

SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE



ASSESEMENT OF FUNCATIONAL OUTCOME OF DISTAL FEMUR FRACTURE OPEN REDUCTION & INTERNAL FIXATION AFTER ONE YEAR POST-FIXATION IN ADULT TRAUMA PATIENTS IN AABET HOSPITAL 2021GC.

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RESEARCH THESIS TO BE SUBMITTED TO ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE; FOR PARTIAL FULFILLMENT OF THE REQUIREMENT OF SPECIALTY CERTIFICATE IN ORTHOPEDICS AND TRAUMATOLOGY.

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SPHMMC, ADDIS ABABA, ETHIOPIA

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Summary

Background: Distal femoral fractures account for approximately 6% of all femoral fractures. These fractures generally occur following high-energy injuries in younger patients and low-energy mechanisms in physiologically older patients, commonly women. The vast majority of fractures, including most distal femur fractures, are fragility fractures, occurring from a fall from standing height or less. Over half of all elderly patients who sustain a distal femur fracture have suffered a separate fragility fracture within 5 years; nearly one-third will sustain another fragility fracture within 3 years after their distal femur fracture.

Operative treatment of distal femoral fractures in young adults remains a challenge, as these are usually high-energy injuries with complex intra-articular fracture patterns and extensive metaphyseal comminution.

Although it accounts for 6% of overall femur fractures, improper treatment and improper post operation rehabilitation protocol can results in knee stiffness and osteoarthritis. Following operative fixation, functional outcome was predominantly good or excellent. Knee stiffness was the leading complication.

Objective: The study aims at assessing Functional outcome and associated factors of open reduction and internal fixation of distal femoral fracture at AaBET Hospital, in patients for whom fixation was done from Year 1/1/2017-30/12/2020G.C after one year post surgery.

Methodology: A cross-sectional study conducted to assess functional outcome and associated factors after open reduction and internal fixation of distal femoral fracture.

Data was collected from medical chart of the patients, major OR Logbook and remote-eye local network x-ray software of patients on follow-up in orthopedic surgical clinic. Data collection time was over 2 months (November and March, 2022), among patients who are on follow up at AaBET Hospital orthopedic surgical clinic. Descriptive data analysis method used. Data was collected using check list and entered in EpiData version 3.01 and analyzed using SPSS version 25. Texts, tables and figures were used to present the results. A p-value of <0.05 from this analysis was considered significant.

Results: Most patients were younger age group and RTA became leading cause for Distal femur fracture.

Functional outcome after ORIF of distal femur fracture is good to fair. Retrograde nailing was main implant option and comparable outcome with other type of fixation.

Conclusion & recommendation: Aabet Hospital and orthopedic department should formulate standard post- operative rehabilitation protocol for distal femur fracture patients for whom ORIF done. And operating physician should discourses with patients.

Preventive policy formulation and enforcement in road safety

Key words: Distal femur fracture, Open reduction and internal fixation, Knee society score

Abbreviations and Acronyms

GC-Gregorian Calendar

SPHMMC-Saint paul's millennium medical college

EDHS-Ethiopian demographic health survey

ORIF-Open Reduction Internal Fixation

MIPPO-Minimal invasive percutaneous plate osteosynthesis

IMN-Intra- medullary Nailing

LP-Locking Plate

LISS-Less invasive stabilization system

AO- Arbeitsgemeinschaft fur Oseosysthesesfragen

ROM-Range of Motion

RIMN-Reamed intramedullary nail

LLC-Long leg cast

CBP-Condylar butters plate

IAF-Intra articular fracture

KNH-Kenyatta national hospital

VAS-Visual analog scale

ASIF- Association for the study of internal fixation

OR-Operation Room

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1. Introduction

1.1 Background

Based on the common principles of the AO classification, type A fractures include extra-articular fractures and type B fractures are partial articular fractures, meaning parts of the articular surface remains in contact with the diaphysis of the femur. Type C fractures include complete articular fractures with both condyles being detached from the diaphysis(1).

Distal femur fractures occur at approximately one-tenth the rate of proximal femur fractures and make up 6% of all femur fractures. The most common high-energy mechanism of injury is a traffic accident (53%) and the most common low-energy mechanism is a fall at home (33%)(2).

Successful management requires a deep knowledge of the regional anatomy, a comprehensive clinical and radiographic evaluation, an understanding of the 'personality' of the fracture, and selection of the appropriate device. As with all fractures, understanding the deforming forces involved is critical for successful operative management. Shortening of the fracture with varus and extension of the distal articular segment is the typical deformity. The varus and extension deformities are due to the unopposed pull of the hip adductors and gastrocnemius muscles respectively. Problems associated with surgery include infection, mal-union, non-union, varus collapse, loss of fixation, diminished knee motion, difficult fixation in osteoporotic bone and short distal fragment. In a systematic review of acute distal femur fracture treatment, found overall, the average non-union rate of 6.0%, fixation failure rate of 3.3%, deep infection rate of 2.7% and average secondary surgical procedure rate of 16.8%(3).

1.2 Statement of the problem

These fractures generally occur following high-energy injuries in younger patients and low-energy mechanisms in physiologically older patients, commonly women. Nevertheless, high-energy geriatric trauma does exist. Distal femur fractures were encountered in 5% of geriatric patients who presented to a tertiary level I trauma center following high-energy trauma over a 5-year period. Most distal femur fractures are fragility fractures, occurring from a fall from standing height or less(3).

Due to rapid industrialization and growth of the automobile industry, there is increase in the road traffic accidents. Most of the high velocity injuries are associated with fractures occurring at the distal end of the femur. In view of these potential complications and complexity of the injuries at the distal end of femur, many surgeons agree that large numbers of distal femur fractures are to be managed surgically for better functional outcome and lesser complications. Treatment of fractures of the distal femur is predominantly surgical with nonsurgical management reserved for truly non-displaced fractures and patients whose medical problems preclude safe surgical intervention, as nonsurgical management is associated with worse clinical outcomes. This has shown to lead to low rates of nonunion, malunion, and subsequent bone grafting. Anatomic distal femur plates are still preferred by some, especially for comminuted IAF of the distal femur (AO/OTA 33C3), although rate of nonunion remains a worry, especially with open and high-energy fracture, with rates of 18% to 35%. However, recent study by Wenger and Andersson. Kadimi Hospital, India in 2017, 62 of 191 fractures treated at a non-tertiary referral center found that 8 (4%) patients developed nonunion(4).

