

Original Research Article

Comparative study of functional outcome of inter-trochanteric fractures in adult population treated with modified first generation proximal femoral nail versus second generation proximal femoral nail- PFN-A2

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ABSTRACT

Background: Intertrochanteric fractures are fairly prevalent in elderly, owing to osteoporosis. High velocity trauma is a common cause in younger age groups. Surgical fixation is the choice of treatment. Closed reduction being minimally invasive has lower infection rates and higher union rate. Providing early mobility lowers morbidity. Over time, there have been multiple changes in the implant design. Two screws in femoral head are used in the first generation PFN, compared to a single helical bolt in the subsequent modification i.e. PFNA2.

Methods: Prospective and comparative study was undertaken, from January 2023 to June 2024, including 52 adults (17 males and 35 females) of either sex, with intertrochanteric fracture femur. 26 patients underwent first generation PFN (group A) and 26 underwent PFNA2 (group B). Clinico-radiological evaluation was done at 6 weeks, 3-, 6- and 12-months following surgery. Functional evaluation was based on the mean Harris hip score (HHS). Post-operative pain based on VAS, early mobilization and complications were taken into consideration. Statistics was analysed with Statistical Package for The Social Sciences (IBM SPSS version 22).

Results: There was 100% union rate. The average date of mobilization in group A patient was 1.9 ± 0.8 days and in group B was 2.2 ± 0.7 days. Group A has a statistically significant higher VAS score than group B at 24 hours post-surgery. Weight bearing as tolerated was started on day 1 post surgery in all patients. The mean HHS was significantly higher in group B (71.5 ± 3.8) at 6 weeks follow-up, which on subsequent follow-ups was statistically insignificantly between the two groups. None of the patients had implant failure of any form.

Conclusions: The final outcome was statistically insignificant. There was negligible difference between the first generation PFN and PFNA2 in terms of post-operative stability and fracture union. Hence, both PFN and PFNA2 are equally suitable devices for fixation of inter-trochanteric fracture.

Keywords: Harris hip score, Inter-trochanteric fracture, PFN, PFNA2

INTRODUCTION

Intertrochanteric fractures are extracapsular fractures occurring in the proximal part of the femur at the level of the greater and the lesser trochanters.¹ Intertrochanteric

fractures are prevalent amongst geriatric age groups, owing to osteoporosis; commonly occurring due to a fall.² However, high velocity trauma to the hip can also lead to the occurrence of such type of fractures in adolescents and young adults.³ Intertrochanteric fractures accounts for

almost half of all hip fractures amongst patients aged 60 years or above encountered in practice.⁴ Patients aged 80 years or above having almost six times higher risk of suffering from an intertrochanteric fracture.^{5,6} This region of femur is similar to other fractures in the metaphyseal region with regard to the difficulty in obtaining a stable fixation. Intertrochanteric fractures can lead to significant pain, morbidity, and even mortality if left unmanaged.⁷

The current consensus is that the best treatment for the management of intertrochanteric fractures is surgery, with early closed reduction and internal fixation using an implant. One of the most commonly used such implants is the proximal femoral nail (PFN). It is an intramedullary device designed for the stabilization of peri-trochanteric femoral fractures.⁸ PFNs are biomechanically advantageous over extramedullary fixation, with respect to the stability of the fracture fixation, healing time, minimizing the stress on the fracture site and faster time for rehabilitation. However, despite these advantages, intramedullary implants have their own set of complications, such as screw cut-out, back out, Z effect, varus collapse, and rotational instability.⁹ Various modifications to the PFN designs have been made over the years, which come with their own sets of advantages as well as certain drawbacks.

