

Original Research Article

A prospective study for the treatment of femur bone fracture following femur plate fixation with a screws to achieve initial stability and early mobilization

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ABSTRACT

Background: Fractures of the femur are relatively common, most often is caused by high-energy trauma in young and low-energy trauma in older persons. Femur fractures were classified according to Arbeitsgemeinschaft für Osteosynthesefragen system which included proximal, diaphyseal and distal.

Methods: 30 patients prospective data was collected with a year of follow up. Clinical and radiological follow-ups were conducted at four weeks, twenty-four week, and forty-eight week after the discharge to check the bone union and implant-related complications. Three different plates were used for the treatment of fracture as per the fracture type (4.5/5.0 mm wise-lock distal femur plate, 4.5/5.0 mm wise-lock proximal femoral plate, 4.5/5.0 mm wise-lock proximal lateral femur plate (type II), 4.5/5.0mm wise-lock osteotomy medial distal femur plate). The patient's health status was evaluated by American Society of Anesthesiologists grade and the visual analog score (VSA) was also obtained.

Results: The gradual decrease of the VSA score showed the results of the good significance related to pain management. The continued physiotherapy under the supervisor of physiotherapists in all patients after discharge helps in good recovery and earlier mobilization. In the series of our 30 patients, no biomechanical complication was observed related to implant plate and screw-like loosening, bend, corrosion, etc.

Conclusions: Femoral system (Auxein Medical Private Limited, India) is effective as a treatment for femur bone union. Definitive treatment of femur bone fracture fixation with Femoral System have good rate of success of mobilization and bone union in this study.

Keywords: Femur fracture, Medial end, Diaphyseal fracture, Partial articular fracture, Simple fracture, Proximal femur plate, Distal fracture, Locking plate, Nonunion, Outcomes

INTRODUCTION

A femoral fracture is a break in the thigh bone, which is called the femur. It runs from the hip to the knee. It is the longest and strongest bone in the body. In every part of the femur, there is a remarkable adaptation of the inner structure by which the bony material is arranged in the paths of the maximum internal stresses by which it can

withstand those stresses with minimum material required.¹ It usually requires a great deal of force to break the femur. Fractures of the femur are one of the common fractures encountered by an orthopedic surgeon. The incidence of these fractures and the problems subsequent to them seems to be increasing. In 1564, Ambrose Pare was the first physician to diagnose a fracture of the hip and distinguish it from a dislocated hip. His treatment

included splint and bed rest.² Plating of fractures began in 1895 when Lane first introduced a metal plate for use in internal fixation and then gradually the invention starts and according to the type of fracture, different types of plates, nails, etc. were formed.³ A femur fracture divided into three parts proximal which includes the head of the femur bone, diaphyseal the stem part of the femur bone and the distal is the end part of the femur toward the join of the tibia bone. Fractures of the femur are relatively common, most often is caused by high-energy trauma in young persons and low-energy trauma in older persons. Fractures were classified using the AO system; they included distal, proximal, diaphyseal 33-A1 (3), 33-A2 (6), 33-A3 (2), and 33-C3 (3).^{4,13} 10-34% femur bone fracture has subtrochanteric type of fractures and the Distal end of the femur bone has a 6% chance of fracture apart from this proximal femur fracture have a 50% chance.⁵⁻⁷ Furthermore, the type of stable fracture and unstable fracture affects mobility until the complete bony union is achieved.⁸ Some other methods of bone fracture healing were also there but in that cases the reoperation rate is reported higher in percentage like of dynamic hip screw (DHS) and intramedullary nails is reported to be 8.2% and 3–12.7% respectively Hence, plates are designed to apply in minimally invasive fashion to preserve local biology and avoid problems with fracture healing and infection.⁷⁻⁹ The goals of surgery include anatomic reduction, gentle tissue handling, and stable primary fixation to ensure rapid fracture healing with an optimal functional outcome. This prospective study aimed to treat femur bone fracture following femur plate fixation with screws to achieve initial stability and early mobilization.

METHODS

This was a prospective study directed from April 2018 to March 2019 with a one-year development that received femoral system. A total of 30 consecutive patients were taken from Mesoamerican University, Quetzaltenango, Guatemala who meets the inclusion criteria: skeletally mature male or female above 18 years had femur bone fracture were included and the exclusion criteria: neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care or severe infection to the operative site. Any uncontrolled systemic disease that, in the opinion of the investigator, would preclude participation in the study or put the subject at risk due to study procedures. Subject with rapid joint disease, bone absorption, osteopenia, and/or osteoporosis or having suspected or documented metal allergy or intolerance were excluded in this study. The study carried out in accordance with good clinical practice. Demographic data was given in Table 2.

