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A Comparative Study On Treatment Outcome Of Comminuted Femoral Shaft Fractures By Locking Plate Versus Open Interlocking Intramedullary Nail

Dr. Kazi Mizanur Rahman[1*], Prof. (Dr.) Nakul Kumar Dutta[2], Dr. Krishno Priyo Dash[3]
[1]Junior Consultant (Orthopaedic surgery), MBBS, MS (Orthopaedic surgery),Upazila Health Complex, Sreenagar, Munshigonj, Bangladesh.
[2]Professor (Orthopaedic surgery), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh
[3]Associate Professor (Orthopaedic surgery), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

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***Corresponding author**
Dr. Kazi Mizanur Rahman

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Abstract: Femoral fractures are one of the commonest fractures encountered in orthopaedic practice. There are three basic modes of internal fixation of femoral diaphyseal fractures in the adult age group: plate and screws, intramedullary Kuntscher nailing, and interlocking nailing. The aim of this study is the compare to outcome of results between locking compression plate and interlocking nail in comminuted femoral diaphyseal fracture. This was an experimental clinical trial, which include 18 patients having comminuted femoral diaphyseal fracture, out of which 9 patients treated by open interlocking nail was considered as group I and 9 patients treated by locking compression plate was considered as group II, in the Department of Orthopaedic Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), during period of July 2010 – June 2012, RESULTS: In this study the age was 34.4 ± 8.3 years in group-I and 42.7 ± 11.5 years in group-II. Motor vehicle accident was the commonest cause of fracture found in 55.6% in group-I and 66.7% in group-II. Post-operative mean duration of hospital stay was 10.4±2.54 days in group-I and 10.5±2.95 days in group-II. In group-I, out of 9 cases, 8 (88.9%) united with mean time of 14.41 ± 2.50 weeks. In group-II out of 9 cases, 09 (100%) cases united with the mean time of 13.72 ± 1.98 weeks. The final outcome, satisfactory results in group-I were achieved with 07 (77.8%) cases while in group-II with 08 (88.9%) cases. unsatisfactory results were seen with 02 (22.2%) cases in group-I and 01 (11.1%) cases in group-II. In the conclusion, we can say, on the statistical point of view no significant difference between locking compression plate and open interlocking nail.
Keywords: Treatment outcome, Comminuted femoral Shaft fractures, Locking plate, Open interlocking intramedullary nail.

INTRODUCTION

IN 1965, the Swiss AO group published the first manual on internal fixation. They popularized the term anatomic reduction and rigid fixation. This principle has evolved over the past three decades. Today, the objectives are to obtain stable fixation but to do so with the least possible disturbance of the soft tissue [1]. It is difficult to achieve union of an ununited fracture of the femoral shaft or osteotomy when the intrinsic or extrinsic blood supply has been damaged by infection or multiple operations, or if bone has been lost or is abnormal. The results of internal fixation with an intramedullary nail or a conventional plate combined with autogenous corticocancellous or vascularized bone grafts or allografts are unpredictable [2]. Many methods have been suggested to treat femoral nonunion, including double plating and autogenous bone graft [3], acute, custom made retrograde intramedullary rods [4], acute lengthening and human morphogenetic protein [5], vascularized fibular graft [6], custom model titanium plating [7], and the use of wave plates. Operative treatment of femoral fractures results in a 12.5% nonunion rate [8].

Treatment of femoral nonunion is difficult, particularly if many previous operations were performed, bone is osteoporotic or complicated by infection, and the knee is stiff. The ununited fracture should be adequately immobilized, and the biological condition around should be optimum for healing. The work of Kolodziej *et al.* [9] showed that locking the screws improves the stability of the construct, particularly in osteoporotic bone and when the near cortex is deficient. Also, the presence of the nut prevents the screw from stripping the threads in the bone as the screw is advanced [10]. The nuts also keep