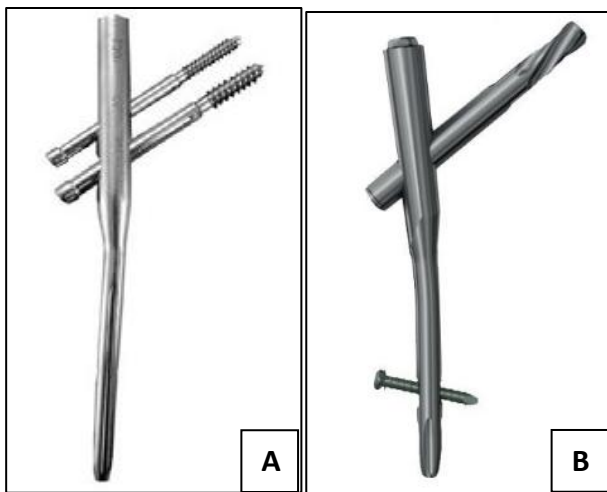


Figure 1: A) Modified first generation PFN; B) second generation PFN.

The modified first generation PFN has two (different size) proximal locking bolts that are screwed into the femoral head. This size difference is the leading cause of screw back out, owing to the Z effect and reverse Z effect. The second generation PFN (Figure B), known as the proximal femoral nail anti-rotation (PFNA2), unlike the traditional PFN has a single helical blade.¹⁰ This provides extra anchorage to the device by the preservation of the bone stock as well as the compaction of the cancellous bone around it. The twin screws that are part of the traditional PFN, although has been postulated to provide more stability, needs accurate placement of the screws, and are

therefore associated with operative difficulties and postoperative adverse events.¹¹

India has the world's largest population, and the country is currently undergoing a rapid demographic transition, characterized by a rapid increase in the proportion of population in the geriatric age group.¹² Since this age group is at the highest risk of suffering from intertrochanteric fractures, research efforts should be focused on the identification of the best modality to manage this condition.¹³ In this context, the present study was conducted to compare and contrast the closed reduction of intertrochanteric fractures using either first generation PFN or second generation PFNA2 amongst patients presenting to a tertiary care teaching hospital of West Bengal, India.

METHODS

Study type and design

The present study was an institution-based observational study with a prospective analytical design.

Study setting

This study was conducted in the department of orthopedics of the KPC Medical College and Hospital of Kolkata, West Bengal, India.

Study duration

The study was conducted from January 2023 to June 2024.

Study population

The study population consisted of adult patients of either sex undergoing closed reduction and internal fixation for intertrochanteric fracture of femur.

Sample size/design

Sample size was 52, obtained by using the formula-

Sample size calculation

$$n = \frac{(Z_{1-\frac{\alpha}{2}})^2 \cdot [p_1(1-p_1) + p_2(1-p_2)]}{d^2}$$

p_1 = proportion of patients in group 1 with implant related complications = 7/23=0.3043

p_2 = proportion of patients in group 2 with implant related complications= 1/25=0.04

$(Z_{1-\frac{\alpha}{2}})$ = upper $(\frac{\alpha}{2})\%$ point of the standard normal curve.

Here $\alpha = 0.05$ and the value of $(Z_{1-\frac{\alpha}{2}}) = 1.96$

d=absolute allowable error =0.20

n= sample size

$$\begin{aligned} \therefore n &= \frac{(1.96)^2 \times [0.3043(1-0.3043) + 0.04(1-0.04)]}{(0.2)^2} \\ &= \frac{3.8416 \times [(0.3043 \times 0.6957) + (0.04 \times 0.96)]}{0.04} \\ &= \frac{3.8416 \times [0.2117 + 0.0384]}{0.04} \\ &= \frac{3.8416 \times 0.2501}{0.04} \\ &= \frac{0.9607}{0.04} \\ &= 24.01 \end{aligned}$$

Sample size = 24 in each group

Considering a drop-out rate of 10%, final minimum required sample size will be

$$[48 + (10\% \text{ of } 48)] = 52$$

Inclusion criteria

Patients aged 18 years or above of either sex. Patients admitted to the study institution and undergoing treatment for intertrochanteric fractures of femur.

Exclusion criteria

Patients not providing written informed consent. Patients with polytrauma, open fractures, and pathological fractures. Patients unfit for surgery. Drop-outs from follow-up.

Study variables

The variables estimated as a part of the present study were:

Function, absence of deformity and range of movement (by Harris hip score). Post-operative pain, using VAS score. Intra-operative blood loss. Mobilization/day of weight-bearing. Complications, including wound dehiscence, infection, non-union, cut-out, screw migration, neurological (palsy).