The indications for surgery were femur bone fracture. Femoral system (Auxein Medical Private Limited, Sonapat, Haryana, India) was used for femur bone fracture union. Treatment was carefully performed by a

qualified orthopaedic specialist (Investigator). Indigenously planned and manufacture femoral plate system (4.5/5.0 mm wise-lock distal femur plate, 4.5/5.0 mm wise-lock proximal femoral plate, 4.5/5.0 mm wise-lock proximal lateral femur plate (type II), 4.5/5.0 mm wise-lock osteotomy medial distal femur plate, along with the screws 5.0 mm wise lock screw, self-tapping, 4.5 mm cortical screw, self-tapping) were used as per the bone fracture classification (universally accepted orthopaedic trauma Arbeitsgemeinschaft für Osteosynthesefragen classification) and bone stabilization was done (Figure 2).¹³ The orthopedic implants used in the surgery was prepared from stainless steel alloy as per ISO 5832-1 (implants for surgery - metallic materials - part 1: wrought stainless steel) and titanium alloy Ti-6AL-4V as per ISO 5832-3 (implants for surgery - metallic materials - part 3: wrought titanium 6-aluminum 4-vanadium alloy).

American society of anesthesiologists (ASA) score is used as it is the global score that assesses the physical status of patients before medical procedure it assess the physical status of the patient; the physiological derangement that the procedure will cause; the skill and experience of the operator; the skill and experience of the anaesthetist (including the choice of anaesthetic); and the physiological support service in the perioperative period (including pre-operative optimisation and critical care.

Table 1: ASA grade categorization.

The ASA score was calculated as under	
Grade I	A normal healthy patient
Grade II	A patient with mild systemic disease
Grade III	A patient with severe systemic disease
Grade IV	A patient with severe systemic disease that is a constant threat to life
Grade V	A moribund patient who is not expected to survive without the operation

Pain scale was also recorded from the patient using the visual analog scale (VAS). As per clinical practice the percentage of pain relief, assessed by VAS, is often considered as a measure of the efficacy of treatment. However, as illustrated in the present study, the validity of VAS estimates performed by patients with chronic pain may be unsatisfactory (Figure 1). The amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous ± their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. Operationally a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they feel represents their perception of their current state.

Patients were followed up on 4 weeks (1 month), 24 week (6 month), and 48 weeks (1 year) after the

discharge. Swelling, pain, high redness and in some cases open fracture was also observed.

Intravenous antibiotics – 1 dose of injection cefuroxime axetil 1.5 gm and injection amikacin 500 mg dose just before starting the surgery. Post-operatively injectable cefuroxime axetil and amikacin is given for 5 days. Oral cefuroxime was given until suture removal. The post-operative and mobilization protocol was the same for all patients. The patient was kept in a well-equipped, pre-fumigated room. Post-operative X-ray of operative leg (femur bone) was taken.

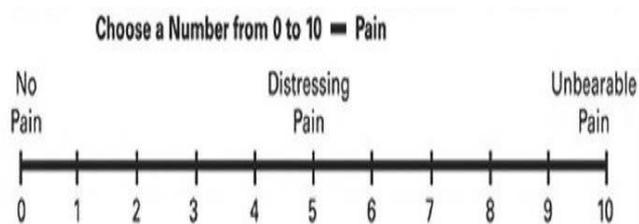


Figure 1: VAS scoring.

