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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

Background: The incidence of femoral shaft fractures is on raise because of fast and 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. This study conducted to analyse the results of fractures of femur treated by interlocking nail AO type.

Methods: This was a prospective study of patients who underwent reamed intramedullary nailing for the fracture shaft of the femur. Postoperatively all patients were initiated on the rehabilitation protocol based on the fracture pattern. 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, radiological with fracture healing.

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.

Conclusions: 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. From this sample study we concluded the femur interlocking nail is a good implant for the treatment of femoral shaft fractures because of its load sharing, close insertion, rotational stability, restoration of anatomic length alignment and early mobilization.

Keywords: Fracture shaft of femur, interlocking reamed intramedullary nail, functional outcome

Introduction

The femur is largest and longest bone of the body with abundant blood supply. In recent era due to increase in the availability of the high speed vehicle and increased number of the high energy road traffic accident has led to increase in number of the complex fracture of the femur bone. Femoral shaft fractures are usually the result of high energy trauma such as road traffic accidents. The annual incidence of fracture shaft femur is approximately 10 per 100,000 people^[1]. Our study focuses on the economically producing and active young people with range of 18 to 60 years who has sustained fracture shaft of femur.

The femoral shaft fractures may be closed where the overlying skin is intact or open where the fracture site is communicating with the wound leading to increased chances of infection.

The fractures are classified according to anatomy of the fracture lines, commonly described as transverse fracture, oblique fracture, comminuted fractures, spiral fractures.

AO/OTA classification is an advanced and complex classification scheme which is commonly used, based on the fracture pattern and location, femoral shaft fractures are coded as 32 and divided into three categories (A,B,C) and ultimately 27 different patterns according to the AO/OTA system^[2].

Most femoral shaft fractures are treated surgically. Several studies have indicated that early surgical stabilisation is associated with a reduction of complications and mortality^[3].

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An intramedullary nail is a metal rod that is inserted into the medullary cavity of a bone and across the fracture in order to provide a solid support for the fractured bone. Intramedullary nailing is currently considered the “gold standard” for treatment of femoral shaft fractures^[4].

Proposed advantages of intramedullary nailing include short hospital-stay, rapid union of the fracture and early functional use of the limb^[5]. These good results are attributed to preservation of the hematoma, biological fixation, soft tissue respect and preservation.

Methods

Study design - Prospective observational analytical study

Setting - Tertiary care teaching hospital (MIOT hospitals, Chennai)

Study population - Include all patients presenting to the hospital with acute shaft of femur fracture during study duration.

Duration of Study - 1-January 2016 to 31-May-2017

Inclusion Criteria

All patients with age 18 to 60 years from both sexes presenting to the MIOT hospitals with fracture shaft of femur.

Exclusion Criteria

- Patients below the age of 18 years and above 60 years
- Patients having bilateral shaft of femur fracture
- Patients having other fracture on the same limb or the other limbs.
- Patients having irregular follow-ups.
- Patients having treatment elsewhere for the same cause.
- Patients having neurovascular deficiency of the concerned limb.
- Patients with immunosuppression –pharmacological or disease induced.
- Patients having neuropsychological ailments.
- Patients refusing to take treatment.
- Patients with deformity of at least one lower limb i.e. Polio, major joint contractures, and amputees.

A written informed consent was taken from patients to be included in the study.

- Detailed clinical history with special reference to cause of the fracture, time of diagnosis, mode of onset, past and present surgical history and personal history.
- Detailed general and systemic examination was carried out
- Initial evaluation by first classifying them with AO/Gustillo-Anderson Classification
- Initial resuscitation done and temporary stabilization of fracture is stabilized with Thomas splint.
- Neurovascular status of the limb concerned is noted.
- Any other major system like nervous system, respiratory system, circulatory system involvement is noted.
- Soft tissue condition and skin condition of the limb examined and noted. Whether consultant opinion of plastic surgeon has/had been sought at any time is also noted.
- Any other significant co-existent conditions are to be documented.
- Digital photographs of the limb and of the X-rays are collected
- Each reconstructive (skeletal and soft tissue) surgery will be recorded (written and photographic documentation) and complications documented.
- Assessment of the lower extremity functional score and Thoresen’s criteria at the 1st, 3rd and 6th month of the operation.

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.

Our Surgical Technique of AO Intramedullary Reamed Femur Interlocking Nail

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.

Post op antibiotic protocol of injection Cefoperazone and Sulbactam combination with dose of 1.5 gm two doses for closed nailing and in case of the compound fracture injection Metronidazole 500 mg tds iv in combination with piperacilin and sulbacum combination 4.5 gm iv tds and it was changed according to the culture and sensitivity reactions and was continued till 5 days post op.

Injection low molecular weight heparin 0.4 ml sc was given till mobilization was started and changed over to the tab. Aspirin 75 mg at the time of discharge for 2 weeks after discharge.

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. (Figure1)

Results

The present study was conducted in the department of orthopedics at MIOT international, Chennai between 1-January-2016 to 31-May-2017 102 adult patients with femoral shaft fractures were selected for the present study. A total number of 2082 bony injuries were reported MIOT hospital Emergency during the above said period. Out of which 1085 were lower

limb fractures. The femoral fractures were 352(16.91% of total fracture) and the femoral shaft fractures are 137. By deducting patients who come under exclusion criteria, 102 patients were selected for the present study. Among 102 patients 24 patients lost the follow up during the study period so was excluded from the study so 78 patients were included in our study. Amongst the 78 patients in study 64 were males (82.05%) and 14 were females (17.95%). Side of fracture is more on both right (60%) side. The most common mechanism of injury is road traffic accident in 68 cases out of 78 (87.18%).