the plate away from the bone, which prevents local bone necrosis induced by pressure of the plate and preserves the periosteal blood supply [11]. In case of the use of conventional plates, the part of the plate opposite the fracture only is away from bone, but in the case of a locked plate, the whole plate is away from bone. In cases with atrophic nonunion, we did not use bone graft, but the atrophic bone ends were resected until healthy bleeding bone was reached. Thus, the locked plate has both mechanical and biological advantages and can be used as a method of treatment in femoral nonunion especially, when the near cortex is deficient or the bone is porotic. Locked plate fixation is rigid enough for bone healing and to allow early postoperative mobilization, with good functional outcome [9]. Comminuted femoral shaft fractures have been treated in the past by prolonged traction [12], open nailing and circlage wiring, and open reduction and internal fixation with plates and screws. With its introduction the locking femoral nail has become the most commonly used form of treatment at most centers [13-16]. However locked nailing significantly increases the radiation exposure to the surgeon's hand and is more difficult to perform and requires prolonged operative time. Alternatively, such fractures may be treated by closed unlocked nailing followed by mobilization of the patients in a functional cast brace. However, very few studies have been published reporting on the results of these methods of treatment [18, 17].

Currently, the level of loading that leads to failure of the hardware in a fractured femur is unknown. Improvements in the design of the nails, including the elimination of welds and an increase in the amount of material in cross section, may have greatly improved the fatigue characteristics of these locking devices, distinguishing them from their predecessors. Failure of locking screws or nails used to stabilize fractures of the femoral shaft has been rare in our experience. Therefore, these studies design to determine the outcome of results between locking compression plate and interlocking nail in comminuted femoral diaphyseal fracture.

OBJECTIVES OF STUDY

General objectives

- To compare the outcome of results between locking compression plate and open interlocking nail in comminuted femoral diaphyseal fracture.

Specific objectives

- To assess fracture healing time by follow up both clinically & radiologically. To evaluate post-operative complications of locking compression plate and interlocking nail in comminuted femoral diaphyseal fracture.
- To compare and monitor any sort of disability or activity of daily living. To determine the range of motion in hip and knee joints in affected limbs.

METHODS AND MATERIALS

We conducted an experimental clinical trial in the Department of Orthopaedic Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh during the period of July 2010 to June 2012 with an approval from the ethical committee of the Bangabandhu Sheikh Mujib Medical University (BSMMU) Dhaka, Bangladesh. We selected a total number of 18 patients (Because of non-availability of the patients) following a purposive sampling technique maintaining inclusion and exclusion criteria. In Group I included nine patients treated by open interlocking nail and Group II included nine patients treated by locking compression plate. Patients of both sex and any age with comminuted femoral diaphyseal fracture, admitted in the Department of orthopedic surgery, BSMMU.

Inclusion criteria

- Patients having comminuted femoral diaphyseal fracture of 20 to 70 years age group of both sexes
- Two to 28 weeks old fracture shaft of the femur
- Any site-diaphyseal fractures of femoral shaft between 5 cm distal to lesser trochanter and 9 cm proximal to the joint line of knee.
- Fracture femoral shaft with or without neuro vascular involvement.
- Failure of previous surgery.

Exclusion criteria

- Recent fracture (less than 1 week)
- Infected non-union
- Pathological fracture
- Fracture in children
- Persistence of wound
- Unstable medical illness

A questionnaire was prepared by the researcher considering key variables like age, sex, presenting complaints, clinical findings, associated medical condition, investigations, per-operative findings and outcome of the surgery which was verified by the guide and the data was collected by the researcher himself. For valid statistical analysis, outcome categories were regrouped. Excellent and good categories were considered as satisfactory; fair and poor categories were considered as unsatisfactory. A total of 18 consecutive comminuted femoral diaphyseal fracture managed surgically by open interlocking nail consider as group I and locking compression plate consider as group II between July 2010 to June 2012. All patients were complete clinical follow up and radiologic follow up. All operations we performed under spinal anesthesia through a lateral approach with extra periosteal dissection leaving a thin cuff of muscle covering the bone. All possible efforts were made to

