



**St. Paul's Hospital
Millennium Medical College**
የቅዱስ ጳውሎስ ሆስፒታል ሚሌኒየም ሕክምና ኮሌጅ

**SAINT PAUL HOSPITAL MILLENNIUM MEDICAL
COLLEGE**

Department of Orthopedics and Traumatology

Factors Associated with Knee Range of Motion in
Retrograde Traumatic Femur Shaft Nailing at Addis
Ababa Burn Emergency and Trauma Hospital, Addis
Ababa, Ethiopia

Samuel Kebede (M.D)

Advisors: Dr.ZegeneTaye (Consultant Orthopaedic
Surgeon)

Mebratu Abraha (B.Sc., MSc)

**A thesis submitted as a partial fulfilment of postgraduate study in
Orthopaedics and Traumatology.**

August, 2019

**SAINT PAUL HOSPITAL MILLENNIUM MEDICAL
COLLEGE**

Department of Orthopedics and Traumatology

A Retrospective Study on Factors Associated with
Knee Range of Motion in Retrograde Traumatic Femur
Shaft Nailing at Addis Ababa Burn Emergency and
Trauma Hospital from August 2015 to August 2018,
Addis Ababa, Ethiopia

Samuel Kebede (M.D)

Table of Contents

Acknowledgment.....	V
ACRONYMS	VI
List of tables.....	VII
List of figures.....	VII
Abstract	VIII
1.Introduction.....	1
1.1Background.....	1
1.1Statement of the Problem	3
1.2 Literature Review.....	5
1.3 Justification of the study.....	6
2. Objectives.....	7
2.1 General Objective.....	7
2.2 Specific Objective.....	7
3. Methods and Materials.....	8
3.1 Study Setting.....	8
3.2 Study design.....	8
3.3 Population.....	8
3.3.1 Source Population.....	8
3.3.2 Study Population.....	8
3.4 Inclusion and Exclusion Criteria	9
3.4.1 Inclusion Criteria.....	9
3.4.2 Exclusion criteria.....	9
3.5 Sample Size.....	9
3.6 Sampling procedures.....	9
3.7 Methods of Data Collection.....	9

3. 8Study Variables.....	10
3.8.1 Independent Variable.....	10
3.8.2 Dependent Variable.....	10
3.9 Operational Definition.....	10
3. 10 Data Processing and Analysis.....	11
3.11 Ethical considerations.....	11
4. Result.....	12
5. Discussion.....	16
6. Limitation of the study.....	18
7. Conclusion and Recommendation.....	19
8. Reference.....	20
9. Annex.....	22

Acknowledgment

First I would like to express our deepest gratitude to our almighty GOD. Next I would like to acknowledge the Saint Paul's Hospital Millennium Medical College for giving permission and funding me to conduct this research project. Finally I would like to express my appreciation to my advisors for their relentless effort guiding me throughout the process.

ACRONYMS

AaBET	Addis Ababa Burn, Emergency and Trauma Hospital
AO	Arbeitsgemeinschaft für Osteosynthesefragen
AOR	Adjusted Odds Ratio
CI	Confidence Interval
HHS	Harris Hip Score
HSS	Hospital for Special Surgeries
KSS	Knee Society Score
OTA	Orthopedic Trauma Association
PTA	Para-patellar approach
SIGN	Surgical Implant Generation Network
SMFA	Short Musculoskeletal Functional Assessment
SPMMCH	Saint Paul Millennium Medical College and Hospital
SPSS	Statistical package for social science
TAH	TikurAnbessa Hospital
TTA	Trans-patellar approach

List of tables

Table 1: Demographic data of Patients among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Table 2: Pre-operative Information among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Table 3: Factors associated with knee range of motion among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019. n=71

List of figures

Fig 1: Method of fracture reduction among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Fig 2: Knee range of motion among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Abstract

Background: Each year around 20-50 million people are injured in road traffic accidents. Developing countries account for ninety percent of these injuries. Femoral shaft fracture is among the most common fractures encountered in orthopaedic surgery practice and can be cause of prolonged morbidity and extensive disability unless treatment is appropriate. Treatment of femur fracture evolve through time from conservative methods like traction to operative management with locking intramedullary nails. Currently, closed locking femoral nail is the standard of treatment for femoral shaft fracture, but it is technically demanding and requires fluoroscopy and fracture table. Since January 2008, SIGN nail which is a solid interlocking intramedullary device designed, manufactured and distributed by SIGN, become available. The surgical approach for insertion of nail can be antegrade or retrograde. Studies With specially designed retrograde nails showed acceptable knee functional outcomes, but long term studies have showed lower limb pain, knee stiffness were seen with this method. This will significantly implicate on socio-economic performance and overall satisfaction of patients.

Objective: To identify factors associated with knee range of motion after retrograde femur shaft nailing.

Methods: A facility based retrospective cross-sectional study will be conducted among all patients with femur shaft fracture who were treated with retrograde SIGN nail at AaBET hospital during the study period and fulfil inclusion criteria and lack exclusion criteria. A self-prepared data collection sheet was developed by review of literature used to document the data in English and data was collected from patient medical record charts, operation note, patient imaging record, and SIGN surgical database system. . Data entry was performed by using Epi-info version 3.5.4 and SPSS version 20 for analysis. Simple tabulation and descriptive statistics used to describe general characteristics of patients and their fractures. Binary and Multivariate logistic regression was be used to assess the significant association between the independent factors and the outcome variable.

Result: So 71 patient medical chart records were available for analysis. Among the 71 patients, 51 (71.8%) patients are male the rest 20 (28.2%) are female patients. The average age of patients was 34.35 (SD=13.92) years and patients between age range of 17to 76 underwent the procedure. Road traffic accident is the most common cause of femur shaft fracture accounting for 47.9% of cases. In 50.7% of cases the middle third segment of the femur is involved. The mean time from injury to intramedullary nail insertion is 12.97days (SD=13.481) with days ranging from 0 to 94 days. Radiographic fracture union was seen in 98.6% (n=70 patients) of cases. Good range of motion was seen in 78.9% (n=56 patients) and poor range of motion was seen in 21.1% (n=15 patients). Using multivariate logistic regression, age ((AOR 1.074, 95% CI (1.013, 1.139)) and time from injury to intra-medullary nail insertion (AOR 1.112, 95% CI (1.022, 1.209)) were shown to be statistically associated with knee range of motion.

