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A RANDOMIZED CONTROL STUDY TO EVALUATE OUTCOME OF PROXIMAL FEMORAL NAIL VERSUS PROXIMAL FEMORAL NAIL A2 IN INTERTROCHANTERIC FRACTURES

Orthopaedics

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ABSTRACT

Background: Unstable intertrochanteric fractures are common in the elderly, often requiring surgical management for optimal outcomes. Proximal Femoral Nailing (PFN) and Proximal Femoral Nailing Anti-rotation for Asia (PFNA2) are two commonly used implants. This study aims to compare their effectiveness in terms of surgical parameters, functional outcomes, and complications. **Methods:** A randomized comparative study was conducted on 70 patients with unstable intertrochanteric fractures (Boyd & Griffin types III and IV) at a single center. Patients were randomly allocated into PFN and PFNA2 groups, with 35 patients in each. Outcomes assessed over six months included surgical parameters (operative time, blood loss, and hospital stay), functional outcomes (lower extremity functional score and range of motion), and complications. **Results:** PFNA2 demonstrated significantly shorter operative time (56.4 vs. 112.3 minutes; $p<0.01$), lower blood loss (82.1 vs. 190.6 mL; $p<0.01$), and shorter hospital stay (5.9 vs. 6.6 days; $p=0.021$). Functional outcomes, including lower extremity functional scores and time to weight-bearing, were comparable between groups. However, the overall complication rate was significantly lower with PFNA2 (5.7% vs. 25.7%; $p=0.045$). Implant-related issues such as loosening and re-operations were more common with PFN. **Conclusions:** PFNA2 is superior to PFN in terms of operative efficiency and safety, making it a preferred choice for managing unstable intertrochanteric fractures, particularly in elderly osteoporotic patients. Functional outcomes were comparable, but the reduced complication rate with PFNA2 supports its use.

KEYWORDS

Unstable intertrochanteric fractures, Proximal femoral nail, PFNA2, Elderly fractures, Randomized comparative study

INTRODUCTION

The hip joint is a critical weight-bearing structure essential for mobility and stability. Among various types of hip fractures, intertrochanteric fractures are particularly significant due to their high prevalence and profound impact on the aging population. These fractures account for approximately 50% of all proximal femoral fractures, with an estimated annual global incidence of 150,000 cases. The incidence rates are 63 and 34 per 100,000 population per year for elderly females and males, respectively. [1] The number of hip fractures is expected to reach 6 million worldwide by 2050, with 70% occurring in Asia, Latin America, the Middle East, and Africa [2,3,4]. Elderly females are disproportionately affected, with a female-to-male ratio ranging from 2:1 to 8:1, attributed to postmenopausal bone metabolism changes [5].

Intertrochanteric fractures are broadly categorized as stable or unstable, with unstable fractures posing significant challenges in achieving anatomical reduction and functional recovery.[6] Conservative management, though rarely indicated, is associated with high mortality rates and complications, such as malunion, respiratory infections, pressure sores, and deep venous thrombosis, which advocate for surgical intervention [7]. Internal fixation with devices like the Proximal Femoral Nail (PFN) has shown benefits, including reduced operative blood loss, faster recovery, and better long-term outcomes due to its biomechanical alignment closer to the femoral axis [8].

Recent advancements have introduced the Proximal Femoral Nail Anti-Rotation 2 (PFNA2), which is designed with a proximal angulation of 5° to suit smaller femurs, commonly seen in Asian populations. Its helical blade mechanism enhances cancellous bone compaction and rotational stability, reducing the load on the femoral head [9]. However, while PFNA2 shows promise, comprehensive comparative studies are lacking, and large-scale trials are needed to establish its superiority over PFN in managing unstable intertrochanteric fractures.

This randomized controlled study aims to bridge this gap by comparing the functional outcomes and complication rates between PFN and PFNA2. The results will provide critical insights into the relative efficacy of these devices, contributing to evidence-based advancements in the surgical management of intertrochanteric fractures.

MATERIAL AND METHODS

This randomized controlled study was conducted in the Department of Orthopaedics, Swami Dayanand Hospital, Dilshad Garden, New Delhi, from May 2022 to May 2023. The study included patients of both genders admitted with unstable intertrochanteric fractures classified as Boyd & Griffin type III and IV. The objective was to evaluate and compare the outcomes of Proximal Femoral Nail (PFN) and Proximal Femoral Nail Anti-Rotation 2 (PFNA2) in these fractures.