minimize the exposure of the fracture ends in closed fractures. Restoration of length, axial and rotational alignment was achieved. A standard Locking Compression Plate was used with 4.5 mm cortical screws locked into the plate holes by 4.5 mm nuts placed on the undersurface of the plate. At least four locked screws were used on either side of the fracture. Statistical analyses were carried out by using the Statistical Package for Social Sciences version 16.0 for Windows (SPSS Inc., Chicago, Illinois, USA). The mean values were calculated for continuous variables. The quantitative observations were indicated by frequencies and percentages. Statistical testing was performed using the unpaired t test or Mann-Whitney U test for continuous data. A chi-square test, Fisher Exact test, and CI calculation for categorical data P values <0.05 were considered as statistically significant or a 95% confidence interval. Prior to the commencement of this study, the research protocol was approved by the Ethical Committee of Bangabandhu Sheikh Mujib Medical University. The aims and objectives of the study were explained to the patients in easily understandable local language and then informed consent was taken from each patient. It would be assured that all informed and records were kept confidential and the procedure would be helpful for both the doctor and the patients in making rational approach of the case management.

RESULTS

For statistical analysis overall results were assessed as either satisfactory or unsatisfactory. Excellent and good results were accepted as (E+G) satisfactory, while fair and poor results were regarded as being unsatisfactory (F+P). Analysis was done by applying Chi-square test to compare the outcome of results of two groups. Data was expressed, Group-I= Open Interlocking Intramedullary nail, Group-II= Locking compression plate, ns= not significant, n= No of cases.

Table-1: Distribution of subjects by socio-economic and demographic characteristics (n=18)

Age (in years)	Group-1(N=9)		Group-2(n=9)		t-value	p-value
	n	%	n	%	1.756	0.098^{ns}
20-29	1	11.1	3	33`3		
30-39	3	33.3	2	22.2		
40-49	2	22.2	1	11.1		
50-59	1	11.1	1	11.1		
60-69	2	22.2	2	22.2		
Mean± SD	34.4±8.3		42.7±11.5			
Range	(20-68)		(22 -69)			
Age(sex)						
Male	7	77.8	6	66.7		0.500^{ns}
Female	2	22.2	3	33.3		
Occupation						
Farmer	1	11.1	2	22.2		
Businessman	1	11.1	2	22.2		
House wife	1	11.1	3	33.3		
Labourer	2	22.2	1	11.1		
Service holder	1	11.1	1	11.1		
Driver	2	22.2	0	0		
Student	1	11.1	0	0		

Table-2: Distribution of subjects by causes of injury, side involvement and previous treatment (n=18)

Descriptions	Group-1(N=9)		Group-2(n=9)		Total		p-value
Causes of injury	n	%	n	%	n	%	
Motor vehicle accident	5	55.6	6	66.7	11	61.1	
Fall from height	2	22.2	1	11.1	3	16.7	0.935^{ns}
Assault	1	11.1	1	11.1	2	11.1	
Blunt Trauma (others)	1	11.1	1	11.1	2	11.1	
Side involvement							
Right	3	33.3	4	44.4			0.500^{ns}
Left	6	66.7	5	55.6			
Previous treatment							
Upper tibial skeletal traction	7	77.8	6	66.7			
Others (by kabiraz)	2	22.2	3	33.3			

Table-3: Distribution of subjects by time interval between injury and surgery, Post-operative hospital stay, Time taken for union (n=18)

Treatment Method	No of Cases	Age of Injuries(days)		Mean in days	T value	p-value
Time interval		Minimum	Maximum			
Group-I	9	9	20	12.3 ±2.5	1.203	0.246^{ns}
GROUP-II	9	8	20	14.4 ±4.6		
Post-operative hospital stay						
Group-I	9	8	15	10.4 ±2.54	0.694	0.497^{ns}
GROUP-II	9	9	15	10.5 ±2.95		
Time taken for union (Weeks)						
Group-I	9	12	24	14.4 ±2.50	0.649	0.525^{ns}
GROUP-II	9	10	20	13.72 ±1.98		