Following operative fixation, functional outcome was predominantly good or excellent. Knee stiffness was the leading complication. Young socio-economically active individuals formed the majority of those with these injuries, with a male: female ratio of 1.6:1 Road Traffic Accidents (RTA) was the leading cause (5).

However to the best knowledge of the investigator, studies conducted regarding functional outcome and associated factors after fixation of distal femoral fracture patients in Ethiopia are limited. This study will generate evidence on magnitude of problem of distal femoral fracture, associated factors and functional outcome after open reduction and internal fixation of distal femur. To the scope of the researcher, no similar study is done at the study area among people diagnosed and fixed for distal femur fracture. Therefore, this study is aimed at assessing the functional outcome and associated factors with ORIF of distal femoral fracture among patients treated for distal femur fracture and on follow-up at AaBET Hospital in orthopedics surgical clinic

1.3 Significance of the study

The findings from this study will help the followings:

AaBET Hospital : The hospitals could use the study result as a base line for future studies,for academic purpose and it will help patient management by formulating their own Hospital based post-operative rehabilitation protocol for better functional out come after fracture fixation.

Federal Minister of Health: The study result could help find an important direction to organize and strengthen health services in collaboration with respective health facilities.

Locally Based Governmental, and Non-Governmental Organizations and Researchers: The study results could also be used as baseline information for locally based organizations and researchers working similar issue.

2. Literature review

Distal femoral fractures cause significant morbidity and mortality, especially in the elderly. In Kenya a retrospective cross sectional study carried out by Oduor at KNH, in 2013, Forty six patients were recruited by consecutive sampling after they underwent open reduction and internal fixation, patients were followed up for a period of three months the incidence was found to be higher in the younger, socio- economically active age group. The leading cause in this fracture was motor vehicle accidents. Surgical treatment of these difficult fractures has evolved over time. The goals of surgical treatment are anatomical reconstitution of the articular surface; reduction of the metaphyseal component of the fracture to the diaphysis and restoration of normal axial alignment, length and rotation; stable internal fixation and early motion and functional rehabilitation of the limb. Problems associated with surgery include infection, mal-union, non-union, varus collapse, loss of fixation, diminished knee motion, difficult fixation in osteoporotic bone and short distal fragment(5).

M. Ehlinger*, G. Ducrot, P. Adam, F. Bonnomet in Haute-pierre Teaching Hospital Center, Strasbourg Academy Hospital, France 2013 rates of infection and nonunion were higher in the open internal fixation group. After a mean follow-up of 6 years nearly 50% of intra-articular fractures showed progression to arthritis on radiological imaging, reported a prospective series in 28 patients treated with retrograde nailing with union in 93%, mal-union in 14% and excellent or good functional results in 75% of cases. There was no difference between results for retro- and anti-grade nailing. The only reported difference was in hip range of motion which was more limited with anti-grade intramedullary nailing, and knee range of motion which was more limited with retrograde nailing, did not observe any difference in functional recovery in a randomized comparison of the treatment of extra-articular fractures by retrograde intramedullary nailing and blade plate. The only element observed was more frequent pain in the knee in the retrograde nailing group, so that fixation material had to be removed in 25% of the cases. The results in the literature do not provide any consensus on the technique; only closed techniques seem to make a difference. It is important to remember that the best results are obtained with techniques in which the surgeon has the most experience (6).

2.2 Distal femoral fracture options of management

Current treatment options broadly include conservative management (cast/splint, traction), external fixation, locked and unlocked plating, lateral fixed- angle device (blade or sliding barrel options), intra- medullary nailing, and arthroplasty. Despite the myriad of techniques available, the primary goal of surgical treatment remains: restoration of the articular unit to the shaft and anatomic alignment while maintaining stability to enable early range of motion (ROM) and rehabilitation(6).

Surgical treatment with open reduction and internal fixation has been recommended since the 1960s and has been shown to be superior to non- operative treatment. Wenzel and colleagues reported on 112 patients treated according to AO principles, 73.5% had good or excellent results. For open reduction, these results were far superior to the 52% satisfactory results reported by Neer and associates. Several other studies that followed reported similar results, and recommended open reduction over non- operative treatment(5).

2.3 Functional outcome after open reduction and internal fixation

Chirurgie University Clinic, Austria, Siliski J.M carried out a study on fifty two patients with distal femoral fractures twenty to one hundred and twenty months after injury. All fractures were treated with internal fixation using ASIF inter fragmentary plates and screws and the results were: average time for return to full weight bearing was 13.6 weeks, average final arc for knee motion was 107°. Two amputations and one arthrodesis were done to treat infection: age did not influence the final results although elderly patients had a longer period of hospitalization. In the average age of the 14 men and 10 women was 46 years (16 - 96); in 4 cases the fracture was open; secondary bone grafting was necessary in 2 patients while one had delayed bone union and required interlocking nailing; there were no re-fractures and no implant failures; in 2 patients varus deformity under 10° were present after completion of bone healing; full weight bearing commenced at 14.2 weeks and bone healing time was 18.7 week s(7).

Chang Gung Memorial Hospital, Chang Gung University in 2016, 87 patients with supra-intercondylar or supracondylar femur fracture from 2004 to 2008, including 30 supra-intercondylar and 24 supracondylar fractures treated with CBPs Evaluated and Union rate of

supraintercondylar fractures was 90 % (27/30) and supracondylar fractures was 91.7 % (22/24) ($P = 0.68$). In supra-intercondylar group, 16.7 % revealed postoperative varus deformity, whereas none in supracondylar group ($P = 0.045$). Knee Society knee score was 73.6 in supraintercondylar group and 85.5 in supracondylar group ($P = 0.009$); and function score was 62.5 in supra-intercondylar group and 83.1 in supracondylar group ($P = 0.023$). A satisfactory result based on modified Mize criteria was achieved in 50 % of supra-intercondylar fractures and in 79.1 % of supracondylar fractures ($P=0.09$)(8).

Marmara University, Pendik Training and Research Hospital stambul, Turkey was made of 13 consecutive patients who were treated surgically for an isolated coronal plane fracture of the distal femur posterior condyle. The patients were evaluated with physical examination, PA and lateral radiographs and CT at the final follow-up examination. Functional outcome was evaluated with the OXFORD knee scoring system and Knee Society Score (KSS). Pain at rest and in activity was assessed using a Visual Analog Scale (VAS). The patients comprised 11 males and 2 females with an average age at surgery of 27.5 years. The mean follow-up period was 93 months (range, 62–134 months). Mean time to fracture healing was 10 weeks (range, 8–12 weeks). The mean ROM was determined as 110 Degree mean KSS 78,4 and mean Oxford knee score 38,2. The mean KSS was 66,5 for medial Hoffa fracture patients and it was 83,8 for lateral Hoffa fracture patients. Varus instability was determined in 1 patient and valgus instability in 1 patient (9).

