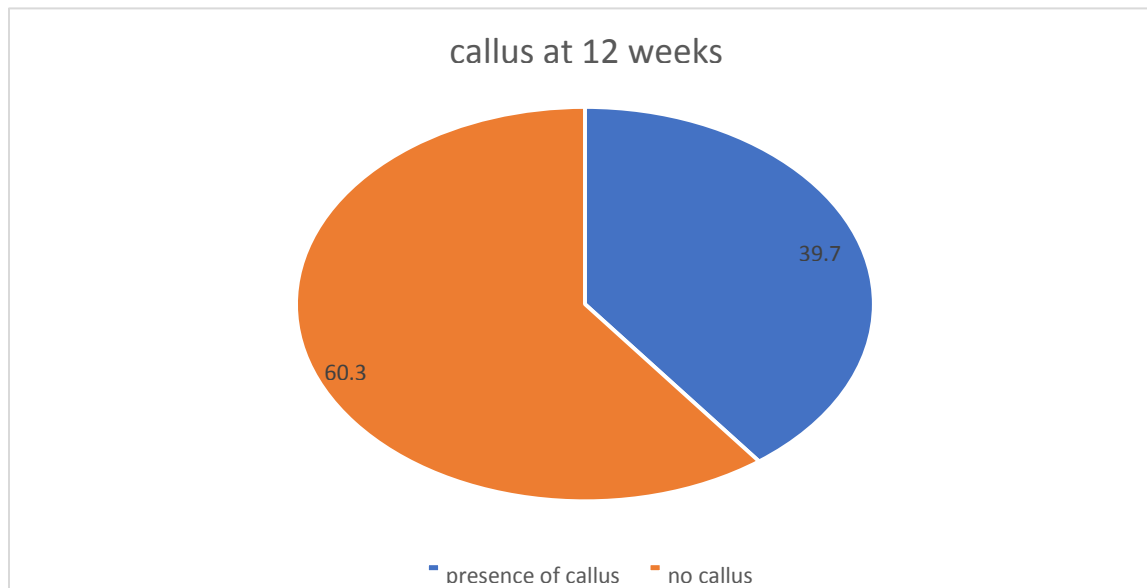
### Presence of Callus at 12 weeks

23(39.7%) patients had visible callus at 12 weeks' post-operative while the rest 35(60.3%) did not show any callus spanning the fracture site

Table 18: Presence of Callus at 12 weeks

Presence of callus at 12 weeks postoperative	Yes	23	39.7%
	No	35	60.3%

**Figure 10: callus at 12 weeks**



Presence or absence of callus had no statistical significance on the knee range of movement (p value 0.258) nor did it depend on the level of comminution (p value 0.109)

In Winquist- Hansen grade 0 to II, 45.45% had callus at 12 weeks whereas only 21.4% of group III to IV had callus at 12 weeks

Table 19: Callus at 12 weeks

		Presence of callus at 12 weeks postoperative				p-value
		No		Yes		
		n	%	n	%	
Grouped Winquist Hansen Grade	Grade 0-II	24	68.6	20	87.0	0.109
	Grade III-IV	11	31.4	3	13.0	
Grouped Knee flexion	0-90	2	5.7	5	21.7	0.258
	91-110	11	31.4	4	17.4	
	111-120	9	25.7	6	26.1	
	121 and above	13	37.1	8	34.8	

