

Original Research Article

Clinical outcomes in the treatment of femoral fracture by using intramedullary femur nailing system

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ABSTRACT

Background: Femoral fractures are frequently occurring fractures that are caused due to large force impaction. The purpose of this study was to clinically evaluate the outcomes of treating femoral fractures with the use of the intramedullary femoral nailing system.

Methods: This retrospective clinical trial consists of 32 patients with femoral fracture and are treated by using an intramedullary femoral nailing system which consists of retrograde femoral nail, gamma nails, expert femoral nail, universal intramedullary cannulated femoral nails that are manufactured by Auxein medical Pvt. Ltd. Sonipat, Haryana, India. There were 32 patients from two different hospitals i.e., first hospital group consist of 15 patients (8 male and 7 female) with mean age of 32 years and the second hospital group consist of 17 patients (9 male and 8 female). The fracture categorization was done on the basis of AO Classification of fracture and physical fitness was categorized by American society of anaesthesiologists. VAS score and HHS was used as a criterion for assessing the clinical outcomes of the patients.

Results: There were 32 patients to whom surgery was performed and follow up time was 1 month, 3 months, 6 months and 12 months. After the final follow up no patient in any group complaint about the complications or any hardware related problem, there were perfect bone union in every patient. Radiological outcomes also showed proper union at 6 months follow up.

Conclusions: For femoral fractures, intramedullary femoral nail gives a better result with high union rate and post-operative composure.

Keywords: Femoral fracture, Intramedullary femoral nailing system, VAS score, Proper union

INTRODUCTION

The femur bone is the longest (48 cm long and 2.34 cm in diameter for average adult male), strongest and heaviest bone amongst all the bones in the human body. The femur's shaft is almost cylindrical and bowed forward.¹ Femur bone can be divided into three parts viz. proximal, diaphyseal and distal.

Fractures of the femoral shaft are frequently occurring fracture and one of the most common fractures treated by

orthopaedic surgeons. These fractures are often associated with serious injuries and can be life-threatening. Mishaps, high impact falls are some of the causes of femoral fracture. There are various ways in which a femur fracture can occur i.e., breaks of the diaphysis, head, and neck. We have used Muller AO classification for the bone classification in this study.

Open or closed reduction and internal fixation have been regarded as effective treatments for this injury. There are various methods for treating femoral fractures. Bone plates

are being used widely for its treatment that results in large skin incisions, more soft tissue dissection and greater blood loss. Given the above-mentioned problems the ideal implant for the treatment of femoral fractures should be an easy-to-handle intramedullary device.² So, the trend has been shifted towards the use of intramedullary femur nailing system. The clinical outcomes are measured by using Parker-Palmer mobility score but this clinical study will focus on using VAS (visual analogue scale) score for measuring clinical outcomes.

This retrospective clinical trial was performed to compare the clinical outcomes and complications with the use of femur nailing system manufactured by Auxein, for treatment of femoral fractures.

METHODS

This retrospective study was held at San Juan De Dios hospital, Philippines from May 2018 to July 2019 and East Avenue medical centre, Philippines from January 2018 to March 2019 and data were collected for patients who were treated with intramedullary femoral nailing system. The following data were collected: age, gender, height, weight, body mass index (BMI), type and side of fracture, American society of anaesthesiologists (ASA) score, date and time of surgery. There were 10 patients with 31 A1-C3 fracture, 18 patients with 32 A1-C3 type of fracture and 4 patients had 31-A3 type of fracture according to the AO classification of fracture as shown in Table 2. Thirty-two patients were treated with intramedullary femoral nailing system by the trained orthopaedic surgeons. The patients were divided into two groups as per the hospital i.e., in group I (San Juan De Dios hospital) and group II (East Avenue medical centre). In group I there were total 15 patients having 8 male and 7 females with mean age of 32 years and in group II, there were 17 patients having 9 male and 8 females with mean age of 50.5 years. There were no control groups created for this study. The surgical procedure adopted for the surgery was defined by the manufacturer as per the surgical technique.

The patient's clinical status was categorized according to the American society of anaesthesiologists (ASA), 19 (10 M and 9 F) were categorized in grade 1 which indicates a normal healthy patient and 13 (6 M and 7 F) were categorized under grade 2 indicating patients having mild systemic disease. Grade 3 patients as per ASA were excluded from the study.

The treatment was done by using the titanium alloy (Ti-6Al-4V) intramedullary femoral nailing system that has been manufactured by Auxein medical Pvt. Ltd. Sonipat, Haryana, India.

VAS score was used as a criterion for pain scale. Follow up period of the patients were 1 month, 3 months, 6 months and 12 months. All the patients treated with intramedullary nails showed the proper union. X-ray after 6 months showed that fusion has started. All the radiological

measurements were evaluated by the same surgeon who did the surgery. No complications were recorded at the final follow up in any patient.

Statistical analysis

Primary outcomes were presented through HHS (hip Harris score) with mean, standard deviation, median minimum and maximum with 95% significance level. HHS score from baseline to each visit was analysed using paired t test at 5% level of significance. All statistical analysis was performed using mini tab 19.

Inclusion criteria

Male or female, having minimum age of 18 years and patients with recent femoral fracture, with times of injury ranging from 12-72 h were included in the study.

Exclusion criteria

Exclusion criteria were patient age older than 65 years, death before surgery, and non-surgical treatment. Subjects with issues of alcohol misuse, subjects who are imprisoned or have pending detainment, subject having infection local to the operative site, patients having any active local infection, patients having allergy to the metal used in nailing system, patients having an issue of neuromuscular disease were also excluded from this study.