Conclusion: Retrograde nailing is an option in the management of diaphysial femur shaft fracture. Its use should be tailored in old age group and in patient with prolonged duration

from injury to intra-medullary nail insertion because of significant association with poor knee range of motion.

1. Introduction

1.1 Background

Humans have never been immune from injury, and doubtless the practice of bone setting was not unfamiliar to our most primitive forebears (1). Fracture, which is a break in continuity of a bone, limb pain, stress and dysfunction of the extremities, as stress conditions have emerged in the first days of the human existence (2). To this day it remains a major cause of morbidity and mortality. The incidence is shown to increase worldwide. In England the incidence of fracture in 2000 was 11.13 in 1,000 per year this number rose to 13.7/1000/year in 2007-2008 (1). A study in Southern Nigeria reported, 216 cases in one year period from July 2013 until July 2014 (4). In Ethiopia, a study at “TikurAnbessa” Hospital (TAH) 422 patients visited the emergency department with fracture in a period between March and August 2007 (5). . The causes of fracture range from road traffic accidents (motor vehicle crashes, motorcycle crashes, pedestrians struck by vehicles), or falls from height (1).

Femur is long bone located between hip joint and knee joint. The proximal end of the femur consists of the head, the neck, the greater trochanter, and the lesser trochanter. The distal end of the femur has medial and lateral condyles. The proximal and distal parts widen into metaphyseal sub-trochanteric and supracondylar regions. The region between the proximal and distal ends is called femoral shaft. The femoral shaft is the portion of the bone between 5 cm distal to the lesser trochanter and 6 cm proximal to the most distal point of the medial femoral condyle (23).

The knee is a complex, compound, condyloid variety of a synovial joint. It actually comprises three functional compartments: the femoro-patellar articulation consists of the patella, or "kneecap", and the patellar groove on the front of the femur through which it slides; and the medial and lateral femoro-tibial articulations linking the femur, or thigh bone, with the tibia, the main bone of the lower leg. The major movement at knee joint is extension and flexion. Extension of the knee joint is defined as the movement of the posterior aspect of the leg away from the posterior surface of the thigh. There is strictly no absolute extension since the position of reference the limb is maximally extended. However, passive extension can be achieved up to 5° or 10° . Active extension goes more than the position of reference rarely and still then only slightly. Flexion is the movement of the posterior aspect of the leg towards the posterior aspect of the thigh. The knee range at flexion varies according the position of the hip and according if the movement is active or passive. Active flexion ranges as far as 140° if the hip is flexed already, and about 120° if the hip is extended. Passive flexion of knee goes as far as 160° and allows the heel to touch the buttocks (24).

Femur is among the commonest body area affected by injuries. In Finland, the incidence of femoral shaft fractures was 9.9 per 100,000 person/year (1). Of the 216 cases of fracture that visited a southern Nigeria hospital femur fracture accounted for 49 (22.69%) of the cases (4). At “TikurAnbessa” Hospital, 202 patients with fracture due to road traffic accidents were x-rayed between March and August 2007. Among these, 32 (15.8%) were diagnosed with femur shaft fracture (5).

Femoral shaft fractures are commonly thought to be primarily associated with severe trauma in young persons. Kootstra studied 335 traumatic femoral shaft fractures in 329 adults in the province of Groningen in the Netherlands. The risk of sustaining a femoral shaft fracture was greatest in men between the ages of 20 and 29 years. The incidence gradually diminished with increasing age, and attained its lowest value in age group 70-79. The marked increase in femoral shaft fracture incidence in females after 50 can only be explained on the basis of a constitutional factor, i.e. the hormonal change during and after the menopause, which is associated with osteoporosis and increased fragility of the femoral shaft.

Femoral shaft fractures require major trauma and can be the cause of prolonged morbidity and extensive disability unless treatment is appropriate (6). Treatment of femur fracture evolved throughout time from ancient Egyptians where they used sticks and bandages to different traction methods (2). In 1940, Kuntscher introduced intramedullary nailing of femoral shaft fractures, which was a turning point in the area of fracture treatment for the long bones. He later added the intramedullary reaming principle in 1952. The intramedullary nailing technique was further improved by the introduction of locking screws by Klemm and Schellmann in 1968. Since then, locked intramedullary nail insertion with reaming has become a standard procedure for almost all femoral diaphyseal fractures (7).

Although both ends of the femur are suitable for nail entry, the antegrade approach through the proximal femur has gained more popularity than the retrograde approach through the distal femur (7). In 1980, Harris reported on the use of implants specifically designed for condylocephalic nailing of pertrochanteric fractures of the hip through the medial femoral condyle [5]. He used the term "retrograde" nailing to distinguish this method from the conventional antegrade approach. With the introduction of intercondylar approaches for the management of supracondylar femoral fractures, the use of the retrograde technique has now been expanded to include femoral shaft fractures (11).

For a long time retrograde nailing has been used by many orthopaedic surgeons only as an alternative to antegrade nailing. Prospective studies comparing antegrade versus retrograde nailing of femoral fractures have reported similar results for both groups with respect to the fracture union rate, incidence of mal-alignment, and limb length inequality were concerned (7). Although the goal is to maximize the knee ROM after fractures, the functional ROM should be considered in order to provide the best alternative results. Various daily activities require a different knee ROM. Functional knee ROM requires 63° of flexion for walking and up to 93° of flexion for standing up from a chair. More motion is required for activities such as getting out of a bathtub (138°), ascending stairs (98.5°), and standing up from a low chair (105°). According to gait analyses and biomechanical studies, patients require at least 83° of flexion to ascend stairs, 90° to 100° to descend stairs, 93° to 105° to rise from a standard or short chair, and >115° to squat or kneel (21).

1.2Statement of the Problem

Each year around 20-50 million people are injured in road traffic accidents. Developing countries account for ninety percent of these injuries (1). Long bone fractures occur in majority of these severe injuries. Femoral shaft fracture is among the most common fractures encountered in orthopaedic surgery practice and can be cause of prolonged morbidity and extensive disability unless treatment is appropriate (2).