Table-4: Distribution of subjects by complications, Pain severity score, activity of daily living, hip flexion of the affected limb, Hip abduction of the affected limb, Knee flexion of affected limb, Functional outcome(n=18)

	Group-1(N=9)		Group-2(n=9)		p-value
	n	%	n	%	
Post-operative complication					
Infection	1	11.1	0	0	
Non Union with implant failure (loosening)	1	11.1	0	0	
Sciatic nerve palsy	0	0	0	0	
Nil	7	77.8	9	100	
Post-operative complication (pain severity score)					
No pain(7)	3	33.3	4	44.4	1.000^{ns}
Mild(8)	5	55.6	3	33.3	
Moderate(3)	1	11.1	2	22.2	
Severe(0)	0	0	0	0	
Mean±SD	11.6	±2.49	11.6	±2.42	
Activity of daily living					
Walk without support	7	77.8	6	66.7	
Walk with a stick	2	22.2	3	33.3	
Walk with a crutch	0	0	O	0	
Hip flexion of the affected limb					
90^{o} or above	8	88.9	7	77.8	0.663^{ns}
70-90^{o}	1	11.1	2	22.2	
40-70^{o}	0	0	0	0	
0-40^{o}	0	0	0	0	
Mean±SD	97.67	±14.39	94.56	±15.39	
Hip abduction of the affected limb					
30^{o} or above	6	66.7	7	77.8	0.765^{ns}
20-30^{o}	2	22.2	1	11.1	
10-20^{o}	1	11.1	1	11.1	
0-10^{o}	0	0	0	0	
Mean±SD	33.33	±8.02	34.67	±10.54	
Knee flexion of affected limb					
90^{o} or above	8	88.9	9	100	0.820^{ns}
60-90^{o}	1	11.1	0	0	
0-60^{o}	0	0	0	0	
Mean±SD	105.22	±14.24	106.67	±12.32	
Functional outcome					
Excellent	7	77.8	6	66.7	0.353^{ns}
Good	1	11.1	3	33.3	
Fair	1	11.1	0	0	
Poor	0	0	0	0	

Table-5: Distribution of patients by limb length discrepancy (n=18)

limb length discrepancy	Group-1(N=9)		Group-2(n=9)		p-value
	n	%	n	%	
None	7	77.8	7	77.8	1.000^{ns}
<1 cm	2	22.2	1	11.1	
1-3 cm	0	0	1	11.1	
3cm or above	0	0	0	0	
Mean ± SD	2.25	±3.30	2.25	±3.20	

Table-6: Distribution of subjects by fracture site (n=18)

Descriptions	Group-1(N=9)		Group-2(n=9)		p-value
	n	%	n	%	
Proximal Third	4	44.4	1	11.11	0.090^{ns}
Middle Third	5	55.6	5	55.6	
Distal Third	0	0	3	33.3	

Table-7: Distribution of subjects by Post-operative infection and causative organism (n=18)

Method of Treatment	No of cases n	Infection n	Percentage %	Causative Organism	Sensitive Antibiotic
Group-I	9	1	11.1	No growth	
GROUP-II	9	0	00		

Table-8: Distribution of subjects by functional outcome between two groups after 6 months (n=18)

Descriptions	Group-1(n=9)		Group-2(n=9)		p-value
	n	%	n	%	
Excellent	3	33.3	4	44.4	
Good	4	44.4	4	44.4	0.766^{ns}
Fair	1	11.1	1	11`1	
Poor	1	11`1	0	0	

Table 9: Distribution of subjects by overall results (n=18)

Descriptions	Group-1(N=9)		Group-2(n=9)		p-value
	n	%	n	%	
Satisfactory (Excellent + Good)	7	77.8	8	88.9	0.500^{ns}
Unsatisfactory (Fair + Poor)	2	22.2	1	11.1	