St. Luke's University Health Network, Bethlehem, USA in 2016 ,of 104 consecutive patients who have a distal femoral fracture and were treated with a submuscular locking plate. The case group comprised of patients with 12-month postoperative range of motion (ROM) $\leq 90^\circ$ or a history of manipulation under anesthesia. The case group was compared with the control group of patients with a 12-month postoperative ROM $>90^\circ$. The possible risk factors were evaluated by univariate and logistic regression analysis. The postoperative ROM and Knee Society clinical rating system was evaluated for the clinical assessment and the distal femoral angle on a whole-extremity scanogram was measured for radiologic assessments. On the other hand, multivariate logistic regression showed that an extensor mechanism injury was the only significant predictor ($p=0.001$; odds ratio, 42.0; 95% confidence interval, 5.0-350.7). The ROM and Knee Society score were significantly lower in the case group; however, the coronal alignment was similar in

the case and control group. Various factors that delay postoperative knee motion place patients at increased risk of knee stiffness. Understanding these risk factors may help surgeons prevent postoperative knee stiffness after distal femoral fractures. In particular, extensor mechanism injury, such as patella fracture or open quadriceps injury was found to be an independent predictable factor associated with knee stiffness (6).

A prospective study conducted from January 2012 to March 2014 at Government Medical College and Hospital (GMCH), Chandigarh with a 2 year follow-up in India, Out of the 25 cases in their study, the mean age of cases in our study was 36.64 years. The youngest patient was of 21 years and oldest patient of 70 years. Most of the cases (80%) were affected by road traffic accident in our study while rest (20%) suffered the fracture from a fall. One case was found to have late complication in the form of mal-union of the distal femur fracture. Radiological union was achieved in all the cases. Most of the cases (44%) attained radiological union in 19-22 weeks. The mean time for radiological union was 19 weeks(10) .

Yopougon University Teaching Hospital, Ivory Coast ,2013,to present their experience using condylar buttress plate in the treatment of distal femoral fractures in west African Hospital. Patient demographics, type of fracture, treatment, complications, results achieved, and follow-up assessment were reviewed. The fractures were classified with the AO system. The mean delay from injury to operation was 15 (range 1–27) days. Iliac bone graft was performed in four patients. Postoperatively, a posterior splint or a plaster cast was applied for 3 weeks. No patient had an intra-articular step-off of more than 2 mm. Sepsis of the operative wound occurred in two patients. Fractures healed in 22 (91.7%) patients with a mean duration of 4 (range 3–8) months. Twenty-four patients were followed up on an average of 15 (range 7–28) months. Varus deformity ($>10^\circ$) was observed in five (20.8%) patients. Knee flexion was less than 90° in 11 (45.3%) cases. Non-union occurred in two (8.3%) patients. Functional results were good to excellent in 11 (45.8%) patients and considered as fair or failure in 13 (54.2%)(11).

Kenyatta national Hospital in 2013, found out Problems associated with surgery include infection, mal-union, non-union, varus collapse, loss of fixation, diminished knee motion, difficult fixation in osteoporotic bone and short distal fragment In a systematic review of acute distal femur fracture treatment,found overall, the average non-union rate of 6.0%, fixation failure rate of 3.3%, deep infection rate of 2.7% and average secondary surgical procedure rate of

16.8%. These problems have been addressed sequentially with evolution of treatment devices. New, minimally invasive techniques including Retrograde Intramedullary Nailing (RIMN), Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO), Less Invasive Stabilization System (LISS), Trans-Articular Approach And Retrograde Plate Osteosynthesis (TARPO) avoids metaphyseal and diaphyseal stripping. Studies elsewhere indicate that these techniques have lowered the rates of non-union, deep infection and implant failure. However, the diminished knee motion component still persists and contributes to adverse functional outcome. Operations done included: In 58.3%, plate and screw fixation, of which 50% were Condylar Blade Plate (CBP), 8.3% Buttress Condylar Plate (BCP); and 41.7% retrograde intramedullary nailing. One patient suffered periprosthetic fracture and had poor function at 3 months while the other was an elderly woman who remained on wheelchair. Four (9%) patients had knee stiffness (below 59° flexion), while 6 (13%) patients had flexion of 60°–89° giving a total of 22% with knee stiffness (5).

Between 2013 and 2017 at a tertiary centre in S.M.S. Medical College, India, Patients with open distal femoral fractures. A total of 46 study participants were recruited and all were included in the analysis. The majority of the participants were in the 25–45 years age group with the mean of 42.9 years (range: 22–96). Road traffic accidents were the leading cause at 31 (67.3%) patients followed by falls from a height at 10 (21.7%). Mild trauma from falls at home contributed 5 (10.9%). Forty-one (89%) patients had good to excellent early functional outcome, 3 (6.5%) had fair, and 2 (4.3%) had a poor early functional outcome (12).

A prospective institutional-based cross-sectional study was conducted from July to October 30/2020, at University of Gondar, comprehensive specialized hospital. The data of 226 participants were collected through face-to-face interviews, patient record review and by physical examination with simple random sampling techniques. Binary logistic regression was used to identify predictors of functional limitation among lower limb fracture with SPSS 25. The strength of the association was present by adjusted odds ratios (OR). One hundred and eighty-two ($n = 182$ (80.5%): 95% CI (74.8 to 85.8) patients with following lower limb fracture have functional limitation. Level of education (AOR = 5.50; 95% CI: 1.707–17.742), presence of hospitalized complication AOR = 3.26; 95% CI (1.147–9.294), severity of pain AOR = 3.19; 95% CI (1.399–7.259), duration of onset AOR = 9.512; 95% CI (3.585–25.237), knee flexion limitation AOR = 7.13; 95% CI (1.926–26.368) were the independent risk factors for functional limitation. The magnitude of functional limitation in following lower limb fracture individual was considerably high in

