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PROSPECTIVE RANDOMISED COMPARATIVE STUDY OF PFN AND PFNA2 PROXIMAL FEMUR NAILS FOR THE TREATMENT OF UNSTABLE INTERTROCHANTERIC FRACTURES

Orthopaedics

Dr. Hemeshwar Harshwardhan Senior Professor and H.O.D., Department Of Orthopaedics J.L.N. Medical College, Ajmer.

Dr. S.K. Bhaskar Senior Professor, Department Of Orthopaedics J.L.N. Medical College, Ajmer.

Dr. Manish Sharma Associate Professor, Department Of Orthopaedics J.L.N. Medical College, Ajmer.

Dr. Dhruv Baradia* 3rd year Post Graduate Student, Department Of Orthopaedics J.L.N. Medical College, Ajmer. *Corresponding Author

ABSTRACT

Background: As the life expectancy increases due to improved medical facilities intertrochanteric fractures are prevalent in the elderly, which leave patients with functional restrictions. Intramedullary devices appear to be highly appropriate due to their biomechanical properties. Intramedullary implant has better biomechanical properties and more resistant to failure. PFNA and PFNA2 are both intramedullary devices with 6 degrees of proximal angulation. The main objective of our study is to analyze both the intramedullary devices as functional outcome and implant related complications. **Material & Methods:** This prospective, randomized, comparative study was conducted in 50 patients with unstable intertrochanteric fractures. They were followed-up clinically and radiologically at 6 week, 3 months and 6 months. A functional assessment was done with the Harris Hip Score (HHS). 50 patients were divided into two groups, group PFNA and group PFNA2 of 25 patients each. **Implant Used:** proximal femoral nail and proximal femoral nail antirotation **Results:** Mean duration of surgery was 49.15 ± 6.50 minutes in group PFN and 42.76 ± 4.50 minutes in group PFNA2 group had a decreased operative time when compared to the PFN group, and the difference was found to be statistically significant with a p = 0.0001. Blood loss was significantly lesser in group PFNA2 as compared to PFN group as showed by the mean number of gauges soaked during surgery was 2.12 ± 0.33 in PFN group and 3.16 ± 0.37 in PFNA2 group (p<0.0001) . In our study mean number of IIT shots was 33.92 ± 2.60 in PFNA2 group as compared to 40.76 ± 3.43 with significant p value (<0.0001) **Conclusion:** PFNA2 reduces the surgery time, blood loss, and image shots number as compared to PFN the functional outcome is significantly better with PFNA2 than PFN. Implant related late complication is more with PFN which was markedly reduced with PFNA2.

KEYWORDS

unstable intertrochantric fractures, PFNA, IIT, PFNA2, antirotation

INTRODUCTION

Intertrochanteric fractures are devastating injuries that most commonly affect the elderly and also in young, have a tremendous impact on both the health care system and society in general. [1] Trochanteric fractures are common in the elderly people. The frequency of these fractures has increased primarily due to the increasing life span and more sedentary lifestyle brought on by urbanization. Trochanteric fractures in younger population occurs due to high velocity trauma, whereas in the elderly population it is most often due to trivial trauma and osteoporotic bones. [1,2] There is increased risk of vascular flow disruption to femoral head with intertrochanteric fractures. The goal for treating such injuries is to reduce displacement and stabilize with implants to allow early mobilization and weight bearing during fracture healing. [3]

Intramedullary implant has better biomechanical properties and more resistant to failure.[4] PFN and PFNA2 are both intramedullary devices with 6 degrees of proximal angulation. For small sized femur as found in Asian population single helical blade PFNA2 is technically better. Biomechanically, helical blade in PFNA2 has a better cut-out resistance level than screws. [5] Intramedullary nails act as internal splints and helps in indirect healing these devices cause minimal trauma to the vascular supply of the bone. [6]

In 2003 AO/ASIF introduced PFNA-2 when compared to PFN, PFNA-2 claimed improved rotation and angular stability with a single screw and a superior functional outcome in treating unstable intertrochanteric fractures.[7]

AIMS AND OBJECTIVES:

To evaluate and compare the functional and radiological outcome of the patient having unstable intertrochanteric fractures treated by two different methods of fixation with PFN and PFNA2, this study was taken up, to find out the efficacy of newer implant PFNA2 over PFN.

MATERIALS AND METHODS

This hospital based prospective randomized comparative study conducted at J. L. N. medical college, Ajmer (India) in the department of orthopaedics.