Treatment of femur fracture evolve through time from conservative methods like traction to operative management with locking intramedullary nails. Conservative method yield less satisfactory results with high rate of mal-union and knee stiffness (3). Starting with introduction of intramedullary nailing by G. Kuntscher during the years surrounding and after World War II, patient survival and outcomes have continued to improve. Improved prevention and management of fracture shortening, angulation, infection, and non-union have made intramedullary nailing the primary treatment for most femoral fractures (2).

Currently, closed locking femoral nail is the standard of treatment for femoral shaft fracture, but it is technically demanding and requires fluoroscopy and fracture table (3). Such methods of femur fracture fixation were not practiced in Ethiopia rather relied on older generation non-locking nails or conservative management until 2008G.c (3), where patients were prone for development of knee stiffness, mal-union, shortening and angulation. Since January 2008, SIGN nail which is a solid interlocking intramedullary device designed, manufactured and distributed by surgical implant generation network (SIGN), become available (4). Introduction of this nail changed patient outcome dramatically, with less hospital stay, early weight bearing, improved knee range of motion (3).The surgical approach for insertion of SIGN nail can be antegrade or retrograde. Antegrade approach to the femur for intramedullary fixation of femur shaft fractures has been extensively described and has been considered the gold standard. However, retrograde approach through the femoral intercondylar notch has been popularized in recent years as an alternative. The indications for use of retrograde approach include patients with ipsilateral femoral neck or intertrochanteric fractures, ipsilateral acetabular or pelvic injuries, obese patients, patients with multiple fractures, bilateral femur shaft fractures and pregnancy (5).

Retrograde approach has advantages being less technically demanding, takes a shorter time and involves lower blood loss than the antegrade approach (6). In Teaching and Referral Hospital in Western Kenya, the number of patients treated with this technique account for 51.6% of 124 patients treated over 2year period (7). In a study done in three hospitals in Addis Ababa city, retrograde nailing technique accounted for 57.7% of 123 femur fractures treated (8). It's clear that there is more inclination towards preferring this technique despite its potential complications.

In Contrary to this, retrograde nailing has potential of violating intra-articular structures and cartilage, raising fear of knee complications like deterioration of knee range of motion, pain, and arthritis (7). This in turn limits the capability of patient from doing simple chores, using latrine, practicing religious rituals and other day to day activities A Korean retrospective case-control study done among fifty-four patients (14 in the case group, 40 in the control group) with distal femur fracture identified high-energy injury, comminuted fracture, intra-articular fracture, extensor mechanism injury, open fracture, temporary external fixation, and cast immobilization (>3 weeks) were identified as risk factors for postoperative range of motion (ROM) $\leq 90^{\circ}$ (21).

In light of this it's important identify factors that will impact knee motion after femur shaft fracture retrograde nailing either as good or poor outcome. Furthermore, this will significantly implicate on post-operative performance and overall satisfaction of patients.

1.3 Literature Review

Institutional based comparative retrospective cross sectional study that evaluated the long-term functional outcome after antegrade or retrograde intramedullary nailing of traumatic femoral shaft fractures but no other injuries to the lower limbs or pelvis were included was conducted on 59 patients in Netherlands. Range of motion (ROM) was measured by a goniometer using the neutral-0-method at a mean of 7.8 years (3.5 years) postoperatively. The mean knee flexion of the affected leg was similar to the unaffected leg ($p = 0.21$). However, the mean knee flexion in the antegrade group was 143degree and in the retrograde group 132 degree ($p = 0.012$).

A prospective comparative study of 62 consecutive limbs with femoral diaphyseal fractures that had interlocking nail fixation through the antegrade or retrograde approaches at Obafemi Awolowo University Teaching Hospitals Complex, Nigeria was done to evaluate the early impact of antegrade and retrograde interlocking nail fixation of femoral diaphyseal fractures on the ipsilateral hip and knee joint range of motion by using goniometer showed that the mean maximum knee flexion angle at 9 months was 119.9⁰ in the retrograde group and 134.5⁰ in the antegrade group ($p = 0.023$) (22).

A hospital based comparative cross sectional study was conducted at a Teaching and Referral Hospital in Western Kenya among 124 patient with femur fracture. Where they compared functional knee outcome after retrograde and antegrade femoral nailing using modified H.S.S rating system for knee. Fifty per cent of patients in the retrograde group had excellent outcomes as compared to 95% in the antegrade group ($p < 0.001$). In the individual groups, the rate of knee stiffness was significantly higher in the retrograde group (40.6%) compared to the Antegrade group (3%) ($p < 0.001$). Overall there was a negative relationship between knee scores and the age of the patients, $r = -.42$, $p < .001$. The relationship between age and the outcome was not significant in antegrade group ($r = -.085$, $p = 0.519$), but was significant in retrograde ($r = -.445$, $p < 0.001$) (8).

A descriptive case series among 140 patient in Orthopaedics and Spine Centre, Ghurki Trust Hospital Lahore, Pakistan was done to determine post-operative functional outcome after performing nailing in a retrograde fashion for distal diaphyseal femoral fracture in terms of knee range of motion, pain and union at 6 weeks, 6 months and at least 1 year follow-up. 140 patients of both sex and age with fractures of distal diaphyseal femoral fracture and were operated using retrograde nailing were included in the study. Knee range of motion were measured using Goniometer. Only 28 patients (20%) among 140 had knee range of motion less than 120⁰ at 6 weeks follow-up while after 1 year follow up only 14(10%) having knee Range of motion less than 120 degree. While among the remaining 14(10%), 5(3.57%) having knee ROM between 100⁰- 120⁰, 4(2.86%) having between 80⁰-100⁰ while the remaining 6(4.29%) having less than that. They concluded retrograde nailing for distal femur shaft fractures having excellent outcome (13).

A prospective study of 36 patients, with distal femoral fractures including supra condylar and inter condylar fractures, treated surgically with retrograde intramedullary interlock nailing, was carried out at department of Orthopaedics and Traumatology, Gandhi Medical College and Hamidia Hospital, Bhopal. Percutaneous patellar tendon splitting approach in was used 26 patients and medial para patellar arthrotomy approach in ten patients. At the time of final follow up more than half of the patients were having range of movement of more than 90° at knee, average being 101.38°. The average range of knee motion in patient with para patellar arthrotomy approach was 67.5° while it was 121.6° in those treated with percutaneous patellar tendon splitting approach. Patients treated with medial para patellar arthrotomy approach were found to be associated with increased incidence of complications and relatively low range of movement at knee joint (19).

