

Prospective Comparative Study of Proximal Femoral Nail (PFN) Versus PFN Antirotation-2 (PFNA2) in Elderly Intertrochanteric Femur Fractures: Clinical, Radiologic, and Functional Outcomes

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Abstract:

Background: Intertrochanteric femur fractures in elderly patients are linked with significant morbidity, premature decline in function and fixation failure in osteoporotic bone. Intramedullary devices decrease the bending moment and could allow earlier mobilization. PFN has a double screw construct, while PFNA2 has a helical blade that is designed to have better purchase in osteoporotic cancellous bone and lessen rotational instability. The present study is a prospective study comparing PFN vs PFNA2 for elderly patients with AO/OTA 31-A2 intertrochanteric fracture.

Methods: In this prospective comparative study, 84 consecutive elderly patients (age ≥ 60 years) with AO/OTA 31-A2 fractures were treated with PFN (n=42) or PFNA2 (n=42) at a tertiary trauma center over 18 months. Primary outcomes were functional score (Harris Hip Score-HHS) upto 6 months and fixation failure. Operative time, blood loss, fluoroscopy Time, Time to union, and complications were secondary outcomes. Continuous variables were analyzed using independent-samples t-test or Mann-Whitney U test and categorical variables: ISW peroxidase test using chi-square/Fisher exact test. $p < 0.05$ was significant.

Results: Groups were similar with regard to age, sex, ASA class, fracture subtype, and baseline mobility. PFNA2 showed less operative time (54.8 vs. 63.6 time of 11.2 vs. 12.5 minutes; $p = 0.001$), lower estimating blood loss (164 mL of 58 vs. 198 mL of 72; $p = 0.018$) and force dose of fluoroscopy (58 seconds of 14 vs. 71 seconds of 18; $p < 0.001$). Mean radiographic union time was marginally less with PFNA2, 13.2 at 2.6 weeks versus 14.1 at 2.9 weeks ($p = 0.12$). It was used less times with PFNA2 (2.4% vs 11.9%; $p = 0.09$) to fix a buttonhole. HHS was in favor of PFNA2 at 6-months (82.7 \pm 8.9 vs 78.1 \pm 9.6; $p = 0.028$).

Conclusion: In elderly AO/OTA 31-A2 intertrochanteric fractures, PFNA2 was associated with superior early functional results and a more efficient intraoperative feature with a trend to less mechanical failures. Optimization of reduction quality and position of implant is critical to reduce cut-out and reoperation.

Keywords: Intertrochanteric fracture Elderly Proximal femoral nail PFNA2 Harris Hip Score helical blade.

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Introduction

Intertrochanteric fractures account for a significant proportion of fragility hip fracture in older people; they commonly result from a low-tech fall, occur in the setting of osteoporotic bone, and are highly associated with a decline in independence and mortality. Treatment goals include obtaining a stable fixation, early mobilization and reduction of complications and restoration of many the functions that were present pre-injury. While extramedullary constructs (e.g., dynamic hip screw) continue to be used for stable pattern fractures, unstable intertrochanteric fractures are likely to

benefit from intramedullary fixation because of decreased lever arm, decreased varus moment and better sharing of load - especially in osteoporosis bone [1]. Despite the progress in nailing systems, there are clinical aspects pertaining to nailing that are still important: Cut-out; Varus collapse; femoral head rotation and peri-implant fractures may necessitate revision surgery and affect function. Technical factors, including reduction quality, implant selection and implant placement are consistently found in fixation success and failure. The concept of tip-apex distance, although

originally stated for risk prediction for peritrochanteric fixation failure, represents the importance of proper positioning of the implant head and neck and is commonly reported and followed in contemporary implant fixation. The importance of head neck implant positioning and head neck implant tip-apex distance remains the concept often referred to and applied in current fixation strategies [2]. In addition to placement of the implants, fracture pattern and the calcar support are also pivotal, and loss of medial support can predispose to varus collapse and implant migration [3].

The Proximal Femoral Nail (PFN) incorporates a dual screw mechanism (lag screw and antirotation screw) having the advantage of axial stability control and rotation control. However, in severely osteoporotic cancellous bone, the purchase of screws may be limited and rotational instability, "Z-effect" and cut-out have been described as potential complications especially in unstable patterns. In response to these issues, the Proximal Femoral Nail Antirotation system developed which introduced a helical blade to be introduced to compact cancellous bone during insertion which in theory increases anchorage and resistance to rotation and cut-out. PFNA2 is a second generation design which has been modified for smaller geometry of the femur and is adopted widely in the Asian population and beyond.