DISCUSSION

Femoral fractures are one of the commonest fractures encountered in orthopedic practice. The operative fixation methods are plate and screws fixation by LCP or broad DCP and intramedullary fixation by kuntscher nail or interlocking nail [19]. The best option for ORIF by interlocking nail with much less complications and good union (the international medical journal, volume 8, number 1, June 2009).In this study 18 patients were selected and each categorized as group I and group II treated by open intramedullary nails and LCP respectively. In this study the mean age was 34.4±8.3 years with range from 20 – 68 years in group-I and 42.7±11.5 years with range from 22 – 69 years in group-II. These figures were compared favorably with other workers. The high incidence of young adult age group points to the higher rate of mobility as well as social violence age group [19] showed the age of the patients ranged between 17 to 43years in the whole study patients and the mean age was 25.91 years treated by locking compression plate and 23.6 years treated by interlocking nail.

In this study 7(77.8%) cases were male and 2(22.2%) cases were female in group-I. In group II 6(66.7%) cases were male and 3(33.3%) cases were female. Male female ratio was 2.6:1. Zairul-Nizam [19] showed male to female ratio was 2.3:1, which is closely resembled with the current study. Similarly, Christensen [20] and Ring *et al.* [2] found male predominant, which were 61.53% and 60.0% respectively. Pandey [21] showed 55.55% and Saha [22] found 87.50% male in their study. Males being the major working force of our society and thus more consistently exposed to the external environment, which probably accounts for this predominance. On the other hand, Healy, white and Mick [23] showed female (61.54%) predominance. In this study motor vehicle accidents were found to be the more common causative factor of the injury accounting 05 (55.6%) in group-I and 6(66.7%) in group-II. Christensen [20] and Ring *et*

al. [2] observed motor vehicle accidents as the major reason for femoral shaft fractures occupying 50% and 40% respectively. In this study right and left side involvement were seen in 3(33.3%) and 6(66.7%) cases respectively in group-I, while right side involvement was seen in 04 (44.4%) cases and left side 05 (55.6%) cases in group-II, Ring *et al*. [2] found 66.76% of the cases with left femoral fracture in their series. In this study it was observed that 77.8% in group I and 66.7% cases received upper tibial skeletal traction. Others (kabiraz) treatment received previously 2(22.2%) and 3(33.3%) in group I and group II respectively. In this series, the time elapsed between injury and surgery was varied from 8 to 20 days in both groups. The mean duration of time elapsed between injury and surgery was 12.3±2.5 days and 14.4±4.6 days in group-I and group-II respectively. The mean difference was not statistically significant (p>0.05 between two groups). Regarding the fracture it was observed in this present study that 4(44.4%) cases in proximal third, 5(55.6%) cases in middle third and none was found in distal third fracture in group-I. In group II, 1(11.1%) cases were in proximal third, 7(77.8%) cases in middle third and 1(11.1%) case in distal third fracture, which were almost similar between two groups, no significant (P>0.05) difference was observed between two groups. In this study it was observed that the mean union time was 14.41 ± 2.50 weeks varied from 12 weeks to 24 weeks in group I. Zairul-Nizam [24] reported that mean union time was 15.45 weeks after treatment in group I. Rosen [25] reported that average healing time for all cases was 26.1 weeks. Similarly, in group-II, the mean union time was 13.72 ± 1.98 weeks with varied from 10 weeks to 20 weeks. There was no significant difference in union time between two groups (p>0.494). Saha [22] reported in his study that mean union time was 16.38(±2.78) weeks which varied from 13-24 weeks. Zairul-Nizam [26] reported that mean union time was 18.73 weeks after treatment. Modabber and Jupiter [27], Muller and Thomas [28] published their studies of treatment of non-union femoral shaft fracture by locking compression plate and interlocking nail with union rate of 100%. White and Mick [29], Rosen [31], Foster *et al*. [31] and Hossain [32] reported that the union rate were 92.0%, 97.0%, 80.0% and 100.0% respectively.

