SHORT-TERM OUTCOME OF PATIENTS WITH CLOSED COMMINUTED FEMORAL SHAFT FRACTURE TREATED WITH LOCKING INTRAMEDULLARY SIGN NAIL AT MUHIMBILI ORTHOPAEDIC INSTITUTE (MOI)

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MMed (Orthopaedics and Traumatology)Dissertation

Muhimbili University of Health and Allied Sciences

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By

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A Dissertation submitted in partial fulfillment of requirement for Degree of Master of Medicine in Orthopaedics and Traumatology of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that, he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: "**Short-term outcome of patients with closed comminuted femoral shaft fracture treated with locking intramedullary SIGN nail at Muhimbili Orthopaedic Institute (MOI)**" submitted in partial fulfillment of requirement for degree of Master of medicine in Orthopaedics and Trauma surgery of Muhimbili University of Health and Allied Sciences

_____

Dr. Cuthbert Nathan Mcharo

Supervisor

Date: _____

DECLARATION AND COPYRIGHT

I, **Felix S. Mrita** declared that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award

Signature: …….. Date: ……..

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DEDICATIONS

This dissertation is dedicated to my beloved wife Rose Mwakapenda and my son Elia Felix Mrita for their love; courage, support and commitments to make sure our family are running smoothly.

ABSTRACT

Comminuted femoral shaft fractures are complex fracture to treat because of increased risk of limb length discrepancies and malrotation deformities. Currently the interlocking intramedullary nail is recommended treatment for comminuted femoral shaft fractures by many international centers.

The SIGN nail program commenced at MOI in October 2008. In this program, unstable comminuted femoral shaft fractures are treated by using interlocking intramedullary SIGN nail. Although anecdotal experience has been positive, the outcome of treatment has not been scientifically evaluated

Objectives :We evaluated the short-term outcome of patients with closed comminuted femoral shaft fracture treated with locking intramedullary nail at MOI-2011

Methodology: A cohort study was done on adult patients with closed comminuted femoral shaft fractures admitted at MOI and being treated by interlocking intramedullary SIGN nail. Ninety one patients met our study inclusion criteria but 11 were lost followup, so we reviewed 80 patients who completed follow ups. A researcher used a structured questionnaire to interview the participants.

These patients were operated by either antegrade or retrograde SIGN nail. Immediately post operatively control radiographs, the lowerlimb length and malrotation deformity were assessed. Then each patient was followed up for a minimum of 18 weeks post operatively.

In followup visits, state of the wound, limb length discrepancy, malrotation deformity, range of motion of the knee joint and callus formation were assessed. The obtained data were analyzed by SPSS version 16.

Results

Comminuted femoral shaft fracture accounted for 20.3% of all adult femoral shaft fractures admitted at MOI. Deep wound infection occurred in 2.5%. Shortening of 2-3cm was seen in 3.8% of patients. No patient has shortening of more than 3cm. External rotation deformity of more than 20 degrees occurred in 6.3%. Internal rotation deformity of more than 15 degrees was seen in 7.9%. Knee flexion of less than 90 degree was encountered in 7.5% of patients. By 12^{th} week 68.8% of patients had callus formation and 95% of patients had union by 18^{th} week.

Conclusion

SIGN nail appears to be an effective treatment for comminuted femoral shaft fractures in developing countries where image intensifiers and fracture tables are not readily available. They have excellent to good outcomes in rate of callus formation, limb length and limb alignment outcomes.

TABLE OF CONTENTS

CERTIFICATION……...ii
DECLARATION AND COPYRIGHT……iii
AKNOWLEDGEMENTS…….…… .iv
DEDICATION……..v
ABSTRACT……..……vi
TABLE OF CONTENTS ……..……..…….……..viii
ABREVIATIONS…….…….…… .x

CHAPTER ONE
1.1 introduction ……..…….……...1
1.1.1.0. Treatment option of comminuted femoral shaft fracture …….……..2
1.1.1.1. Interlocking intramedullary nail……..……..3
1.1.1.2. Operative techniques and indications of SIGN nail……..……..…..….3
1.1.2 Complication ……..…..……4
1.2. Literature review ……..……..….9
1.3. Problem statement and Rationale …….…….…….....13
1.4. Objectives of the study……..…….....14

CHAPTER TWO
2.0. Methodology…….…...…….. 15
2.1. Study design …….....15
2.2. Study area……. 15
2.3. Study period……... 15
2.4. Study population…….…….....15
2.5. Inclusion criteria……..……...15
2.6.Exclusion Criteria ……..…….15
2.7. Sample size estimation and sampling technique…….……..16

2.8. Data collection process……..……..16
2.9. Patients and methods……..……17
2.10. Data Management and Analysis…….……..22
2.11. Ethical consideration ……...22

CHAPTER THREE
3.0. Results……..…..……23

CHAPTER FOUR
4.0. Discussion……..…….……..29
4.1. Study limitation …….……..32

CHAPTER FIVE
CONCLUSION ……..33
RECOMMENDATIONS …….……..33
REFERENCES …….……..……34
Appendix I Consent form- English version …….……39
Appendix II Consent form – Swahili version …….…….…41
Appendix III Interview schedule ……..……....43
Appendix IV Interview schedule- Swahili version …….……..... .48

ABBREVIATIONS

MOI	Muhimbili Orthopaedic Institute
MUHAS	Muhimbili University of Health and Allied Sciences
MOHSW	Ministry of health and social welfare
ORIF	Open Reduction and Internal Fixation
AO	Arbeitsgemeinschaft für Osteosynthefragen
OTA	Orthopaedic Trauma Association
SIGN	Surgical Implant Generation Network
SPSS	Statistical Program for Social Sciences
DCP	Dynamic Compression Plate
IM nail	Intramedullary nail

CHAPTER ONE

1.1 INTRODUCTION

Femoral shaft fractures are among the most common fractures encountered in orthopaedic practice (1). These fractures have age and gender-related bimodal distribution, with injuries occurring most frequently in young males following high-energy trauma. The second peak of injury is among elderly females following falls from standing due to postural instability and osteoporosis (2). These fractures can be classified as spiral, oblique, transverse, comminuted or segmental. Of these fractures comminuted and segmental fractures are difficult to treat because of their vertical and rotational instability as compaired to other femoral shaft fracture types.

Comminuted femoral shaft fracture refers to fractures with multiple bone fragments and multiple fracture lines (3). Wolinsky reported that comminuted femoral shaft fractures were seen in 14% of patients with femoral shaft fractures in a typical urban United State of America city (4).The degree of fracture comminution is often classified using the Winquist-Hansen classification. Fig 1. This classification system, categorizes the fracture into: (1)

i. Type I: - are comminuted fracture which have a small bone fragment, not affecting fracture stability

ii. Type II :- are comminuted fracture with at least 50% cortical contact between major fragments remains to prevent shortening and control rotation

iii. Type III: - are comminuted fracture with a larger butterfly fragment with which has less than 50% cortical contact thus allowing rotation, translation, and shortening

iv. Type IV: - includes comminuted fracture that have no predicted cortical contact between the fracture (segmentally comminuted)

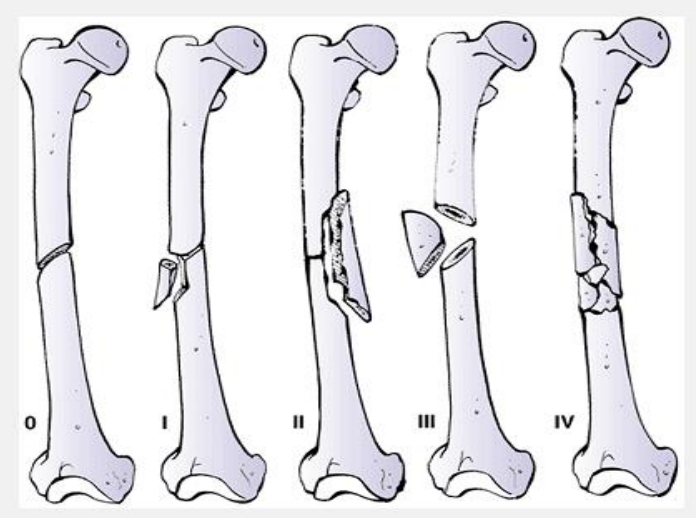


Fig 1. Winguist and Hansen classification of femoral shaft fracture (2).

The type and location of the fracture, the degree of comminution, age of the patient and the patient's socioeconomic demands may influence the method of treatment (1) . The treatment goals in patients with femoral shaft fracture includes: (1) Restoration of alignment rotation and length (2) Preservation of the blood supply to aid union and prevent infection and (3) Rehabilitation of the extremity and the patient (1).

1.1.1.0 Treatment options for Comminute femoral shaft fractures

Comminuted femoral shaft fractures can be treated non-operatively by closed reduction and immobilization with continuous traction (skin/skeletal traction),

casting or bracing. A non operative treatment is used as a temporary treatment, but also it can be used as a definitive treatment in patients with uncontrolled cormobidies (2).

These fractures can also be treated operatively by open reduction and internal fixation (ORIF) using either plate or intramedullary (IM) nailing (1, 2). Among these operative procedures; interlocking IM nailing is considered to be the treatment of choice for most femoral shaft fractures (1).

1.1.1.1 Interlocking Intramedullary nail

Comminuted femoral shaft 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 (5). The optimal time for intramedullary nailing of closed fractures has been an area of controversy; however, current data support early (within 24 hours) nailing for most femoral fractures(1).