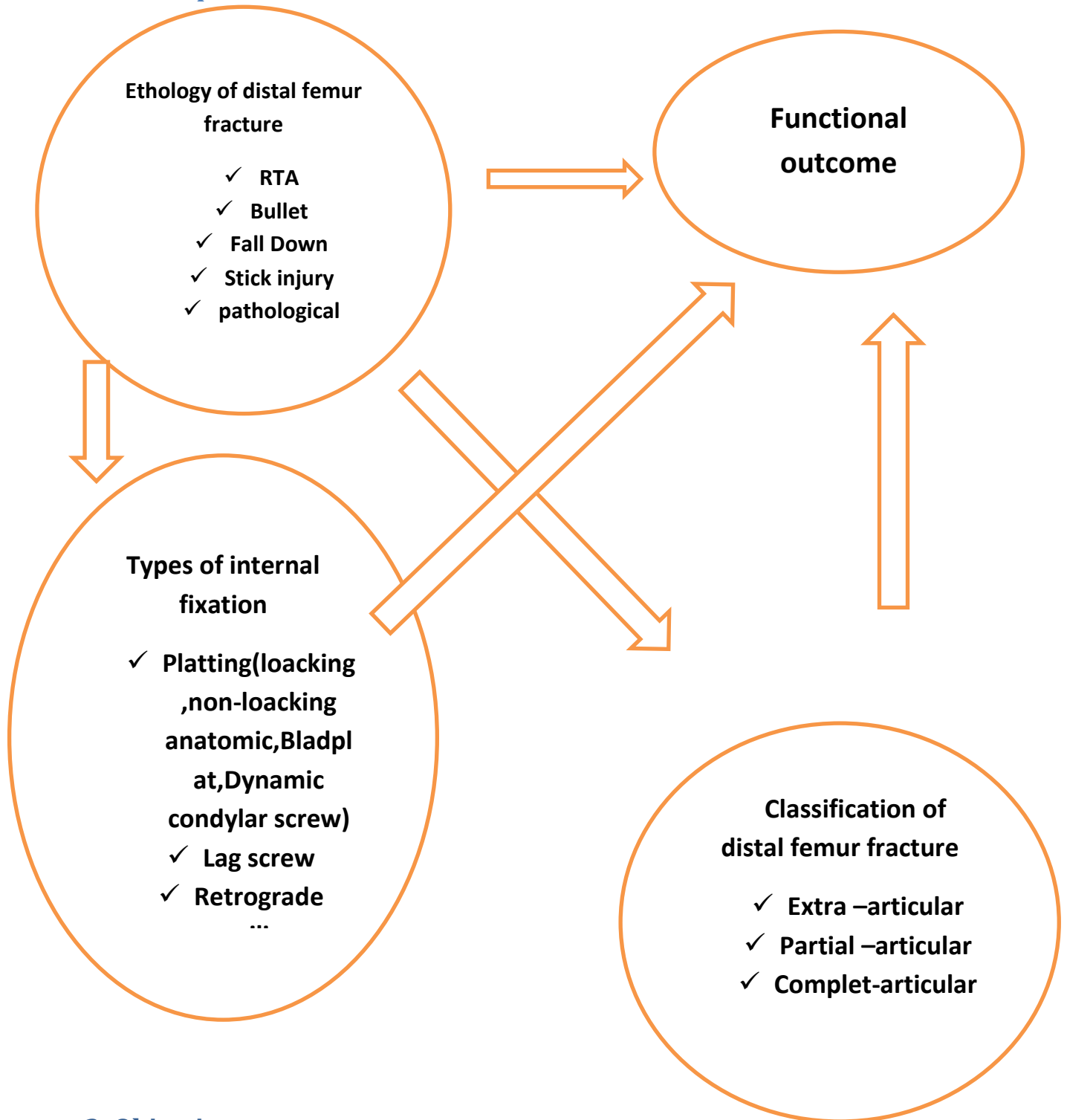
study setup. Level of education, presence of hospitalized complication, severity of pain, duration of onset, knee flexion limitation were the independent risk factors for functional limitation(13).

2.4 Functional outcome measuring tools

A physical examination was performed in retrospective study done in Kenyatta Hospital in 2013, to assess functional outcome of distal femoral fracture, the investigator determined femoro-tibial alignment, knee range of motion, neurovascular status and knee ligament stability 12 weeks after surgery. Bilateral AP radiographs of the knees and a single lateral radiograph of the involved knee were evaluated for residual alignment, time to union and mal-union at 8 and 12 weeks after surgery. Knee range of motion was determined by visual inspection during knee assessment and confirmed with goniometric passive range of motion measurement. One metallic goniometer with a 12.7cm movable arm and a scale marked in 1-degree increments was used to take measurements(5).

The New Knee Society Score - KSS, Developed in 1989, the score was originally an objective tool. With shifting trends, in 2011 it was updated and expanded to a mixed outcome measure that's both objective (physician input) and subjective (patient input). According to its creators, the new score prioritizes the patient perspective to better track patient expectations, satisfaction, and activity levels (14).

2.5 Conceptual frame work



3. Objective

3.1 General objective

To assess functional outcome and associated factors among patients with distal femur fracture treated by open reduction and internal fixation at AaBET Hospital, Addis Ababa, Ethiopia, 1/1/2017-30/12/2020G.C.

3.2 Specific objective

1. To determine functional outcome of patients treated with open reduction and internal fixation for distal femoral fracture at AaBET Hospital orthopedic clinic , Addis Ababa,Ethiopia, 1/1/2017-30/12/2020G.C..
2. To assess mechanism of injury and types of fixation done for distal femoral fracture at AaBET Hospital orthopedic clinic , Addis Ababa,Ethiopia, 1/1/2017-30/12/2020G.C.
3. To assess associated factors among patients with distal femur fracture treated by open reduction and internal fixation at AaBET Hospital, Addis Ababa, Ethiopia, 1/1/2017-30/12/2020G.C.

4. Method

4.1 Study area

An institution-based cross-sectional study was conducted in March 2022 in St Paul's Hospital Millennium Medical College (SPHMMC)/AaBET Hospitals, which are located in Addis Ababa, Ethiopia. SPHMMC was established, first as a Hospital for the destitute in 1968 by the late Emperor Haile-Selassie. It had been serving the needy for more than 5 decades now. In 2007, with the aim of providing better healthcare services to its patients and producing skilled healthcare professionals, it opened a Medical School with a unique integrated curriculum and admission criteria. SPHMMC, as it is known today, was later established through a decree of the Council of Ministers Regulation No. 200/2011 in 2010 GC. Although the establishment as a college entailed a marked reorganization of the structure, the values and the principles of the provision of care in St. Paul's are still preserved. The college provides medical and surgical specialty services to patients who are referred from all over the country, teaching medicine and nursing students and doing basic and applied researches. AaBET Hospital, an affiliated with SPHMMC; is a newly established (2015) 250-bed and 12 intensive care unit (ICU) bed, teaching and public referral hospital. It is one of the biggest emergency and trauma hospitals in the country, provides specialty services in emergency medicine and critical care, trauma and acute care surgery, orthopedics and traumatology, neurosurgery, plastic and reconstructive surgery with especial attention on burn patients and physiotherapy & rehabilitation center. It has 4 operation room tables which give both emergency and elective services with 02 image intensifiers. It has also 09 recovery beds (5 for emergency and 4 for elective patients).

