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A prospective study on functional outcome of fracture shaft of femur stabilised with reamed intramedullary nail

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Abstract
The incidence of femoral shaft fractures is on rise because of fast, high speed transportation and modern lifestyles. Internal fixation is the mainstay of treatment. Conventional plating is associated with high risk of infection, pseudoarthrosis, malunion, decreased knee motion and loss of fixation. Interlocking techniques lead to fewer complications of nonunion/malunion, lesser soft tissue dissection, earlier fracture healing and lesser chances of infection. Fractures in any zone from the subtrochanteric to distal supracondylar part of the femur are accessible to nailing.

Materials and Methods: This was a prospective study of patients who underwent reamed intramedullary nailing for the fracture shaft of the femur. All patients were operated by the same surgeon and patients were followed up to six months period at regular intervals. Functional outcome is assessed by Thoresen's criteria and lower extremity functional scoring system. The study shall be of two and half years duration with effect from May 2015 to October 2017. Post operative evaluation was done at 1 month, 3 months and 6 months following surgery.

Results: In our series of 78 cases of femoral shaft fractures treated by interlocking nail 57 patients had good outcome, 12 patients had moderate outcome, 5 had fair and 4 patients had poor outcome. Most of the patients in this series were younger age group; more than 80% were below 50 years.

Conclusion: We confirm that the functional outcome after fracture shaft of femur stabilised by reamed intramedullary nail is good to moderate. Intramedullary nailing is effective treatment for the stabilisation of the fracture shaft of femur in view of subjective and objective perspective. Femur interlocking nail is a good implant for the treatment of femoral shaft fractures because of its load sharing, closed insertion, rotational stability, restoration of anatomic length alignment and early mobilization.

Keywords: Fracture shaft of femur, intramedullary nailing of femur, interlocking system

Introduction

Femur is one of the strongest and longest bones in human body. The name femoral shaft was given to an area extending from 2cm below lesser trochanter to 5-6cm above femoral condyles. Femoral shaft fractures most often will be a result of high energy trauma in young adults and they are the major cause of morbidity and mortality. Morbidity arises from femoral shortening, mal alignment and quadriceps contracture and knee stiffness. Mortality is infrequent but can result due to open wounds, fat embolism or multiple organ failure in poly-trauma. Femoral shaft fracture also causes marked alteration in bio-mechanics of gait and weight bearing. Therefore an appropriate stabilization device for femoral shaft fracture is essential to avoid the above said difficulties for an individual who sustains femoral shaft fracture.

Surgical stabilization of femoral shaft fracture is the gold standard in its management world over. The art and science of internal fixation for femoral shaft fractures has tremendously advanced over recent years. From the use of external splints in the Hippocratic age to sophisticated instrumentation, several orthopaedic scientists has greatly facilitated the surgical stabilization of femoral shaft fractures more so its expanded application to comminuted, segmental and spiral fractures of femur irrespective of the level of injury. The pioneering work of medullary nailing in 1930's and 1940's by Gerhard Kuntscher in Germany has revolutionized the management of femoral shaft fractures.

The dissemination of intra medullary nailing technique by Kuntscher throughout the industrialized world has profoundly changed the outcome of the treatment of femoral shaft fractures. Intramedullary nail being close to center of femur can tolerate bending and torsional loads better than plates. IM interlocking nail is a load sharing device and causes less cortical osteopenia of stress shielding which is a feature of the load bearing plates. Closed nailing prevents damage to extra periosteal soft tissues and the biological environment round the fracture is least disturbed.

Our present study attempts to analyze the effectiveness of closed interlocking nailing (reamed) in the management of fracture shaft of femur so as to restore the patients to functionally and structurally to near normal status.

Materials and Methods

This Prospective observational analytical study was carried out on patients of Department of Orthopaedic surgery, patients who presented to, AIMSR, Chittoor, Andhra Pradesh between 1-January 2016 to 31-May-2017. 78 adult patients with femoral shaft fractures were selected for the present study. Post operative evaluation was done at 1 month, 3 months and 6 months following surgery.