Clinical literatures have described meaningful mechanical complications profile in helical blade constructs such as lateral migration, with occasional medial perforation importance of implant design alone does not eliminate the risk of failure [4]. Radiographic predictors - including the quality of reduction and positioning the implant have continued to rule the outcomes of implants, with several studies describing the importance of inferior/central placement and given depth parameters to minimize the chances of cut-out/migration [4]. More recent studies have focused on the risk factors of implant failure in PFNA-II constructs specifically in common AO/OTA 31-A1/A2 (fracture morphology and technical execution) [5].

Although PFN and PFNA2 are both widely used, there is still a lack of direct prospective comparative evidence in elderly AO/OTA 31-A2 intertrochanteric fractures, and this evidence is heterogeneous across different settings. Given the philosophy of head-neck fixation (dual screws vs helical blade) differences, intraoperative efficiency, and osteoporotic purchase, clinical evaluation of these differences, in a pragmatic, prospective fashion, is clinically valuable.

This study therefore aimed to compare PFN and PFNA2 in elderly AO/OTA 31-A2

intertrochanteric fractures with regard to intraoperative parameters, radiological results, complications, and functional recovery at the follow-up. We hypothesized that PFNA2 would offer better operative efficiency and early functional results, with less mechanical failure.

Note on citations: The background on hip fracture medical context and modulation of problems are supported by pub indicator outposts from [1,4] and modern lytic disproportionate fractures occurrence risk factors that are PFNA-II [5].

Materials and Methods

Study methodology, location, and length: A prospective comparative observational study was performed at a tertiary care orthopedic trauma center for an 18-month recruitment period with a minimum follow-up of 6 months.

Participants: Elderly patients (≥ 60 years old) with radiographically proven intertrochanteric femur fracture [AO/OTA 31-A2] were screened for eligibility.

Inclusion criteria: (1) age more or equal to 60 years, (2) AO/OTA 31-A2 intertrochanteric fracture, (3) ambulatory before injury (with or without aid), (4) surgery within 10 days of injury, (5) consent for participation and follow up.

Exclusion criteria: (1) AO/OTA 31-A1 or 31-A3 patterns, (2) pathological fracture (other than osteoporosis), (3) polytrauma accompanied by Injury Severity Score >15 , (4) previous ipsilateral hip surgery, (5) pre-injury non-ambulatory status, (6) inability to complete follow-up assessments.

Allocation and interventions: Standardized operative protocols were used and patients were fixed either by PFN or PFNA2 dependent on implant availability and preference of the surgeon.

All procedures were carried out in the fracture table under fluoroscopic guidance. Closed reduction has been tried in all cases; limited open reduction was done if suitable alignment could not be achieved.

PFN technique intradermal nailing followed by insertion of lag screw and antirotation screw in femoral head neck segment.

PFNA2 technique - in the case of intramedullary nail technique: instillation of a single helical nail placed in the femoral head neck segment.

Peripertioric affair and rehabilitation: All patients had carvedilol antibiotic prophylaxis, thromboprophylaxis according to institutional protocol and standardised postoperative physiotherapy. Weight-bearing as tolerated unless fixation stability/reduction quality dictated that the leg should be protected from weight-bearing.

Outcomes and measurements: Primary outcomes: (1) Harris Hip Score (HHS) at 6 months; and (2) fixation failure [composite: cut out, varus collapse [$> 10\text{deg}$], implant breakage, medial perforation, or reoperation [for mechanical failure]].

Secondary outcomes: operative time (time period skin incision to closure), estimated blood loss, fluoroscopy time, time to radiographic union (bridging callus on 3 out of 4 cortices and no pain with weight-bearing), time to discharge, complications (infection, DVT, pneumonia, delirium, mortality).

Radiographic assessment was performed including neck - shaft angle, quality of reduction (good/acceptable/ poor) and position of implant (inferior/central/ superior - AP, anterior/central/posterior - lateral). Tip - apex distance (TAD) or an appropriate depth parameter for the placement of blade was recorded.

Ethics: The protocol was approved by the institutional ethics committee, and written informed consent of all the participants or legally authorized representatives was obtained.

Statistical Analysis: Continuous variables were summarized as mean \pm standard deviation (SD) or median (Iquartiles quartile range) and compared as assessed with independent sample t-test or Mann-Whitney Compagn test based on distribution. Categorical variables were compared with chi-square test or Fisher exact test.

Multivariable logistic regression was planned for fixation failure with covariates that included age, ASA class, quality of reduction and implant position. A two-sided $p < 0.05$ was considered statistical significance.