4.2 Study period

The study was conducted from November 2021 to March 2022G.C.

4.2Study design

A cross-sectional study design was conducted.

4.3 Population

4.3.1 Source population

All patients who have been admitted, open reduction internal fixation done and having follow up at orthopedic surgical clinic at AaBET Hospital in the past 4 years.

4.3.2 Study population

All patients who have been admitted, open reduction internal fixation done and having follow up at orthopedic surgical clinic at AaBET Hospital in the past 4 years and who fulfills the inclusion criteria.

4.4.1 Inclusion criteria

- All patients of age of 18 years or above both male and female and closed or open distal femur fracture according to AO classification are included.
- Those patients who have follow up for at least 6 months.

4.4.2 Exclusion criteria

- Patients with comorbidity, pathological fracture, peri-prosthetic fracture, patients with vascular injury, contralateral or ipsilateral knee injury and poly trauma are excluded
- Those with incomplete investigation results
- Patients who discontinued follow-up before 6 months
- Any prior femur or knee surgery for different pathology

4.5.1 Sample size determination

All patients who fulfill inclusion criteria was be selected.

4.6.2 Sampling method

No sampling technique be used, since small number of study population from Aabet Hospital HMIS data recovered.

4.7 Data collection method and tools

4.7.1. Data collection instruments and measurements

The questionnaire was adopted from different literatures. The questionnaire consists of information on the socio demographic and mechanism of injury status adapted from EDHS.

The New Knee society score: The new Knee Society Knee Scoring System has been developed and validated, in part, to better characterize the expectations, satisfaction, and physical activities of the younger and more diverse population of current patients undergoing TKA. The new score provides sufficient flexibility and depth to capture the diverse lifestyles and activities of our current patients. The score was validated in a thoughtful and methodical fashion confirming internal reliability and analyzed for differential item functioning. The new Knee Society Scoring System is broadly applicable across sex, age, activity level, and implant type.

In conclusion, the new Knee Society Scoring System is a validated and responsive method for assessing objective and subjective outcomes after total and partial knee arthroplasty, or surgery around knee without the ambiguities of the prior scoring system. Score 80-100. Excellent ; Score 70-79. Good ; Score 60-69. Fair ; Score below 60 Poor . Knee Society Knee Scoring System has been developed and validated, in part, to better characterize the expectations, satisfaction, and physical activities of the younger and more diverse population(14).

4.7.2. Data collection procedure

The data was collected using document review by nurses and physicians working in the orthopedic surgical clinic, Remote eye (local net-work for x-ray review), official Telegram page of morning report discussion and Major OR Log Book.

Data on socio demographic and clinical Characteristics of the study participant was collected by review of medical records.

4.7.3. Data collectors

Document review and clinical assessment done by data collectors and principal investigator. The principal investigator will also have supervisory role.

4.8 Study Variables

4.8.1 Dependent Variable

Functional outcome

4.8.2Independent Variables

Socio demographic factors: Age, Sex

Mechanism of injury, Types of fixation, Open/closed distal femur fracture.

4.9 Operational definitions

KSS: Clinical Rating System has been the most popular method of tracking and reporting outcomes after total and partial knee arthroplasty and surgery around knee worldwide.(14)

Distal Femoral Fracture: Involve the distal one third of the femur, consisting of the region between the diaphyseal-metaphyseal junction and the articular surface of the femoral condyles. This is considered to be the terminal 10–15 cm of the distal femur(16).

Mal-union: Fracture has healed in a clinically unacceptable position(17).

Non-union: The incomplete fracture healing within 9 months following injury, along with absence of progressive signs of healing on serial radiographs over the course of three consecutive months(18).

Knee stiffness: Limitation in range of motion is a potential complication after any intra-articular or extra-articular injury. It can be caused by a flexion contracture, an extension contracture or a combined contracture (affecting both flexion and extension) relative to the contralateral side (if healthy)(19).

4.10 Data management and analysis

Data was checked manually for completeness and then entered into Epidata version 3.1 and will be analyzed using SPSS version 25. During the analysis P- value < 0.05 with 95% confidence interval (CI) for OR (odds ratio) was used in judging the significance of the associations. Data is presented using tables and graphs, charts.. Univariate and bivariate analysis between dependent and independent variables will be performed using binary logistic regression. Multivariate analysis will be done to control for possible confounding variable. Data will be presented using tables and graphs, charts.

4.11 Data quality control

To ensure the quality of data, preceding data collection, training of the data collectors carried out for one day by the principal investigator on the objective, relevance of the study and confidentiality of information.

Pretest was done two weeks before actual data collection to check its variability and the questionnaire will be assessed for its clarity, length and completeness and the necessary correction was done accordingly.

4.12 Ethical consideration

A support letter was obtained from SPHMMC institutional review board who have a role of over the site where the conduct of this study.

In addition, informed written consent was obtained from the study participant to confirm their Willingness for participation after explaining the objective of the study. Respondents informed that their name will not be mentioned and information provided by them kept confidential. They will given the chance to ask anything about the study and free to refuse or stop the questionnaire any moment they want. The procedure was confidential.

4.13 Dissemination of results

The results of the study will be presented to the college community using presentation and web posts and the findings will be also published in locally accessible or international journals.

The research paper will also be presented on conferences; the finding of the result will be submitted to the study areas.

5. Result

A total of 69 patients, two patients - unclear documentation or wrong of the MRN on the OR registration book, four patients - chart had No phone number, Two patients - are not willing to be involved in study and three patients-phone not functional.

Calculated Response rate was 84% and the following descriptive data is collected and analyzed.

A total of 58 patients were found to meet the inclusion criteria and their data was analyzed. From the total of 58 patients enrolled in the study 41 were males (70.7%) and 17 were females

(29.3%). Age ranges from 21- 56with a mean of 36.93 and both mode 48 and median had value 34.