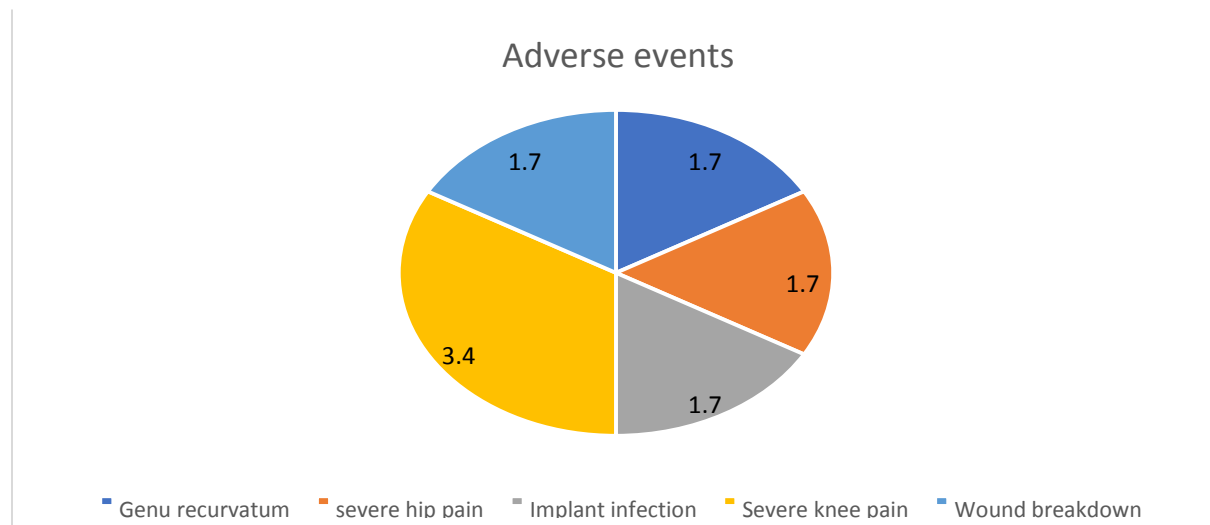
## Adverse effects

There was 1(1.7%) patient who got implant infection and another 1(1.7%) had wound breakdown. 2(1.7%) patient reported severe knee pain that affected their rehabilitation and they had reduced range of movements at the knee. Another 1(1.7%) patient complained severe hip pain though the range of movement was normal. 1(1.7%) lady had genu recurvatum postoperative.

Table 20: Adverse effects

		N	%
Adverse events	Genu Recurvatum	1	1.7
	Severe hip pain	1	1.7
	Implant infection	1	1.7
	Severe knee pain	2	3.4
	Wound breakdown	1	1.7
	none	51	87.9

Figure 11: Adverse effects





## 8.0 DISCUSSION

Diaphyseal femoral fractures are common injuries in our set up and the treatment of these fractures has evolved from the historical non-operative management to the most recent methods of intramedullary nail fixation. Interlocking nails have become popular and greatly expanded the indications for intramedullary nailing of femoral fractures (23)

In the study period of 6 months, 58 patients were recruited and of these 79.3% were males and 20.7% were females with an age range 18-66 year and a mean of 32.6. The time from injury to surgery ranged from 2-107 days and an average of 29 days

Most of the fractures underwent open nailing (98.3%) and this is attributed to delay to surgery as many fractures were not fresh and lack or ease of availability of the image intensifier

Antegrade nailing was the commoner method (98.2%) as only 2 patients underwent retrograde nailing, and both were distal femoral third fractures

The early outcomes of these patients were analysed and compared with other studies

The incidence of angular malalignment of more than 5 degrees in valgus and Varus was 6.9% and 5.2% respectively. The most common location of angular malalignment was in fractures involving the distal third at 43% followed by proximal third at 38% and lowest in middle third at 18.5%. This compared with Ricci WM et al (12) reported a Varus and valgus to be up to 9% in the entire group nailed but differed in the common malalignment location as Ricci et al reported the highest malalignment when the fracture involved the proximal third (30%) and least when the middle third is involved (2%). Ricci et al had nearly half (48.7%) of patients who underwent retrograde nailing unlike in this study where only 1.7% underwent retrograde nailing, this could have contributed to the difference. Borel JC et al (26) found overall incidence of 4.4% using more than 5 degrees of angulation deformity in any plane as the reference, with the incidence going up to 11.7% when he looked at 5 degrees to 15 degrees on both Varus and valgus planes. the difference is attributable to Borel JC having followed up patients with closed nailing only and nailing done between 1 and 36 days (average 9.5) unlike this study where most of the surgery was done open and time before surgery averaged 29 days

