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.\textsuperscript{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.

\section*{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.

\section*{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.

\section*{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.

\section*{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.

\section*{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)                   | Male: 9 (17)                  |
|                 | Female: 7 (15)                 | 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).

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. 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 nailing 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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