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Original Research Article

Clinical outcomes of intramedullary femoral nailing system to treat femoral fracture

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ABSTRACT

Background: Femoral fractures are bone fracture involve femur, common injuries in adults. Intramedullary femoral nailing system is the recommended solution or treatment for fractures due to its high union rates.
Methods: In this clinical inspection 30 patients were selected with bone fracture of femur, and treated by using intramedullary femoral nailing system (universal intramedullary cannulated femoral nail, expert femoral nail, gamma nail and retrograde femoral nail) manufactured by Auxein Medical Private Limited, Sonepat, Haryana, India. There are two types of patients used in this study, one is male (n=18) and another female (n=12). Patients physical fitness was also observed through American Society of Anesthesiologist.
Results: Outcomes record from the patients using visual analog scale. Follow up of the patients were taken on 1st month, 6th month, and 12 months. Post-operative outcomes were good with none of the patients showing non-union of fracture site. There were no complications noticed related to intramedullary femoral nailing system in this study and hardware related complications were not encountered in this study also.
Conclusions: Intramedullary nailing system provide excellent outcomes with high union and low complication rates in the management of bone fracture involve femoral in patients.

Keywords: Femoral fracture, Intramedullary nailing system, Clinical union

INTRODUCTION

The femoral bone is the largest bone of human body. The end toward the hip is called the proximal end. The head of the femoral articulates with the acetabulum in the pelvic bone forming the hip joint, while the distal part of the femoral articulates with the tibia and kneecap forming the knee joint. By most measures the femoral is the strongest bone in the body.

Femoral shaft cracks are common fracture and may result into significant bleakness or even mortality if not enough treated.[1-3] A femoral crack is a bone crack that includes the femoral. They are commonly supported in high-sway injury, for example, vehicle crashes, because of the huge amount of force expected to break the bone. Breaks of the diaphysis, or center of the femoral, are overseen uniquely in contrast to those at the head, neck, and trochanter.[4,5] According to the vector of force applied and amount of force, the femoral fracture may vary. The amount of force increases with the amount of energy absorbed by the femur bone at time of fracture.[6] The pieces of bone may line up correctly or be out of alignment (displaced), and the fracture may be closed (skin intact) or open (the bone has punctured the skin).

The treatment of femoral cracks has experienced huge advancement over the previous century. Prior to the twentieth century, the authoritative treatment strategy was traction or supporting. These strategies were related with a few difficulties, for example, poor control of length and arrangement, pin tract disease, nonunion, and joint solidness because of delayed immobilization.[7,8] Open reduction and interior fixation have diminished a portion of these difficulties by enabling early activation of the patient after medical procedure. The best quality level for treating femoral cracks presently is intramedullary nailing.

The main goal of this prospective study is to treat the femoral fracture with Intramedullary femoral nailing system, manufactured by Auxein, to reduce complication rate associated with the implants.

METHODS

This prospective study was observed at Mesoamerican University, Quetzaltenango, Guatemala from May 2017 to Aug 2018, prospective data were collected for patients who received intramedullary femoral nailing system. Selected patients were differentiated according to Muller AO classification of fractures- long bones with 5 patients having 31-A1, 10 with 31-A2, 9 with 31-A3 and 6 patients with 31-A3. Only patients having good fracture reduction were taken in the study. Average year of patients were 34.6 years, ranges from (19-65) years. 30 patients were observed with femoral fracture treated with Intramedullary femoral nailing system. All surgeons included in the study were trained orthopedic surgeons.

Patients clinical status was categorization according to the American society of Anesthesiologists (ASA), 26 (10 F and 16 M) patients were categorized in grade 1 indicates a normal healthy patient. 4 patients (2F and 2M) were categorized in grade 2 indicates a patient with a mild systemic disease. Patients with ASA grade 3 has been excluded from the study.

A native fabricated implant was utilized according to treatment plan. The treatment was performed by utilizing the Intramedullary femoral nailing system to all patients as shown in (Figure 1-4). Implants used in the surgery process were arranged from titanium alloy (Ti-6AL-4V) and stainless steel (316L) (Auxein Medical Pvt. Ltd, Sonipat).

Pain scale record from the patient using visual analog scale (VAS). Follow up of the patient were taken on 1 month, 6 months and 12 months. All the patients included in the study showed satisfactory bony fusion as judged by solid union (calculus formation). Radiological fusion started was seen earliest on 6th month check X-ray. There were no complications noticed related to intramedullary femoral nailing system biomechanics in study and Hardware related complications were not encountered in this. All radiographic measurements were evaluated by same surgeon.

Figure 1: Universal intramedullary cannulated femoral nail.

Figure 2: Expert femoral nail.

Figure 3: Gamma nail.

Figure 4: Retrograde femoral nail.

Inclusion criteria

Male or female, skeletally mature patient above 18 years, femur fracture.

Exclusion criteria

Subject having any neuromuscular issue which would make an unsatisfactory risk of obsession disappointment or intricacies in postoperative consideration. Subjects with issues of alcohol misuse. Subjects who are imprisoned or have pending detainment. Subject having infection local to the operative site. Any uncontrolled foundational disease that, in the assessment of the Investigator, would block support in the examination (e.g., flimsy medicinal status including uncontrolled raised pulse, cardiovascular ailment, and glycemic control) or put the subject in danger because of study treatment or methods. Subject with joint fracture, bone wear, osteopenia, and osteoporosis. Subject having suspected or documented metal allergy or intolerance.

