

Functional outcome of retrograde nailing versus locked plating of extra-articular distal femoral fractures in adults: A randomized controlled trial

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Abstract

Background: Distal femoral fracture constitutes the supracondylar and intercondylar fractures of femur. These are treated by locking plates as well as with nails. Despite the widespread use of both techniques, there are only few comparative studies. The two clinical techniques used to stabilize distal femur fractures are compared in this study.

Objectives: The aim of this study was to compare plating and nailing in terms of functional outcome using the Hospital for Special Surgery (HSS) Knee Score of operative fixation of extra-articular femur fracture.

Methodology: A randomized controlled trial was conducted with a total of 30 patients presenting to BP Koirala Institute of Health Sciences in a period of twelve months. All skeletally mature (>16 years) adult patients with isolated traumatic closed extra-articular fracture of distal femur without distal neurovascular deficit and giving written and informed consent were included. Patients with re-fractures, poly-trauma, fracture dislocations, pathological fracture and compartment syndrome were excluded. They were operated and followed up at 2, 6, 12 and 24 weeks.

Results: The demographic profiles of the two groups were comparable. There was no significant difference in functional outcome (Hospital for Special Surgery score), union or complications between them.

Conclusion: This study showed that there was no significant difference in terms of functional outcome (Hospital for Special Surgery score), union, fracture alignment, range of motion (knee, hip joint), infection, other outcome measures between plating and nailing in the treatment of distal femoral fracture in adults. Hence, further study is required to come to firm conclusions.

Key words: Distal femur; Fracture; Nailing; Plating.

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INTRODUCTION

Distal femoral fractures constitute the supracondylar and intercondylar fractures of femur. Incidence is highest in women older than 75 years usually associated with low energy injuries and young men (15- 24 years) mostly associated with high energy injuries. Various fixation options are available but no single method of management has overcome all of the problems associated with these injuries. Fixed angle locking plates have become the most commonly used device replacing others¹. The main advantage of an anatomically pre-contoured locked plate is soft-tissue protection using a limited approach^{2,3}. One concern with locking plate constructs is that the high stiffness achieved may limit the amount of callus, resulting in delayed healing or non-union⁴. Retrograde intramedullary femoral nailing is a 'biological' method, which is preferred by some surgeons for its good control of the distal fragment^{5,6,7,8}. Despite the widespread use of both techniques, only few

clinical studies have directly compared locked plates to nails⁹. The purpose of this study is to compare between the two mostly in terms of HSS (Hospital for Special Surgery) Knee score.

METHODOLOGY

The study was a prospective randomized controlled trial conducted at the Department of Orthopaedics, B.P. Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, over a period of twelve months between Sep 2016 to August 2017. Ethical clearance was obtained from the Institutional Review Committee (IRC). All skeletally mature (>16 years) adult patients with isolated traumatic open (Gustilo Grade I and II fractures), closed extra-articular fracture of distal femur without distal neurovascular deficit presenting to Emergency and the outpatient department; giving written and informed consent were included in the study. Patients with re-fractures, poly-trauma, fracture dislocations, pathological fracture and compartment syndrome were excluded.

The null hypothesis was that there is no significant difference in functional outcome between the two implants namely IMILN and Plating for treatment of distal femur in adults. The primary objective of the study was to compare the functional outcome and efficacy of retrograde nailing and plating for treatment of extra articular distal femur fracture. The secondary objectives were to determine the time required for fracture union and complications related to fracture and implant.

The sample size was calculated considering 95% CI and 80 % power of the study and with reference to the study by Gao K et al⁵. The calculated sample size was 15 for each group (total 30). Randomization was done by random number allocation using Microsoft Excel random number generation technique.