Currently at MOI, Surgical Implant Generation Network (SIGN) nail are used in fixation of femoral shaft fractures. The SIGN nail are solid interlocking intramedullary nail subtype, in which both proximal and distal interlocking screws are applied with the help of an external jig, and thus do not require image intensifier (6).

1.1.1.2 Operative Technique and Indications of sign nail

SIGN nail can be used in management of fractures of femur, tibia and humerus (6). For management of femoral fractures, these nails can be inserted via either antegrade or retrograde approach. The decision for the approach depends on the location of the fracture e.g. in proximal and middle third fractures the antegrade nailing is preferred. Retrograde approach is used for distal femoral fractures, multiple injured and in obese patients (6).

Intraoperatively patients are positioned either supine or lateral decubitus when retrograde or antegrade approaches are used, respectively. These nails are inserted by open method. The fracture site is exposed through the anterolateral approach, and the fracture fragments are identified (6). The reduction is performed under direct visualization.

The entry point for antegrade nail is at the tip of greater trochanter and for retrograde nail is through intercondylar femoral notch. The entry points are initiated by curved awl. Then Both proximal and distal fragments are reamed. The reaming starts with smaller reamers and increase reamer sizes until chatter is felt. Once chatter is felt, the proximal fragment is over reamed to allow room for the bend proximal part of the nail. The size of the nail to be used should be 2mm smaller in diameter than the reamer which caused chatter. Then the appropriate nail is assembled (6).

After assembling the nail, it is inserted via the entry points into the medullary canal of both proximal and distal fragments. After reduction is achieved, manual traction is maintained while interlocking screws are inserted. In comminuted fractures the nail should be locked by two screws proximal and 2 screws distal (6).

1.1.2 COMPLICATIONS

Several complications have been reported to occur to patients with comminuted femoral shaft fracture treated with interlocking intramedullary nail. These complications includes infection, angular malunion, limb length discrepancy, rotational malalignment, non union, limited range of motion of knee joint and implant failure.

1.1.2.1 Infection

Deep infection following open or closed intramedullary nailing is a serious complication (1). The infection rate in open IM nail is reported to be between 1.5% and 10% , and less than 1% in closed IM nailing (1). Acute superficial infections responds to simple irrigation, wound debridement, secondary wound closure and antibiotics therapy (5). Deep infection can be treated by surgical drainage and removal of all devitalized tissue, and the wound is usually left open to heal secondarily(1). If the IM nail provides stable fixation, it should be left in place, because its removal may result in an infected nonunion (1). Cultures should be obtained and appropriate antibiotics given for 6 weeks. The patient's progress can be monitored by repeated erythrocyte sedimentation rate (ESR) and C-reactive protein measurements (1).

In Infection with a broken nail or a nail providing little stability, the nail should be removed at the time of open drainage. The fracture should be fixed with a larger nail after reaming or fixed with an external fixator. The wound is left open, and appropriate antibiotics therapy given (5).

1.1.2.2 Limb length discrepancy

Shortening occurs most commonly when there is significant comminution, which makes judgment of length difficult (5). Shortening of up to 1.5 cm is acceptable (7). To reduce the occurrence of limb length discrepancies, preoperative assessment of the contralateral femoral length can be used as a guide to judge the length of the injured extremity (8) .

1.1.2.3 Rotational Malalignment

Rotational malunion is the most common and difficult complication to avoid (5). It occurs in 10% to 20% of patients and these deformities are generally external rotation (7). Yang et al recommend preoperative evaluation of the anteversion angle of the intact femur to provide more accurate assessment of rotation (9). In order to minimize the occurrence of rotational deformities, careful postoperative examination of patients for rotational deformities on the operating table is needed. This deformity is best corrected at the time of the initial surgery rather than bringing the patient back for a repeated surgery (9).

The amount of femoral rotation which can be well tolerated by the patient is largely unknown, but it appears patients with more than 15 degrees of rotational malalignment have significant symptoms and needs operative correction (7, 9-11). These patients presents with functional limitations and have difficulties with demanding activities such as sports, running, and climbing stairs (10). Rotational malalignment was identified in almost half of the patients with unstable fractures (Winquist type 3 and 4) independent of fracture location and patient position at the time of nailing (12).

1.1.2.4 Angular Malalignment

An angular deformity of the femur is defined as angulation of greater than 5 degrees in either coronal (varus-valgus) or sagittal (flexion-extension) planes (2). The use of operative fixation for most femoral diaphyseal fractures has made malunion less common. Periarticular angular deformities are more likely to have an increased effect on the proximate joint than malunion in the mid-diaphyseal portion of the femur. The Overall rate of angular malalignment after medullary nailing is between 7% and 11% (13-15).

Ricci et al studied factors associated with angular deformities after femoral nailing, and established that the high rate of malalignment were in proximal third fractures (30%) compared to distal third (10%) or middle third (2%) fractures. Increased malalignment was seen in unstable fracture patterns (12%) compared to (7%) in stable fracture patterns (15).

1.1.2.5 Non union

Nonunion is uncommon in femoral shaft fractures treated with locking intramedullary nail (5). Most of non-union occur in open fractures, fractures with significant comminution and segmental bone loss especially if treated by a small nonreamed nails (5). When there is no callus formations detected by 12^{th} week post-surgery in open fractures or in fracture treated by nonreamed nails, treatment conversion to a larger reamed interlocking nail. In delayed union or nonunion where the problem seems to be distraction at the fracture site, dynamization may be sufficient if rotational stability will be maintained (5).

1.1.2.6 Knee Stiffness, Knee Pain, and Hip Pain

Some degree of temporary knee stiffness is commonly observed after a fracture femoral shaft (2). Stiffness is thought to be related to the type of treatment, fracture location, and associated injuries. High-energy injury such as motor vehicle crash, multiple procedures, and a delay in union were associated with persistent knee stiffness after treatment in one study (16).

Limited knee flexion is typically caused by scarring of the quadriceps muscles, especially the vastus intermedius, anteriorly in the region of the fracture (2). In these cases, treatment consists of an aggressive rehabilitation program including active knee flexion. If these patients are left untreated, scarring at the knee joint may occur and further complicating management. Knee stiffness usually improves in the first 6 to 12 weeks after surgical stabilization of a femoral shaft (2).

1.1.2.7 Implant failure

Advancement in nail design and biomechanics have made, fatigue failure of these implants less frequently (2).The timing of nail failure is dependent on numerous factors including the size of the implant, type of metal, location of the nonunion, fracture pattern, patient's weight, and the level of patient's activity (2). Franklin et al reported in a review of 60 broken nails in 56 patients that the usual location for fatigue failure of the nail is at the site of nonunion, where the implant deformation is maximal with motion (17). Therefore the broken nails are indicative of femoral nonunion. If a fracture fails to heal, the nail will eventually fatigue and break (2).

1.2 LITERATURE REVIEW

Comminuted femoral shaft fractures are complex fracture to treat because of rotational and vertical instability; and the treatment outcome of these patients poses challenge to surgeons as a result of increased risk of limb length discrepancies and malrotation deformities(18, 19). Many studies have been done on comminuted femoral shaft fractures treated with locking intramedullary nail:

1.2.1 Callus formation

A study on comminuted femoral-shaft fractures treated by interlocking intramedullary nail, by Johnson et al reported that the average time to union was 13.8 weeks (20). Zuckerman and others did a study on treatment of unstable femoral shaft fractures with closed interlocking intramedullary nailing and found the average time to union was 13.5 weeks (21). Union rate of comminuted fractures as reported by White et al was 98.9% of all fractures in mean duration of 4.4 months (22).Winquist et al also reported that fracture union to occur in 99.2% of patients with comminuted femoral shaft fracture treated with interlocking nail (18).

Wiss et al on his study on comminuted and rotationally unstable fractures of the femur treated with interlocking nail revealed fracture union occurred in 98% of cases in a mean duration of 32 weeks (8). Tüzüner et al reported from his study that 97.6% of patients had union within a mean duration of 18.2 weeks (23).

A study done by Kempf et al revealed that 86.5% of patients had fracture consolidation at a mean duration of 4.5 months for the severely comminuted fractures (24). All fractures united in an average of 23.25 weeks ($p < .05$) as reported by Borel et al (25).

Sultan S et al followed up patients with comminuted femoral shaft fractures treated with close Interlocked nailing. All fractures united without additional surgical intervention, and the average time to union was 34 weeks (26).

1.2.2 Limb length discrepancy

The limb length discrepancy outcomes on comminuted femoral shaft fracture treated by interlocking IM nail has been reported by numerous authors. Shortening of more than 2 cm was seen in 2.0% and 4.5% of patients as reported by Winquist et al and Arpacioglu et al respectively (27, 28). White et al studied 92 comminuted femoral shaft fractures patients treated by closed interlocking nail, revealed that 3.3% had shortening between 1 to 2 cm (22).

Søjbjerg et al reported from his study on comminuted femoral fracture treated with closed interlocking nail that shortening of 1 to 2 cm occurred in 7.5% of patients and 5% of patients developed lengthening of about 1 cm (29). Zukerman et al reported from his study that 3.2% of patients had shortening or lengthening of more than 1 cm (21). Borel et al reported shortening was encountered in 6% of patients (25).

Tüzüner et al reported from his study on comminuted femoral shaft fractures treated with interlocking IM nailing, that limb length discrepancy of more than 1cm occurred in 14.3%, and 2.3% of patients had shorterning of more than 2.5cm (23). Also the limb length discrepancy of more than 1cm occurred in 1.8% of patients as reported by Wiss et al (8) . According to Thoresen's criteria, the results were excellent and good in 89% of patients (23).