Rotational malalignment was found to be 15.5% considering more than 20 degrees of rotation and this constituted 13.8% of external rotation and 1.7% of internal rotation. Malrotation according to locations of fracture showed that equal rotation occurred in proximal third (37.5%) and distal (37.5%) and least in middle third at 25% though there was no significant difference on the grouped level of comminution grade in Winquist Hansen classification ( $p$  value  $> 0.05$ )

This is in contrast to the findings of rotational malalignment with Mrita et al (21) in a follow up of 85 patients reporting external rotation malalignment of above 20 degrees in 6.3% and internal rotation malalignment of 15 degrees or more in 8.9% of these patients and by Kempf et al (30) and Johnson and Greenberg (31) who found none. Wiss et al (33) noted 7% with above 10 degrees and Alho et al (28) found 0.8% in a series of 123 with a malalignment of greater than 20 degrees. The differences could be attributed to long wait for surgery and unavailability of an image intensifier. Other contrasting opinions by other authors have been greatly reported with that of Sennerich et al who found more than 10 degrees of 40% and more than 20 degrees of 16% and Bråten et al (15) of more than 10 degrees of 43% and more than 15 degrees of 19% in his series of 110 patients. We used clinical measurements to assess the deformity whereas Sennerich used computerized tomography. Braten performed almost all nailing closed and in supine and distal locking was freehand and most of the patients with rotational deformity had other injuries on the legs. Unlike in our study where most of the fractures were done open and used a distal locking jig and linea aspera was used as a reference for correct rotation

Limb length discrepancy of more than 2cm was found in 7%. Most shortening was in fractures grade III and IV (Winquist and Hansen) which was significant ( $p$  value 0.017) showing the effect of comminution on LLD. Other studies have found differing values with that of Winquist et al (10) limb shortening of above 2 cm was seen in 2.0% and in 4.5% of patients by Arpacioğlu et al (51). Winquist et al performed closed nailing and performed the surgeries early. White et al revealed that 3.3% had shortening between 1 to 2 cm (44) and in Sjøbjerg et al in his study on comminuted femoral fracture treated with closed interlocking nail found shortening of 1 to 2 cm in 7.5% of patients and 5% of patients lengthening of about 1 cm (45). Sjøbjerg fractures were all comminuted and that could be contributing to the difference on LLD

Many other authors have had contrasting opinions with the like of Zukerman et al showing from his study that 3.2% of patients had shortening or lengthening of more than 1 cm (46). Zukermans surgeries were done closed unlike most of the patients in this study. Tüzüner et al (55) from his study on comminuted femoral shaft fractures that limb LLD of more than 1cm occurred in 14.3%, and 2.3% of patients had shortening of more than 2.5cm. These studies did not specify the extent of comminution

The range of movement of the knee was good to excellent in most of the patients (87.9%) attaining over 90 degrees of flexion. The effect of the method of nailing antegrade vs retrograde was not possible to statistically compare due to the numbers. other authors like Bitta et al from his study in Tanzania reported that knee flexion below 90 degrees was seen in 3.3% of study participants treated with antegrade and it occurred in 20% patients treated by retrograde nail. The difference was statistically significant. The surgeries were done open. Moumni M. et al (61) and Sahmir Sadic et al (34) hip and knee joints range of motion being comparable between the injured and the normal leg, regardless of the antegrade or retrograde intramedullary femoral nailing technique. Lelei et al (50) did open nailing and had a comparable group of antegrade and retrograde nailing. He concluded that knee stiffness was higher in retrograde group than in Antegrade in his 2 years follow up of 124 patients. Normal Hip range of movement was maintained in most of the patients in this study

In this study, 23(39.7%) patients had visible callus 12 weeks' post-operative while the rest 35(60.3%) did not show any callus. This compared to Mrita et al (21) reported thirty-five percent of patients having callus formation by 12th week post-surgery with no effective change with the number of locking screws used, whereas Christopher et al (53) reported minimal callus for secondary bone healing at 12 weeks (20% ). At the time of surgery some fractures which had stayed for long already had some callus and it was difficult to say if the callus at 12 weeks was post-operative or had appeared before.