The patients were administered analgesics and traction was applied to the affected limb. A prior informed and written consent was taken from each patient after explaining about the procedures, complications and possible outcomes. A thorough general physical and systemic examination was carried out to look for underlying exclusion criteria. All cases were admitted, history was obtained and clinical examination was done with recording of any distal neurovascular deficit. Diagnosis was confirmed by x-ray of the thigh with knee on lateral and antero-posterior views. Classification of the fracture was done according to AO classification. Skeletal traction was applied. Relevant pre-operative

investigations were sent. After the patient was found to be fit for anaesthesia the patient was planned for surgery on elective basis.

The same type and strength of pre-operative antibiotics (cefuroxime 1.5 mg IV stat and amikacin 500mg IV stat) was administered in all cases within one hour of incision and continued for the same duration (48 hours) post operatively for all patients with closed fractures. Patients with open fractures were also randomized and given additional metronidazole 500 mg IV for 5 days. After adequate anaesthesia, the patient was positioned in supine position on the fracture table for group A (plating) and in radiolucent table for group B (retrograde nailing).

The further surgical exposure step was different as per the study groups.

In the plating group, whenever possible Minimally Invasive percutaneous plate osteosynthesis (MIPPO) was done; in cases which needed to be openly reduced or later converted to open; a lateral skin incision was made along the postero-lateral border of femur extending from lateral femoral epicondyle, exact length of incision depending on length of plate being applied. A plane was made between vastus lateralis muscle and lateral intermuscular septum, which covers the hamstring muscles. A distal femoral locking plate of adequate length was applied on the lateral surface of femur.

In the nailing group, a midline longitudinal skin incision was made over the knee. A medial para-patellar arthrotomy was done and a nail of adequate length and diameter was inserted through the intercondylar notch of femur just anterior to the attachment of posterior cruciate ligament (PCL). Locking bolts were applied proximally and distally under image guidance.

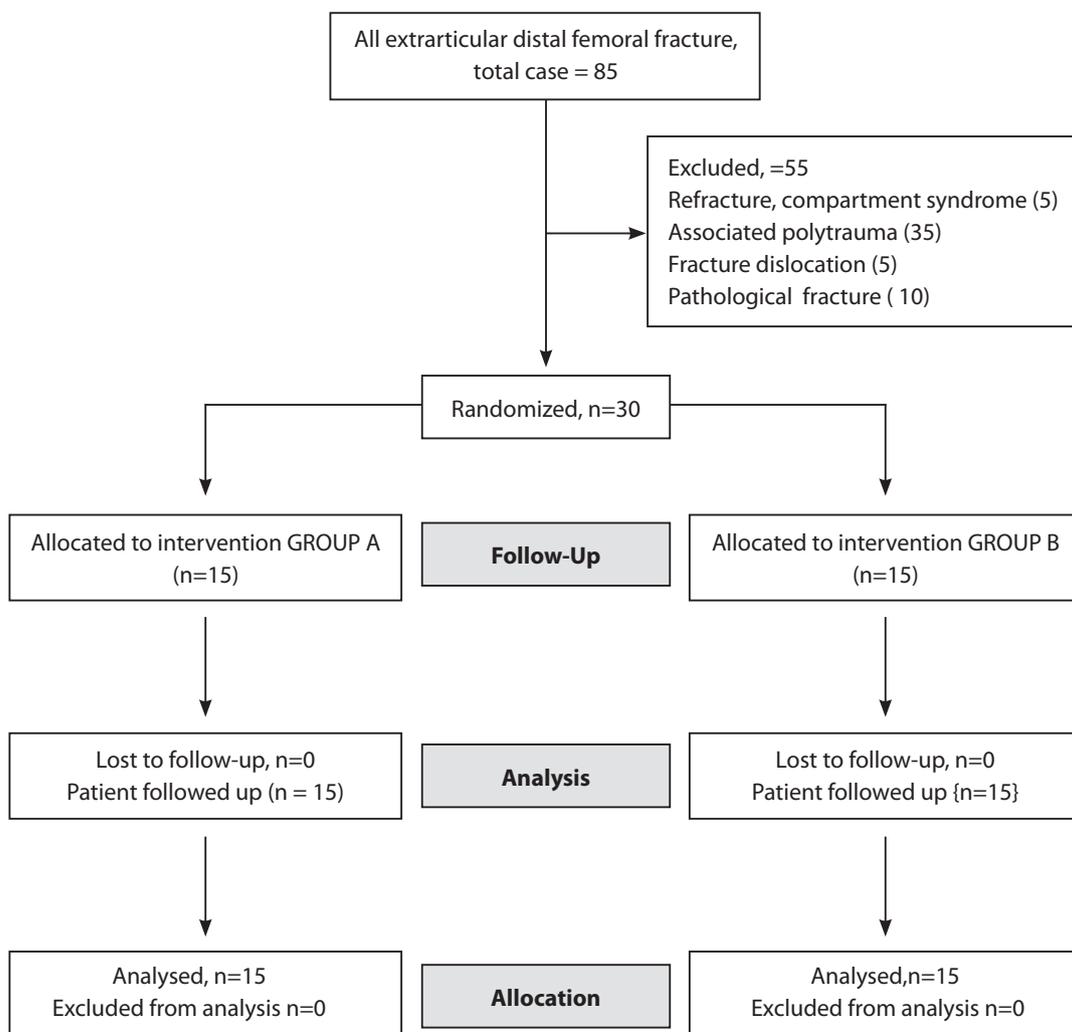
All the intraoperative parameters like blood loss, duration of surgery were noted as per pro forma and recorded. Antibiotics were administered parenterally for similar duration in both groups. On the 2nd post-operative day, the surgical wound was inspected and range of motion (ROM), quadriceps and hamstring strengthening exercises were taught by trained physiotherapists. Non weight bearing axillary crutch walking was taught. No post-op splinting of the limb was done. Check x-ray was done to see adequate placement of implants. Post-operative complications e.g. excessive soakage, post-operative distal neurovascular deficit if any and pain (VAS – Visual Analogue Scale score) was noted and recorded. The wound was inspected on second post-operative day and the patient discharged if satisfactory.