1.2.3 Rotational deformity

Several studies have reported an increased risk of limb malrotation outcomes among comminuted femoral shaft fracture patients treated with interlocking

intramedullary nail. Hansen et al and Winquist et al reported from their studies that 1.7% and 2.3% of patients had malrotation deformity of more than 20 degrees respectively(18, 27).

Wiss D A and others reported from their study that external rotation deformities occurred in 7.0% of patients (8). Søjbjerg et al reported from his study external rotation deformity of 5 - 10^0 occurred in 7.5% of patients (29). Borel et al did a study on complex femoral fractures treated by closed locked nail in adults and found external rotation deformity of 10-35 degrees occurred in 6% of patients (25).

Arpacioglu and others did a study on 46 patients with comminuted fracture treated with interlocking IM nail and found that 2.2% of patients had an internal rotation of 10 degrees. By Thoresen criteria, 88.6% of patients had excellent or good limb alignment outcomes (28). White et al studied 92 comminuted femoral shaft fractures patients treated by closed locking nail and reported that significant rotatory deformities did not occur (22).

1.2.4 Infection

Winquist and Hansen Jr studied comminuted femoral shaft fractures treated by intramedullary nailing, and found that the infection rate was 0.4 % (18). In another study by Winquist et al it was reported that infection occurred in 0.9% of patients (27). Kempf et al did a study on closed locked intramedullary nailing in comminuted fracture and reported that infection occurred in 1.9 % of patients (24).Wiss et al reported that no patient developed deep wound infection (8).

Anastopoulos et al did a study in 108 patients with severely comminuted and segmental femoral shaft fractures treated by closed intramedullary interlocked nailing and reported that no patient developed infections (30). Also Søjbjerg et al reported from his study that no patient developed infection (29).

1.2.5 Range of motion of knee joint

Wiss et al did a study on interlocking nail for treatment of segmental fractures of femur and reported that no patient had a flexion contracture and 2 patients (0.06%) had less than 90 degree flexion (8). Søjbjerg JO and others did the study on interlocking nail of comminuted and unstable fracture of femur; found 7.5% of patients had knee flexion of 60^0 to 90 degrees (29).

Nipatasaj et al showed that all patients had more than 90 degrees flexion of the knee within 2 weeks and resumed full range of motion of the knee within 2 months post-operatively (31).Bitta et al from his study in Tanzania reported from his study that there was no big difference in Knee flexion outcomes among patients treated with antegrade or retrograde nailing. Retrograde nailing did not result in significantly higher knee complications compared to antegrade nailing (32).

1.3 RATIONALE AND PROBLEM STATEMENT

Femoral shaft fractures are among the leading cause of admission and bed occupancy at MOI and accounted for 18.4% of all patients admitted in trauma wards on each months (33). The burden of comminuted femoral shaft fracture at MOI is anecdotally high; although the exact proportion is unknown (33).

Interlocking intramedullary nailing is currently advocated to be the treatment of choice for femoral shaft fractures by many authors (8, 22, 24).

The development of the SIGN nail, which is an intramedullary nail subtype, allows interlocking screws to be applied without image intensifier. This characteristic has led the SIGN nail to be increasingly used in resource limited environments, especially in developing countries like Tanzania.

The SIGN nail program commenced at MOI in October 2008. In this program, unstable comminuted femoral shaft fractures are treated by using interlocking intramedullary nailing. Although anecdotal experience has been positive, the outcome of treatment has not been scientifically evaluated.

The purpose of this study was to evaluate the outcome of comminuted femoral shaft fractures treated by interlocking SIGN nail. The findings will be utilized to develop a validated treatment protocol for these patients at MOI

1.4 OBJECTIVES OF THE STUDY

1.4.1. Broad Objective

To determine the short-term outcome of patients with comminuted femoral shaft fractures treated with interlocking intramedullary SIGN nails at MOI- March 2011-February 2012

1.4.2 Specific Objectives

i. To determine the proportion of patients with comminuted femoral shaft fracture among patients with femoral shaft fracture admitted at MOI

ii. To determine the proportion of patients who developed infection post surgery among patients with comminuted femoral shaft facture treated with SIGN nail

iii. To determine the rate of callus formation among patients with comminuted femoral shaft fractures treated with SIGN nail

iv. To determine the proportion of patients with limb length discrepancy among patients with comminuted femoral shaft fractures treated with SIGN-Nail.

v. To determine the proportion of patients with limb rotational deformity among patients with comminuted femoral shaft fractures treated with SIGN-Nail

vi. To determine the proportion of patients with abnormal range of motion of knee joint among comminuted femoral shaft fracture patients treated with SIGN nail

CHAPTER TWO

2. METHODOLOGY

2.1. Study design: This was a hospital based cohort study

2.2. Study area:

Muhimbili Orthopaedic Institute (MOI) is located within Muhimbili complex in Dar-es-salaam-Tanzania. It is a tertiary hospital specialized in Orthopedics, Traumatology and Neurosurgery. It receives patients from all over the country and from neighboring countries. It has total bed capacity of 181 beds. The total in patient admision for year 2010/2011 was 6601 patients, with more than 4500 operation done per year.

2.3. Study period

This study was conducted from March 2011 to February 2012

2.4. Study population:

Patients aged 18 years or above admitted at MOI with femoral shaft fractures.

2.5. Inclusion criteria:

Patients aged 18 years or above admitted at MOI with closed comminuted femoral shaft fracture treated with SIGN nail, and consented to participate in our study.

2.6. Exclusion criteria:

i. Pathological fractures

ii. Patients with bilateral femoral fractures

iii. Patients with deformity of at least one lower limb i.e. Polio, major joint contractures, and amputees.

iv. Patient with other underlying uncontrolled commobidy conditions i.e. Diabetes mellitus, hypertension

v. Open comminuted fractures

vi. Patients who refused to participate

2.7. Sample size estimation and sampling technique:

Number of emergency attended per month is 820, for 3 months - 2460 patients (33).

Number of femoral fractures per month is 90 patients, for 3 months –270 patients (33).Proportion of patients with femoral fractures= 270/2460= 11%,

It was observed half of femoral shaft fractures were comminuted fractures,

Proportion of comminution among femoral fracture is % = 50/100x11= 5.5%

Sample size will be estimated by using the following formula

$n = Z^2/d^2 (p (100-p))$

95% confidence interval (Z) =1.96

Error rate = d = 5% and P = 5.5%

$n = (1.96/5)^2 x (5.5(100-5.5) =80$

Hence minimum sample size = 80

Due to loss follow-up the sample size for the study was 85 patients

Consecutive patients who met the study inclusion criteria and consented to participate in the study were enrolled until our sample size reached

2.8. Data collection process

Pre- test for data collection tools was conducted by a researcher for the purpose of finding out if it provides the required information. Necessary changes were made so as to obtain the required information.

One research assistant with knowledge and experience in research was recruited. She was trained on the study objectives and being oriented to data collection tools.

The researcher and trained research assistant provided information about the study to prospective study participants and obtained consent from those willing to participate. The researcher or assistant interviewed the participants using a pretested structured questionnaire. Patients were evaluated on the day of admission and after surgery. These patients were followed- up at 2^{nd}, $6^{th,}$ 12^{th} and 18^{th} week post surgery, where state of the wound, limb length, rotation deformity, range of motion of knee joint and callus formation were assessed and documented in a hand-written form.

Other tools involved in data collection were tape measure to measure true limb length, goniometer to measure limb rotation deformities and range of movement of knee joint.

2.10 Patients and methods

2.10.1 Preoperative

Adult patients with closed comminuted femoral shaft fractures treated with interlocking intramedullary nail were included in the study after consent to participate. Pre-operative x-rays i.e. anteroposterior and lateral views of patient's affected femur were assessed and classified by the researcher and confirmed by a radiologist. The levels of femoral shaft fracture comminution were classified by using Winquist and Hansen classification.

2.10.2 Operative procedure

Open reduction with interlocking IM SIGN nails were performed on all patients. Most of patients were operated within 24 hours of admission. Prophylactic antibiotics, typically 3^{rd} generation cephalosporins such as ceftriaxone (Rocephine) were given during induction of anaesthesia. Antegrade nail was performed to those patients with proximal or middle third fractures, and retrograde nail was performed on distal third fractures and in obese patients. Patients were placed lateral decubitus or supine position on a standard operating table when antegrade or retrograde nail performed respectively. The reduction was performed under direct visualization with manual traction and manipulation. Image intensifier and fracture tables were not used.

The nail was inserted through the tip of the greater trochanter for antegrade nails and through the intercondylar notch for retrograde nails .After insertion the SIGN nail was locked by 2, 3 or 4 interlocking screws based on individual surgeon decision. Cerclage wires were not used to stabilize the fracture fragments in any case.

2.10.3 Postoperative care and follow-ups

An immediate post-operative examination by the researcher was used to assess the lower limb length and rotational deformities, and postoperative x-rays were obtained. Patients began physiotherapy programme before being discharged.

After being discharged study participants were requested to attend a follow-up clinic on the 2^{nd} week post operatively. At this visit the researcher assessed the surgical wound, lower limb length and rotational alignment by physical examination; no plain radiographs were taken.

Additional followed-up visit were scheduled at 6^{th}, 12^{th} and 18^{th} weeks postoperatively. During these visits anteroposterior and lateral femur X rays were obtained, The union was assessed by number of cortices (0 to 4) bridged by callus (34). Physical examination was also performed to assess range of knee motion, limb length, and malrotation deformity.