		AGE			Cumulative Percent
		Frequency	Percent	Valid Percent	
Valid	21	6	10.3	10.3	10.3
	26	8	13.8	13.8	24.1
	30	4	6.9	6.9	31.0
	31	6	10.3	10.3	41.4
	32	2	3.4	3.4	44.8
	34	4	6.9	6.9	51.7
	35	2	3.4	3.4	55.2
	38	3	5.2	5.2	60.3
	40	2	3.4	3.4	63.8
	43	2	3.4	3.4	67.2
	45	2	3.4	3.4	70.7
	48	9	15.5	15.5	86.2
	52	3	5.2	5.2	91.4
	54	3	5.2	5.2	96.6
	56	2	3.4	3.4	100.0
	Total	58	100.0	100.0	

Table 1 :Age frequency distribution

The most common mechanism of injury was road traffic accident accounts for 46(79.3 %)of mechanism of the injury rest 5(8.6%) Bullet injury and 7(12.1%) FDA.

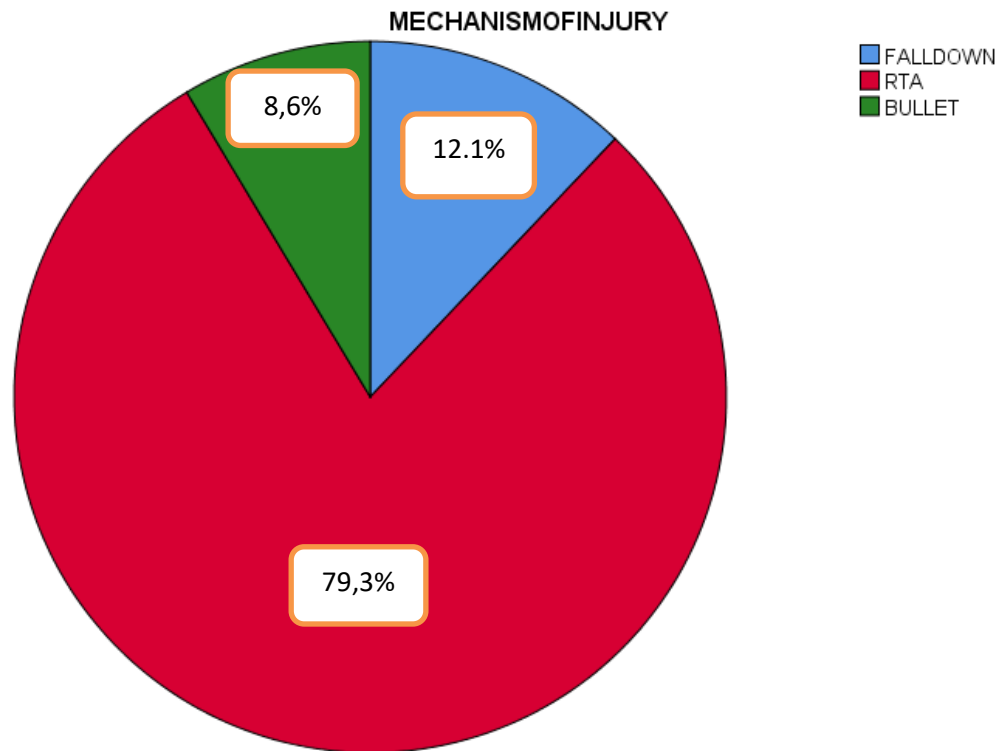


Figure1: shows mechanism of injury

From total of 58 patients diagnosed with distal femur fracture 31 patients(53.4%) nailing, 18 patients(31%) plating, 6 patients(10.3%) lag screw and 2 patients(3.4%) was done.

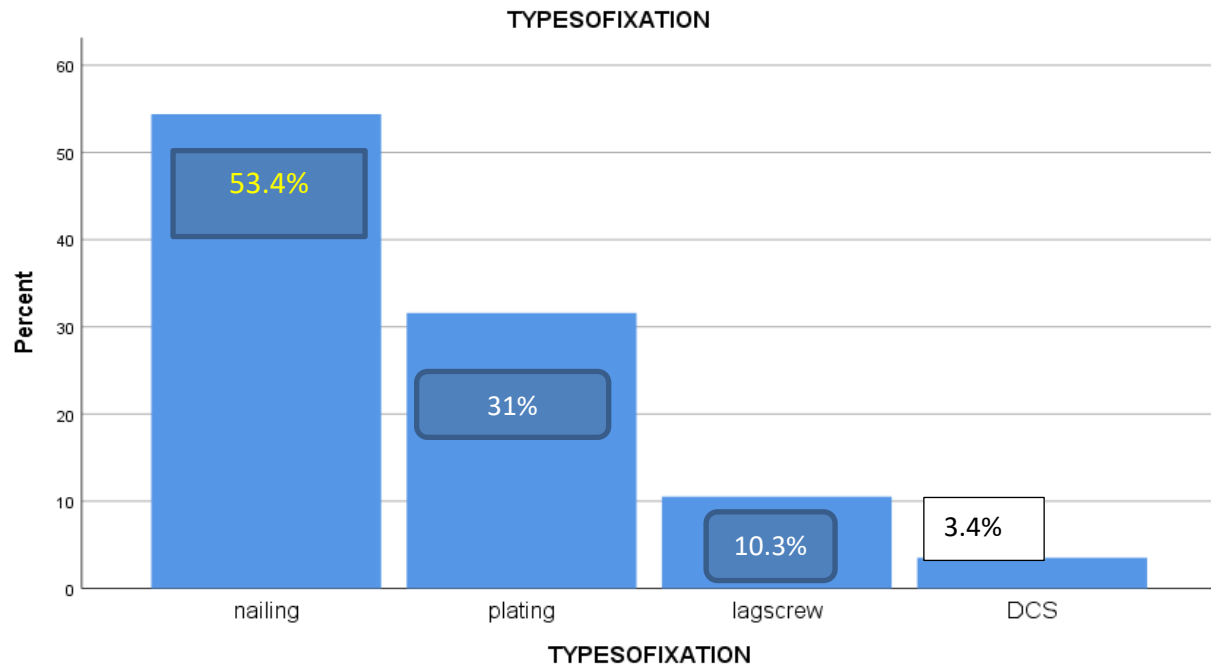


Figure2: shows Types of Fixation

Based on AO Classification from 58 patients involved in my study most are complete articular fracture types 43.1%. and most patients present to Hospital less than 24hr (43.1%) after they sustain injury.