Study techniques

From past records, it was observed that on an average, 10 to 15 patients with intertrochanteric fracture of femur attended the outpatient department of orthopedics/emergency department, per month. Therefore, all adult patients with intertrochanteric femur fractures, of either sex were selected, who attended the OPD/emergency department.

The complete data was collected from the patients by history taking, clinical examination and laboratory investigations, which are warranted, as per hospital protocol for obtaining pre-anaesthetic fitness.

Intra-operatively, the average blood loss (in ml) and the average duration of surgery were compared.

Post operatively, the cases were followed up for one year, at intervals of 6 weeks, 3 months, 6 months and 1 year from the day of operation. Harris hip score was calculated at each follow-up. The post-operative pain relief, post-operative mobilization day, range of movement, post-operative x-ray, clinical findings and complications (if any) were compared as well.

Statistical analysis

Data was entered in Microsoft Excel sheet after scrutiny. The tables, charts, diagrams were constructed as per our objective. In addition to that, rates, ratios, relative risk, confidence intervals, odds ratios were obtained in relation to the objective. Various statistical tools and techniques were used for significance testing, using Z, t, χ^2 , F, etc, wherever applicable. Statistics was analysed with Statistical Package for The Social Sciences (IBM SPSS version 22).

Surgical Steps

All fractures were reduced and fixed under C-arm guidance on a fracture table. We tried to achieve a positive or neutral calcar balance post reduction of the fractures and prior to fixation with the PFN.

Group A (modified first generation PFN)

Patient was positioned supine on a fracture table under spinal anaesthesia. The non-affected limb was kept out of the way, to ensure free access of the C-arm for easy AP and lateral views. The C-arm screen was placed on the opposite side of the surgeon. After fracture reduction under fluoroscopic guidance in AP and lateral views, antiseptic dressing and draping of the affected limb was performed. A 2-5cm, slightly posteriorly curved skin incision was made, just proximal to the tip of the greater trochanter. Subcutaneous tissue, fat, fascia and the gluteal muscles were cut in line with the skin incision, to expose the tip of the greater trochanter. Under fluoroscopic guidance, a bone awl was introduced, just medial to the tip of the greater trochanter in AP and approximately at the centre of the neck in lateral views. It was extended till the level of the lesser trochanter, following which a guide wire was introduced into the medullary cavity. After entry point enlargement by a proximal reamer, an appropriately sized nail was introduced (ranging from 170 to 240 millimetres in length and 8 to 12 millimetres in diameter) and its position was confirmed with the help of fluoroscopy. Through slots in the nail, two guide wires were introduced for the femoral neck screw (11 mm) and the anti-rotation

screw (6.5 mm). Sizes of the screws were measured. Appropriately sized drill bits were passed through the guide wires for reaming. The anti-rotation screw was passed first, followed by passing of the femoral neck screw. Traction was released before applying final compression. The 3.5 mm distal locking screw was given through a small incision using the guide. Finally, wash was given using normal saline and the wound was closed in layers using number 0-1 vicryl and 2-0 monofilament (Ethylon) for the skin.

Group B [second generation proximal femoral nail (PFNA2)]