Patients with reduced range of knee movements were scheduled to attend a regular physiotherapy. Those patients, who had no callus formation at the 18^{th} week, were considered to have delayed union. And the appropriate treatment for delayed union was given.

Radiological union was defined as the presence of bridging callus across at least three cortices, and fractures were considered healed when the patients had radiological union, no tenderness to palpation and was able to bear weight without experiencing thigh pain (34).

2.10.4 Measurement of limb length discrepancy

True Limb length discrepancy was determined by comparing the true limb length of affected and normal limb. The patient was asked to lie supine on examination table with the body as straight as possible (35).

Before taking measurements of affected limb, the normal limb must be placed in the identical position and there should not be tilting of pelvis as determined by a line joining the two anterior superior iliac spine (ASIS) (36).

To assess true limb length discrepancy, the examiner identifies patient's ASIS and place the free end of the tape measure onto it. The patient is asked to hold the end in place so that the examiner can unwind the tape measure in a straight line towards the distal tip of medial malleolus.

The examiner records the distance and performs the same on contralateral lower extremity. If the lengths differ significantly, a true limb length discrepancy is present (35-37). The difference of 5mm or less are difficult to accurately assess by this method of measurement (35).

If the affected limb length is shorter than the normal limb, it means there is shorterning deformity, and if affected limb is longer than normal limb, it indicates the presence of limb lengthening deformity (35, 37).

2.10.5 Measurement of rotation deformity

Lower limb malrotation deformities i.e. internal/external rotation were assessed clinically by observing the position of the patella in relation to a tight held tape measure extended from ASIS to the second toe on the same side.

If patellar is in line with the tape measure it indicate no rotation deformity present, if the patella lies lateral to the tape measure it indicates presence of external rotation deformity and if patella lies medial to the tape measure it indicates the presence of internal rotation deformity.

The degree of limb rotation deformity was assessed in patient at resting position, the patient is asked to lie comfortably on examination table with hips and knee extended, and then by using goniometer the angle between an imaginary line along medial border of the foot and vertical axis is measured (35). These measurements were done in a normal limb, followed by an affected limb and then, angles obtained were compaired (35).

If both angles are the same it means no limb rotation deformity was present, if the affected limb rotation angle is larger than the normal limb rotation angle it means angle difference is the degree of external rotation deformity. If the affected side rotation angle is less than the normal limb rotation angle it means the angle difference is the degree of internal rotation deformity (35).

2.10.6 Measurement of range of knee motion

Knee extension is first assessed with the patient in supine position. The examiner raises both of the patient's feet in the air, holding the medial malleoli together. Because flexion is normally symmetric the knee should fall to the same level. This is an indication of passive extension (38).

Knee flexion was assessed by asking a supine patient to flex the knee as far as possible (38). A goniometer is placed on the lateral aspect of flexed knee to measure the degree of knee flexion. The two sides are compaired (38, 39).

NOTE:

Malunion was defined as more than 5 degrees of angular deformity in the sagittal or coronal planes, malrotation of at least 10 degrees, and more than one centimeter of limb length discrepancy as compared with the uninjured side. Outcomes were classified using the Thoresen scoring system. Table 1

Table 1 .Thoresen criteria showing mal-alignment and the range of knee motion with their degree outcome score range from excellent to poor.(40)

Variables	**Excellent**	**Good**	**Fair**	**Poor**
Malalighment				
Varus/valgus(degree)	<5	5	10	>10
Procuvatum/recurvatum(degree)	5	10	15	>15
Internal rotation (degree)	5	10	15	>15
External rotation (degree)	10	15	20	>20
Shortening (in cm)	1	2	3	>3
Range of motion (knee)				
Flexion (degree)	>120	120	90	<90
Extension deficit (degree)	5	10	15	>15
Pain or swelling	None	Sporadic	Minor significant	Severe

2.11. Data Management and Analysis

Data obtained were managed by statistical software (SPSS version 16). Continuous variables were summarized by mean & standard deviation and comparisons were made using student t- test.

Categorical variables were summarized by frequency tables and comparisons were made using the Chi square or Fischer's exact test. The level of significance was set at 5%.

2.12. Ethical consideration

Ethical clearance was obtained from the ethical clearance committee of MUHAS. The aims of study were explained to the patients. The participants were allowed to ask questions about the study. During and after the study period, the patient's confidentiality was maintained. The obtained information was used for research purpose only. The participants in this study signed the consent after agreeing to participate.

CHAPTER THREE

3.0. RESULTS

A total of 522 adult patients with femoral shaft fractures were admitted at MOI during this study period (March 2011 to February 2012). Among these, 106 patients had comminuted femoral shaft fracture, which accounted for 20.3% of all adult femoral shaft fractures admitted. Of these, 91 patients met the study inclusion criteria. Of the enrolled patients, 88% (80/91) were male. The age ranged from 18 to 84 years with a mean age of 33 years (SD 11.6). The majority of patients were in the third and fourth decade, which accounted 49.5% and 28.6 %, respectively. Fig 2

There were 11 patients (12%) lost to follow up, and among these, 5 patients were lost to follow up after discharge from the hospital and 6 patients were lost to follow up after the 6 week visit. The remaining 80 patients completed a minimum of 18 weeks of follow up after surgery.

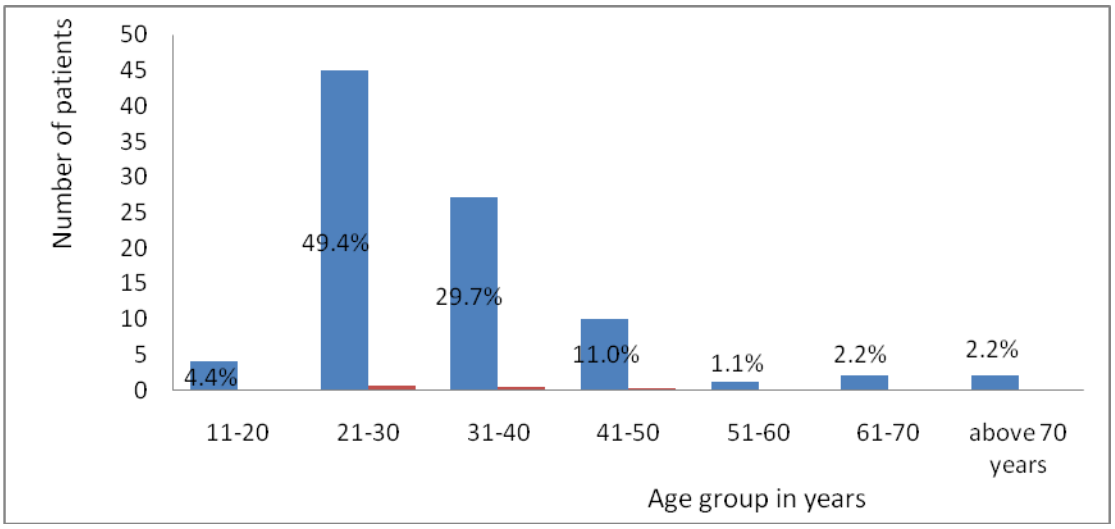


Figure 2: Age distribution of adult patients with closed comminuted femoral shaft fracture admitted at MOI from March to October 2011.

Fracture classification

The degree of fracture comminution was classified according to Winquist and Hansen classification. Type II, III, IV and segmental fractures were encountered in 27.5 %, 38.5%, 18.7 % and 15.4 % respectively.

Hospital stay

Forty eight patients (59.3 %) were operated within 24 hours of arrival to the hospital. Those operated after 48hours from arrival accounted for 24.2%. The reasons for delayed operation included low Haemoglobin level and hemodynamically unstable patients. Clinically stable patients (30.8%) were discharged 24 hours posts operatively.

Post-operative infection

Four patients (5%) developed post-operative surgical site infection. Deep infections were encountered in 2 patients (2.5%), and superficial infections occurred in 2 patients (2.5%).

Callus formation

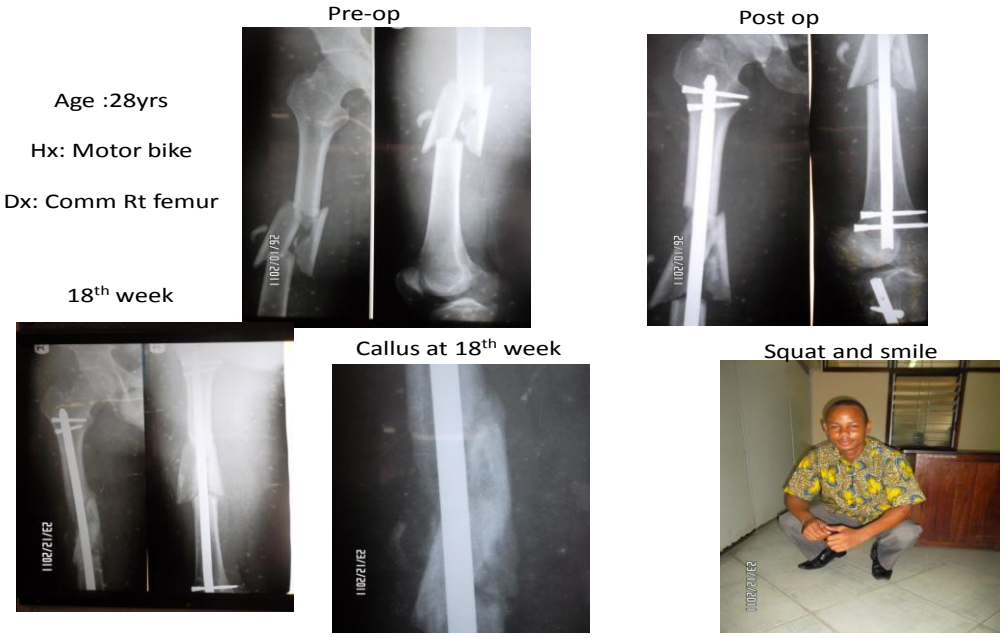
Fifty five patients (68.8%) had callus formation by 12^{th} week. The mean duration to callus formation was 10.9 +/- 5.3 weeks. Ninety five percent of patients (*n=80*) had callus formation by 18^{th} week post surgery. Only 4 (5%) patients had no callus by 18^{th} week. There was no statistical significance difference in time to callus formation between patients treated with 3 or 4 interlocking screws (P- value = 1.0). *Table 2*