Inclusion criteria

1. with closed unstable intertrochanteric femur fracture (AO/OTA 31-A2)
2. Patients aged >18 yrs

Exclusion criteria

1. Open intertrochanteric fracture,
2. Pathological intertrochanteric fracture,
3. medically unfit patient and closed intertrochanteric femur fractures (AO/OTA-31-A1, 31-A3)

The study included 50 patients with unstable intertrochanteric fractures treated with either PFN or PFNA2. All patients were randomly divided into two groups with 25 patients each using computer generated table of random numbers; Group PFN (n=25) – managed by the using of PFN technique and Group PFNA2 (n=25) – managed by the using of PFNA2 technique who were followed up for a minimum of nine months.

The blood loss was measured by surgical sponge method (carrying capacity of completely soaked sponge 10x10cm = 10cc ± 2cc) and noted, counting of image intensifier shots (IIT), Duration of surgery (time from skin incision to application of skin suture) was also noted.

Postoperatively AP and lateral X-rays of the pelvis and proximal femur was taken at the 6-week, 3 month and 6 months and radiological union time was recorded. Functional outcome was assessed by using modified Harris hip scoring system.

Statistical Analysis

All the data was entered in MS Excel spreadsheet and statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Quantitative variables were compared using unpaired t-test/Mann-Whitney test and qualitative variables were correlated using Chi-

square test/Fisher's exact test. A p-value of less than 0.05 was considered significant.

RESULTS

Our study consisted of 50 cases of intertrochanteric fractures of femur treated surgically by PFN in 25 cases and PFNA2 in 25 cases. In our study, the mean age of the patients in the PFN group was 62.76 ± 13.48 years and that in the PFNA2 group was 64.24 ± 10.83 years . The difference was found to be statistically insignificant (p = 0.671). Mean duration of surgery was 49.15 ± 6.50 minutes in group PFN and 42.76 ± 4.50 minutes in group PFNA2 group had a decreased operative time when compared to the PFN group, and the difference was found to be statistically significant with a p = 0.0001.

Table – 1: comparison of duration of surgery

Patient`s characteristics	Group – PFN (n=25)	Group – PFNA2 (n=25)	P value
Duration of surgery (minutes)	49.16 ± 6.50	42.76 ± 4.50	0.0001 *

Values are expressed as mean ± standard deviation for quantitative data and ratio for qualitative data.

P<0.05 is considered significant *= student t test, # = Chi square test Blood loss was significantly lesser in group PFNA2 as compared to PFN group as showed by the mean number of gauges soaked during surgery was 2.12 ± 0.33 in PFN group and 3.16 ± 0.37 in PFNA2 group (p<0.0001). The mean fluoroscopy time was recorded as mean number of Image intensifier shots (IIT). In our study mean number of IIT shots was 33.92 ± 2.60 in PFNA2 group as compared to 40.76 ± 3.43 with significant p value (<0.0001). **[Table-2]**

Table -2: Comparison of blood loss, X ray exposure in two groups

	Group – PFN (n=25)	Group – PFNA2 (n=25)	P-value
Mean number of gauges soaked	3.16 ± 0.37	2.12 ± 0.33	<0.0001*
Mean number of IIT shots	40.76 ± 3.43	33.92 ± 2.60	<0.0001*

Values are expressed as mean ± standard deviation for quantitative data P<0.05 is considered significant *= student t test

On follow up of the patients mean radiological union time was comparable among both groups. This was 4.92 ± 0.86 months in PFN group and 4.66 ± 0.53 months in PFNA2 group with insignificant p value (0.204). **[Table-3]**

Table -3: Comparison of mean radiological union time

	Group – PFN (n=25)	Group – PFNA2 (n=25)	P-value
Mean time for radiological union (months)	4.92 ± 0.86	4.66 ± 0.53	0.204*

Values are expressed as mean ± standard deviation P<0.05 is considered significant *= student t test,

The mean Harris hip score in the PFN group was 84.80 ± 9.84, and in the PFNA2 group was 86.24 ± 7.48. The difference was statistically not significant with a p value = 0.563 **[Table 4]**.

Table -4: Mean Harris Hip score at different time interval postoperatively

HHS score at	Group PFN (n= 25)		Group PFNA2 (n= 25)		P value
	Mean	SD	Mean	SD	
6 weeks	78.32	9.24	82.60	7.50	0.078 *
3 months	83.08	9.68	84.48	7.95	0.579 *
6 months	84.80	9.84	86.24	7.48	0.563 *

Values are expressed as mean ± standard deviation P<0.05 is considered significant *= student t test

The functional outcome according to Harris Hip score was excellent in 36%, good in 28%, fair in 24% and poor in 12% patients in Group PFN and in Group PFNA2 - excellent in 60%, good in 24%, fair in 12% and poor in 4% patients in Group II. This was statistically insignificant (p>0.05) **[Table 5]**.