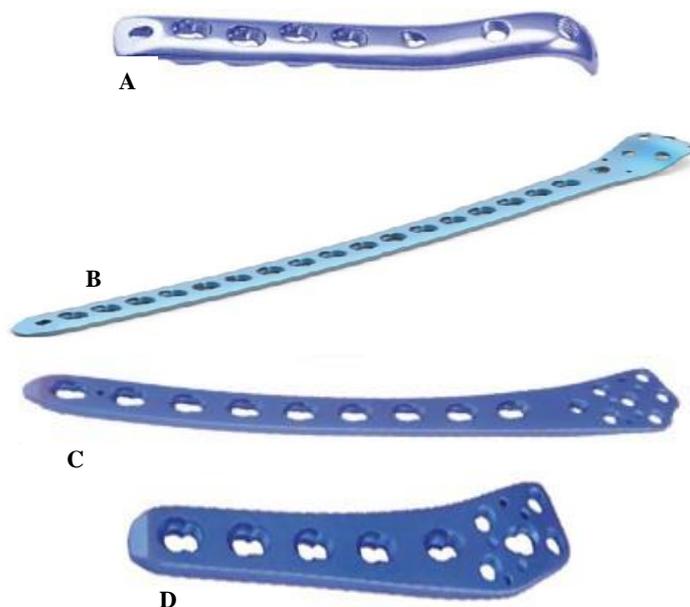


Figure 2: Femoral system, (A) 4.5-5.0 mm wise-lock proximal femoral plate, (B) 4.5-5.0 mm wise-lock proximal femoral lateral plate Type-II, (C) 4.5/5.0 mm wise-lock distal femur plate and (D) 4.5-5.0 mm wise-lock osteotomy lateral distal femur plate.

RESULTS

After surgery, all patients were mobilized as soon without any restrictions being placed on leg movements or partially weight-bearing. During this period, supporting aids were instructed to the patient. Patients were discharged home as soon as able from the hospital. The length of hospital stay includes the total stays on the hospital ward and rehabilitation wards till discharge home. Intravenous antibiotics were given both before and after operation 24 hours to help prevent infection. For open fractures, the antibiotics were given until the wound was clean. Pain medication was available to ensure comfort. The active muscle strengthening exercise was increased slowly day by day as per the radiographical finding. Patients were followed up on 4 weeks (1 month), 24 weeks (6 month), and 48 weeks (1 year) after the discharge.

In our study, femur fracture was classified as per AO classification under proximal (31 A-C), diaphyseal (32 A-C) and distal (33 A-C) in which proximal fracture have 6.66% rate of occurrence, diaphyseal fracture have 40%

rate of occurrence and distal fracture have 60% of the rate of fracture occurrence. 33-B1 type of fracture involved in 2 patients, 32-A1 type of fracture in 6 patients, 32-B2 type of fracture in 5 patients, 33-B1 type of fracture in 12 patients and 33-A1 type of fracture in 5 patients. According to ASA grade, 26 patient was felt in Grade 1 (healthy individual) and 4 felt under Grade-II (A patient with mild systematic disease) none of the patients fell in the category of grade III (A patient with severe systemic disease), Grade IV (A patient with severe systemic disease that is a constant threat to life) and grade V (A moribund patient who is not expected to survive without the operation). Male (18) patients were more susceptible to the study rather than females (12) (Table 2).

At the time of fracture swelling, redness and unbearable pain were reported by the patients. The reason for fracture was mostly the road accident, sports injury and slip or fall. Physical therapy post-surgery after femur surgery starts immediately. Under the supervision of a physical therapist sit on the edge of the bed and stand with support. While patients were often encouraged to stand and sit (with assistance if needed) within twenty-

four hours after surgery, walking is approached gradually and in a guided manner to avoid injury and complications. Mobility was also checked after 1 month every patient was able to partially bearing weight as suggested by the physician, after 6 months of assessment, 46% of the patients were able to walk and few required support of clutches whereas 6.6% of patients were not able to walk, they need full assistances, After a year of follow up, good satisfactory rate of device performances was observed, as 93.3% of patients were back to normal work and able to walk, the rest of the 6.6% were the patient were also able to walk but with the support of clutches since old age patients were fell in this category (Table 3). All the patients included in the study showed satisfactory bony fusion as judged by a solid union (callus formation). Radiological fusion started was seen completely on the 6th-month check X-ray (Figure 3). As per surgeon, Clinical union was defined as visible callus bridging the fracture in at least three cortices in radiographs and the patients could use their legs without significant pain or weakness. According to the VAS, the average VAS after 1 month was 4, after 6 months 2.1, and after 1 year was 0.13 which shows the good significances in the pain reduction. All were the medical complications occurs after surgery. There were no complications noticed related to femoral system biomechanics in the study and hardware related complications were not encountered in this. No implant-related complications have been found like implant loosening, bending, corrosion, related size issue, etc.

Table 2: General characteristics (n=30).

Demographics	N	%
Mean age (in years)	34.3	
Sex		
Male	18	60
Female	12	40
Dominant side		
Right side of leg	25	83.3
Left side of leg	5	16.6
Mode of injury		
Road accidents	18	60
Fall and slip	6	20
Sports	6	20
Other	0	-
ASA		
Grade I	26	86.6
Grade II	4	13.3
Grade III	0	-
Grade IV	0	-
Grade V	0	-
Type of fracture		
*Proximal fracture	2	6.66
Diaphyseal fracture	12	40.0
Distal fracture	18	60.0

*2 cases of proximal fracture have occurred along with the diaphyseal and distal fracture as multiple types.