Presence or absence of callus had no statistical significance on the knee range of movement (p value 0.258) nor did it depend on the level of comminution (p value 0.109).

## **9.0 CONCLUSION**

Most diaphyseal femur fractures occur in males than females and road traffic accidents were found to be the major mechanisms of injury to the diaphysis of the femur. The average number of days from the time of injury to surgery is 29 days

Most fractures occur in the middle third of the femur and most were Winquist Hansen grade 1 with the right and the left femur being equally involved in closed diaphyseal femoral fractures. Angular and rotational alignment was good to excellent using the Thoresen criteria in most of the patients and the limb length obtained after the surgery was also good to excellent using the same criteria

Knee and hip range of motion was good and compared to other studies. Callus formation after 12 weeks was seen in less than half of the patients in our study

## **10.0 RECOMENDATIONS**

- 1) A follow up study on the long term and functional outcome
- 2) A similar study in a private institution to give a view on the outcome on the same method of treatment
- 3) A study to compare differences in outcomes on antegrade and retrograde nailing of diaphyseal femoral fractures

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## 12.0 APPENDIX

### DATA COLLECTION SHEET.

Study number.....

#### A) PATIENT DATA

1. Inpatient number.....
2. Age in years .....
3. Sex:  M  
F
4. Date of injury .....
5. Mechanism of injury.....
6. Date of surgery .....
7. Days from the time of injury to surgery.....

#### B) FRACTURE DATA

1. Site of the fracture
  - a. Proximal third diaphysis.....
  - b. Mid-third diaphysis.....
  - c. Distal third diaphysis .....
2. Side injured
  - a. Left.....
  - b. Right.....

3. Winqvist – Hansen grade

- a. grade 0
- b. Grade I
- c. Grade II
- d. Grade III
- e. Grade IV

4. Method of locked intramedullary nailing

- a. Lateral positioning.....
- b. Supine positioning.....
- c. Closed nailing.....
- d. Open nailing.....
- e. Antegrade nailing.....
- f. Retrograde nailing.....
- g. Number of proximal locking screws.....
- h. Number of distal locking screws.....

5. Fracture pattern

- i) Angular malalignment degrees
  - a) Varus.....
  - b) Valgus.....
- ii) Rotational malalignment degrees
  - a) External rotation.....
  - b) Internal rotation.....
  - c) LLD in centimetres.....

- 6. Knee range of motion at 3 months' post-operative
  - a) Flexion.....
  - b) Extension .....
- 7. Hip range of motion at 3 months' post-operative.
  - a. Flexion .....
  - b. Extension .....
  - c. Adduction .....
  - d. Abduction .....
  - e. Internal rotation .....
  - f. External rotation.....
- 8. Presence of callus at 12 weeks postoperative
  - a. Yes .....
  - b. No .....

Any adverse event.....

## CONSENT FORM

### **PATIENT CONSENT FORM FOR PARTICIPATION IN THE STUDY**

Study Identification Number: \_\_\_\_\_

Date: \_\_\_\_\_

**Consent explanation form (To inform you about the research)**

**Certificate of consent (signatures)**

#### **PART 1: CONSENT EXPLANATION FORM STUDY**

##### **TITLE**

**EARLY OUTCOME OF LOCKED INTRAMEDULLARY NAILING OF DIAPHYSEAL FEMORAL FRACTURES AT KENYATTA NATIONAL HOSPITAL**

##### **INVESTIGATOR'S STATEMENT**

My name is Dr Laichena Jeremiah a postgraduate student at the University of Nairobi – department of Orthopaedic Surgery. I am conducting a study on early outcome of locked intramedullary nailing of diaphyseal femoral fractures at Kenyatta National Hospital. Requesting you to participate in this research study. The purpose of this consent form helps you understand more about the study

Please read through it carefully and ask any questions about the study. The investigator will be available to answer any queries that come up during the study and thereafter.