RESULTS

Out of 30 patients, 12 women (40%) and 18 (60%) were included in the study. The average mean age of patients was 34.6 years shown in Table 1. In study, femur fracture was classified under 31-A3, 31-A2, 31-A1 and 31-B2, 31-A3 involved in 9 patients, 31-A2 in 10 patients, 31-A1 in 5 patients, and 31-B2 in 6 patients as shown in Table 2.

In this study, according to ASA grade, 26 patients were felt in grade 1 (healthy individual) and 4 felt under grade II (A

patient with mild systematic disease). Male (n=18) patients were more susceptible in the study. At time of fracture swelling, redness and unbearable pain was reported by the patients. Reason of fracture was mostly the road accident (18) then sports injury (6) and slip and fall (6). Anesthesia was given to the patients (general anesthesia (22), spinal anesthesia (5) and nerve blocker anesthesia (3)). Wound dressing was also changed or remove. Physical therapy post-surgery after femur surgery starts immediately. Under the supervision of a physical advisor sit on the edge of the bed and remain with help. While patients were regularly urged to stand and sit (with help if necessary) inside twenty-four hours after medical procedure, walking approached and in a guided behavior to avoid injury and inconveniences. Anti-toxins given intravenously for 24 hours to help prevent disease.

Table 1: Demography data.

Average age (range)		34.6 (range, 19-65 years)
Gender N (%)	**Male**	18 (60)
	Female	12 (40)

Table 2: Fracture classification.

Fracture type (AO classification)	N (%)
31-A1	5 (16.67)
31-A2	10 (33.33)
31-A3	9 (30)
31-B2	6 (20)

Table 3: Evaluation parameter.

Evaluation parameter	Satisfied N (%)	Not satisfied N (%)
Pain	28 (93.33)	2 (6.67)
Weight bearing	29 (96.67)	1 (3.33)
Aesthetics	28 (93.33)	2 (6.67)

Table 4: VAS score.

Follow-up time	VAS score (%)
1 month	52
6 months	29
12 months	5

Clinical assessment for pain, aesthetic appearance and fulfillment with treatment was appraised by patients on a VAS score (most extreme score, 10 focuses) at the final development in (Table 3). Pain medication was available to ensure comfort. According to Visual Analog Scale, the average VAS after 1 month was 5.2, after 6 month 2.9, and after 1 year .5. All the patients included in the study showed satisfactory bony fusion as judged by solid union (callus formation). Radiological fusion started was seen earliest on 6rd month check X-ray.

DISCUSSION

To stay away from unnecessary morbidity, femoral fracture should be enough overseen utilizing sound orthopedic standards. The objective of treatment of these cracks is to accomplish association in adequate arrangement while avoiding unnecessary morbidity. In this investigation, femoral shaft breaks were seen as multiple times more typical in males than females. This is probably because males are more involved in rigorous activities to earn an income and hence more at risk of the injury. This pattern is similar to the findings of Akinyoola et al and Sekimpi et al.[9,10]

The main causes of femoral fracture were road crashes in this study accounting for 94.5% of all cases. This is similar to reports from Deepak et al and Sekimpi et al the most common cause of road traffic crashes was examined of femoral diaphyseal fractures.[11]

Using the demographic data of the patients, VAS score can become a standard way that can decide the standards of the surgical outcome and the parameters to be adopted to make it successful. Considering pain scores and comparing the VAS outcome of different studies that also includes demographic data as well as biomechanics under controlled trials can be sufficient to recommend the treatment plans.[12] As for the current study the trial was conducted after every six months and the outcome was presented by calculating the VAS score. This has shown good acceptance outcomes. The assessment should include good tissue growth followed by bone quality, aesthetics with independence in the society and low risk of the surgery. With a follow up of 16 months the study stressed upon bone growth to be a major aspect for the satiability of the plating system.

A study conducted by Salawu et al selected 43 adults patients had a mean age of 36.9±11.7 years. Using Thoresen's criteria, excellent results were obtained in 93% and poor results in 4.7% of patients.[13]

Weight bearing is a major factor of the outcomes to complete the surgical procedure. The problem of weight can face elderly patient while the younger patients may not face the weight bearing but management being non operative can reduce their ability to reduce the ability to return to work due to delay. With skin also involved its related complications cannot be ignored which carries 1-95% of functional bracing.[14,15] A comparative study between the operative and non-operative side shows no sign of complications and hardware related Complications. The study bared good results for the younger patients as for the elder's frequent consequences were observed.

This present study represents the treatment of femoral fractures surgically by using Intramedullary femoral nailing system, which are designed and manufactured in house by Auxein Medical Pvt. Limited. Major complications like nerve palsy and infection has been

reported by many studies but none was reflected in the outcome of our evaluation.

CONCLUSION

Femoral fractures are the common bone fracture occurs due to traffic crashes with mostly adults' patients. Intramedullary nailing system is only method to treat the fracture and gives good clinical and radiological outcomes. Comment of patients after surgery is very important to prevent the avoidable complications. Detailed instructions should thus be provided to patients along with close follow up to ensure good results.

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