A retrospective cross-sectional study among fifty-four multiply injured patients with a total of fifty-nine fractures of the shaft of the femur treated with external fixation followed by planned conversion to intramedullary nail fixation were evaluated. The purpose of the investigation was to determine whether external fixation followed by planned conversion to intramedullary nail fixation is an appropriate alternative for the management of fractures of the femur in patients who are poor candidates for immediate intramedullary nailing. All fractures of the shaft of the femur were stabilized with a unilateral external fixator within the first twenty-four hours after the injury. The duration of external fixation averaged seven days (range, one to forty-nine days) before the fixation with the static interlocked intramedullary nail. Forty-nine of the nailing procedures were antegrade, and ten were retrograde. For fifty-five of the fifty-nine fractures, the external fixation was converted to intramedullary nail fixation in a one-stage procedure. The other four fractures were associated with draining pin sites, and skeletal traction to allow pin-site healing was used for an average of ten days (range, eight to fifteen days) after fixator removal and before intramedullary nailing. The average range of motion of the knee was 107 degrees (range, 60 to 140 degrees) (20).

1.4 Justification of the study

Since the advent of retrograde intramedullary nailing into Ethiopian orthopaedic surgical arena, up to my knowledge there is no published research on either functional outcome of knee after the procedure or factors affecting knee range of motion after nailing. Though there are couple international researches on knee function after retrograde femur nailing, the type of nail and the technical procedure is different from type of nail used in Ethiopia. On top of this, it's a common scenario in the local setting to use the method outside its proposed indications. So with these problems in mind the research will try to identify factors that influence knee range of motion after retrograde intramedullary nailing done for femur shaft fractures.

2. Objectives

2.1 General Objective

To identify factors associated with knee range of motion after retrograde femur shaft nailing.

2.2 Specific Objective

To describe factors associated good knee range of motion after retrograde femur shaft nailing

To describe factors associated poor knee range of motion after retrograde femur shaft nailing

3. Methods and Materials

3.1 Study Setting

The study will be conducted at Addis Ababa Burn, Emergency and Trauma Hospital (AaBET). It was established in August 2015 G.C as an affiliate center of Saint Paul Millennium Medical College and Hospital (SPMMCH). It's is located in Arada sub-city, in northwestern part of Addis Ababa, capital city of Ethiopia. The hospital is established with an intent of providing service for patients with emergency medical conditions, trauma related condition and those patients with burn injury. It has 37 emergency beds, 11 intensive care unit beds, 22 neurosurgery beds, 10 general surgery beds and 65 orthopedic bed. There are four operation tables where the surgical departments share among themselves for elective and emergency cases. Since the start of the hospital, the orthopedic department provided surgeries for patient who came from different corners of the country. During the study period SIGN nails where the only intramedullary nails used for treatment femur fractures in adult patients. The hospital is one of the few centers in the country, where SIGN surgeries are provided for femur, tibia and humerus fractures. During the study period there were a total of six SIGN surgeons, whom were approved by the company were involved in the treatment of patients. The surgeries during the study period were done by these SIGN surgeons using the SIGN manual with little modification.

3.2 Study design

A facility based retrospective cross sectional study during a period from August 2015 to August 2018 G.C. on patients treated using retrograde intramedullary nail.

3.3 Population

3.3.1 Source Population

All femur shaft fracture patient charts who were treated with SIGN nail at AaBET hospital

3.3.2 Study Population

All patient charts with femur shaft fracture who were treated with retrograde SIGN nail at AaBET hospital during August 2015 to August 2018 G.C.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion Criteria

- Patients with isolated traumatic femur shaft fracture treated with retrograde intra-medullary nail and has no other injuries to the lower limb and pelvis.
- Patients with minimum of six month follow-up visits.
- Patients with pre-operative x-ray and a minimum 2 post-operative follow up x-rays.

3.4.2 Exclusion criteria

- Patients with incomplete medical records
- Previous history of trauma to lower limb
- Patients who had previous operations around the knee.

3.5 Sample Size

There were a total of 82 patient treated with retrograde SIGN nail for isolated femur shaft fractures during the study period as collected from operation registry and cross checked with the SIGN data base.

3.6 Sampling procedures

All patients who meet the inclusion criteria were included.

3.7 Methods of Data Collection

Checklist was developed based on study objectives and available literature. Data was collected from patient medical record charts, operation registry, patient imaging record, and SIGN surgical database system was utilized.

3.8 Study Variables

3.8.1 Independent Variable

General Category

- Gender
- Age
- Co-morbid medical condition
- Associated Injuries

Preoperative Condition

- Mechanism of Injury
- Location of the fracture on the femur shaft
- Type of fracture
- Associated injury
- Degree of soft tissue injury

Intraoperative Condition

- Operation Time
- Time from injury to intramedullary nail insertion
- Surgical approach
- Type of nail
- Fracture Reduction

Post-operative Condition

- Angular mal-alignment
- Radiological union
- Physiotherapy

3.8.2 Dependent Variable

Knee range of motion

3.9 Operational Definition/Standard Definition

Type of fracture: defined using AO/OTA

(Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic trauma association) classification for femur shaft fracture evaluating preoperative x-ray

Degree of soft tissue injury: defined using Gustillo-Anderson open fracture classification system.

Operation Time: time lapsed from skin incision to skin closure measured using minutes

Time from injury to intramedullary nail insertion: time lapsed from injury date to operation date where intramedullary nail inserted defined used days.

Surgical Approach: surgical method used for insertion of the nail.

Paratendinous: surgical approach which utilizes tissue plane lateral or medial to patellar tendon without splitting the tendon.

Transtendinous: Surgical approach which split patellar tendon longitudinally.

Fracture reduction method: surgical technique used to reduce the fracture ends.

Closed method: reduction technique which is used to bring fracture ends into place without skin incision over the fracture site

Minimally Open method: reduction technique using not more than two finger breadth wide surgical incision at fracture site to bring fracture ends into place

Open method: reduction technique utilizing surgical incision more than two finger breadth at fracture site to bring fracture ends into place.