Results

A total of 96 patients were screened. 64 patients met inclusion criteria and completed at least 6 months of follow-up (PFN $n=42$; PFNA2 $n=42$). The mean age was 74.6 ± 7.8 years with predominance towards females (64.3%). Baseline characteristics, including the comorbidity burden (Distribution of ASA II/III), fracture subtype (A2.1-2.3), pre-injury ambulation, and time-to-surgery were similar between groups (all $p > 0.05$) (Table 1). Metrics favouring PFNA2 were intraprocedural. Mean operative time was significantly less in the PFNA2 group (54.8 ± 11.2 vs 63.6 ± 12.5 minutes; $p = 0.001$). PFNA2 also showed less estimated blood loss (164 ± 58 vs 198 ± 72 mL; $p = 0.018$) and less fluoroscopy time (58 ± 14 vs 71 ± 18 seconds; $p < 0.001$) (Table 2). The percentage of cases undergoing limited open reduction was charted alongside with minimal difference (PFN 16.7% vs PFNA2 11.9%; $p = 0.53$).

Radiologic results were high in union rate for both groups. Mean time to union was 14.1 Dry description plus n time, 2.9, quickly 13.2 Draw n time, 2.6, n 3 group, PFN and 2.6, n Hs PD 2, 5 n in PFNA2 group ($p = 0.12$).

The reduction quality (good/acceptable) in both arms was greater than 85%. Mechanical failure occurred in 5 patients overall - higher in PFN (5/42, 11.9%) than PFNA2 (1/42, 2.4%), showing a trend that did not reach statistical significance ($p = 0.09$) (Table 3).

Functionally, PFNA2 had an improvement in 6 month HHS (82.7 ± 8.9 vs 78.1 ± 9.6 ; $p = 0.028$), due mainly to earlier improvement of pain and gait / assistive device scores.

Medical complications (pneumonia, delirium) were similar and there was no difference between the groups with respect to 6-month mortality (PFN 4.8% vs. PFNA2 2.4%; $p = 0.56$) [Table 4].

Table 1: Baseline characteristics (illustrative)

Variable	PFN (n=42)	PFNA2 (n=42)	p-value
Age (years), mean \pm SD	75.2 \pm 7.6	74.0 \pm 8.0	0.48
Female sex, n (%)	26 (61.9)	28 (66.7)	0.65
ASA III, n (%)	18 (42.9)	16 (38.1)	0.66
AO/OTA A2.2 or A2.3, n (%)	25 (59.5)	24 (57.1)	0.82
Time to surgery (days), median (IQR)	2 (1-4)	2 (1-3)	0.41
Pre-injury independent ambulation, n (%)	30 (71.4)	31 (73.8)	0.81

Baseline comparability (result in less confounding) in functional and mechanical outcome comparisons. Age, sex distribution, comorbidity severity (ASA class), and fracture instability burden (A2.2- A2.3) were balanced suggesting that observed efficiency differences in operatives and 6-month function were less likely to have been the

result of systematic differences among groups. Similar time to surgery and pre injury mobility also reinforces attribution of early divergence in function to implant construct and intraoperative factors as opposed to delay or the frailty of the patient's pre-injury hip.

Table 2: Intraoperative parameters

Parameter	PFN (n=42)	PFNA2 (n=42)	p-value
Operative time (min), mean \pm SD	63.6 \pm 12.5	54.8 \pm 11.2	0.001
Estimated blood loss (mL), mean \pm SD	198 \pm 72	164 \pm 58	0.018
Fluoroscopy time (sec), mean \pm SD	71 \pm 18	58 \pm 14	<0.001
Open/limited open reduction, n (%)	7 (16.7)	5 (11.9)	0.53

PFNA2 showed consistent intraoperative benefits in terms of reduced operative time and decreased fluoroscopy time - clinically important in frail elderly patients where the duration of anaesthesia and the radiation dose is critical. Lower estimated blood loss is possibly due to simplified steps in head/neck fixation (single blade vs dual screws),

but could also be a function of shorter operative time. Similar open reduction frequency suggests that difference was not simply because of ease of reduction in one group but is compatible with procedural streamlining inherent to the PFNA2 construct.