Table 2: Time at 1st callus formation among patients with closed comminuted femoral shaft fracture treated with locking IM against the number of interlocking screws used

		Time at 1ST callus detected				
		No callus	6th week	12th week	18th week	**Total**
Number of Interlocking screws	**3 screws**	1(4.8%)	8(38.0%)	8(38.0%)	4(19.0%)	21(100%)
	4 screws	3(5.1%)	19(32.2%)	20(33.9%)	17(28.8%)	59(100%)
	Total	4(5.0%)	27(33.8%)	28(35.0%)	21(26.2%)	80(100%)

Fischer exact test P-value: 1.0

Figure 2: The patient who had comminuted fracture showing pre operative and post-operative x-rays and patients squatting



Limb length discrepancy

Limb shortening of 2 to 3cm occurred in 3.8% of patients (*n=80*). No patients had shortening of more than 3cm. According to Thoresen criteria 96.2 % of patients had excellent to good limb length outcome. There was no statistically significant difference in limb length outcome between patients treated with 3 or 4 interlocking screws. (P-value: 1.0) .*Table 3*

Table.2. Limb length outcome of patients with closed comminuted femoral shaft fracture treated with SIGN nail at MOI against number of interlocking screw used

		Limb length at 18th week			**Total**
		Normal	Shortening (1-2cm)	Shortening (2-3cm)	
Interlocking screw	3 screws	17(81.0%)	4(19.0%)	0(0.0%)	21(100.0%)
	4 screws	47(79.7%)	9(15.3%)	3(5.0%)	59(100.0%)
	Total	64(80.0%)	13(16.2%)	3(3.8%)	80(100.0%)

Fischer exact test p value: 1.0

Rotational deformity

External rotation deformity of more than 20 degrees was seen in 6.3% (*n=80*) of patients. Internal rotation deformity of more than 15 degrees occurred in 8.9%. According to Thoresen criteria 76.3% of patients had excellent limb alignment outcome. *Table 4*

Table 4: The distribution of limb alignment outcome at 18th week post- surgery among patients with closed comminuted femoral shaft fracture treated with SIGN nail at MOI between March 2011 and February 2012

Status	Frequency	Percent (%)	Thoresen score
Normal limb alignment	51	63.8	Excellent
External rotation deformity			
11-15 degrees	10	12.5	Good
16-20 degrees	3	3.8	Fair
21-25 degrees	2	2.5	Poor
More than 25 degree	3	3.8	Poor
Internal rotation deformity			
11-15 degree	4	5.0	Fair
16-20 degree	1	1.3	Poor
20-25 degree	3	3.8	Poor
More than 25 degree	3	3.8	Poor
Total	80	100.0	

By Thoresen criteria 76.3% of patients had excellent limb-rotation outcome.

Range of movement of knee joint

Overall knee flexion of less than 90 degree was encountered in 7.5% of patients. Knee flexion of less than 90 degrees was seen in 3.3% of patients treated with antegrade and it occurred in 20% patients treated by retrograde nail. The difference was statistically significant (P value: 0.032). By Thoresen criteria excellent to good knee flexion deficit was encountered in 87.5% of patients. *Table 5*

Table 5: Distribution of ranges of degree of knee flexion of affected limb among patients with closed comminuted femoral shaft fracture treated with SIGN nail at MOI between March 2011 and February 2012.

	Knee flexion				**Total**
	Less than 90^0	$91\text{-}110^0$	$111\text{-}120^0$	$>120^0$	
Antegrade	2(3.3%)	4(6.7%)	1(1.6%)	53(88.3%)	60(100.0%)
Retrograde	4(20.0%)	0(0.0%)	1(5.0%)	15(75.0%)	20(100.0%)
Total	6(7.5%)	4(5.0%)	2(2.5%)	68(85.0%)	80(100.0%)

Fisher exact test P value: 0.032

CHAPTER FOUR

DISCUSSION

Comminuted femoral shaft fractures are difficult to treat because of higher risk of limb length discrepancy and malrotation deformities (18, 19). This study reported the outcome of 80 patients with comminuted fractures treated with locked intramedullary nailing using the SIGN system. Comminuted femoral shaft fracture accounted for 20.3% (n=522) of all adult femoral shaft fractures admitted during study period.

In this series deep wound infection was encountered in 2 patients (2.5%). Impants were removed in both patients who had deep wound infections, followed by thorough debridment and antibiotic therapy. Nearly equivalent results were obtained by Kempf et al who reported deep infection was seen in 1.9% (n=52) (24). However, the infection rate is higher than that reported by Hansen Jr et al and Winguist et al that infection to occurred in 0.4% and 0.9%, respectively (18, 27). The observed difference might be due to the high rate of open reduction in this study, which is necessary in the absence of fluoroscopic imaging. The observed infection rate might also be due to early discharge and wound care being performed improperly by patients at home.

More than half of the patients (68.8%) had callus formation by the 12^{th} week postoperatively, and the mean time to callus formation was 10.7 weeks. These results were similar to what had been found in studies done by Johnson et al, Zukerman et al and Arpiciglu et al whom revealed average time to union ranged between 13.5 to 16.5 weeks (20, 21, 28). But contrary results were reported by Webb LX et al whose results showed mean time to callus formation was 18 weeks (41). Clinical radiological union of patients in this study was seen in 95% of patients by the 18^{th} week. These results were lower compaired to radiological union seen in 98% and 98.9% of patients as reported by Wiss DA et al and White GM et al at mean duration 4.4 months respectively (8, 22).

The lowered percentage in fracture union observed in this study might be due to the short followup time. There is also variability between studies in the definition of fracture

union. It is concluded that there was no difference in average time to callus formation between open and closed interlocking nails.

Normal limb length was seen in 80% of patients. Limb shortening of more than 2cm was encountered in only 3.8% of patients. By Thoresen criteria score, 96.2% of patients had excellent or good limb length outcome. These results concurred to what obtained by Winguist et al and Arpaiciglu et al who showed shortening of more than 2cm were encountered in 2% and 4.5% respectively(18, 28). Shortening of 1-2 cm in this study was seen in 16.2% of patients, these results were similar also to what reported by Kempf I et al that shortening of 0.5 to 2.5cm occurred in 21% of patient (24). The results were higher compared to those obtained by Wiss et al, Zukerman et al and White et al whom revealed shorterning of 1-2 cm occurred in 1.8%, 3.2% and 3.3 % respectively (8, 21, 22). This difference in results might be due to the fact that in other studies patients affected limb length were compaired with normal limbs and maintained by traction table and the length of nail was estimated from radiograph of normal contralateral femora. Improved limb length outcome by open nailing of comminuted femoral fracture can be obtained by maintaining traction after aligning fracture fragments and before locking the intramedullary nail. Also this study revealed that, there was no statistically significant difference in limb shorterning outcome between patients treated with 3or 4 interlocking screws (P-value > 0.05)

External rotation deformity of more than 20 degrees occurred in 6.3% of patients and internal rotation of more than 15 degree was encountered in 7.9%. According to Thoresen criteria score 76.3% of patients had excellent limb alignment outcome. These results concurred with what was obtained by Bowel et al and Wiss et al whose studies showed external rotation deformity of more than 20 degrees occurred in 6 % and 7 % respectively(8, 25).

But contrary result was obtained in studies by Winguist et al and Hansen et al which revealed rotation deformity of more than 20 degree occurred in 2.3% and 1.7% respectively (18, 27). The obtained difference may be due to the fact that in other studies intra operatively limb alignment is maintained by traction table before locking the nail.

Rotational outcomes in resource limited areas with no fracture table can be improved by assessing and maintaining proper alignment of the affected limb before and during locking the nail.

The overall knee flexion of less than 90 degrees was encountered in 7.5% of patients at the 18^{th} week. The rate of knee stiffness was higher among patients treated with retrograde compared with antegrade nailing. These results concurred with Søjbjerg et al who reported that 7.5% of patients had knee flexion of 60^{0} to 90 degrees (29). Contrary results were reported by Wiss et al, that no patient had a knee flexion contracture and 2 patients (0.06%) had less than 90 degrees knee flexion(8). Nipatasaj et al reported that all patients had more than 90 degree knee flexion at 2 weeks post operatively (31). The difference may be due to lack of regular physiotherapy in this setting. Also these results were contrary to what was reported by Bitta et al that there was no difference in knee flexion outcomes between patients treated with antegrade and retrograde nail (32) . The observed difference might be due to the fact that all of the patients had severe injury (comminuted fractures); which delayed the initiation of knee flexion exercise.

4.1. STUDY LIMITATIONS

i. There was no randomization of treatment, such as the number of screws, which can lead to confounding bias

ii. The follow up was limited to 18 weeks, which is not adequate to fully assess the rate of radiographic union or the rate of deep infection.

iii. There is no a standardized method for assessing radiographic union, which limits the ability to determine radiographic union.