Physiotherapy: any physical therapy administered by a physiotherapist within the first six month post-operative period and documented on the chart

Angular mal-alignment: defined as $>10^0$ angulation either on frontal or sagittal plane and measured radiographically.

Radiological Union: defined by x-ray appearance of cortical bridging callus on at least three of the four cortices.

Knee range of motion: defined as first registered active range of knee flexion measurement on patient chart after six month of post-operative period. Measurement greater than 90^0 will be taken as Good knee range of motion, and measurement less or equal to 90^0 as poor knee range of motion.

3. 10 Data Processing and Analysis

A self-prepared data collection sheet developed by review of literature was used to document the data in English. The prepared data collection sheet includes the general information about the patient, preoperative condition of the fracture, intraoperative methods used and post-operative variables to determine the outcome. Data entry and analysis was performed using Epi-info version 3.5.4 and SPSS version 20. Simple tabulation and descriptive statistics was used to describe general characteristics of patients and their fractures. Bivariate and Multivariate logistic regression was used to determine the effect of factors on the outcome variable. A p-value < 0.05 was considered statistically significant.

3.11 Ethical considerations

Ethical clearance was obtained from the Research and Publications Office of SPHMMC and research committee of orthopedic and traumatology department of SPHMMC and permission was obtained from the Medical director office of AaBET hospital. Patient's data confidentiality was strongly kept.

4. Results

There were a total of 82 patients that underwent retrograde SIGN nail for an isolated femur shaft fracture during the study period. Of these 82 patients, 6 medical charts were not available during the data collection period and 5 medical charts have missing data. So 71 patient medical chart records were available for analysis. Among the 71 patients, 51 (71.8%) patients are male the rest 20 (28.2%) are female patients. The average age of patients was 34.35 (SD=13.92) years and patients between age range of 17to 76 underwent the procedure. Patients between 17 to30 years of age is the account for majority of cases. Majority of patients 60 (84.5%) don't have medical co-morbidities. Eighty point three percent of patients (57 patients) had no associated injuries; of those patients who had associated injuries head injury is the commonest accounting for 8.5% (n=6 cases) of patients.

Table 1: Demographic data of Patients among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Variables		Frequency	Percent (%)
Age	17-30 years	22	31.0
	31-45 years	18	25.4
	36-60 years	15	21.1
	60 and above	16	22.5
Sex	Male	51	71.8
	Female	20	28.2

Road traffic accident is the most common cause of femur shaft fracture accounting for 47.9% of cases. Fall down from a height is the second causes of femur shat fracture comprising of 21.1% of cases. In 50.7% the right femur is affected and in majority 50.7% of cases the middle third segment of the femur is involved. Majority of the fractures are closed fractures accounting for 76.1% of cases. According to AO/OTA classification 32A account for 54.9% of fracture patterns. Skeletal traction is used in majority of cases as initial method of fracture stabilization accounting for 74.6%.

Table 2: Pre-operative Information among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Variable		Frequency	Percentage
Mechanism of Injury	Road Traffic Accident	34	47.9%
	Fall down from height	15	21.1%
	Assault with a stick	5	7.0%
	Bullet Injury	7	9.9%
	Other	10	14.1%
Site of Injury	Right	36	50.7%
	Left	35	49.3%

Level of the fracture segment on the femur shaft	Proximal 3 rd	4	5.6%
	Middle 3 rd	36	50.7%
	Distal 3 rd	31	43.7%
Degree of Soft tissue Injury	Closed	54	76.1%
	GAI	5	7%
	GAI	5	7%
	GAIIA	7	9.9%
	GAIIB	0	0%
	GAIIC	0	0%
Type of fracture pattern (AO/OTA)	32A	39	54.9%
	32B	23	32.4%
	32C	9	12.7%
Method of initial stabilization of fracture	Skeletal Traction	53	74.6%
	Plaster of Paris	3	4.2%
	External Fixator	5	7%
	None	10	14.1%

The mean time from injury to intramedullary nail insertion is 12.97days (SD=13.481) with days ranging from 0 to 94 days. Majority of patients underwent treatment using standard SIGN nail which account for 76.1% cases treated the rest of cases (23.9%) were treated using SIGN fin nail. Most of patients 97.2% underwent para-tendinous surgical approach for insertion of retrograde nail, the rest 2.8% were treated using trans-tendinous approach for retrograde nail insertion. Open fracture reduction method accounted for 77.5% of cases, minimally open fracture reduction method was utilized in 18.3% of cases and in 4.2% of cases closed fracture reduction method was used.

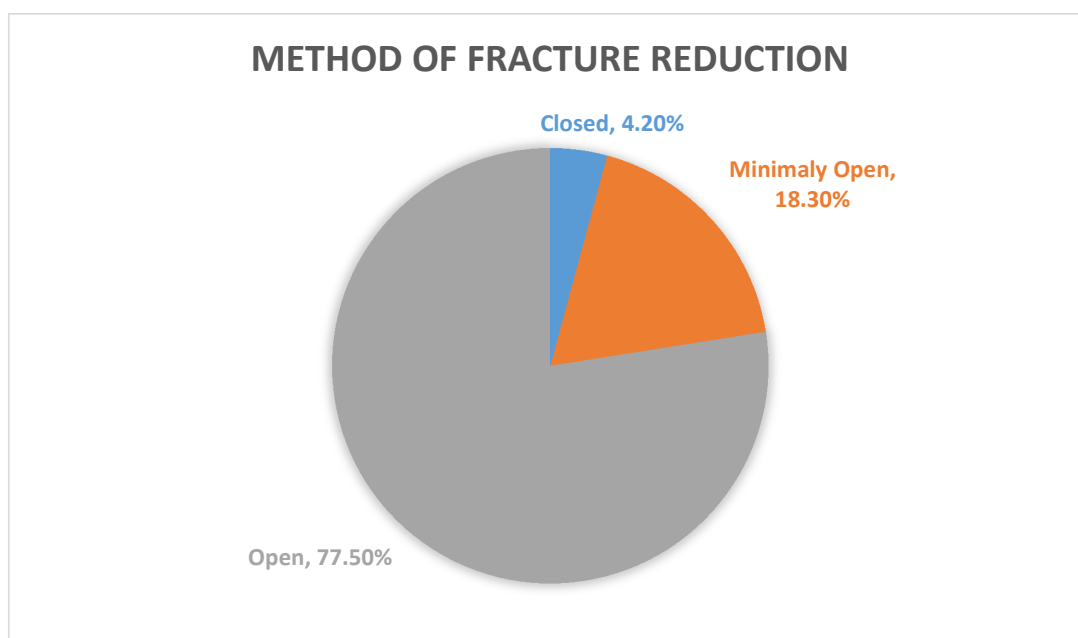


Fig 1: Method of fracture reduction among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

Radiographic fracture union was seen in 98.6% (n=70 patients) of cases only 1(1.4%) patient didn't show radiological union after six month of follow-up. Angular mal-alignment greater than 10 degree was not seen in patients. Physiotherapy was prescribed in only 26.8% (n=19 patients) of cases. Good range of motion was seen in 78.9% (n=56 patients) and poor range of motion was seen in 21.1% (n=15 patients).