## **STUDY BACKGROUND**

Diaphyseal femoral fractures are common injuries seen at Kenyatta National Hospital. Locked Intramedullary nailing is now commonly used for the treatment of diaphyseal femoral fractures and functional outcomes are good. Intramedullary nailing surgeries are carried out by orthopaedic surgeons and residents at their various levels of training.

Major complications of intramedullary nailing are minimal internationally. Among the outcomes described in various studies is angular and rotational malalignment, LLD, range of motion of the knee and hip joints. This is an observational study aimed to determine angular and rotational malalignment, LLD, range of motion of the knee and hip and appearance of callus at 12 weeks post-operatively and thereof provide local data in which we can compare the outcome in our local setup and compare the results with the international standards

## **STUDY OBJECTIVE**

The objective of the study is to determine the early outcomes of diaphyseal femur fractures treated by locked intramedullary nail at Kenyatta National Hospital

## **VOLUNTARINESS OF PARTICIPATION**

This study will be fully voluntary and there will be no financial rewards for participation. Patients participating are free to withdraw at any point during the study.

## **CONFIDENTIALITY**

The information you provide will be held strictly confidential and only used for the purpose of the study. Information obtained will be kept under lock and key and soft copy information shall be password protected. No specific information of any participant will be revealed to any person without their permission in writing. Your name will not appear on any of the records used for this study.

## **BENEFITS OF PARTICIPATION**

This is an observational study and all the participants in the study will be followed up in the clinic in the stipulated time, the normal scheduled orthopaedic reviews will be used and in case of any unacceptable outcome the patients will be sent for review by the orthopaedic surgeon for appropriate management

## **RISKS OF PARTICIPATION**

Follow up is through clinical examination and the normal scheduled post-operative radiographs. You will not be exposed to any other additional risk

## **DURATION OF THE STUDY**

The duration of the study is 12 weeks

## **RIGHT OF WITHDRAWAL**

You are free to choose whether or not you will be willing to participate. No penalties for withdrawing from the study

## **COMPENSATION**

There is no compensation for participating in this study.



**CONSENT CERTIFICATE:**

**I..... freely give consent of myself /my proxy..... to take part in the research study carried out by Dr Laichena Jeremiah, the nature of which he/ his research assistant has explained to me. I understand that my participation in the study is purely voluntary and that I am free to withdraw this consent at any time. I also understand that withdrawing my consent will not affect the quality of care given to myself/my proxy at the Kenyatta National Hospital.**

**Signature of participant/Guardian/Next of kin.....**

**Date.....**

**I certify that the above consent has been freely given in my presence**

**Witness Name.....**

**Witness Signature.....**

**Date.....**

Left thumb print if participant illiterate
--

**STATEMENT BY THE RESEARCHER**

The information relating to this study as contained in the information sheet has been accurately read to the participant. I confirm that I have ensured the understanding of its contents by the participant who understands that: Declining to give consent or otherwise participate in this study will not affect the quality of care given at this institution, all information provided by the participant will be kept strictly confidential, the conclusions from this study may be used to influence local clinical and surgical practice

I further confirm that the participant has been allowed to seek clarification of all aspects of this study and that he/she has freely and willingly given consent. The participant has also been provided with a copy of the Informed consent form.

Name of researcher/ Research assistant.....

Signature.....

Date.....

**IN CASE OF ANY QUERRIES: WHO  
TO CONTACT**

For any questions about the study or your participation in the study you can contact the main investigator on;

1. Dr Jeremiah M Laichena.

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For any questions on your rights as a research participant, you can contact the KNH/ERC whose task is to ensure research participants are protected from harm

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## SWAHILI VERSION

### STAKABADHI YA IDHINI

Jina langu ni Dr Laichena Jeremiah, mwanafunzi katika Kitivo cha masomo ya Udaktari, Chuo kikuu cha Nairobi. Ninafanya utafiti kuhusu **‘Matokeo ya upasuaji kwa kutumia misumari ya kufunga ndani ya fupa la paja**