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 economically reproductive group and mean age is 33.70 years.

Mean time for fracture union 18 weeks

5 (6.41%) patients had superficial infection, 2 (2.41%) patients had deep infection, 1(1.28%) patient had incidence of iatrogenic femoral neck fracture and fat embolism each.

Thoresen's criteria in our study is shown in figure 1.

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. (Table1)

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.



Fig 1: pre op and 6 months follow up.

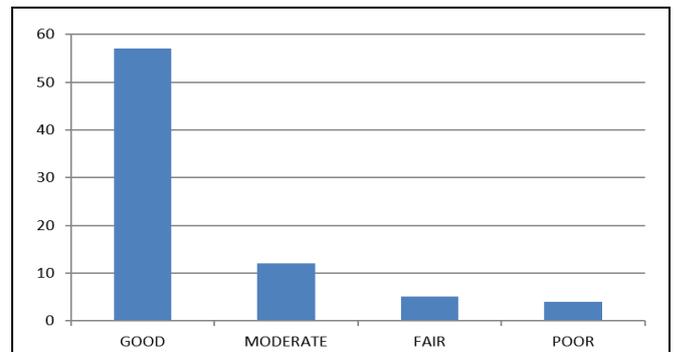


Fig 2: Thoresen's criteria in our study

Table 1: Comparison of lower extremity functional score in different fracture pattern.

		Descriptives							
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
LEFS 1st month	A1	6	24.50	3.674	1.500	20.64	28.36	18	29
	A2	12	24.58	2.539	.733	22.97	26.20	20	28
	A3	29	25.07	6.907	1.283	22.44	27.70	18	58
	B1	5	26.00	2.739	1.225	22.60	29.40	22	29
	B2	10	25.10	2.846	.900	23.06	27.14	18	28
	B3	3	26.33	2.887	1.667	19.16	33.50	23	28
	C1	3	28.33	.577	.333	26.90	29.77	28	29
	C2	9	25.33	.866	.289	24.67	26.00	24	26
	C3	1	21.00	21	21
	Total	78	25.17	4.647	.526	24.12	26.21	18	58
LEFS 3rd month	A1	6	51.83	14.428	5.890	36.69	66.97	24	63
	A2	12	55.58	9.539	2.754	49.52	61.64	34	65
	A3	29	57.17	10.265	1.906	53.27	61.08	25	75
	B1	5	63.60	7.570	3.385	54.20	73.00	52	70
	B2	10	57.70	9.298	2.940	51.05	64.35	36	68
	B3	3	62.67	1.155	.667	59.80	65.54	62	64
	C1	3	57.67	5.508	3.180	43.99	71.35	52	63
	C2	9	59.22	7.855	2.618	53.18	65.26	46	72
	C3	1	68.00	68	68
	Total	78	57.60	9.669	1.095	55.42	59.78	24	75
LEFS 6th month	A1	6	67.50	18.501	7.553	48.08	86.92	30	78
	A2	12	71.92	7.012	2.024	67.46	76.37	60	80
	A3	29	71.76	10.137	1.882	67.90	75.61	30	80
	B1	5	72.60	5.814	2.600	65.38	79.82	64	79
	B2	10	72.70	8.301	2.625	66.76	78.64	54	80
	B3	3	78.33	2.887	1.667	71.16	85.50	75	80
	C1	3	76.00	3.464	2.000	67.39	84.61	72	78
	C2	9	75.11	5.988	1.996	70.51	79.71	60	80
	C3	1	74.00	74	74
	Total	78	72.46	9.248	1.047	70.38	74.55	30	80

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			

Discussion

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 2)

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 *et al.* [5] 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 Thoresen5 *et al.* comminuted fractures were the common followed by transverse and then the spiral pattern. In the series of WISS8 *et al.* comminuted fractures predominated.

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.

The average time of radiological union was 18 weeks in the present study whereas in Gross Kempf *et al.* (1985) [13] and in

Thoresen *et al.* (1985) [5] 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) [8] it is 26 weeks which is very high compared to ours. Union time was 39.4 weeks in a series of Claworthy *et al.* [14], who had used AO undreamed nail, compared to our study of reamed intramedullary nail, where the radiological union time is 18 weeks. (Table 3)

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 mal-alignment, stiff knee and pain. No case reported with shortening which is very low compared to GROSS and Kempf [13] where 11(21.1%) patients out of 52 had shortening.

Table 2: mean age compared to various studies

Serial number	Previous studies	Mean age
1	Wiss <i>et al.</i> [8]	29
2	Thoresen's <i>et al.</i> [5]	28
3	Mukherjee D. A [9]	29
4	Meena RC [10]	35
5	Our study	33.7

Table 3: mean fracture healing time in different studies:

	N	Union (WK)
Johnson <i>et al.</i> [11]	24	13.8
Kempf <i>et al.</i> [13]	52	19.5
Christie <i>et al.</i> [18]	120	17
Brumback <i>et al.</i> [12]	87	19
Søjbjerg <i>et al.</i> [19]	40	12
Alho <i>et al.</i> [20]	123	13
Wiss <i>et al.</i> [8]	33	32
Clatworthy <i>et al.</i> [14]	22	28.6
Reynder and Broos [17]	54	19.6
Our study	78	18

Limitation

1. The effect of the functional outcome was not measured when the other bone was fracture in the same or the other limb there.
2. The outcome of the reamed intramedullary nail in the patient with polytrauma is another debate, in view of reaming and timing of operation both ways.
3. Outcome of the reamed intramedullary nail in patient having bilateral fracture shaft of femur was not assessed.
4. Functional outcome in patient with neurological deficient limb was not evaluated.

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