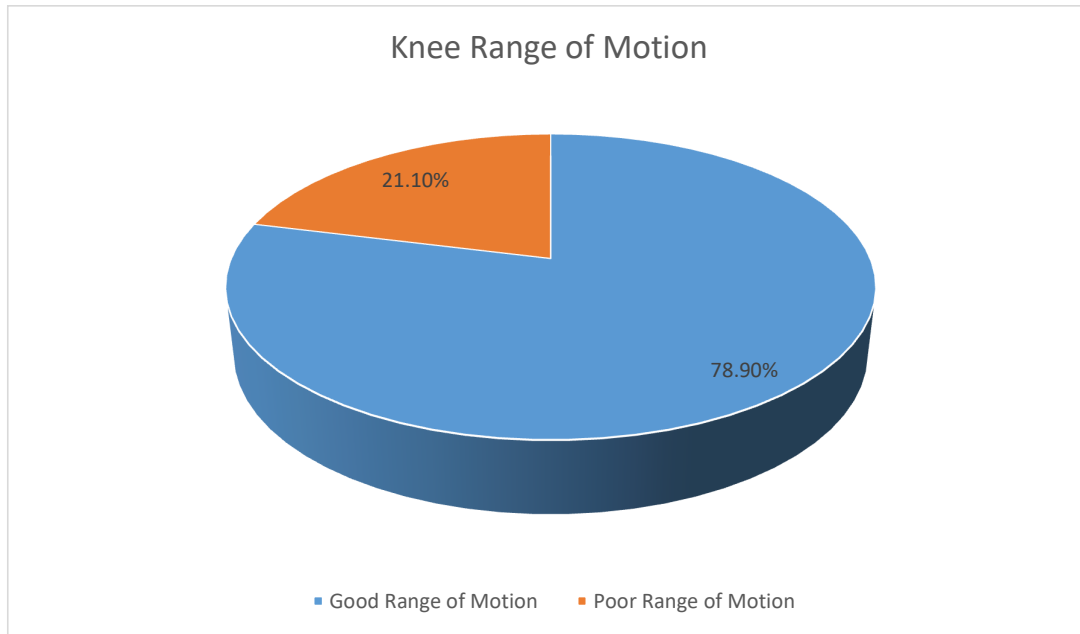


Fig 2: Knee range of motion among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019

4.1 Factors Associated with Knee range of motion

Bivariate Analysis

Binary Logistic regression was done for age, sex, associated injuries, level of fracture on femur segment, method of initial stabilization, degree of soft tissue injury, time from injury to intramedullary injury, surgical approach, fracture method of reduction, and physiotherapy. Age, level of fracture on femur segment (distal 3rd), time from injury to intramedullary nail insertion, method of fracture reduction (open fracture reduction method), physiotherapy have fulfilled the minimum requirement (P-value < 0.2 significance level) for knee range of motion were further analyzed with multivariate logistic analysis.

Multivariate Logistic Analysis

Using multivariate logistic regression analysis method, factors age, level of fracture on femur segment, time from injury to intra-medullary nail insertion, method of fracture reduction and physiotherapy were analyzed.

From the above mentioned factors that were analyzed using multivariate logistic regression, age ((AOR 1.074, 95% CI (1.013, 1.139)) and time from injury to intra-medullary nail insertion (AOR 1.112, 95% CI (1.022, 1.209)) were shown to be statistically associated with knee range of motion.

Table 3: Factors associated with knee range of motion among patient treated with retrograde SIGN nail for an isolated traumatic femur shaft fracture at AaBET hospital, Addis Ababa, Ethiopia, 2019. n=71

Variables		Knee Range of motion		AOR,95% (CI)
		Knee range of flexion greater than 90	Knee range of flexion less than or equal to 90	
Gender	Male	40	11	1
	Female	16	4	1.10 (0.305,3.968)
Age				1.074 (1.013, 1.139)**
Associated Injury	Head Injury	4	2	1
	Abdominal Injury	0	2	323094973 (0, inf.)
	Others	4	1	0.50(0.31, 7.994)
	Two Systems	0	1	3230949730 (0, inf.)
	No injury	48	9	0.375 (0.6, 2.363)
Level of fracture	Proximal 3 rd	3	1	1
	Middle 3 rd	33	3	0.606 (0.056, 6.547)
	Distal 3 rd	20	11	0.165 (0.041, 0.665)*
Degree of soft tissue injury	Closed	42	12	1
	GAI	5	0	0.00
	GAI	4	1	0.714(0.123,4.155)
	GAIIIa	5	2	0.625(0.04, 9.650)
Method of initial stabilization	Skeletal traction	42	11	1
	Plaster of Paris	2	2	0.00
	External Fixator	3	2	7.636 (0.633, 92.156)
	None	10	0	2.545 (0.378, 17.162)
Time from injury to intramedullary nail insertion				1.112 (1.022, 1.209)**
Surgical approach	Para-Tendinous	55	14	1
	Trans-Tendinous	1	1	3.929 (0.231, 66.786)
Method fracture reduction	Closed	3	0	1
	Minimally Open	12	1	
	Open	41	14	0.244(0.029, 2.050)
Physiotherapy	Yes	13	6	
	No	43	9	

* Significant association (p-value < 0.2 in bivariate)

**Significant association (p-value<0.05in multivariate analysis)

5. Discussion

The study was the first in its kind to show factors associated with knee range of motion in patient that undergone retrograde SIGN nail in isolated femur shaft fracture at AaBET hospital Addis Ababa, Ethiopia.