CHAPTER FIVE

5. CONCLUSION

- The comminuted femoral shaft fracture treated with interlocking intramedullary SIGN nail has excellent to good outcome in rate of callus formation, limb length and limb alignment outcomes.

- There was no difference in treatment outcome for comminuted femoral shaft fracture treated by open or closed interlocking nail in terms of limb length, time to callus formation and limb malrotation based on historical control

- SIGN nail appears to be an effective treatment for comminuted femoral shaft fractures in developing countries where image intensifiers and fracture tables are not readily available.

5.1 RECOMMENDATIONS

i. Patients with comminuted femoral shaft are best treated with interlocking intramedullary nail (SIGN nail) as it has best results in terms of high rate of union, and less limb length discrepancy and malrotation deformity

ii. Retrograde nail should be avoided in severe comminuted femoral shaft fractures, and only be used when there is absolute indication, followed by regular knee physiotherapy.

REFERENCIES

1. Paige whittle, George W. Wood II; Campbell's operative orthopaedics 11th edition, part VX chapter 51 fractures of shaft of femur

2. Rockwood and Green. Fractures in adults. Fracture shaft of femur. Chapter 47. Pg 1848-1914

3. John N. Delahay and Scott T. Sauer; Essentials of Orthopaedic Surgery. Third edition. Chapter 2: Skeletal trauma pg. 40-84

4. Ostrum RF, Verghese GB, Santner TJ. The lack of association between femoral shaft fractures and hypotensive shock. J Orthop Trauma 1993; 7(4):338-342.

5. Michael W. Chapman (MD); Chapman's Orthopaedic Surgery. Part II chapter 20, Femoral diaphyseal fracture

6. Zikler LG. Technique manual of SIGN IM and interlocking screw system insertion and extraction guide.. 2010 November 03;26-33.

7. Braten M, Terjesen T, Rossvoll I. Torsional deformity after intramedullary nailing of femoral shaft fractures. J Bone Joint Surg (Br) 1993;75:799-803

8. Wiss DA; Fleming CH; Matta J M; Clark D. Comminuted and Rotationally Unstable Fractures of the Femur Treated with an Interlocking Nail. Clinical Orthopaedics & Related Research. 212:35-47, November 1986

9. Yang KH, Han DY, Jahng JS, et al. Prevention of Malrotation Deformity in Femoral Shaft Fracture. J Orthop Trauma 1998; 12:558.
10. Jaarsma RL, Pakvis DF, Verdonschot N, et al. Rotational malalignment after intramedullary nailing of femoral fractures. J Orthop Trauma 2004; 18(7):403-409.

11. Kim JJ, Kim E, Kim KY. Predicting the rotationally neutral state of the femur by comparing the shape of the contralateral lesser trochanter. Orthopedics 2001; 24(11):1069-1070

12. Tornetta P 3rd, Ritz G, Kantor A. Femoral torsion after interlocked nailing of unstable femoral fractures. J Trauma 1995; 38(2):213-219

13. Wolinsky PR, McCarty E, Shyr Y, et al. Reamed intramedullary nailing of the femur: 551 cases. J Trauma 1999; 46(3):392-399.

14. Karpos PA, McFerran MA, Johnson KD. Intramedullary nailing of acute femoral shaft fractures using manual traction without a fracture table.J Orthop Trauma 1995;9(1):57-62

15. Ricci WM, Bellabarba C, Lewis R, et al. Angular malalignment after intramedullary nailing of femoral shaft fractures. J Orthop Trauma 2001;15(2):90-95

16. Ikpeme JO.Quadricepsplasty following femoral shaft fractures. Injury 1993;24(2):104-108

17. Franklin JL, Winquist RA, Benirschke SK, et al. broken intramedullary nails. J Bone Joint Surg Am 1988; 70(10):1463-1471

18. Winquist RA, Hansen ST Jr. Comminuted fractures of the femoral shaft treated by intramedullary nailing. Ortho Clinica North America 1980 July; 11(3):633-48.

19. Deshmukh RG, Lou KK, Neo CB, Yew KS, Rozman I, George JA technique to obtain correct rotational alignment during closed locked intramedullary nailing of the femur. Injury1998 Apr;29 (3):207-10

20. Johnson KD, Johnston DWC and B Parker Comminuted femoral-shaft fractures: treatment by roller traction, cerclage wires and an intramedullary nail, or an interlocking intramedullary nail. J Bone Joint Surg (Am) 1984:66-A:1222-35

21. Zuckerman JD, Veith RG, Johnson KD, Bach AW. Treatment of unstable femoral shaft fractures with closed interlocking intramedullary nailing. J Orthopaedic &Trauma 1987; 1(3):209-18.

22. White GM, Healy WL, Brumback RJ, Burgess AR, Brooker AF. The treatment of fractures of the femoral shaft with the Brooker-Wills distal locking intramedullary nail. J Bone Joint Surg (AM) 1986 Jul; 68(6):865-76

23. Tüzüner T, Subaşi M, Kapukaya A, Necmioğlu NS. Treatment of femoral shaft fractures with interlocking intramedullary nailing. Acta Orthopedica Traumatology Turkey. 2002; 36(3):211-9.

24. Kempf I, Grosse A, Beck G. Closed locked intramedullary nailing. Its application to comminuted fractures of the femur. J Bone Joint Surg (Am) 1985 Jun;67(5):709-20

25. Borel JC, Dujardin F, Thomine JM, Biga N. Closed locked nailing of complex femoral fractures in adults. Apropos of 68 cases]. Rev Chir Orthop Reparative Appa1993;79(7):553-64

26. Sultan S. Interlocked nailing of comminuted fractures shaft of femur. J Ayoub Med Coll Abottabad 2001 Jul-Sep;13(3):14-5

27. RA Winquist, ST Hansen and DK Clawson .Closed intramedullary nailing of femoral fractures. A report of five hundred and twenty cases. J Bone Joint Surg (Am) 1984:66-A: 529-39.

28. Arpacioğlu MO, Akmaz I, Mahiroğullari M, Kiral A, Rodop O. Treatment of femoral shaft fractures by interlocking intramedullary nailing in adults]. Acta Orthopedica Traumatology Turkey 2003; 37(3):203-12

29. Søjbjerg JO, Eiskjaer S, Møller-Larsen F. Locked nailing of comminuted and unstable fractures of the femur. J Bone Joint Surg (BR) 1990 Jan; 72(1):23-5.

30. Anastopoulos G, Asimakopoulos A, Exarchou E, Pantazopoulos T. Closed interlocked nailing in comminuted and segmental femoral shaft fractures. J Trauma: 1993 Nov; 35(5):772-5

31. Nipatasaj P, Bhovati V, Patanakumjorn D, Jirarachvaro S. Closed intramedullary nailing for femoral shaft fracture in Ratchaburi Hospital. J Med Ass Thai 1995 Aug;78(8):419-23

32. Bitta et al. Retrograde versus antegrade nail in management of femoral shaft fracture at MOI

33. MOI EMD registry books. 2010

34. Whelan MB, MD Mckee, G.H Guyat. interobserver and intraobserver variation in assessment of healing of tibia after intramedullary fixation. JBJS. 2002;84-B:15-8

35. John M. Martell BR. The orthopaedic physical examination- Reider second edition 1999;chapter 5( ):168-84**.**

36. Das S. examination of injury around the hip. a manual in clinical surgery icluding special investigation and differencial diagnosis- 5th Edition. 2000;chapter 13:147-52.

37. McRae R. Hip assessment. Pocketbook of orthopaedics and fractures Second edition 2006;Chapter 9:116-9.

38. Reider B. knee examination. The orthopaedic physical exam Reider second edition. 1999;chapter 6:216-9

39. McRae R. the knee. Pocketbook of orthopaedics and fractures Second edition. 2006;chapter 10:150-2.
40. Thoresen BO, Alho EA, Stromsoe K, et al. interlocking intramedullary nailing in femoral shaft fractures. A report of 48 cases. J Bone Joint Surg (Am) 1985;67:1313–20

41. Webb LX, Gristina, Anthony G, Fowler, H. Leslie. Unstable Femoral Shaft Fractures: A Comparison of Interlocking Nailing Versus Traction and Casting Methods. Journal of orthopaedic Trauma. 2(1) :10-12, 1988

APPENDIX

Appendix I: Informed Consent Form

Consent to participate in the study titled "The short-term outcome of comminuted femoral shaft fractures patients treated with locking intramedullary nail at MOI-2011

Greetings: I am Dr. Felix Mrita; a postgraduate student doing a research on the outcome of patients with closed comminuted femoral shaft fracture treated with locking intramedullary nail at MOI- 2011

Purpose of the Study: To determine the short-term outcome of closed comminuted femoral shaft fractures patients treated with locking intramedullary nail at MOI- 2011

What participation involves: If you agree to participate in this study, you will be asked questions and examined before and be followed up after the operation.

Confidentiality: All information collected will be entered into computer with only an identification number; no name included.

Risk: We expect no harm to happen to you during the course of this study.

Rights to withdraw: Taking part in this study is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual treatment protocol of the Institute for all patients with comminuted femoral shaft.

Benefits: If you agree to participate in this study, you will be followed-up closely and be assessed on the progress of your condition by the investigating doctor. We hope that the obtained information from this study will benefit others.

Who to contact: If you have any other questions regarding this study, feel free to contact me, the investigator, Dr. Felix Mrita, Muhimbili Orthopaedic Institute, P.O. Box 65474, Tel no.0713439493 Dar es Salaam.