Under strict aseptic conditions, the affected limb was prepared with an antiseptic solution and draped appropriately for hip surgery while the patient lay in a supine position. An incision of suitable size, ranging from 2 to 5 centimetres proximal to the tip of the greater trochanter and slightly curved posteriorly, was meticulously made. Using fluoroscopic guidance, a bone awl was positioned just medial to the tip of the greater trochanter in the anteroposterior (AP) view and approximately at the center of the neck in the lateral view. The bone awl was then introduced to create the proximal entry point, extending it until the level of the lesser trochanter. A guide-wire was carefully inserted into the medullary cavity, with its placement verified under C-arm guidance. The proximal entry point was further enlarged using a proximal reamer. The alignment of the fracture was assessed under fluoroscopy and corrected, if necessary, by appropriate instrumentation. Reaming of the medullary cavity was performed to ensure a snug fit of the nail. A nail of appropriate size (ranging from 170 to 240 millimetres in length and 8 to 12 millimetres in diameter) was inserted into the medullary cavity, attached to the guide. The longer 240 mm nail was generally avoided due to difficulties encountered in inserting it into the cavity. The position of the nail was confirmed by fluoroscopy. A 3.2-millimeter guide wire was passed through the slot in the nail via the guide and positioned 5 millimetres from the subchondral bone. The length of the helical blade was determined, which was then hammered into the femoral head, ensuring it did not penetrate the subchondral bone. Traction was released before applying compression to the fracture. The 3.5 millimetre distal cortical screw was inserted via the guide through a small incision. Finally, the wound was closed in layers using number 0-1 vicryl and 2-0 monofilament (Ethylon) for the skin.

RESULTS

It was observed that the mean time taken from injury to presentation to the study institution for group A participants was 6.6 ± 2.2 days, and that for group B participants was 6.7 ± 2.1 days. The difference between the two groups was not found to be statistically significant on analysis.

Table 1: Distribution of study participants according to their mean time taken from injury to presentation (days) (n=52).

Time taken to presentation (days)	Group A (n=26)	Group B (n=26)	P value
Mean	6.6	6.7	0.950
SD	2.2	2.1	

Table 2: Distribution of study participants according to their mean operating time (minutes) (n=52).

Operation time (minutes)	Group A (n=26)	Group B (n=26)	P value
Mean	39.6	30.1	<0.001*
SD	6.7	4.4	

*Statistically significant.

It was observed that the mean operating time for group A participants was 39.6 ± 6.7 minutes, while that for group B participants was 30.1 ± 4.4 minutes. The difference between the two groups was found to be statistically significant on analysis.

Table 3: Distribution of study participants according to their mean intraoperative blood loss (ml) (n=52).

Blood loss (ml)	Group A (n=26)	Group B (n=26)	P value
Mean	88.1	73.5	<0.001*
SD	11.2	12.7	

*Statistically significant.

It was observed that the mean blood loss in participants of group A was 88.1 ± 11.2 ml and for group B was 73.5 ± 12.7 ml. The difference between the two groups was statistically significant on analysis.

Table 4: Distribution of study participants according to their mean visual analogue scale (VAS) scores at 0, 24, and 48 hours postoperatively (n=52).

VAS score (mean $\pm$ SD)	Group A (n=26)	Group B (n=26)	P value
0 hour	1.2 ± 0.4	1 ± 0.8	0.462
24 hours	4.3 ± 1.2	3.9 ± 1.1	0.028
48 hours	3.9 ± 1.4	3.6 ± 1.3	0.703

It was observed that the group A participants had statistically significantly higher VAS score at 24 hours postoperative period than their group B counterparts. However, at 48 hours, there was no significant differences between the VAS score in the two study groups.

It was observed that the mean time taken for group A participants for mobilization was 1.9 ± 0.8 days, while that for group B participants was 2.2 ± 0.7 days. The difference was however, not found to be statistically significant on analysis.

Table 5: Distribution of study participants according to their mean time for mobilization (days) (n=52).

Time for mobilization (days)	Group A (n=26)	Group B (n=26)	P value
Mean	1.9	2.2	0.282
SD	0.8	0.7	

Table 6: Distribution of study participants according to their mean total hospital stay (days) (n=52).

Hospital stay (days)	Group A (n=26)	Group B (n=26)	P value
Mean	8.8	7.9	0.044
SD	1.6	1.9	

It was observed that the mean total hospital stay for group A participants was 8.8 ± 1.5 days, while that for group B participants was 7.9 ± 1.9 days. The difference between the two study groups was statistically significant on analysis (p value 0.044).