The study showed that male account for 71.8% of patient treated during the study period. This is comparable to a study done in three hospitals in Addis Ababa which revealed the percentage of male patients to be 76.5 % (3). Our result is also comparable from a study in Kenya which showed male to account for 77% of their cases (8). Another study from Nigeria showed the male percentage to be 63.3% which is lower but comparable to our finding (22). A study from Netherlands showed male to account for 89.4% of their patient population (10). The significance difference might arise due to difference (smaller sample size $n=19$) in the Dutch study. The mean age of our population was 34.35 (SD=13.92) years which is similar (mean=34years) to a study done in three hospitals in Addis Ababa (3). The mean age of a study from Nigeria was 37.0 (SD=15.2years) which is comparable to our result. A study from Pakistan showed the mean age of patients to be 31.81 ± 7.117 which is also comparable with our finding (13). A study from Netherlands showed the mean age in there study to be 37 years which is within range our findings (10). These demographics demonstrate that femoral shaft fractures are most common in males at their very productive age and this might have far reaching direct and indirect social economic effect within the society.

In our study road traffic accident is the major cause of femur shaft fracture accounting for 47.9% of cases. This finding is also similar to finding from other studies in Addis Ababa hospital which showed road traffic accident to be a major cause femur fracture(3). Another study at black lion hospital (Ethiopia) showed that road traffic accident accounted for 49.7% of the fractures which is comparable to our result (5).

When we consider the level of fracture, our result showed middle third of the femur accounted for majority of fracture constituting 50.7% and distal third accounted for 43.7% of fracture levels. A study in three hospitals in Addis Ababa Showed middle third femur fracture to 39.4% and distal third to be 38.9% (4) which still signifies middle third fracture take majority share being treated with retrograde nailing. This is similar with our study findings. In Nigerian study middle third fracture level accounted for 61% and distal third accounted for 29.2% which is comparable to our findings (22) In a Kenyan study distal third fracture comprise 60% of fractures while middle third accounted for 40% of fracture levels (8). This difference might be explained by the difference in treatment protocol with use retrograde nailing.

The mean time from injury to intramedullary nail insertion is 12.97days (SD=13.481) in our study. Comparable results were seen in a Kenyan study which showed the mean time from

injury to intramedullary nail insertion to be 10 +7.2 days (8). Our mean time from injury to intramedullary nail insertion is higher than that of a study from Pakistan which showed the mean time to be 2.7days (13); and Indian hospital the mean time is 7 days which is lower than our mean time. This can be accounted by large case burden due to the hospital being a trauma centre. In addition the nail used in our set-up is brought from abroad by a donation, so lack stock at times might contribute for longer pre-operative period.

When we consider radiological union, our results showed that 98.6% cases showed radiological union. This is comparable to a study from India which showed 95% fracture union (16). While a study from Nigeria showed 100% union rate after retrograde nailing which is higher than our result but its closely comparable to our finding (22).

Good knee range of motion was seen in 78.9% (knee flexion greater than 90 degree) of patients and 21.1% of patients have poor knee range of motion (knee flexion less than or equal to 90 degree) in our study. Similar results were seen from a study in South Korea where the poor knee range of motion was 18.6% and good knee range of motion was 81.4%(21). In a Kenyan study 92.2% of patients had good to excellent outcomes (8). An Indian study showed poor outcomes in 5% of cases (16). In Pakistani study where they used SIGN nail for fracture fixation the excellent and good outcome were 99.9% (13).These variation might be accounted for by difference in outcome measurement tool and sample size. In Kenyan study HSS with 124 patients (8), HSS with 20 patients in India (16) and KSS with 140 patients in Pakistani study.

In multivariate logistic regression analysis age is shown to be associated with knee range of motion. For 1yr increment in age there is 1.074 (p-value <0.007) times increased risk of a patient having knee range of motion less or equal to 90 degree. This might be due to motivational issues such as willingness to move the knee after surgery, increased probability of onset of arthritis and decreased level of independence. Similar association has been seen in a Kenyan study, where they showed negative relationship between age and knee function (8).

Another factor that is shown to be associated with knee range of motion is time from injury to intramedullary nail insertion. In our study a 1 day delay in surgery will increase the risk of having knee range of motion less or equal to 90 degree by 1.112 times (p- value <0.006). This might be due to accelerated fibrosis around quadriceps muscle, pain, lack of pre-operative rehabilitation, and delay in presentation to hospital. Prolonged immobilization was ascribed as one of risk factors for knee stiffness in South Korean study (21).

In our study, the findings didn't show statistically significant level of association between gender, associated injuries, level of fracture on the femur shaft, degree of soft tissue injury, initial fracture stabilization method and surgical approach.

6. Limitation of the study

The limitation include the limitation of a retrospective study. Another limitation is of the study is its sample size being small. Other potential risk factors like osteoarthritis, knee effusion, were not included in the study, which might be considered as a limitation of the study.

7. Conclusion and Recommendation

7.1 Conclusion

Retrograde nailing has an excellent union rate (98.6%) and 78.9% good knee range of motion which makes it an option in the management of diaphysial femur shaft fracture. Its use should be tailored in old age group and in patient with prolonged duration from injury to intra-medullary nail insertion because of significant association with poor knee range of motion.

7.2 Recommendation

To the Department of Orthopaedics and Traumatology, Saint Paul Hospital Millennium Medical College.

- The department should develop a treatment protocol for patients with femur shaft fracture so as to enable a standardized uniform management for patients.
- A timely surgical treatment of patient after they arrive at the hospital
- Along with physiotherapy and rehabilitation unit, the department work on rehabilitation protocol for post-operative patients
- The department should also look for other nail options so as not to relay only on donation from SIGN organization.