The patients were followed up at 2, 6, 12 and 24 weeks. It was an 'Intention to treat analysis', therefore even though the sample size is small but yet sufficient, we considered everyone who was randomized being part of the study irrespective of the outcome and the follow-up duration completed. The surgical wound was inspected at two weeks and sutures removed. Patients were then followed up in out-patient department at six weeks with check x-rays. Patients were taught range of motion exercise, exercise of knee joint and isometric quadriceps exercises. Range of motion, clinical and radiological signs of fracture union, deformity, and time taken for functional recovery was assessed as per the pro forma. Both groups were advised for non-weight bearing crutch walking till six weeks. After that, the plating group was continued with non-weight bearing crutch walking while

the nailing group was allowed partial weight bearing after six weeks. At the end of three and six months, results were graded using the HSS score. Statistical Package for the Social Sciences (SPSS) software was used for statistical analysis and $p < 0.05$ was considered statistically significant. Collected data were entered in Microsoft Excel 2013 and converted into SPSS version 11.5 for statistical analysis. For descriptive analysis- proportion, percentage, mean and standard deviation were calculated. Graphical and tabular presentations were made. For inferential statistics- Chi-square test for categorical data, t-test or Mann Whitney U test for continuous data was applied to find out the significant differences between the two groups (retrograde IMLIN group and plating group) with study variables at 95% confidence interval where $p\text{-value} = 0.05$. Fisher's Exact test was used for test of independence.

RESULTS

CONSORT DIAGRAM



A total of 30 cases were operated over the study period of which 14 were males and 16 were females. Most of them were in the 36-45 years age group (n=30). The mode of injury was similar between the groups. All of these variables were not statistically significant suggesting that randomization was successful (Table 1).

The timing of presentation after surgery and injury to surgery time was not statistically significant (Table 2). The amount of blood loss (mean haemoglobin difference) was not significant between the two groups (Table 10). The early post-operative complications were similar in both groups. One patient in the plating group developed late infection (Table 3, 4). The patient was managed with IV and local antibiotics for two weeks after which the infection subsided.