FRACTUREPATTERN

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Extraarticular	17	29.3	29.3	29.3
	Partialarticular	16	27.6	27.6	56.9
	Complearticular	25	43.1	43.1	100.0
	Total	58	100.0	100.0	

Table 2:shows Fracture pattern

TIME OF PRESENTATION

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	LESSTHAN24HR	25	43.1	43.1	43.1
	24-72HR	24	41.4	41.4	84.5
	>72HR	9	15.5	15.5	100.0
	Total	58	100.0	100.0	

Table3: shows Time of Presentation

Functional outcome for patients involved in my study 25patients(43,1%) have good knee society score(KSS),16(27.6%) fair knee society score,11(19%) excellent knee society score and 6(10.3%) had poor knee society score.

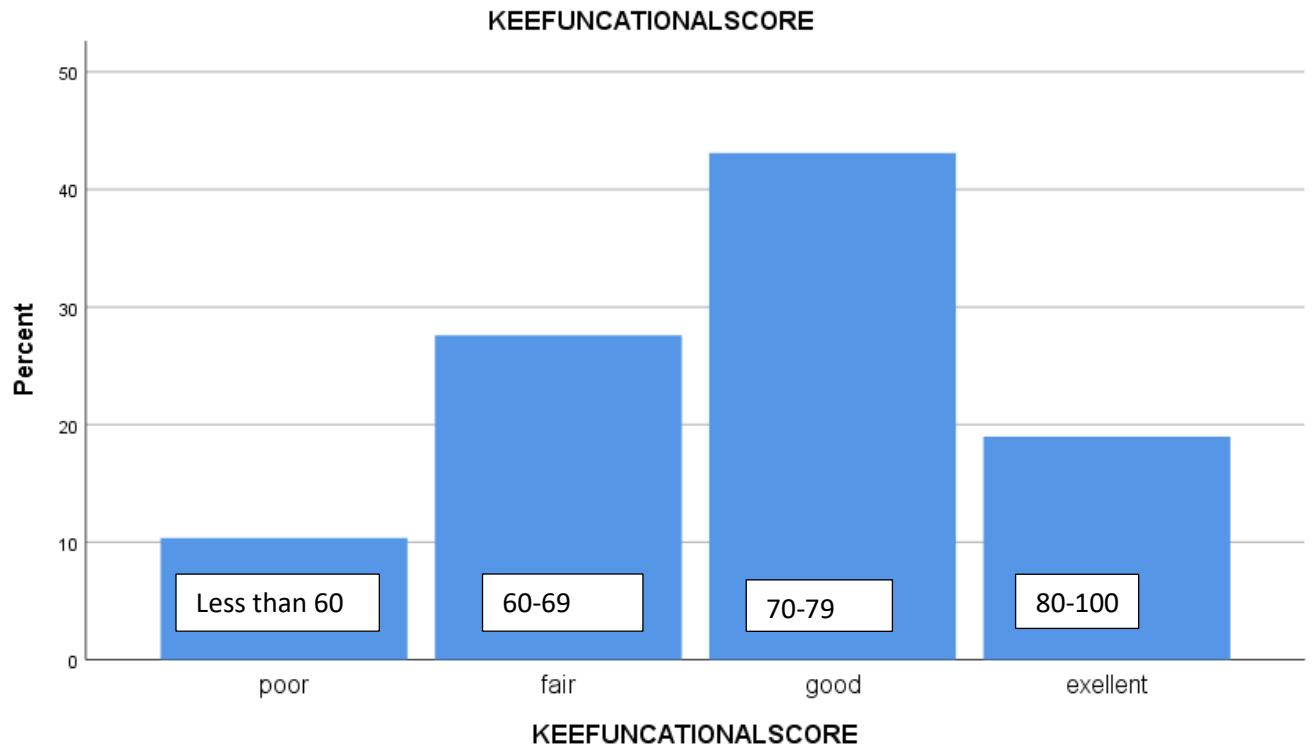


Figure 3: shows knee society score

Among patients diagnosed with complete articular fracture twenty five of them 10(then) fair functional score,6(six) good functional score ,6(six) poor functional and 3 (three) poor functional outcome.

Most of operated patients 52(89.7%) achieve fracture union during followup period and 45(77.6%) patients return to pre-injury activity.

FRACTUREPATTERN * KEEFUNCATIONALSORE Cross tabulation

Count

		KEEFUNCATIONALSORE				
		poor	Fair	Good	exellent	Total
FRACTUREPATTERNE	Extraarticular	0	2	11	4	17
	Partialarticular	0	4	8	4	16
	Complearticular	6	10	6	3	25
Total		6	16	25	11	58

Table: 4 shows fracture pattern.

The Spearman chi-squire test was used to assess the association between KSS as functional outcome score and different variables.(at 95% CI,Statically significant at P of <0.05).

There is statically significant association between fracture pattern and knee society score (p=0.013) among patients.

Knee society score with fracture pattern P-Value is 0.013,so I reject null Hypothesis , the value labeled is depend on each other.chi-square test of independence was used to check for relationship between fracture pattern and knee society score was found to be Low negative statically significant(r=-0.433 and P Value is P<0.001) Hence HI supported. This shows that fracture pattern goes from extra-articular to intra-articular leads to decreased functional score.

Those variables with p-value of <0.013 in the bivariable analysis were taken to multivariable logistic regression analysis to see whether they have true association or not.

The probability of Patients with complete -intra articular fracture having poor knee functional score was 6.6 times.($p < 0.011$)

6. Discussion

In this study 60.2% patients were in younger age group. The leading cause of injury leading to distal femur fracture was RTA 79.3%. which is the same with study done in Kenya at KNH, in 2013, Forty six patients were recruited by consecutive sampling after they underwent open reduction and internal fixation, patients were followed up for a period of three months the incidence was found to be higher in the younger, socio- economically active age group. The leading cause in this fracture was motor vehicle accidents(5).

Most of patients involved in this study achieved fracture union post-operatively 52(89.7%). Union rate is almost comparable with Review of the literature By M. Ehlinger*, G. Ducrot, P. Adam, F. Bonnomet in Hautepierre Teaching Hospital Center, Strasbourg Academy Hospital, France 2013 After a mean follow-up of 6 years a prospective series in 28 patients treated with retrograde nailing with union in 93%, mal-union in 14% and excellent or good functional results in 75% of cases(6).

Out of the 58 cases in this study, the mean age of cases in our study was 36 years and SD 10.74 years. The youngest patient was of 21 years and oldest patient of 56 years. this is almost comparable with A prospective study conducted from January 2012 to March 2014 at Government Medical College and Hospital (GMCH), Chandigarh with a 2 year follow-up in India, Out of the 25 cases in their study, the mean age of cases in our study was 36.64 years. The youngest patient was of 21 years and oldest patient of 70 year. One case was found to have late complication in the form of mal-union of the distal femur fracture. Radiological union was achieved in all the cases. Most of the cases (44%) attained radiological union in 19-22 weeks. The mean time for radiological union was 19 weeks(10).