In group-II, all of 9 cases of femoral shaft fracture both clinically and radio logically was found to unite. The union rate was 100%. Saha [22] reported in his study union rate was 100%, femoral shaft fracture treated by locking compression plate. Regarding the post-operative infection it was observed in this series that 11.1% infection occurred in group-I, which were superficial and managed by dressing with antibiotic. Ring *et al.* [2] reported infection 6.6%, Chowdhury [9] showed 6.4%, Mannan [32] reported 5.26%, Hossaine [33] obtained 12.1% superficial infection. In group-II, there was no infection during post-operative follow up period. Sana [24]-reported in his study 6.25% infection, which was superficial and was managed by dressing and antibiotics. Zairul-Nizam [19] showed the complications encountered were more commonly found in the interlocking nailing group reported by Zairul-Nizam [16] and the authors speculate that the techniques involved in interlocking nailing are more demanding than other methods as reflected by the longer operating time and higher intra-operative blood loss. About the post-operative complications it was observed in this current study that 11.1% case had post-operative infection, 11.1% screw loosening with non-union, 77.8% had no complications in group-I, whereas no complication occurred in group-II. About the post-operative pain it was observed in this current study that 3(33.3%) cases had no pain, mild pain 05(55.6%) cases and moderate 1(11.1%) in group-I. Similarly, in group II 4(44.4%) had no pain, mild pain 03(33.3%) cases and moderate pain 2(22.2%) cases at the end of 24 weeks (6 months follow up). The mean pain of severity score was found 11.6±2.49 and 11.6±2.42 in group I and group II respectively. The mean pain severity score was almost similar between two group, which was not significant (P>0.05) between two groups.

Regarding the post-operative activity of daily living 7(77.8%) and 6(66.7%) patient in group I and group II respectively walk without support, 02 (22.2%) patients walk with a sticke in group I, and 03 (33.3%) in group II. Patient walk with a crutch was not found in any group. In this study, in group-I, 07 (77.8%) cases had excellent functional outcome. 01(11.1%) cases had good, 01 (11.1%) case had fair outcome. In group-II, 06 (66.7%) cases had excellent functional outcome and 03 (33.3%) cases had good outcome. Sana [24] reported 5 (31.25%) cases had excellent functional outcome, 9 (56.25%) cases had good, 1 (6.25%) case had fair outcome and 1 (6.25%) case had poor outcome .Final outcome was analyzed on the basis of functional outcome, time taken for union, infection and sciatic nerve palsy .In group-I, there was excellent result in 03 (33.3%) cases, good in 04 (44.4%) cases, fair 01 (11.1%) cases and poor in 01 (11.1%) case whereas in group-II, excellent result in 04 (44.4) cases, good in 04 (44.4%) cases, fair in 01 (11.1%) cases. In this present study in group-I, satisfactory overall results was found in 07 (77.8%) cases and unsatisfactory in 02 (22.2%) cases and in group-II satisfactory overall results in 8 (88.9%) cases and unsatisfactory in 01 (11.1%) cases. Similarly, Zairul-Nizam [19] showed 60.0% and 83.3% had excellent final function in group I and group II respectively, which is comparable with the current study. In this study statistically overall result showed there was no significant difference between two groups (p>0.50), but 1 patient was needed second surgical procedure as surgical toileting for infection in group-I.

LIMITATIONS OF THE STUDY

Small sample size due to unavailability of the patient's longer duration of post-operative follow-up makes it difficult to obtain necessary data from the

patient. The study and follow-up period was short in comparable with other series. Strictly maintaining the inclusion and exclusion criteria. Due to lack of logistic support and surgical expertise close interlocking nailing was not done.

CONCLUSION AND RECOMMENDATIONS

This study showed satisfactory outcome in group-I 07(77.8%) cases and in group-II 08(88.9%) cases. Statistically overall result showed there was no significant difference between group-I (open interlocking intramedullary nail) and group-II (locking compression plate). So, it is concluded that femoral shaft fracture can be treated by either locking compression plate or open interlocking nail. Similar type of study should be performed on large sample size. Follow up of similar type of study should be done in prolong period. Adequate facilities and expertise should be available. Close interlocking nailing could be the best option for treatment of recent comminuted femoral shaft fracture.

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