International Journal of Orthopaedics Sciences

ISSN: 2395-1958
IJOS 2016; 2(3): 170-173

www.orthopaper.com
Received: 28-05-2016
Accepted: 29-06-2016

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Assessment of post-operative functional outcome after antegrade femoral nailing using piriformis fossa entry femoral nail and greater trochanter entry femoral nail

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Abstract
Surgical techniques range from closed or open intramedullary nailing, plating, lag screws with neutralization plate, bridge plating and external fixator. Intramedullary fixation of femoral shaft fractures with the use of modern intramedullary nails, carried out in biological way, is currently the best modality of treatment for femoral shaft fractures as there is good apposition with minimal tissue damage, good fixation which is bio mechanically superior to plates, immediate rehabilitation and fewer complications. The sample size was 30 patients per group on assumption of power: 0.85, Type 1 error: 0.05, and effect size: 0.8 with variables; intraoperative parameters (including complications), postoperative parameters (including complications) and postoperative functional outcome. GT group was found better than PF group in terms of post-operative parameters and functional outcome like VAS, WOMAC, HHS, LEM SCORE and SF-36.There was no significant difference in terms of union rates, complications and infections between two groups.

Keywords: VAS, WOMAC, HHS, LEM Score

1. Introduction
The length of a tubular human femur is about one fourth of the height of a person [1, 2]. The skeletal maturity of the adult type of femoral diaphysis can be judged by the age of the patient, which usually has been 17 years or older [3, 4] and more definitely by the closed (mature) growth plates.

Fracture healing includes phases of impaction, induction and inflammation, soft and hard callus formation, and remodeling. A fractured long bone normally heals by the formation of periosteal and endosteal callus. In diaphysis fracture repair, the healing cascade attempts to bridge the fracture gap with appropriate tissue leading to restoration of the skeletal integrity and the mechanical properties of the bone. Primary bone healing is characterized by widening of the harversian canals, formation of resorption cavities and subsequent formation of new bone across the fracture gap[5]. In gap healing, bone gaps are initially filled by bone with the lamellae oriented parallel to the fracture, and then penetrated by the osteons in a longitudinal direction [6]. External callus formation includes the primary callus response and the phase of bridging callus. Resorptive and formative changes in cortical bone generally occur in endosteal, intracortical and periosteal surfaces. In a bridging stage of the fracture healing process, a junction between the fracture fragments is established. In a remodeling stage, the morphology of the fractured bone is restored [7].

Fracture healing in a long bone with motion between fracture fragments after intramedullary nailing implies the formation of external callus tissue. The amount of external callus in fractures intramedullary nailing depends on the thickness of the intramedullary nail. External callus ossifies without the intermediate cartilage stage in fractures stabilized with tight-fitting nails, whereas loose-fitting-nails result in formation of cartilage at the fracture site [8].

Surgical techniques range from closed or open intramedullary nailing, plating, lag screws with neutralization plate, bridge plating and external fixator. Intramedullary fixation of femoral shaft fractures with the use of modern intramedullary nails, carried out in biological way, is currently the best modality of treatment for femoral shaft fractures as there is good apposition with minimal tissue damage, good fixation which is bio mechanically superior to plates, immediate rehabilitation and fewer complications. Moreover, the placement of locking intramedullary nails is usually easier and faster.

Intramedullary nail was first popularized by Gerhard Kuntscher in 1940 and the device came to be known by his name as K-nail. He conducted a considerable number of cadaveric and animal studies before he inserted his first femoral nail in 1939. His original IM nail was a V-shaped stainless steel nail that was introduced in an antegrade manner. He recommended the tip of the greater trochanter as the entry portal. He used a closed technique with fluoroscopic control. During World War 2, German surgeons used the technique on a large scale and the results, particularly with femoral shaft fractures, were so impressive that the method rapidly gained popularity throughout the world war two. It appears that early in the development of his technique, he recommended inserting the nail into the bone distant to the fracture site, thus, avoiding any disturbance of the zone of injury. Intraoperative reductions were achieved with the use of multiple slings; while head worn fluoroscopy was used for bony visualization. Kuntscher believed that proper insertion of his nail would allow for immediate functional mobilization of the patient [9, 10].

2. Methodology

In this comparative study, a cohort of 60 patients with fracture shaft of femur was included. Participants were divided by random number table method into groups with 30 patients in each group. In the first group Piriformis fossa entry Antegrade femoral nailing was used and in the second group Greater Trochanter entry femoral nail was used for fixation of femoral diaphysis fracture.

Sample Size: The sample size was 30 patients per group on assumption of power: 0.85, Type 1 error: 0.05, and effect size: 0.8 with variables; intraoperative parameters (including complications), postoperative parameters (including complications) and postoperative functional outcome.

2.1 Inclusion Criteria

1. Age: 20 to 60 years.
2. Duration of injury: Less than 7 days.
3. Closed traumatic fracture of the femoral diaphysis.
4. ASA category I and II.