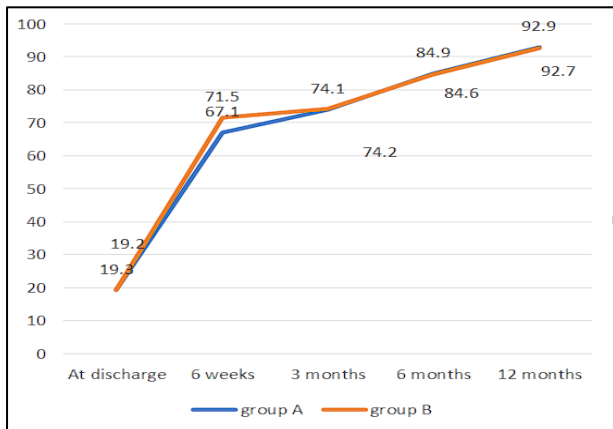


Figure 2: Distribution of study participants according to their mean Harris hip score scores at discharge, 6 weeks, 3 months, 6 months, and 12 months postoperatively (n=52).

It was observed that the mean Harris hip score of the group B participants was statistically significantly higher than the group A participants at 6 weeks of observation. During the other periods of observation, the difference in HHS between the two groups was not found to be statistically significant.

It was observed that the mean time taken for partial weight bearing in the group A participants was 5.2 ± 0.8 weeks and that of the group B participants was 7.2 ± 0.8 weeks, a difference which was statistically significant on analysis. On the other hand, the time taken for complete weight bearing for the group A and group B participants was 12.2 ± 1.1 weeks and 12.5 ± 1.1 weeks respectively, a difference that was not statistically significant on analysis.

Table 8: Distribution of study participants according to their mean time taken for partial and complete weight bearing (weeks) (n=52).

Time to weight bearing (mean $\pm$ SD)	Group A (n=26)	Group B (n=26)	P value
Partial	5.2 ± 0.8	7.2 ± 0.8	<0.001
Complete	12.2 ± 1.1	12.5 ± 1.1	0.254

Table 9: Distribution of study participants according to their incidence of callus formation at 12 months postoperative (n=52).

Callus formation	Group A (%)	Group B (%)	P value
Yes	26 (100)	26 (100)	1.000
No	0 (0)	0 (0)	
Total	26 (100)	26 (100)	

It was observed that all of the group A and group B participants had callus formation at 12 months of observation. This difference was not found to be statistically significant.

DISCUSSION

Two groups of 26 patients each undertook the present study, being divided into group A and group B. The mean age was closely matched between the groups, with group A presenting a mean age of 79.1 years, characterized by a standard deviation of 2.8 years, while group B reported a mean age of 79.3 years, with a slightly higher standard deviation of 3.8 years.¹⁴⁻¹⁶

Group A had a mean presentation time of 6.6 ± 2.2 days, while Group B reported a slightly higher mean of 6.7 ± 2.1 days (Table 1).

One of the crucial metrics evaluated in the present study was the operating time required for each surgical procedure. The results demonstrated a significant difference in the mean operating times; group A had a mean operating time of 39.6 ± 6.7 minutes, whereas group B had a substantially shorter duration of 30.1 ± 4.4 minutes (p value <0.001). Shorter operating times, as seen with the PFN-A2 group, are generally preferred in orthopedic surgeries as they can potentially reduce the risk of perioperative complications such as infections and blood loss (Table 2).

Regarding the intraoperative blood loss in the patients (Table 3), it was observed that group A experienced a mean blood loss of 88.1 ± 11.2 ml, whereas group B had significantly less, averaging 73.5 ± 12.7 ml. This difference was statistically significant (p value <0.001).²⁸

Another key aspect explored in the present study was the postoperative pain experienced by patients, as measured by the visual analogue scale (VAS). The findings demonstrated that immediately postoperatively, participants in group A reported a similar VAS score (mean 1.2 ± 0.4) compared to those in group B (mean 1 ± 0.8). At 24 hours and 48 hours post-surgery, the VAS scores were 4.3 ± 1.2 versus 3.9 ± 1.1 and 3.9 ± 1.4 versus 3.6 ± 1.3 , in group A versus group B respectively (Table 4). However, the difference between VAS scores at 48 hours showed no significant differences between groups.