In this study in regard types of fixation 31(53.4%) nailing, 18(31%) plating, 6(10.3%) Lag screw, and 2(3.4%) of patients done. In comparison with Retrospective cross-sectional study done in Kenyatta National Hospital in 2013,). Operations done included: In 58.3%, plate and screw fixation, of which 50% were Condylar Blade Plate (CBP), 8.3% Buttress Condylar Plate (BCP); and 41.7% retrograde intramedullary nailing, higher choice of nailing for fixation in this study (10).

For total of 58 patients involved in this study Functional outcome for patients assessed and the following result came out, 25 patients (43.1%) have good knee society score (KSS), 16 (27.6%) fair knee society score, 11 (19%) excellent knee society score and 6 (10.3%) had poor knee society

score. In comparison with Retrospective cohort study done in china Chang Gung Memorial Hospital, Chang Gung University in 2016, 87 patients with supra-intercondylar or supracondylar femur fracture from 2004 to 2008, including 30 supra-intercondylar and 24 supracondylar fractures treated with CBPs Evaluated and Union rate of supraintercondylar fractures was 90 % (27/30) and supracondylar fractures was 91.7 % (22/24) ($P = 0.68$). Knee Society knee score was 73.6 (good) in supraintercondylar group and 85.5(excellent) in supracondylar group ($P = 0.009$); and function score was 62.5 in supra-intercondylar group. even though sample size were smaller in their study functional outcome was comparable(6).

In this study among 58 patients ORIF done for distal femur fracture 17(27.3%) developed knee stuffiness post operatively , Retrospective crosssectional study done in Kenyatta national Hospital in 2013, found out Problems associated with surgery knee stiffness wasong 22%of patients(5).

7. Limitation of study

small sample size due to limited number of patients operated and single study area.

It excludes those charts with incomplete information, which could affect the overall prevalence of the outcome.

Pre- injury functional states of patient were not known.

8. Conclusion

Young populations were commonly injured age groups in our study which also showed male predominance. Road traffic accidents were the commonest mechanism of injury leading to the fracture followed by bullet injury and fall down accident.

Following operative fixation, functional outcome was predominantly good or excellent. Knee stiffness was the leading complication.

Retrograde nailing was done for most of patients involved in this study and functional outcome were similar with other types of fixation.

9. Recommendations

Hospital and orthopedic department should formulate standard post- operative rehabilitation protocol for distal femur fracture patients for whom ORIF done. And operating physician should discouse with patients.

Preventive policy formulation and enforcement in road safety.

Relevant authority should institute robust road safety campaign especially for pedestrians and drivers.

Further study is recommended to determine risk factors for those with poor functional outcome.

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6. Budget Break Down

Budget category	Units	Unit cost	Multiplying factor	total cost
1.material				
Paper	Packs	120	7	480
Pencil	Packs	10	1	10
Pen	Packs	30	1	30
Eraser	Unit	10	4	40
Fastener	Unit	10	4	40
Questionnaire duplication	Units	5	60	300
Print(proposal &research report)	Units	50	4	200
Photocopy	Units	50	4	200
Binding	Units	30	4	1200
Flash disk	Unit	450	450	900
CD	Units	10	5×10	50
2. personnel				
Data collector per diem	Person	200birr/day	200×30×2	12,000
Chart retrieval(card room workers)	Person	5 birr /chart	148×5	740
Investigator per diem	Person	150 birr/day	150×30	4500
Sub total				22,960
3. Contingency	Birr	10%	22,960×0.1	2296
Total	Birr			24,446

Table2. Budget breakdown

8. ANNEX 1

Data abstraction form for Data extraction

1. Patient Demography

- I. Hospital Number (registration number):
- II. Age in years
- III. Sex M.....F
- IV. Occupation type:

2. Comorbidities (specify): _____

3. Mechanism of injury

- I. Fall down injury
- II. Road traffic accident
- III. Gunshot injury
- IV. Other (specify)

4. Fracture line pattern (circle the appropriate):

- I. Simple transverse
- II. Simple spiral
- III. Simple oblique
- IV. Metaphysial comminution
- V. Intra-articular extension

5. Time from injury to presentation

- I. < 24 hours

- II. 24-72 hours
- III. > 72 hours
- IV. Not available

6. Timing from presentation to Surgery

- I. Immediate (in the first 24 hrs)
- II. Early (in the first week)
- III. Delayed (2nd week to 4th week)

7. Postoperative conditions

- I. Postoperative infection
 - i. Yes
 - ii. No
- II. Reoperation
 - i. Yes
 - ii. No
 - iii. If yes specify the reason.....
- III. Time to full weight bearing:
 - i. < 8 Weeks
 - ii. 8 -12 Weeks
 - iii. > 12 WEEK
- IV. Return to pre injury activity
 - i. Yes
 - ii. No

If no specify why_____

V. Knee society score

Part 1 - Knee Score

1. Pain

- I. None
- II. Mild/occasional
- III. Mild (stairs only)
- IV. Mild (walking and stair)
- V. Moderate (occasional)
- VI. Moderate (continual)
- VII. Sever

2. Flexion Contracture

- I. None
- II. 5-10degree
- III. 10-15degree
- IV. 15-20degree
- V. >20degree

3. Extension lag

- I. None
- II. <10degree
- III. 10-20degree
- IV. >20degree

4. Total Range of Flexion_____

5. Alignment (Varus & Valgus)_____

6. Antero-posterior stability (maximum movement in any position)_____

7. Mediolateral stability (maximum movement in any position)_____

Part 2 – Function

1. Walking

- I. >10blocks
- II. 5-10blocks
- III. <5blocks
- IV. Housebound
- V. Unable

2. Stairs

- I. Normal up and down
- II. Normal up, down with rail
- III. Up and down with rail
- IV. Up with rail,down unable
- V. Unable

3. Walking aids used

- I. None used
- II. Use of cane / walking stick
- III. Two canes/stick
- IV. Crutches/frame

TOTAL SCORE_____/100

Assurance of Investigator

I the undersigned resident agree to accept all responsibilities for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Research and Publication Directorate and /or Department of Public Health of St. Paul's Hospital Millennium Medical College.

Name of the

Resident: _____

Signature: _____

Date: _____

Approval of Advisors

Name of Public Health

Advisor: _____

Signature: _____

Date: _____

Name of Clinical Advisor:

Signature: _____

Date: _____