Signs of healing were present in all except one case of plating at 12 weeks (Table 5), which showed signs of healing at 24 weeks. All cases were ambulatory with either partial or full weight bearing in 12 weeks (Table 6).

Pain measured with VAS score showed gradual improvement in pain over time in both the groups. The VAS score was significant at six weeks in the nailing group (Table 7). The reason may be because the knee joint is opened with mobilization of capsule or cartilage during the surgical approach or pain can be due to nail impingement on patella.

The functional score (HSS score) was comparable between the groups at final follow up (Table 9).

Table 1: Demographic profile of the patients

Characteristics	Group		p-value
	Plating	Nailing	
Mean Age \pm SD (years)	36.6 \pm 17.5	45.5 \pm 19.1	0.197
Sex	Male	8	0.273
	Female	7	
Mode	Road Traffic Accident	8	0.693
	Fall from Ht/ Slip on ground	5	
	Physical assault	2	
Nature of fracture	Closed	13	1
	Open	2	

Table 2: Distribution of different variables among two groups

Injury and hospital arrival time	Plating	Nailing	p-value	Remarks
<12 hours	10	9	0.943	Not-significant
12 hours - 1 day	3	3		
>1 day - 1 week	1	2		
>1 week	1	1		
Injury- Surgery Interval	Plating	Nailing	p-value	Remarks
Upto 1 day	1	0	0.131	Not significant
1 day -1 week	13	10		
> 1 week	1	5		

Table 3: Early post-operative complications

	Plating	Nailing	p-value	Remarks
Redness/surgical site discharge	4	1	0.321	Not significant
Swelling	3	3		
None	8	11		
Post-op pain VAS Score (mean \pm SD)	8.26 \pm 0.59	8.067 \pm 0.79	0.443	Not significant

Table 4: Delayed post-operative complications

Infection	Plating	Nailing	p-value	Remarks
Present	1	0	0.309	Not-significant
Absent	14	15		

Table 5: Analysis of clinico-radiological union at 12 weeks

Radiological signs of union (callus formation) between the two groups (Fisher's Test) at 12 weeks

Callus	Plating	Nailing	p-value	Remarks
Present	14	15	0.309	Not significant
Absent	1	0		

Clinical signs of union between the two groups (Fisher's Test) at 12 weeks.

Clinical signs of union	Plating	Nailing	p-value	Remarks
Present	14	15	0.309	Not-significant
Absent	1	0		

Table 6: Ambulatory status at 12 weeks

Ambulatory status	Plating	Nailing	p-value	Remarks
Non weight bearing	0	0	0.705	Not significant
Partial weight bearing	6	5		
Full weight bearing	9	10		

Table 7: VAS score for pain at different follow-up

VAS score (mean ± SD)	Plating	Nailing	p-value	Remarks
Post- op	8.26 ±0.59	8.067±0.79	0.443	
2 weeks	2.80 ±1.01	3.26 ±0.79	0.172	significant
6 weeks	2.067 ±0.88	2.80 ±0.67	0.016	At 6 weeks
12 weeks	1.20 ±1.08	1.26 ±1.22	0.876	

Table 8: Range of motion (Hip, knee)

(a) ROM knee between the two groups at different stages of follow-up

ROM knee (mean + SD)	Plating (degree)	Nailing (degree)	p-value	Remarks
2 weeks	84 + 8.28	87.33 + 5.93	0.216	Not significant
6 weeks	100.66 + 10.99	102.0 + 8.61	0.714	
12 weeks	106.6 + 9.75	107.33 + 8.83	0.846	

(b) ROM hip between the two groups at different stages of follow-up

ROM hip (mean + SD)	Plating	Nailing	p-value	Remarks
2 weeks	53.0+/-17.29	65.0+/-9.81	0.027	Significant at 2 and 6 weeks and not at 12 weeks
6 weeks	75.33+/-20.30	86.66+/-8.16	0.055	
12 weeks	94.00+/-21.89	104.0+/-9.85	0.118	