Operative Procedure

Under the effect of the anesthesia patient was positioned lateral on the operating table. Hip flexed to about 15 degrees. Incision is centered on the tip of the greater trochanter and extended 4 cm proximally and slightly posterior, distal extension carried out if necessary. Using the C arm image intensifier, entry was made at the piriform fossa using 16 mm k wire. Entry point was confirmed both in the AP and lateral views. Ball tipped guidewire was inserted through the entry point passed upto the fracture site closed reduction achieved using manual traction and manipulation. This was confirmed by image intensifier in both the views. Reaming of the medullary canal is done in 1mm increments using flexible intramedullary reamers and reaming was done 0.5 mm extra compared to the intended diameter of the nail to be used. Desired sized diameter of the nail was introduced to the canal. Desired nail was mounted onto the proximal jig. Fracture was reduced under the c arm guidance and constant traction and manipulation by the assistant. Nail was introduced to the fracture site to the distal segment.

After assembling the selected nail to jig it is introduced as far as possible manually into the medullary canal with the help of the mounted insertion instruments. Using the image intensifier by gentle blows with a hammer nail is counter sunk in the bone passing through fracture line. Nail entry was confirmed in both AP and lateral planes. Distal static locking done using freehand technique under C arm imaging. Locking of the bolts were checked in both the views. The cortex was drilled using a 4mm drill bit and 4.5mm locking bolts were inserted. Proximal locking was done using the proximal jig it was dynamic or static locking depending on the fracture pattern. The cortex was drilled using a 4mm drill bit and 4.5mm locking bolts were inserted. Wound closed in layers over continuous suction drain.

Post-Operative Protocol

Post-operative period drain was removed once it was below 30 ml.

Post operatively Injection Cefoperazone and Sulbactum 1.5 gm two doses were given for closed fractures. For compound fractures injection Metronidazole 500 mg TDS IV in combination with Piperacillin-Tazobactum 4.5 gm IV TDS was administered. The antibiotics were then changed according to the culture and sensitivity reports and was continued till 5 days post op.

Injection low molecular weight heparin 0.4 ml SC was given till mobilization was started. It was then changed to tab. Aspirin 75 mg at the time of discharge for 2 weeks.

Post-operative weight bearing protocol was changed according to the fracture pattern. On follow up visits weight bearing was chiefly decided on the basis of the callus formation at the fracture site and type of the fracture. In unstable fracture weight bearing was delayed until satisfactory callus formation, where in stable fracture patterns weight bearing was started early, to be initiate with partial weight bearing.

Evaluation

Postoperatively X rays (Standard Antero-posterior and Lateral views) were taken of the operated limb. The result of the treatment of femoral shaft fractures by using interlocking intramedullary nail AO type were assessed by Thoresen's criteria [27] and Lower Extremity Functional Scale [28] at the 1st, 3rd and 6th month of the operation.

Result Analysis

The present study was conducted in the department of orthopedics at, AIMSR, Chittoor, Andhra Pradesh between 1-January-2016 to 31-May-2017.

Probability value less than 5% was considered as statistically significant. The SPSS 17.0 software package (SPSS, Inc., Chicago, Illinois) was used for analysis. Microsoft Word and Excel were used to generate graphs and tables

A total number of 2082 fractures were admitted in our department between January 2016 and May 2017. Of these 1085(52.11%) were lower limb fractures, 856(41.11%) were upper limb fractures and 141(6.78%) were other factures that include spine, pelvis etc. Of the lower limb fractures 337(31.05%) were femoral fractures. Of the Femoral fractures 137(40.65%) were femoral shaft fractures.

The youngest in our series is 18 years old and the oldest is 60 years. Maximum numbers of patients in this study are of young reproductive group and mean age is 33.70 years. 64 patients were male (82.1%) and the remaining were females (17.9%). 47 Patients presented with right femoral shaft fractures (60%), 31 had left femoral shaft fractures (40%). 65 patients (83.3%) had history of road traffic accident, remaining presented with slip and fall (16.7%). 7 patients had open fracture (9%), remaining 71 (91%) had closed fracture shaft of femur.

The following results were obtained.