Table -5: Functional outcome of fracture in both groups

Functional outcome	Group PFN		Group PFNA2		X2 value	p value
	No.	%	No.	%		
Excellent	9	36.00	15	60.00	2.885	0.089 #
Good	7	28.00	6	24.00	0.104	0.747 #
Fair	6	24.00	3	12.00	1.220	0.269 #
Poor	3	12.00	1	4.00	1.087	0.297 #
Total	25	100	25	100.00		

Values are expressed as ratio for qualitative data. P<0.05 is considered significant # = Chi square test

In our study, comparable complications occurred in both groups (p=0.171). Z effect was found in 2 patients (8.00%), broken implant was found in 1 patient (4.00%) and screw cut out in 1 patient (4.00%) in group PFN in comparison to Z effect in 1 patient (4.00%) and broken implant in 1 patient (4.00%) in group PFNA2. [Figure -1]

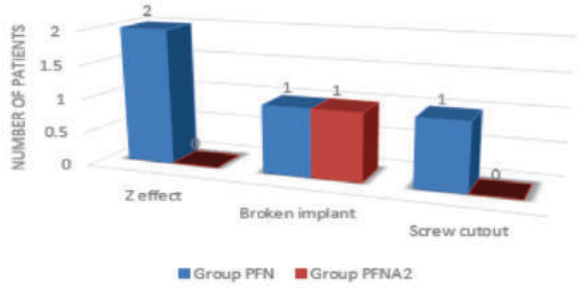

Figure-1: Complications and adverse effects

DISCUSSION

Various nail designs and augmentation techniques introduced in market to enhance the fixation in both stable and unstable intertrochanteric fracture. For osteoporotic bones, the helical blade device was introduced in PFNA2 [8]. The cancellous bone remains in place as the helical blade is inserted into the proximal femur, preserving the bone stalk. High stress concentration that is subject to multiple deforming forces, slow healing time because of old age, high incidence of complications reported after surgical treatment.

PFN is a newly created intramedullary implant that was developed based on knowledge gained from the gamma nail.

The proximal femoral nail with an antirotational hip pin and a reduced distal shaft diameter that minimizes stress concentration were consequently developed by the **Arbeitsgemeinschaft für Osteosynthesefragen** (AO ASIF) in 1996 to prevent these failures.

The present study was conducted on 50 patients with trochanteric fractures managed surgically using either PFN or PFNA2. The mean age of patients in group PFN was 62.76 ± 13.48 years ranging from 40 – 85 years and in group PFNA2 was 64.24 ± 10.83 years ranging from 42 – 85 years. Maximum patients were in the age group of 61 – 75 years (14 patients in group PFN and 13 patients in group PFNA2). **Gadhe SS et al** [9] conducted a study on PFNA vs PFNA 2 in unstable intertrochanteric fractures in 50 patients and mean age was found to be 67.56 ± 15.13 years. **Mandal MA et al** [10] compared the PFN vs PFNA 2 in intertrochanteric fractures on 60 patients and found the mean age 66.23 ± 9.74 yrs in PFNA2 groups and 63.6 ± 11.67 yrs in PFN group which was non significant. **Harisankar M et al** [11] found the mean age of the patients in the PFN group was 75.33 years and that in the PFNA2 group was 72.59 years.

In our study mean duration of surgery among both groups. In group PFN more duration for surgery was required (49.16 ± 6.50 min.) as compared to group PFNA2 (42.76 ± 4.50 min.) p= 0.0001. Similarly, **Mohan N.S et al** [13] showed significantly shorter surgery duration in PFNA2 (50 Minutes) as compared to PFN group (80 minutes). However, in the study done by **Mandal MA et al** [10] found that there was similar duration of surgery in both groups (49.53 min in PFNA2 group and 52.07 min in PFN group with p = 0.12.

In our study there was significantly less blood loss in PFNA2 group (2.12 ± 0.33 gauges) as compared to PFN group (3.16 ± 0.37 gauges). Mean IIT shots was significantly lesser in PFNA2 (33.92 ± 2.60) as compared to PFN (40.76 ± 3.43), p<0.0001. Average blood loss in

study done by **Mohan NS et al** [13] in PFN group was 82.67 ± 13.3 ml and in PFNA2 group was 73.33 ± 12.2 ml. **Karapinar L et al** [14] in their study average blood loss was 127 ml. Number of IIT shots in PFN group was 38.33 ± 4.71 and in PFNA2 group 34.67±2.81 Comparable with **Harshwardhn H et al.** [15]. Radiological union at 6 months in PFN group was 93.3% with average union time 16 weeks and in PFNA2 group was 100% with average union time was 14 weeks.