8. Reference

1. Sean EN, Rockwood and Green's Fractures in Adults. 8th edition. Philadelphia: Wolters Kluwer; 2015
2. Muminagic SN. History of Bone fracture: Treatment and Immobilization. MSM, 2011; 23(2): 111-116
3. Ahmed E. Outcome of SIGN Nail Initiative in Treatment of Long Bone Fractures in Addis Ababa, Ethiopia. East and Central African Journal of Surgery. 2011 July/August;16 (2): 88-96
4. Igbo OE, Isaac OA, Eronimeh O. Road Traffic Accidents and Bone Fractures in Ughelli, Nigeria. IOSR Journal of Dental and Medical Sciences. Apr. 2015; 14 (4): 21-25
5. Admassie D, Yirga T, Wamisho BL. Adult limb fractures in TikurAnbessa Hospital caused by road traffic injuries: Half year plain radiographic pattern. Ethiopian Journal of Health Development. 2010;24(1): 61-63
6. Abubeih H. Retrograde femoral intramedullary nail in femoral shaft fractures. AAMJ. Sep, 2012; 10(3): 247-266
7. Daglar B, Gungor E, Delialioglu O, Karakus D, Ersoz M, AdilTasbas B. Comparison of Knee Function After Antegrade and Retrograde Intramedullary Nailing for Diaphyseal Femoral Fractures: Results of Isokinetic Evaluation. JOT. Oct 2009; 23(9): 640-644
8. Njoroge AN, Mwangi HR, Lelei LK. Functional Outcomes of the Knee after Retrograde and Antegrade Intramedullary Nailing for Femoral Shaft Fractures. The ANNALS of AFRICAN SURGERY. July 2013; 10 (2): 12-16
9. Sadic S, Custovic S, Smajic N, Fazlic M, Vujadinovic A, Hrustic A, Jasarevic A. Complications and Functional Recovery in Treatment of Femoral Shaft Fractures with Unreamed Intramedullary Nailing. Med Arh. 2014 Feb; 68(1): 30-33
10. Moumni M, Voogd E, Jan ten Duis H, Wendt K. Long-term functional outcome following intramedullary nailing of femoral shaft fractures. Injury, Int. J. Care Injured. 2012; 43:1154–1158
11. Nakamura T, Yokoyama K, Saita Y, Aoki S, Tsukamoto M, Itoman T. Functional outcome of retrograde intramedullary nailing for femoral fractures. European Journal of Orthopaedic Surgery & Traumatology. 2001;11: 29-33
12. Papadokostakis G, Papakostidis C, Dimitriou R, Giannoudis PV. The role and efficacy of retrograding nailing for the treatment of diaphyseal and distal femoral fractures: a systematic review of the literature. Injury, Int. J. Care Injured. 2005; 36: 813—822
13. Shafiq M, Ahmed A, Ullah K, Akram R, Zaman AU, Javed S, Aziz A. Outcome of Retrograde Femur Nail, is it implant of choice for distal shaft of femur fracture. The Professional Medical Journal. 2018; 25(3):364-370
14. Andrzejewski K, Panasiuk M, Grzegorzewski A, Synder M. Comparison of Knee Function in Patients with a Healed Fracture of the Femoral Shaft Fixed with Retrograde and Antegrade Intramedullary Nailing. OrtopediaTraumatologiaRehabilitacja. 2013; 5(6): 395-405
15. Katsoulis E, Court-Brown C, Giannoudis PV. Incidence and aetiology of anterior knee pain after intramedullary nailing of the femur and tibia. THE JOURNAL OF BONE AND JOINT SURGERY. May 2006; 88 (5): 576-580

16. Singh R, Charak S, Chib M, Muzafar K, Haseeb M. Outcome of Retrograde Interlocking Intramedullary Nailing for Fracture Shaft of Femur and Extra-articular Distal Femur. *International Journal of Scientific Study*. July 2017; 5(4): 54-58
17. De Campos J, Vangsness CT Jr, Merritt PO. Ipsilateral knee injury with femoral fracture. Examination under anesthesia and arthroscopic evaluation. *ClinOrthopRelatRes*.1994;(300):178–182.
18. Acharya KN, Rao MR. Retrograde nailing for distal third femoral shaft fractures: a prospective study. *Journal of Orthopaedic Surgery*. 2006;14(3):253-8
19. Abhishek P, Suneet T, Sanjiv G. Role of supracondylar nailing in distal femoral fractures. *Journal of Evolution of Medical and Dental Sciences* 2014; 3 (38): 9741-9750
20. Nowotarski PJ, Turen CH, Brumback RJ, Scarboro JM. Conversion of external fixation to intramedullary nailing for fractures of the shaft of the femur in multiply injured patients. *J Bone Joint Surg Am*. 2000 Jun;82(6):781-8.
21. Dong-Wook S, Hyoung-Soo K, Ph.D., Woo-Young C. Risk Factors for Knee Stiffness in Distal Femoral Fractures. *J Korean FractSoc* 2018;31(4):123-131
22. ToluseA ,Asuquo J , IkemÁ I, Esan O, Akinyoola A. Comparison of Effect of Retrograde and Antegrade Approaches to Interlocking Nail Fixation of Femoral Diaphyseal Fractures on Ipsilateral Hip and Knee Joint Motion. *West African Journal of Medicine* 2014;33(1): 21-25
23. Sari S. Femoral shaft fractures in adults: Epidemiology, fracture patterns, nonunions, and fatigue fractures. From the Department of Orthopaedics and Traumatology, and the Department of Pediatric Surgery, University of Helsinki; and the Research Institute of Military Medicine, Central Military Hospital, Helsinki, 2005
24. Martina P. Rehabilitation after Fracture of the Diaphysis of Femur. Charles University, 2010

Questionnaire

A. General Category

- ## B. Pre-operative Information

- 22

C. Intra-Operative Information

1. Operation Date_____
2. Time from injury to intramedullary nail insertion_____days
3. Type of nail: a. Standard SIGN Nail_____ b. SIGN Fin Nail _____
4. Surgical Approach: a. Para-tendinous_____ b. Trans-tendinous_____
5. Method of Reaming: a. No Reaming_____ b. Power Reaming_____
- c. Hand Reaming_____
6. Fracture Reduction Method: a. Closed_____ b. Minimally open_____
- c. Open_____

D. Post-operative Information

1. Radiological union: a. Yes_____ b. No_____
2. Angular Mal-alignment: a. Yes_____ b. No_____
3. Physiotherapy a. Yes___b. No_____
4. Knee range of motion: a. knee flexion greater than 90⁰_____
- b. knee flexion less or equal to 90⁰_____