If you have any questions concerning your rights as a participant, you may contact Prof. M. Aboud, Chairman of the college research and publication committee, P.O. Box 65001, Dar es Salaam. Telephone: 2150302/6.

Signature

Do you agree to participate. .....

Participant does not agree…….

I, ……..have read the consent form and my questions have been answered and I agree to participate in this study.

Signature of Participant……..

Signature of Investigator…….

Date of signed consent…….

Appendix II: Informed Consent form – Kiswahili Version

Ruhusa ya Kushiriki Utafiti Kuhusu kuangalia matokeo ya matibabu ya wagonjwa wenye mivunjiko ya mifupa ya paja Kwa kutumia vyuma vinavyowekwa ndani ya uboho wa mfupa wa paja katika taasisi ya mifupa MOI-2011

Salaam!

Mimi naitwa Dr. Felix Mrita ni mwanafunzi wa udhamili chuo kikuu cha tiba Muhimbili. Nachunguza matokeo yatokanayo na upasuaji wa mifupa ya paja kwa kutumia vyuma vya ndani ya uboho

Dhumuni la utafiti huu: Kupata taarifa muhimu ya matokeo ya matibabu ya mifupa kwa kutumia vyuma vilivyotajwa hapo juu na kutoa mapendekezo ya uboreshaji.

Ushiriki: Kama unakubali kushiriki kwenye utafiti huu, utaulizwa maswali, utachunguzwa kwa kina na utafuatiliwa hata baada ya upasuaji katika kliniki yetu

Usiri: Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitanukuliwa.

Madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu

Haki ya kujitoa kwenye utafiti: Kushiriki katika utafiti huu ni hiari, na kutokubali kushiriki au kujitoa hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtu mvunjiko wa mifupa ya paja.

Kutokea kwa madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu. Hata hivyo kama madhara ya mwili yatatokea kutokana na utafiti huu, utatibiwa kulingana na kanuni na taratibu za matibabu ya Tanzania.

Faida ya kusiriki kwenye utafiti: Kama utakubali kushiriki kwenye utafiti huu, Faida utakazopata ni pamoja na kuonwa na kufuatiliwa kwa ukaribu na daktari anayefanya utafiti. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia

Kwa mawasiliano zaidi: Kama una maswali or maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Dr. Felix Mrita, Muhimbili Orthopaedic Institute, P.O. Box 65474, simu: 0713439493 DSM. Kama una maswali kuhusu haki yako kama mshiriki wasiliana na Prof. M. Aboud, Mwenyekiti wa kamati ya utafiti, P.O. Box 65001, DSM. Simu 2150302/6.

Saini:

Je, umekubali kushiriki? .....

Mshiriki hajakubali kushiriki……

Mimi……. nimesoma maelezo na kuyaelewa vizuri, na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki……...

Sahihi ya Mtafiti……

Tarehe …….

Appendix III: Research Questionnaire

TITLE: S*hort-term outcome of patients with closed comminuted femoral shaft fracture treated with locking intramedullary SIGN nail at Muhimbili Orthopaedic Institute-2011*

I.PREOPERATIVE EVALUATION

1. Form number: ……
2. Registration NO. …….
3. Age: ……. Sex: a) Male b) Female …….
4. Place of residency: …… Phone no: …….
5. Date of injury: ……Date of operation: ……
6. Date of discharge …….
7. Post operative hospital stay

    a) < 2 days b) 2-5 days c) More than 5 day: Specify ……..……

8. Cause of injury:

    a) Motor vehicle b) Motor bike c) pedestrian d) Falling from height

    e) Sports f) Others: specify……..

9. Side of femoral fracture

    a) Right b) Left femur c) Bilateral femoral shaft fractures

10. Anatomical location of fracture

    a) Proximal 1/3 b) Middle 1/3 c) Distal 1/3

11. Classification of comminuted femoral shaft fracture by Winguist – Hansen classification:

    a) Type I b) Type II c) Type III d) Type IV e) Segmental

12. Other associated injuries:

    a) Present b) absent ……. If absent go QN 16

13. Other associated injuries:

    a) Head injury: specify ……..

    b) Pelvic injury c) Visceral injury d) Chest injury: specify ……

    c) 0ther injury: specify ……

II.POST-OPERATIVE EVALUATION AND MANAGEMENT

14. Post op control x-rays- alignment:

    a) Good alignment b) Mal alignment .If good alignment go QN 19

15. If malignment

    a) Varus b) Valgus c) Anterior angulations d) Posterior angulations

16. Degree of angulations of mal-alignment

    a) Less than 5^0 b) 5^0- 10^0 degrees c) 10^0-15^0 degrees d) More than 15^0 degrees

17. Affected Limb length post operatively:

    a) Normal length b) Shortening c) Lengthening

18. If there is change in limb length: specify ……..

    a) Less than 1 cm b) 1 cm- 2cm c) More than 2 cm

19. Limb rotation deformity:

    a) Yes b) No …….. if no go QN 24

20. If yes(there is rotational deformity):

    a) External rotation b) Internal rotation

21. Degree of rotational deformity:

    a) < 5 degrees b) 5-10 degrees c) 10 -15 degrees d) More than 15 degrees

22. Number of interlocking screw:

    a) Two screws b) Three screws c) Four screws

I. POST OPERATIVE PATIENT FOLLOW-UP

23. Limb length deformity:

    a) At 2 weeks i) Yes…… If yes specify (type and cm)…….

       ii) No

    b) At 6 weeks i) Yes…… If yes specify (type and cm)…….

       ii) No

    c) At 12 weeks i) Yes…… If yes specify (type and cm)……

    d) At 18 weeks i) yes … If yes specify (type and cm)……

       ii) No

24. Limb rotation deformity

a. At 2 weeks i) present ….. Specify (type/degree) ……

ii) Absent

b. At 6 weeks i) Present ……. Specify (type/ degree)…….

ii) Absent

c. At 12 weeks i) present …….specify (type/degree) ……..

ii) Absent

d. At 18 weeks i) present …… specify ……

ii) Absent

25. Wound infection:

a) At 2 week post op i) Present ……. Specify …… ii) Absent

b) At 6 weeks i) Present ……. Specify ……. ii) Absent

c) At 12 weeks i) Present ……. Specify ……. ii) Absent

d) At 18 weeks i) Present ……. Specify ……. ii) Absent

26. Callus formation on control X-ray :

a) At 6^{th} week i) Yes…… ii) No……

b) At 12^{th} week i) Yes …. ii) No ….

c) At 18^{th} weeks i) Yes …. ii) No ….

27. Range of movement of affected knee at 18^{th} week post surgery:

    a) Less than 90^0 flexion

    b) $91\text{-}110^0$ flexion

    c) $111\text{-}135^0$ flexion

    d) More than 135^0 flexion

28. Implant failure:

    a) Present b) Absent

29. Failure due to:

    a) Fractured locking screw b) Fractured nail c) Fractured bone

Appendix IV: Dodoso la Utafiti

Utafiti wa kuangalia matokeo ya matibu ya wagonjwa wenye mivunjiko ya mifupa ya paja kwa kutumia vyuma vinavyowekwa ndani ya uboho wa mfupa wa paja katika taasisi ya mifupa MOI-2011

I. <u>HALI YA MGONJWA KABLA YA OPARESHENI</u>

1. Namba ya fomu: ……

2. Namba ya faili: …….

3. Umri: ……. Jinsia: a) Mme b) Mke …….

4. Mahali anapoishi: …… Namba ya simu: …….

5. Tarehe ya kuumia: ……Tarehe ya oparesheni: ……

6. Tarehe ya kutoka hospitali …….

7. Siku za kukaa hospitali baada ya operasheni

   b) < 2 siku b) siku 2-5 c) zaidi ya siku 5: sababu ……..……

8. Sababu ya kuumia:

   b) Ajali ya gari b) Ajali ya pikipiki c) Mwenda kwa miguu d) kuanguka

   f) Kwenye michezo f) mengineyo: Taja……..

9. Mfupa wa paja uliovunjika:

   b) kulia b) kushoto c) kulia na kushoto

10. Sehemu iliyovunjika:

    b) juu 1/3 b) katikati 1/3 c) chini 1/3

11. Aina ya mvunjiko wa mfupa wa paja kutumia Winguist – Hansen classification:

    b) Type I b) Type II c) Type III d) Type IV e) Segmental

12. Je, kunasehemu nyingine zilizoumia:

    b) Ndiyo b) hapana ……. Kama hapana nenda swali la 16

13. Sehemu nyingine zilizoumia:

    d) Kichwani: Taja aina ……..

    e) Kiuno c) tumboni d) kifua: Taja ……

    f) Sehemu nyingine: Taja ……

II. <u>HALI YA MGONJWA BAADA YA OPERATION</u>

14. Mpangilio (alignment) wa mifupa baada ya operation-

    b) mzuri b) mpangilio usio mzuri (umepinda) …….kama mzuri nenda swali la 19

15. Kama si mzuri (umepinda)

    b) Kwa nje b) kwa ndani c) kwa mbele d) kwa nyuma

16. Digrii ya kupinda

    b) $< 5^0$ b) 5^0- 10^0 degrees c) 10^0-15^0 degrees d) $> 15^0$ degrees

17. Urefu wa mguu ulioumia baada ya opareshen:

b) Urefu sawa b) umekua mfupi c) umerefuka

18. Mabadiliko ya urefu wa mguu: Taja ……..

b) < 1 cm b) 1 cm- 2cm c) > 2 cm

19. Rotesheni mbaya ya mguu

b) Ipo b) haipo .. kama hapana nenda swali la 24

20. Kama ipo (aina ya Rotesheni):

b) Kwa nje b) kwa ndani

21. Kiasi cha rotesheni:

a) < 5 digrii b) 5-10 digrii c) 10 -15 digrii d) > 15 digrii

22. Namba of interlocking screw:

b) mbili b) tatu c) nne

III. MAENDELEO YA MGONJWA BAADA YA OPARESHENI

23. Mabadiliko ya urefu wa mguu baada ya opareshen:

e) Wiki ya 2 i) ndiyo…… Kama ndiyo Taja ……

ii) Hapana

f) Wiki ya 6 i) ndiyo…… Kama ndiyo taja …….