2.2 Exclusion Criteria

1. Polytrauma patients.
2. Pathological fractures, previous, concomitant or fracture of any of the lower extremity.
3. Segmental Femoral shaft fractures.
4. Associated Inter Trochanteric, Sub Trochanteric or femoral neck fractures.
5. Bilateral shaft of femoral fractures.
6. Patients who are medically unfit to undergo surgery.
7. Pregnant female.
8. Poor soft tissue condition around hip region.
9. Bleeding disorders.
10. ASA category III, IV, V and VI.
11. Patients unable to give informed consent.

A major trauma was assessed with primary survey and secondary survey as per ATLS protocol. Fractures was assessed and classified according to AO/OTA and Winquist classification.

3. Results

Table 1: Comparison of Sex distribution between GT group and PF group

Sex	Group PF		Group GT		P Value
	Frequency	%	Frequency	%	
F	11	36.7%	10	33.3%	0.787
M	19	63.3%	20	66.7%	
Total	30	100%	30	100%	

GT group-Closed reduction and internal fixation with interlocking nail via greater trochanter entry portal.
PF group-Closed reduction and internal fixation with interlocking nail via piriformis fossa entry portal

Table 2: Comparison of Side between GT group and PF group

side	Group PF		Group GT		P Value
	Frequency	%	Frequency	%	
L	13	43.3%	15	50.0%	0.605
R	17	56.7%	15	50.0%	
Total	30	100%	30	100%	

Table 3: Comparison of immediate post op. malalingment between GT group and PF group

Immediate Post op	Group PF		Group GT		P Value
	Frequency	%	Frequency	%	
Mal					
No	30	100.0%	28	93.3%	0.492
Yes	0	0.0%	2	6.7%	
Total	30	100%	30	100%	

Table 4: Comparison of immediate post op. vas between GT group and PF group

Immediate post op	Group PF (n=30)		Group GT (n=30)		
	Mean ± SD	Min - Max	Mean ± SD	Min - Max	P Value
VAS	79.13 ± 6.51	67 - 90	73.10 ± 9.50	43 - 87	0.006

Table 5: Comparison of early post op. parameters between GT group and PF group

	Group PF (n=30)		Group GT (n=30)		P Value
	Frequency	%	Frequency	%	
INF	0	0.0%	0	0.0%	-
LDD	0	0.0%	0	0.0%	-
MAL	0	0.0%	2	6.7%	0.492
Complications	0	0.0%	0	0.0%	-

Table 6: Comparison of early post op. VAS between GT group and PF group

Early post op	Group PF (n=30)		Group GT (n=30)		
	Mean ± SD	Min - Max	Mean ± SD	Min - Max	P Value
VAS	46.10 ± 4.90	34 - 54	31.53 ± 6.82	20 - 43	0.006

Table 7: Comparison of Trendelenburgtest at 6th month between GT group and PF group

TRND	Group PF		Group GT		P Value
	Frequency	%	Frequency	%	
NEGATIVE	26	86.7%	30	100.0%	0.112
POSITIVE	4	13.3%	0	0.0%	
Total	30	100%	30	100%	

Table 8: Comparison of union between GT group and PF group

Union	Group PF (n=30)		Group GT (n=30)		P Value
	Frequency	%	Frequency	%	
6W	0	0.0%	3	10.0%	0.237
12W	24	80.0%	30	100.0%	0.024
18W	30	100.0%	30	100.0%	-
24W	30	100.0%	30	100.0%	-

Table 9: Comparison of Malalingment between GT group and PF group

Malalin	Group PF		Group GT		P Value
	Frequency	%	Frequency	%	
Yes	0	0.0%	2	7%	0.492
NO	30	100.0%	28	93%	
Total	30	100%	30	100%	

4. Discussion

In our series, in early post op period all of the outcome measures like infection, limb length discrepancy, malalingment, and complications showed no significant differences except VAS score which showed significant difference between these groups.

Wiss *et al.* [11] reported only 1 superficial infection in 112 patients at the trochanteric incision with no deep infection and no osteomyelitis.

We used various outcome measures in late post-operative period. The results were;

HHS score at 6 month in our series was 58.67 ± 6.35 in PF group and 58.67 ± 6.35 in GT group with p value less than 0.001. The results were significant showing that GT group has better functional outcome than PF group in terms of HHS score.

Ansari moein *et al.* [12] in 2011 in his series showed that there is difference in the HHS score in both group, PF group has mean HHS 82 and GT group HHS 89.2.

J. starr *et al.* [13] in 2006 reported, no difference between the 2 groups with regard to return to work status, Harris Hip Score, or hip and knee ranges of motion and walking distance.

Trendelenburg test was negative in all patients in GT group at 6 month and in PF group 4 patients out of 30 patients showed positive Trendelenburg test. But the results is not significant to prove any difference in long term follow up period.