RESULTS

There was total 32 patients 17 males (53.13%) and 15 females (46.87%) were included in the study as shown in Table 1. The average operating time was 62 minutes, the average fluoroscopy time was 14 seconds. At the time of fracture and hospitalization swelling, redness and unbearable pain was reported by the patients. There were 28 fractures that occurred due to mishap between vehicles, 2 had fracture due to sports injury and 2 had fracture due to fall from a height. At the time of surgery anaesthesia was given to all the patients and wound dressing were also removed. There was physiotherapist who provided the physical therapy to the patients after the femur surgery and various activities were done by the patients as per the recommendation of the physiotherapists. Various post-surgery treatments were done for the early activation of the femur bone after surgery. Functional results assessed by HHS system gave excellent result in 18 (56.25%) cases, good in 10 (31.25%) cases and fair in 4 (12.5%) cases (Table 5).

Clinical assessment for pain, aesthetic appearance (Table 3) and fulfilment with treatment was appraised by patients with a VAS score (most extreme score, 10 focuses) at the final follow up. Various pain medication techniques were available to enable the early activation of treated femur fracture. As per the visual analogue scale, the average VAS after 1 month was 4.5, after 3 months 2.1 and after 6 month 1.2 and 12 months the VAS score was 0.2 (Table 4). There were 2 patients who complained about irritation and

infection at first follow up but later at subsequent follow-ups no patient complained about any health-related complications. There was no complication seen at the final follow up and, in each case, there was proper union of bone.

Table 1: Demographic data.

Variables	Group I	Group II
Average age (year)	32 (range, 31-33)	50.5 (50-51)
Gender, N (%)	Male: 8 (15) Female: 7 (15)	Male: 9 (17) Female: 8 (17)

Table 2: Fracture classification.

Fracture type (AO classification)	N (%)
31 A1-C3	10 (31.25)
32 A1-C3	18 (56.25)
31 A3	4 (12.5)

Table 3: Evaluation parameter.

Evaluation parameter	Satisfied, N (%)	Un satisfied, N (%)
Pain	30 (93.75)	2 (6.25)
Weight bearing	29 (90.62)	3 (9.37)
Aesthetics	31 (96.88)	1 (3.12)

Table 4: VAS score.

Follow-up time	VAS score (%)
1 month	45
3 months	21
6 months	12
12 months	2

Table 5: Anatomical results.

Anatomical results	Frequency	Percentage (%)
Restriction of hip ROM	3	9.37
Restriction of knee ROM	1	3.12
Shortening >1 cm	1	3.12

DISCUSSION

Femoral fractures are a common obstacle in orthopaedic trauma. There can be various types of fractures including proximal, diaphyseal and distal region fractures. There are various methods for treatment of femoral fracture viz. skeletal traction, bone plates, intramedullary nailing, rehabilitation. However, more frequently femoral fractures are seen to be treated with intramedullary nails, such as gamma nails, proximal femur nailing anti-rotation, and retrograde femoral nails (Figure 1-4).



Figure 1: Retrograde femoral nail.

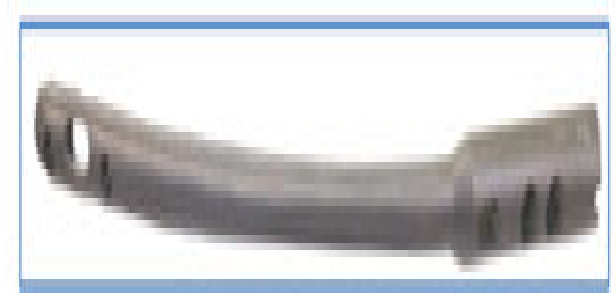


Figure 2: Expert femoral nail.

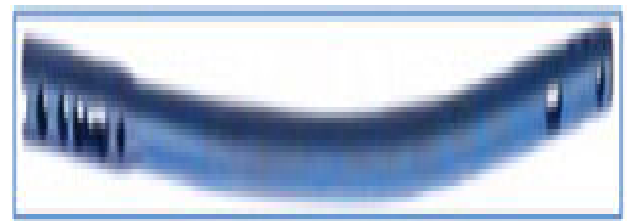


Figure 3: Universal intramedullary cannulated femoral nail.



Figure 4: Gamma nail.

Major complications like infection, irritation, and implant failure have been reported by previous studies with the use of intramedullary nails. In our study, intramedullary nail was used and there were 32 patients, among which none had complaint about pain, infection, or irritation at the final follow up. No complication was obtained at final follow up. There was a small difference between VAS score of the both groups. The VAS score has shown good acceptance outcomes. So, the gold standard for treatment of femoral fracture is intramedullary nail. If we consider for full weight bearing, it has been suggested that intramedullary nail fixation is of first choice, regardless of any factor in treating femur fractures.^{3,4}

A study conducted by Huang et al, in which 23 patients were included out of which none had any implant failure and the complication was also not obtained at the final follow up.⁵ This is similar to finding of us.

The main limitation of our study was the small sample size and relatively short-term follow-up of 12 months. Despite these limitations, the results were satisfactory as we had assumed before the starting of this clinical study.

CONCLUSION

Femoral fractures are frequently occurring fractures that are being treated by the orthopaedic surgeon and this result due to an exorbitant force impaction. The best method for treatment of femoral fracture is using intramedullary nFails and it gives the good clinical outcomes. Most of the complications of femoral nailing are related to surgeons, patients and instruments, and it can be prevented by proper surgery and post-operative care. This method is adequately minimally invasive technique and is mostly preferred by surgeons.

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

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