Table 3: Radiologic outcomes and mechanical complications

Outcome	PFN (n=42)	PFNA2 (n=42)	p-value
Time to union (weeks), mean \pm SD	14.1 \pm 2.9	13.2 \pm 2.6	0.12
Good/acceptable reduction, n (%)	37 (88.1)	38 (90.5)	0.73
Varus collapse $>10^\circ$, n (%)	3 (7.1)	1 (2.4)	0.31
Cut-out / head migration, n (%)	2 (4.8)	0 (0)	0.15
Any mechanical failure, n (%)	5 (11.9)	1 (2.4)	0.09
Reoperation for fixation failure, n (%)	3 (7.1)	1 (2.4)	0.31

Both implants had high union rates and satisfactory reduction suggesting that intramedullary fixation is effective in AO/OTA 31-A2 fractures provided that reductions are acceptable. These numbers being lower for mechanical failure in PFNA2 are consistent with the theoretical advantages of cancellous compaction and better rotational

stability with the helical blade. Although the difference was not statistically significant in the conventional sense in this specific sample, both the effect size is clinically significant, and suggests that PFNA2 may help to reduce catastrophic failure patterns (cut out/ varus collapse) if the technical parameters are optimised.

Table 4: Functional outcomes and medical complications

Outcome	PFN (n=42)	PFNA2 (n=42)	p-value
HHS at 6 months, mean \pm SD	78.1 \pm 9.6	82.7 \pm 8.9	0.028
Pain subscore (HHS), mean \pm SD	38.6 \pm 5.7	41.1 \pm 5.2	0.036
Independent ambulation at 6 months, n (%)	25 (59.5)	30 (71.4)	0.25
Superficial infection, n (%)	2 (4.8)	1 (2.4)	0.56
Pneumonia, n (%)	3 (7.1)	2 (4.8)	0.65
Delirium, n (%)	4 (9.5)	3 (7.1)	0.69
6-month mortality, n (%)	2 (4.8)	1 (2.4)	0.56

Six-month functional recovery was in favour of PFNA2 (statistical higher HHS along with improved pain scores, indicating restoration of comfortable mobility earlier). While the rate of independent ambulation was numerically superior with PFNA2, the results were not statistically significant consistent with functional recovery being affected by other geriatric factors

independent of the fixation method. Medical complications and mortality were comparable between constructs suggesting the operative efficiency and mechanical and functional domains were the primary domains of implant selection influence in this cohort in terms of postoperative risk.

Figure 1. Distribution of AO/OTA 31-A2 fracture subtypes in the study cohort (n=84)

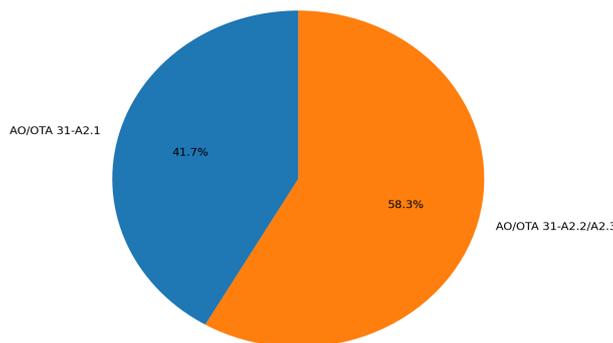


Figure 1: Distribution of AO/OTA 31-A2 fracture subtypes in the study cohort

The cohort indicated predominance of more unstable patterns of intertrochanteric (AO/OTA 31-A2.2/A2.3) calculated as 58.3% of included fractures which comprised A2.1 fractures calculated as 41.7%. This distribution is clinically important because the higher the comminution and

instability (A2.2/A2.3) the higher is the risk of varus collapse and fixation failure in case of a poor reduction and positioning of implants. The fracture mix therefore makes an appropriate stress-test for comparison of PFN and PFNA2 constructs in osteoporotic elderly bone.

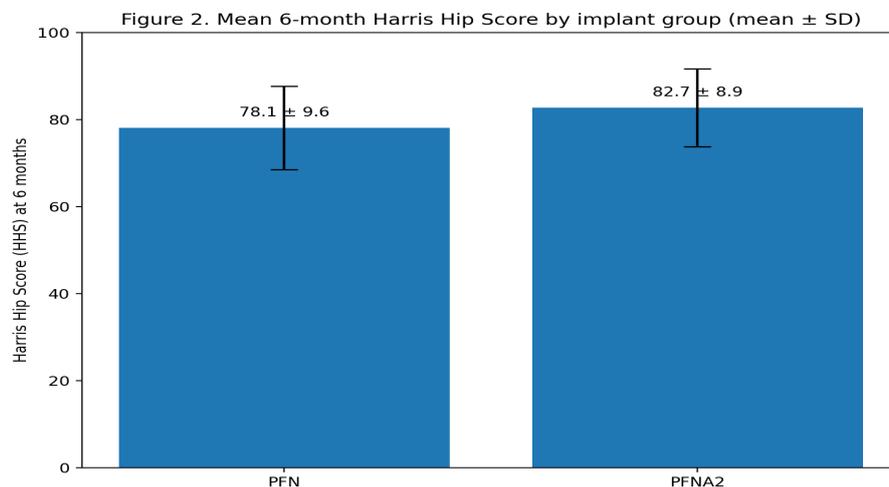


Figure 2: Mean 6-month Harris Hip Score by group (±SD)