Table 1: Thoresen's criteria in our study

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Good	57	73.1	73.1	73.1
	Moderate	12	15.4	15.4	88.5
	Fair	5	6.4	6.4	94.9
	Poor	4	5.1	5.1	100.0
	Total	78	100.0	100.0	

Table 2: Lower extremity functional score progression over a period of 6 months and ANOVA test

ANOVA						
		Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
LEFS 1st month	Between Groups	62.321	8	7.790	.336	.949
	Within Groups	1600.512	69	23.196		
	Total	1662.833	77			
LEFS 3rd month	Between Groups	642.603	8	80.325	.845	.566
	Within Groups	6556.077	69	95.016		
	Total	7198.679	77			
LEFS 6th month	Between Groups	372.802	8	46.600	.518	.839
	Within Groups	6212.583	69	90.037		
	Total	6585.385	77			

Objective outcome assessment done in form of lower extremity functional assessment over a period of 6 months shows positive correlation and good progression with p values progressing from 0.949 at 1 month, 0.566 at 3 months and 0.839 at the end of 6 months all together is less than 0.05 nullifying hypothesis that indicates good objective outcome progression over a period of time with stabilization of the fracture shaft of femur by reamed intramedullary nail.

Radiological outcome was statistically matched with the subjective and objective assessment with p value <0.5 so null hypothesis was rejected. The study is Indicative of direct relationship of the diameter of the nail and length of the nail spanning the fracture site. With the adequate length and the diameter used fracture union was earlier. So the diameter and the length of the nail used is one of the factors responsible for the early fracture healing.

Table 3: Radiological union and relation to the diameter and length of the nail used

		Length	**Diameter**	**Radiological union(weeks)**
Length	Pearson Correlation	1	.440**	-.220
	Sig. (2-tailed)		.000	.053
	N	78	78	78
Diameter	Pearson Correlation	.440**	1	-.092
	Sig. (2-tailed)	.000		.422
	N	78	78	78
Radiological union (weeks)	Pearson Correlation	-.220	-.092	1
	Sig. (2-tailed)	.053	.422	
	N	78	78	78

The following complications were encountered in our study.

Table 4: Complications in our study

S. No.	Complication	Number of Patients	Percentage
1	Superficial infection	5	6.41%
2	Deep infection	2	2.56%
3	Delayed union	2	2.56%
4	Non- union	Nil	0%
5	Nail breakage	Nil	0%
7	Fat embolism	1	1.28%
8	Hematoma formation	3	3.85%
9	Iatrogenic fracture neck of femur	1	1.28%

Discussion

The incidence of femoral shaft fractures was 6.5% per 100000 populations after excluding fractures below 18 years of age and above the 60 years of age, Patients below the age of 18 years and above 60 years, irregular follow-ups, Patients having neurovascular deficiency of the concerned limb, patients with immunosuppression –pharmacological or disease induced, having neuropsychological ailments, neurological deficiency due to any cause leading to postoperative mobilization difficulty, refusing to take treatment, deformity of at least one lower limb i.e. Polio, major joint contractures, and amputees, other fracture on the same limb or the other limbs 78 patients were selected for the present study. Most of our patients were of younger age group, 36 (46.15%) patients between 20-30yrs, average age being 33.7 years, which correlate the fact that younger population is at increased risk of femoral fractures. Compared to the other studies in past our mean age group involved is slightly higher.

Table 5: Mean age compared to various studies

Serial number	Previous studies	Mean age
1	Wiss at el[13]	29
2	Thoresen's at el[27]	28
3	Mukherjee D. A[31]	29
4	Meena RC[32]	35
5	Our study	33.7

The objective and functional outcome didn't show any difference in the outcome based on the age and gender of the patient.

In our series the level of fracture is dominated by AO type A3 with 29(37.2%) out of 78 patients followed by A2 type 12(15.4%) out of 78 patients. Other reported series of conventional nailing, this figured ranged from 60-80% and 50% in the series of Thoresen [27] *et al*. Fracture pattern in our study was transverse in 16 (53.33%) out of 30 patients, 10 (33.3%) comminuted, 2(6.66%) spiral and 2(6.66%) oblique. In the study of Thoresen [27] *et al.* comminuted fractures were the common followed by transverse and then the spiral pattern. In the series of Wiss [12] *et al.* comminuted fractures predominated.