ii) Hapana

g) Wiki ya 12 i) ndiyo…… Kama ndiyo taja ……

ii) Hapana

h) Wiki ya 16 i) ndiyo … Kama ndiyo taja ……

ii) Hapana

24. Rotesheni ya mguu

a) Wiki ya 2 i) ndiyo…… Kama ndiyo taja …….

ii) Hapana

b) Wiki ya 6 i) ndiyo…… Kama ndiyo taja …….

ii) Hapana

c) Wiki ya 12 i) ndiyo…… Kama ndiyo taja …….

ii) Hapana

d) Wiki ya 16 i) ndiyo …… Kama ndiyo taja …….

ii) Hapana

25. Maendeleo ya kidonda cha oparesheni:

a) Wiki ya 2 i) mabaya…… Kama mabaya taja …….

ii) Mazuri

b) Wiki ya 6 i) mabaya…… Kama mabaya taja …….

ii) Mazuri

c) Wiki ya 12 i) mabaya…… Kama mabaya taja …….

ii) Mazuri

d) Wiki ya 16 i) mabaya …… Kama mabaya taja …….

ii) Mazuri

26. Dalili za mfupa kutengeneza kalusi:

d) Wiki ya 6 i) ndiyo…… ii) hapana……

e) Wiki ya 12 i) ndiyo …. ii) Hapana ….

f) Wiki ya 16 i) ndiyo …. ii) Hapana ….

27. Kifaa kimeshindwa kufanya kazi:

b) ndiyo b) hapana

28. Kimeshindwa kufanya kazi kwa sababu:

b) screw zimevunjika b) chuma kimevunjika c) mfupa umevunjika

1. Paige whittle GWWI. fracture of shaft of femur. Campbell's operative orthopaedics 11th edition(part vx):chapter 51.

2. Green Ra. Fracture shaft of femur. Rockwood and Green Fractures in adults Chapter 47( ):1848-914

3. Sauer JNDaST. Skeletal trauma Essentials of Orthopaedic Surgery. Third edition(Chapter 2): 40-84.

4. Ostrum RF VG, Santner TJ,. The lack of association between femoral shaft fractures and hypotensive shock. J Orthop Trauma 1993;7(4):338-42.

5. Chapman MW. Femoral diaphyseal fracture pg Chapman's Orthopaedic Surgery.Part II(chapter 20).

6. Zikler LG. Technique manual of SIGN IM and interlocking screw system insertion and extraction guide. . 2010 November 03;www.sign-post.org(Revision TM):26-33.

7. Braten M TT, Rossvoll I. Torsional deformity after intramedullary nailing of femoral shaft fractures. Measurement of anteversion angles in 110 patients. J Bone Joint Surg Br 1993; 75(5):799-803.

8. Wiss DA FC, Matta J M, Clark D. Comminuted and Rotationally Unstable Fractures of the Femur Treated with an Interlocking Nail. Clinical Orthopaedics & Related Research. 1986 November;212:35-47.

9. Yang KH HD, Jahng JS,. Prevention of Malrotation Deformity in Femoral Shaft Fracture. J Orthop Trauma 1998;12:558.

10. Jaarsma RL PD, Verdonschot N. Rotational malalignment after intramedullary nailing of femoral fractures. J Orthop Trauma 2004; 18(7):403-9.

11. Kim JJ KE, Kim KY. Predicting the rotationally neutral state of the femur by comparing the shape of the contralateral lesser trochanter. Orthopedics 2001;24(11):1069-70.

12. Tornetta P 3rd RG, Kantor A. Femoral torsion after interlocked nailing of unstable femoral fractures. J Trauma. 1995; 38(2):213-9.

13. Wolinsky PR ME, Shyr Y. Reamed intramedullary nailing of the femur: 551 cases. J Trauma. 1999;46(3):392-9.

14. Karpos PA MM, Johnson KD. Intramedullary nailing of acute femoral shaft fractures using manual traction without a fracture table. J Orthop Trauma 1995;9(1):57-62.

15. Ricci WM BC, Lewis R. Angular malalignment after intramedullary nailing of femoral shaft fractures J Orthop Trauma 2001;15(2):90-5.

16. Ikpeme J. Quadricepsplasty following femoral shaft fractures. Injury 1993;24(2):104-8.

17. Franklin JL WR, Benirschke SK. Broken intramedullary nails. J Bone Joint Surg Am 1988; 70(10):1463-71.

18. Winquist RA HSJ. Comminuted fractures of the femoral shaft treated by intramedullary nailing. Ortho Clinica North America 1980 July;11((3)):633-48.

19. Deshmukh RG LK, Neo CB, Yew KS, Rozman I, George JA technique to obtain correct rotational alignment during closed locked intramedullary nailing of the femur. Injury. 1998 Apr;29 (3):207-10.

20. Johnson KD JDaBP. Comminuted femoral-shaft fractures: treatment by roller traction, cerclage wires and an intramedullary nail, or an interlocking intramedullary nail. . J Bone Joint Surg (Am) 1984;66-A:1222-35.

21. Zuckerman JD VR, Johnson KD, Bach AW. Treatment of unstable femoral shaft fractures with closed interlocking intramedullary nailing. J Orthopaedic &Trauma 1987; 1((3)):209-18.

22. White GM HW, Brumback RJ, Burgess AR, Brooker AF. The treatment of fractures of the femoral shaft with the Brooker-Wills distal locking intramedullary nail. J Bone Joint Surg (AM) 1986 July; 68((6)):865-76.

23. Tüzüner T SM, Kapukaya A, Necmioğlu NS Treatment of femoral shaft fractures with interlocking intramedullary nailing. Acta Orthopedica Traumatology Turkey. 2002; 36((3)):211-9.

24. Kempf I GA, Beck G. Closed locked intramedullary nailing. Its application to comminuted fractures of the femur. J Bone Joint Surg (Am) 1985 june 67((5)):709-20.

25. Borel JC DF, Thomine JM, Biga N. Closed locked nailing of complex femoral fractures in adults{Apropos of 68 cases]. . Rev Chir Orthop Reparative Appa. 1993;79(7):553-64.

26. Sultan S. Interlocked nailing of comminuted fractures shaft of femur. J Ayoub Med Coll Abottabad 2001 Jul-Sep;13(3):14-5.

27. RA Winquist SHaDC. Closed intramedullary nailing of femoral fractures. A report of five hundred and twenty cases. J Bone Joint Surg (Am) 1984;66-A 529-39.

28. Arpacioğlu MO AI, Mahiroğullari M, Kiral A, Rodop O. Treatment of femoral shaft fractures by interlocking intramedullary nailing in adults
Acta Orthopedica Traumatology Turkey
2003;; 37((3)):203-12.

29. Søjbjerg JO ES, Møller-Larsen F. . Locked nailing of comminuted and unstable fractures of the femur. J Bone Joint Surg (BR) 1990 Jan; 72(1):23-5.

30. Anastopoulos G AA, Exarchou E, Pantazopoulos T. Closed interlocked nailing in comminuted and segmental femoral shaft fractures. J Trauma. 1993 Nov; 35(5):772-5.

31. Nipatasaj P BV, Patanakumjorn D, Jirarachvaro S. Closed intramedullary nailing for femoral shaft fracture in Ratchaburi Hospital. J Med Ass Thai 1995 Aug;78(8):419-23.

32. Bitta. Retrograde versus antegrade reamed interlocking femoral nailing: a comperative prospective study at muhimbili orthopaedic institute (moi). 2010.

33. EMD M. Registry books. . 2010

34. DB Whelan MB, MD Mckee, G.H Guyat. interobserver and intraobserver variation in assessment of healing of tibia after intramedullary fixation. JBJS. 2002;84-B:15-8.

35. John M. Martell BR. The orthopaedic physical examination- Reider second edition 1999;chapter 5( ):168-84.

36. Das S. examination of injury around the hip. a manual in clinical surgery icluding special investigation and differencial diagnosis- 5th Edition. 2000;chapter 13:147-52.

37. McRae R. Hip assessment. Pocketbook of orthopaedics and fractures Second edition 2006;Chapter 9:116-9.

38. Reider B. knee examination. The orthopaedic physical exam Reider second edition. 1999;chapter 6:216-9.

39. McRae R. the knee. Pocketbook of orthopaedics and fractures Second edition. 2006;chapter 10:150-2.

40. Thoresen BO AE, Stromsoe K. Interlocking intramedullary nailing in femoral shaft fractures. A report of 48 cases. J Bone Joint Surg (Am) 1985.;67(9):1313–20.

41. Webb LX lG, Anthony G.; Fowler, H. Leslie. Unstable Femoral Shaft Fractures: A Comparison of Interlocking Nailing Versus Traction and Casting Methods. Journal of orthopaedic Trauma. 1988; 2(1): 10-2.