Ningependa kukualika kujumuishwa kwenye utafiti huu. Kujumuishwa kwako ni kwa hiari na unayo haki kujiondoa kwenye utafiti huu wakati wowote. Idhini yako ya kujumuika unaweza kuipa maramoja baada ya kusoma nakala hii ama baada ya muda wa kufikiria. Unao uhuru wa kuuliza maswali yoyote kuhusu utafiti huu kutoka kwangu ama msaidizi wangu

Ukikubali kujumuishwa kwenye utafiti,maelezo yako binafsi pamoja na maelezo ya ugonjwa wako yatachukuliwa.

Utapatiwa hakikisho ya kwamba maelezo yote utakayotoa yatawekwa siri wala hakuna atakayeona maelezo haya isipokuwa watafiti na watu waliokubaliwa na kamati ya uadilifu ya Hospitali kuu ya Kenyatta ikishirikiana na Chuo kikuu cha Nairobi. Nambari zitatumwa badala ya majina ili kuinga maelezo yako.

Maelezo yatachukuliwa kwa njia ya maswali pamoja na uchunguzi wa kimatibabu. Utafiti huu hautakuweka katika hatari yoyote. Kujiondoa kwako hakutaadhiri kiwango cha matibabu utakachopatiwa katika hospitali hii.

Ruhusa ya kufanya utafiti huu umepatiwa kutoka Kamati ya Uadilifu wa Utafiti ya Hospitali kuu ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi, kupitia Mwenyekiti wa Idara ya Upasuaji, Kitivo cha Masomo ya Udaktari, Chuo Kikuu cha Nairobi.

### IDHINI

**Mimi..... nimekubali kwa hiari yangu/hiari ya mgonjwa niliyemsimamia.....kujumuishwa kwenye utafiti unaoendeshwa na Dr Laichena Jeremiah, baada ya kupewa maelezo kamili na yeye/ msaidizi wake. Ninaelewa kuwa kujumuika kwangu ni kwa hiari na nina uhuru wa**

**kujiondoa wakati wowote. Naelewa kwamba kujiondoa kwangu hakutaathiri kwa vyovyote kiwango cha huduma nitakayopokea katika Hospitali Kuu ya Kenyatta.**

**Jina la mgonjwa/Msimamizi wa mgonjwa.....**

**Sahihi.....**

**Tarehe.....**

**Nimeshuhudia ya kwamba idhini ya mhusika imetolewa kwa hiari yake mwenyewe**

**Jina la shahidi.....**

**Sahihi ya shahidi.....**

**Tarehe.....**

**Sehemu ya tatu: Idhibati ya Mtafiti mkuu**

<p><b>Alama ya kidole gumba cha .... kushoto(mgonjwa asiyejua kuandika)</b></p>
---

Ninatoa idhibati ya kwamba maelezo kuhusu utafiti huu yametolewa kikamilifu kwa mhusika, na kwamba nimemsaidia kuelewa kwamba: Kutotoa idhini ama kujiondoa kwenye utafiti huu hautaathiri kwa vyovyote kiwango cha matibabu atakayopata katika hospitali hii, Maelezo yote yatakayotolewa yatawekwa siri, Matokeo ya utafiti huu yanaweza kutumiwa katika kuchangia ujuzi wa kubaini ugonjwa unaochunguzwa.

Ninatoa idhibati pia ya kuwa mhusika amekubaliwa kuuliza maswali yoyote kuhusu utafiti huu na kwamba ametoa idhini kwa hiari bila kulazimishwa. Mhusika pia amepewa nakala ya stakabadhi ya idhini.

**Jina la mtafiti/ mtafiti msaidizi.....**

**Sahihi.....**

**Tarehe.....**

**Ikiwa unahitaji maelezo zaidi kuhusu utafiti huu, tafadhali wasiliana na wafuatao:**

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## **KNH STUDY REGISTRATION**



**KNH – UON ERC CERTIFICATE**