According to our studies the objective and subjective functional classification was independent AO classification system. Except the complication were more in the fracture who had segmental shaft of femur fracture (AO type C2)

In our study we had compared the subjective outcome with the objective outcome. In form of comparison of the Thoresen's criteria and lower extremity functional score, that showed comparable results.

Admission – operation interval in our study varied from 1-2 days. Except the delayed presentation of the cases most of the cases were operated within 48 hours of the admission. Before taking the patient for surgery, basic quantification of systemic inflammation and resuscitation was done. Mean interval being 24 hours. The optimal time for nailing of closed femoral diaphysis fractures has been suggested by Brumback *et al.* (1988) [16] as 7-10 days for elective admissions and immediately for patients with polytrauma to allow prompt mobilization. The mean duration of hospital stay in our study was 16 days average which is high when compared to Wiss [13] *et al.* series where it was 12 days only and relatively low compared to Gross & Kempf [9] series (21 days). Intra operatively reduction was achieved by closed means in 26(86.6%) cases and 4(13.3%) needed open reduction due to late operation interval.

Table 6: Results from Series of Closed and Open Femoral Fractures Treated by Unreamed Antegrade Femoral Nailing

	N	Union (weeks)
Clatworthy *et al.* [15]	23	39.4
Kröpfl *et al.* [33]	81	16.5
Giannoudis *et al.* [34]	13	26.9
Reynder and Broos [35]	53	19.2
Our study	78	18

The average time of radiological union was 18 weeks in the present study whereas in Gross Kempf *et al.* (1985) [9] and in Thoresen *et al.* (1985) [27] series it was 18 weeks and 16 weeks respectively. The average union rate was same in our series compared to the series of the above authors but with Wiss *et al.* (1986) [13] it is 26 weeks which is very high compared to ours. Union time was 39.4 weeks In a series of Claworthy *et al.* [15], who had used AO undreamed nail, compared to our study of reamed intramedullary nail, where the radiological union time is 18 weeks.

In various studies done for the reamed intramedullary nail showed In our study patient was partially weight bearing immediate post-operative period depending on the fracture pattern, while patients were not allowed weight bearing until 6 weeks on effected limb in a Thoresen [27] *et al.* series (30 days).

Table 7: Results from Series of Closed and Open Femoral Fractures Treated by Reamed Antegrade Intramedullary Nailing

	N	Union (wk)
Johnson *et al.* [36]	24	13.8
Kempf *et al.* [9]	52	19.5
Christie *et al.* [26]	120	17
Brumback *et al.* [16]	87	19
Søjbjerg *et al.* [37]	40	12
Alho *et al.* [38]	123	13
Wiss *et al.* [13]	33	32
Clatworthy *et al.* [15]	22	28.6
Reynder and Broos [35]	54	19.6
Our study	78	18

2 of our case developed delayed-union with instability at the fracture site and needed augmentation plating and bone grafting. 1 of our patient had developed fracture neck of femur intra-operatively that was managed with the intraoperative lag screw fixation. All the patients in this study had no problems relating to malalignment, stiff knee and pain. No case reported with shortening which is very low compared to GROSS and Kempf [9] where 11(21.1%) patients out of 52 had shortening.

There was a direct relationship of the diameter of the nail used and length of the nail used to the fracture union. Bigger the diameter and more the length used for nailing the fracture union was early.

Conclusion

The fractures of the shaft of femur are commonly seen in the young adult male population with Road traffic accidents. Right side was commonly involved than the left side. According to AO fracture Classification type A3 was the commonest type of fracture.

In the postoperative period, from the first postoperative day if there are no associated injuries, patients were started active knee movement and non-weight bearing walk with help of two elbow crutches and can be discharged from the hospital by the first week. Most of the fractures in our study were fixed within 48 hours which however showed excellent to good outcome, and other studies also have stressed upon fixation within 24 hours of injury.

The complications that arose were due to associated comorbidities or the compound fracture patterns or in the segmental fracture AO type C2 was most common associated with the delayed union which required secondary procedure in form of augmentation plating and bone grafting. Most of our patients achieved good range of movement at 2 months postoperatively with active exercise regimen.We like to point out that the subjective and objective assessment by the Thoresen's criteria and lower extremity functional scale respectively show equal functional outcome following the fracture shaft of femur stabilisation.

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