Table 9: HSS Score criteria for final outcome between 2 groups

	No. of patients	HSS (mean + SD)	p-value
Plating	15	66.1+/-13.1	0.157
Nailing	15	71.7+/-7.1	

Table 10: The pre-op Hb (Independent Samples T-test) between the 2 groups

Variable(mean+/-SD)	Plating	Nailing	p-value	Remark
Hb pre-op	11.453+/-1.780	11.51+/-1.989	0.812	
Hb post-op	10.3133+/-1.78	10.71+/-1.996	0.906	Not significant
Hb difference	1.1467+/-0.360	0.74+/-0.279	0.543	

Table 11: Implant failure between 2 groups at 12 weeks

Implant failure	Plating	Nailing	p-value	Remarks
Present	0	0	N/A	N/A
Absent	15	15		



Figure 1: Post-operative x-ray at 12 weeks of plating group



Figure 2: Post-operative x-ray at 12 weeks of nailing group

DISCUSSION

The treatment of extra-articular distal femoral fracture is done mainly through plating or nailing. In our study, the amount of blood loss (mean haemoglobin difference) was not significant between the two groups, which was different to the study by Gao K et al where mean blood loss was more in nailing group as compared to the plating group. The MIPPO technique in the study more commonly used for plating may be the possible cause for less blood loss as compared to retrograde nailing where knee joint is opened⁵.

In our study, there was no significant difference in the occurrence of early post-operative complications (redness, discharge from surgical site, limb swelling) between the two groups. Seven patients (23%) in the plating group and four patients (13.3%) in nailing had early post-operative complication. In a study by Gupta et al, no complications were noticed in patients of plating group, but limitation of this study was that the patients were not randomized to each group⁷.

Pain was evaluated using VAS score. It gradually decreased over a passage of time after operation and it

was found that the difference in pain between the two groups was significant at six weeks, the pain was found to be more in the nailing group. During retrograde nailing the knee joint is opened, the mobilization of capsule or cartilage during the surgical approach may be the reason for pain during weight bearing or pain can be due to nail impingement on patella. The result was similar to a study by Hartin et al where they had concluded that more pain in nailing group was the reason for a greater trend of revision surgery for implant removal in the nailing group¹³.

The average ROM of knee joint was more for nailing group with respect to plating group at different follow-up; although it was not significant statistically, our result was similar to the study of Gao K et al.

In a one-year follow-up study by Markmiller et al average hip ROM was found more for plating group¹⁶.

We found the difference between ROM hip significant at 2 and 6 weeks, the less ROM hip in plating group may be because, during surgical approach for plating we divide the tensor fascia lata (TFL), which assist in flexion, medial

rotation and abduction of hip joint, thus hip joint motion remains compromised till the muscle heals²².

In our study, there was no significant difference between the groups in fracture union at 12 weeks follow-up¹⁰. HSS score criteria for evaluation of final outcome was similar for both groups with mean score of 66.1 for plating group and 71.7 for nailing group. No significant difference (p-value=0.157) was noted between the two groups as regard to final outcome. This result was similar to the study by Gao K et al⁵.

Our study had limitations due to a smaller number of sample size and less duration of follow-up due to which removal of implants after union could not be evaluated and late complications such as arthritis of the knee joint could not be studied. Also, the note of the fracture pattern according to AO was not done and power of

muscles around the knee and hip was not assessed between the groups which would have added to the value of the study.

CONCLUSION

Both treatment methods were identical in terms of functional outcome (HSS score), union, ROM (knee, hip joint), infection, implant failure and other outcome measures between plating and nailing till follow-up of six months in the treatment of distal femoral fracture in adults. Hence, both can be chosen as a method of treatment according to clinical judgement. However, further research with larger sample size and longer follow-up will be needed to validate the findings of this study.

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Source(s) of support: None

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