In PFN 10% had residual thigh pain, 6.66% had Z effect, 6.66% had screw cut out, 6.66% had malunion and 3.33% had broken implant as complications and in PFNA 2, 6.66% had residual thigh pain, 3.33% had screw cut out 6.66% had malunion and 3.33% had broken implant.

This is comparable to study done by **Kashid MR et al** [16] in PFN 50% had excellent, 20% had Very good, 10% had good and 20% had poor outcome, in PFNA 2, 60% had had excellent, 20% had Very good, 5% had good and 15% had poor outcome in the patients with 1 year follow up. **GN Kiran Kumar et al.** [17] and **Yu.W.Zhang et al** [18]. In their study, Harris hip score was excellent in 15 (35.7%), good in 18 (42.8%), fair in 6 (14.2%), poor in 3 (7.1%). This is comparable to our study.

In our study, excellent outcome was seen in 9 (36%) and in 15 (60%), good in 7 (28%) and 6 (24%), Fair in 6 (24%0 and 3 (12%) and poor outcome was seen in 3 (12%) and 1 (4%) in group PFN and PFNA2 respectively. Both groups were comparable regarding functional outcome.

In the study done by **Li M et al.** [19], Statistical analysis revealed an average operation time of 45.7 min (range, 35–110 min), average intraoperative blood loss of 115.2 mL (range, 65–430 mL), The Harris hip score was 85.6 ± 17.5 points (range, 65–100 points) and included 41 excellent cases (25.15%), 92 good cases (56.44%), 26 moderate cases (15.95%), and 4 poor cases (2.45%) for a positive outcome rate of 81.60% The patients comprised 69 men and 94 women with a mean age of 74.7 ± 13.0 years.

In our study mean time of radiological union was faster in group PFNA2 (4.66 ± 0.53 months) as compared to group PFN (4.92 ± 0.86 months). The difference between both groups was statistically insignificant, p=0.204. Similar results were found in study done by **Jungho Park et al.** [12] who observed similar time of bone union in the screw proximal femoral nail groups (3.82 months) and helical proximal nail group (3.43 months), and this was not significantly different. However, in contrary to our results **Mandal MA et al** [10] the radiological union at 6 months in PFN group was 93.3% with average union time 16 weeks and in PFNA2 group was 100% with average union time was 14 weeks that was statistically significant p<0.0001.

CONCLUSION:

From the results of our study, we can conclude that use of helical blade PFN is certainly better in unstable intertrochanteric fracture than screw PFN in terms of reduced surgery time, lesser blood loss, and lesser image shots number as compared to PFN. Once fracture union occurs, functional outcomes are comparable regardless of implant type.

The number of implant related complications however, is less when a helical blade device is used, indicating its biomechanical superiority over a dual screw design. PFNA2 has a superior performance over PFN in the setting of osteoporosis, which is attributed to compaction of cancellous bone by the helical blade. Nevertheless, no implant design, however, can make up for suboptimal reduction or suboptimal implant placement in these fractures.

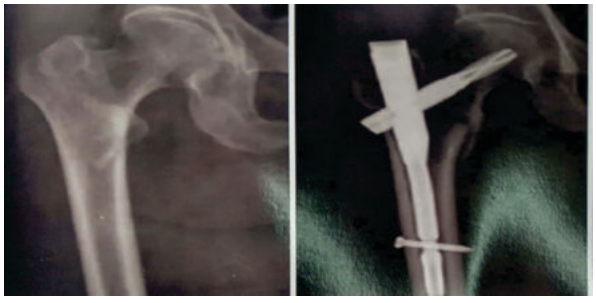

Figure 2 :Pre and post op xray of unstable intertrochanteric fracture treated with PFNA2

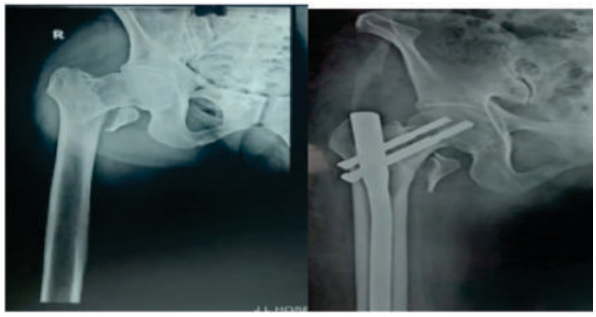

Figure 3: pre and post op xray of unstable intertrochanteric fracture treated with PFN

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