In the present study, one of the objectives was to compare the mean time to mobilization between the two groups. Mean time to mobilization is a critical factor in the recovery process as early mobilization is associated with reduced complications like deep vein thrombosis and pulmonary embolism, and can facilitate quicker recovery of function. The findings indicated that group A participants began mobilizing at a mean of 1.9 ± 0.8 days post-surgery, whereas group B participants took slightly longer, with a mean of 2.2 ± 0.7 days. Despite the apparent difference in mobilization times, the statistical analysis revealed that this difference was not significant (p value > 0.05) (Table 5).

It was seen that group A participants had a mean hospital stay of 8.8 ± 1.5 days. In contrast, group B participants, who were treated with the newer PFNA-2, had a shorter mean stay of 7.9 ± 1.9 days (Table 6). Shorter hospitalizations can lead to significant cost savings for healthcare systems and reduce the burden on hospital resources, which is especially pertinent in high-volume surgical centers.²⁹ Moreover, a shorter stay in the hospital typically correlates with a faster return to normal life for patients, which is a critical outcome measure in the elderly population prone to intertrochanteric fractures.³⁰

Initial observations at 6 weeks post-surgery indicated that group B participants, those treated with PFNA-2, had a statistically significantly higher mean Harris Hip Score compared to group A. This early outcome suggests that PFNA-2 might offer advantages in terms of quicker early recovery in hip function or reduced pain levels, which are significant factors in the rehabilitation of elderly patients following hip fractures. However, as the observation period extended to 3, 6, and 12 months, the Harris hip scores in group B remained higher than those in group A, but these differences were not statistically significant (Figure 2).

The results further indicated a notable difference in the time taken for partial weight-bearing between the two groups. Participants in group A, treated with first generation PFN, achieved partial weight-bearing at an average of 5.2 ± 0.8 weeks post-surgery. In contrast, those in Group B, who received PFNA-2, took significantly longer, with an average of 7.2 ± 0.8 weeks (Table 8). This statistically significant difference (p value < 0.001) suggests that first generation PFN may allow for a quicker

transition to partial weight-bearing, which is an essential step in the rehabilitation process. Earlier partial weight-bearing can be crucial for reducing the risks associated with prolonged immobility, such as muscle atrophy and the potential for deep vein thrombosis.³¹

Regarding the outcomes of the surgery in the patients, it was seen that over a 6-month observation period, callus formation- an indicator of bone healing- was noted in 84.6% of participants in group A and 76.9% of those in group B. This difference in early callus formation, while suggesting a slight advantage for first generation PFN in terms of early bone healing, was not statistically significant, indicating that both devices are comparably effective over time. By the 12-month follow-up, all participants in both groups had demonstrated callus formation, confirming that both first generation PFN and PFNA-2 ultimately provide effective structural support for bone healing, irrespective of the initial differences at the 6-month mark (Table 8).

CONCLUSION

Our study aimed to evaluate the clinical and surgical outcomes of modified first generation PFN and PFNA-2 in treating intertrochanteric fractures in two groups of Indian adults, revealing that both devices are effective but have different advantages. Demographic characteristics such as age, gender, side of injury, and comorbid conditions like hypertension, diabetes, and hypothyroidism were similarly distributed between the two groups, ensuring that the outcome differences were attributable to the devices rather than patient characteristics. Statistically significant findings included shorter operating times and reduced blood loss with PFNA-2. This suggests that PFNA-2 may enhance surgical efficiency and reduce perioperative morbidity. Although PFNA-2 led to a quicker reduction in immediate postoperative pain, the scores leveled between the groups after 24 and 48 hours. Group B (PFNA-2) showed a statistically significant faster return to partial weight-bearing, although both devices supported a similar timeline for full weight-bearing.

Despite the initial rapid recovery with PFNA-2, long-term outcomes such as callus formation at 12 months and the Harris hip score beyond the initial 6 weeks showed no significant differences, indicating that both devices are comparable in facilitating long-term bone healing and functional recovery. The similar rates of complications, including non-significant differences in infection rates, further support the conclusion that both PFNA and PFNA-2 are safe and effective, with PFNA-2 providing some advantages in surgical efficiency and early post-operative recovery.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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