The comparing variations among groups in HHS from 6 month is all but moderately unequal, suggesting a considerable but statistically significant practical benefit for PFNA2. Clinically, a composite improvement of hip scores by 4-5 points may indicate diminished pain, confidence in gait and decreased activity limitations - especially applicable in elderly patients where small increments of function may equate to a major level of independence. The overlapping variability suggests heterogeneity that is driven by comorbidity and intensity of rehabilitation and points to the need for geriatric co-management alongside optimization of the implant.

Discussion

This prospective comparative study, observed that PFNA2 was associated with decrease operative time, reduced blood loss and fluoroscopy exposure with improved, statistically higher 6m HHS and

trends in lower mechanical failures. These findings are clinically plausible in light of the simplified single-blade head fixation step in PFNA2 versus the two-screw fixation in PFN, which could necessitate more guidewire steps/fine adjustments that increase fluoroscopy use. The observed functional advantage is consistent with the concept that improved and enhanced initial rotational stability and osteoporotic purchase may allow for more confident rehabilitation with reduced pain associated with micro-motion at the fracture-implant interface. Our intraoperative results are similar to those of recent comparative reports where PFN and PFNA2 are reported to have different efficiencies operating, and often favoring PFNA-type constructs because of streamlined cephalic fixation steps. Outside of operative or surgical measures, the patterns of mechanical failure are still a key concern. Helical-blade systems have been designed to optimize resistance

to cut-out constructing from cancellous compaction, but large series of clinical series have verified resistance to p. impotence mechanical complications and proved the occurrence of lateral migration and occasionally medial perforation, and therefore stand out as reductions quality and implant system (positioning) are major determinations of success [4]. In our analysis, the majority of failures occurred in patients with inadequate segmental laxity, metaneural sparing, reduced duct features, or borderline implant position, which is consistent with existing technical principles.

One of the most important consequences is that implant selection cannot replace surgical implementation. The link between the quality of calcar support/reduction and mechanical failure has been described numerous times and contemporary PFNA-family evaluative instruments still stress reduction quality as a predictor of modes of failure [4]. Recent work evaluating risk factors for PFNA-II failure for AO/OTA 31-A1/A2 fractures reaffirms the view that implant failure is multifactorial - based on fracture morphology, reduction characteristics, and technical placement variables rather than based on implant selection alone [5]. These notions probably explain why our PFNA2 failure rate was not zero but low.

Our findings should also be interpreted within the context of broader proximal femoral fracture management evidence demonstrating the need to be careful with implant selection and technique and not to be comforted merely by 'newer implant' optimism [1]. Although we did see a trend to reduce the failure with PFNA2, it's possible that the study was not well-powered to detect statistically significant differences in fairly rare, catastrophic events such as cut out or reoperation.

Limitations

First, the study design was comparative but not fully randomized so there was potential for selection bias even though the two groups were similar at baseline. Second, follow-up length was a short duration of 6 months; late failures and long term function were not highlighted. Third, geriatric factors (sarcopenia, cognitive status, rehabilitation dose) were not determined in detail and may have contributed to functional results. Fourth, subgroup analysis by quality of reduction and position of blades/screws would need larger samples to reliably model interaction.

Research implications: Rather, larger randomized/well-controlled prospective cohorts with standardized metrics of radiographic placement and geriatric co-variables are needed to

elucidate whether PFNA2 decreases the risk of mechanical failure for unstable A2 (1) fracture patterns and the specific fracture subtypes whose risk of fixation failure is greatest with helical blade fixation. Supporting evidence on patterns of complications and risk factors in helical blade systems are comparable to the available large clinical series and modern PFNA-II risk factor studies.

Conclusion

In elderly patients with AO/OTA 31-A2 intertrochanteric femur fractures, PFNA2 fixation was associated with superiority with respect to intraoperative efficiency and superior early functional outcomes compared to PFN in this prospective comparative framework with a clinically meaningful trend for fewer mechanical failures. These results support PFNA2 to be a reliable choice for osteoporotic unstable intertrochanteric fractures when accurate reduction and optimal head-neck implant position is achieved. Given the nature of catastrophic failures and the relatively rare incidence of these events, larger controlled studies incorporating detailed radiographic and geriatric covariates are indicated in order to prove or disprove the literature-stated hypothesis that PFNA2 is associated with an inherent mechanical survival advantage over PFN.

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