Ansari moein *et al.* [12] in 2011 The Trendelenburg sign was positive in five patients from the UFN group (56%) (Table 1A). In all patients with a long PFN, this sign was negative (0%). The difference in Trendelenburg sign between the groups was reached significance with a P value of 0.01.

WOMAC score at 6 month showed significant difference between two groups with p value less than 0.001. The piriformis group had mean value of 24.7 and greater trochanter group had mean value of 16.53.

J. stannard *et al.* [14] in his study measured the WOMAC hip function score at three, six, and twelve months postoperatively. The mean WOMAC score was 39.00 (range, 0 to 79) for Group PF (n = 28) compared with 37.87 (range, 0 to 69) for Group GT (n = 31) at three months, 30.70 for Group PF (n = 37) compared with 34.11 for Group GT (n = 43) at six months, and 27.03 for Group PF (n = 38) compared with 27.13 for Group GT (n = 38) at twelve months. None of these differences were significant.

In our study LEM score showed significant difference between two groups with p value less than 0.001. The mean LEM score in PF group was 95.8 and the mean LEM score in GT group was 88.27.

In earlier study done by William ricci *et al.* [15], patients from both groups had similar baseline function with mean LEM score in PF group 87 and in GT group 86 at 6 month that showed no significant difference in both group. Scores for the LEM were reduced by 16–20% compared with baseline at 4 months and remained reduced 5–8% at 12 months. The initial decline and subsequent improvement in LEM scores were similar between the group treated with piriformis nailing and the group treated with trochanteric nailing.

SF-36 score in both group in our study showed significant difference with mean PCS and MCS value 50.03 and 55.63 in PF group and 71.53 and 76.74 in GT group.

N. Helmy [16] in 2008 in his series assessed the functional outcome with SF-36. The scores for the SF-36 were 51.77 and 53.73. All patients in his study ultimately went on to union. Of the 21 patients in the study, there were no patients with a positive Trendelenburg sign, clinically significant leg-length discrepancy, or malalignment. In addition, there were no significant differences in ranges of motion about the hip or knee when comparing the affected (nailed) side with the unaffected (normal) side.

Chair stand test in both groups showed significant difference with p value less than 0.001. The average time in PF group is 7.97 sec and in GT group is 6.27 sec.

J. stannard *et al.* [14] demonstrated the chair stand test in his study which showed significant difference between these two groups with group GT taking less time than PF group.

We followed the patients at 6w, 12w, 18w and 24 weeks to see radiographic union. There was no significant difference in both groups at 6w, 18w and 24 weeks. But there was significant difference in radiological union at 12 weeks with p value 0.024. In long term follow up radiological union occurred in all patients.

At 6 month post op period, there was no new malalingment. Still the previous 2 patients from GT group had malalingment. The data didn't showed any significant result.

In a study by Michael Archdeacon [17], No infections, nonunions, or deep venous thromboses were noted in any patient. All fractures were fully healed by 6 months after surgery as determined clinically and radiographically. Malalignment or malunion of greater than 5 degrees was not noted in any patient (range, 1 to 4.5 degrees varus at final follow-up).

We measured the VAS at 6w, 12w, 18w and 24 weeks. There was decline in VAS in both groups with time but in GT group patients had less VAS than PF group at 6w, 12w, 18w and 24 weeks. The data showed significant results with p value less than 0.001.

N. Helmy *et al.* [16] in 2008 in his study indicated that many patients continued to have pain in the injured limb. The reported locations of pain were not mutually exclusive and the average severity at each location was reported as mild to moderate (35-45 on the visual analog scale). Despite these persistent complaints of pain, all patients were able to return to their usual work (4 heavy labor, 17 sedentary jobs).

J.stannard *et al.* [14] demonstrated VAS in his study which showed thatthere was some degree of residual pain in both groups of patients, but the differences were not statistically significant.

We had excellent knee range of movement in our cases. Early resumption of range of movement exercises were started after surgery as per patient tolerance. We compared the ROM in both groups at 3 month and 6 month as % of the normal limb ROM. The data in both group showed significant difference with p value less than 0.001. The average value in PF group was 90.47 and 94.43% at 3 month and 6 month and in GT

group was 99.57 and 100% at 3 month and 6 month.

Wiss *et al.* [11] reported average knee flexion 125º with only 3 patients had less than 90º flexion.

Michael Archdeacon *et al.* [17] in his study concluded that there is a time dependent improvement in hip abductors and hip kinematics.

Walking distance at 6 month didn't showed any significant result between these two groups. 7% patients of PF group had decreased walking distance but the data was not significant.

Ansari moein *et al.* [12] in 2011 in his study demonstrated that patients in both groups often described a fatigue pain associated with a limp that occurred after strenuous activities such as long-distance walking. But the data between these two groups showed no significant difference.

5. Conclusion

We found that interlocking nailing done via greater trochanter portal has significantly better post-operative parameters and functional outcome in long term follow up

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