Figure 3: Radiological films, (A-C) proximal femur fracture has occurred in one of our patient, in which pre-operative and post-operative radiological images were taken, (D and E) diaphyseal femur fracture has occurred in one of our patient, in which pre-operative and post-operative radiological images were taken and (F-I) distal femur fracture has occurred in one of our patient, in which pre-operative and post-operative radiological images were taken.

DISCUSSION

Femoral system (Auxein Medical Private Limited, India) is effective as a treatment for femur bone union. Definitive treatment of femur bone fracture fixation with femoral system (4.5/5.0 mm wise-lock distal femur plate, 4.5/5.0 mm wise-lock proximal femoral plate, 4.5/5.0 mm wise-lock proximal lateral femur plate (type II), 4.5/5.0 mm wise-lock osteotomy medial distal femur plate, along with the screws 5.0 mm wise lock screw, self-tapping, 4.5 mm cortical screw, self-tapping) have good rate of success of mobilization and bone union in this study (Figure 3). The rate of reoperation in percentage was quite higher in DHS and intramedullary nails, which was reported to be 8.2% and 3–12.7% respectively whereas in the case of femoral system re-operational rate was negligible, none of the patients had to undergo for reoperation surgery.^{7,9}

The union rate was generally of 13-14 weeks but in Auxein medical's femoral system union rate was of 24 weeks approx. since the union is considered as visible femur fracture healing through radiological assessments without any pain in leg movement, walking and sitting standing.^{7,9}

A study conducted by Young et al has average 78 scores of Harris hip score (HHS), it is a good mean of analyzing clinician-based outcome tool which is frequently used for the evaluation of patients who had the fracture related to femur bone and hip like total hip replacement, hemiarthroplasty (Surgery of Austin Moor or Thompson), etc. The HHS was developed for the assessment of the results of hip surgery and is intended to evaluate various hip disabilities and methods of treatment in an adult population. The domains covered are wide varieties of aspects related to both hip and femur bone-like pain, function, absence of deformity, and range of motion.¹⁰ Whereas of the studies conducted by Weng et al and Perisano et al has obtains knee society score, it is also a clinical rating system, was developed to rate both the knee prosthesis function and patients functional abilities after total knee arthroplasty.^{11,12} In their study 50% and 66.7% of recovery scores respectively in their sample size, but both the literature have different aspects of the obtaining scores since only locking plates were not used, they associate them with the hip prosthesis, and hence the score was low.¹² VAS was utilized the technique for the appraisal of varieties in power of agony which also shows the excellent decrease in pain scale of the patients by time of last follow up its average value obtained was 0.13. This shows excellent pain management.

The femoral system (locking plate system) has few advantages over other specialized devices which is utilized for fracture obsession like intramedullary nails or DHS-DCS since the femoral system's plates have multi-directional and small diameter screws for the obsession of plate head. These plates can give great to-brilliant

treatment to complex fractures in various anatomic areas.⁷ The use of a femoral system locking plate prevents the collapse and the osteosynthesis by plate and screw causes much more rigid fixation.¹³ Locking plates have picked up support since they are less intrusive, less problematic and give the normal state of stability.⁴

The femoral system i.e., locking plates have transformed into an essential strategy for treating breaks of the femur bone. They are favoured for giving an especially enduring form that requires unimportant periosteal stripping. Besides, for being less really mentioning and prominent than front line plates; they also crash less.

Implant related complications, non-union is the major cause reported after surgery but in our study, no case of non-union, mal union or delayed union was observed.^{5,6,9-11,14-16} Non implant related clinical complications, infection has the highest rate of occurrences, because surgical sites were usually more prone to infection which can either be a deep infection or superficial infection.^{4,10,11,14,15} In our study neither of the patients were affected with either of the types of infection, proper sterilization of implants was done before surgery as well as patients were on very high vigilance during the period of hospitalization with the sterilized environment conditions.

There are limitations to this study that should be considered. First, we cannot provide data regarding the socioeconomic characteristics of the patients. However, our data indicated that the patients were similar concerning their ability to function in daily life. Thus, we believe that any influence of socioeconomic class is likely to be small or not present. It can be argued that patients in a higher socioeconomic class may have had access to better postoperative care at home; however, we do not believe it is likely that this would have affected the results. Secondly, a long follow up has not been recorded. Thirdly, co-morbid conditions were not recorded properly since the health status of the patient was checked by the investigator based on the current position of the patient.

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Ethical approval: The study was approved by the institutional ethics committee

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