Sample Size and Randomization

Based on the prevalence of excellent to good outcomes for PFN (71%) and PFNA2 (83%) as reported by Sharma A et al., the sample size was calculated as 70 patients. They were randomly divided into two equal groups of 35 each using computer-generated random numbers.

Inclusion And Exclusion Criteria

Patients aged 18 years or older, fit for surgery, and presenting with unstable intertrochanteric fractures (Boyd & Griffin type III and IV) were included. Patients with compound fractures, stable fractures (Boyd & Griffin type I and II), neuromuscular diseases, unfit for surgery, or unwilling to consent were excluded.

Methodology

Patients underwent clinical evaluation and X-rays (pelvis AP and lateral views) for fracture assessment. Skin traction was applied for initial stabilization. Preoperative investigations included blood tests, urine analysis, and, for patients over 40 years, ECG, chest X-ray, and serological tests (HIV, HBsAg).

Fractures were reduced on a fracture table using closed methods under image intensifier guidance, ensuring alignment and rotational stability. Two intramedullary devices, PFN and PFNA2, were used based on group allocation. Preoperative antibiotics were administered 30 minutes before surgery and continued postoperatively for 24–48 hours.

Postoperative Care

Patients were mobilized early, with non-weight-bearing exercises initiated on the second postoperative day. Weight-bearing was gradually introduced based on fracture stability and fixation adequacy. Sutures were removed after 10–14 days.

Follow-Up And Outcome Assessment

Patients were followed at 1 week, 6 weeks, 3 months, and 6 months.

Functional outcomes were assessed using the Lower Extremity Functional Scale (LEFS), focusing on wound healing, range of motion, weight-bearing ability, and complications such as infection, implant failure, non-union, malunion, and limb length discrepancy.

Statistical Analysis

Data were analyzed using SPSS v21. Qualitative variables were assessed with Chi-Square and Fisher's exact tests, while quantitative data were analyzed using ANOVA and unpaired t-tests. Results with a $p<0.05$ were considered statistically significant. Visual representations were prepared using Microsoft Excel 2021.

RESULTS

Table 1 shows the demographic and clinical characteristics of the study groups (PFN and PFNA2). The average age of participants was comparable between groups. Females comprised a higher proportion in both groups, with slightly more in the PFNA2 group. Most fractures were of Boyd & Griffin Type III. The primary mode of injury was trivial falls, followed by road traffic accidents. Diabetes and hypertension were the most common systemic comorbidities, with a significant portion of patients having both conditions.

Table 1: Demographic And Clinical Characteristics

	Variables	PFN	PFNA2	Total
Age	Age (Mean ± SD)	68.11 ± 12.3	69.40 ± 12.1	68.76 ± 12.2
Gender	Female (n, %)	20, 57.1%	25, 71.4%	45, 64.3%
	Male (n, %)	15, 42.9%	10, 28.6%	25, 35.7%
Fracture Type	Type III (n, %)	25, 71.4%	21, 60.0%	46, 65.7%
	Type IV (n, %)	10, 28.6%	14, 40.0%	24, 34.3%
Mode of Injury	Trivial Fall (n, %)	16, 45.7%	17, 48.6%	33, 47.1%
	Fall from Height (n, %)	2, 5.7%	3, 8.6%	5, 7.1%
	RTA (n, %)	17, 48.6%	15, 42.9%	32, 45.7%
Systemic Comorbidity	DM (n, %)	9, 25.7%	9, 25.7%	18, 25.7%
	HT (n, %)	5, 14.3%	7, 20.0%	12, 17.1%
	DM & HT (n, %)	16, 45.7%	16, 45.7%	32, 45.7%
	Others (n, %)	1, 2.9%	2, 5.7%	3, 4.3%
No Systemic Comorbidity	(n, %)	4, 11.4%	1, 2.9%	5, 7.1%

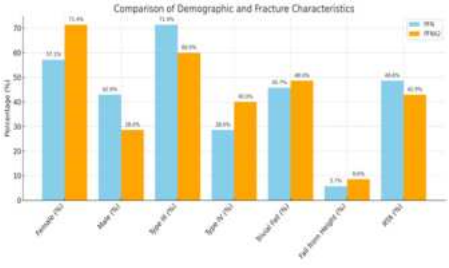


Table 2 compares the intra-operative and post-operative parameters of PFN and PFNA2 groups. PFNA2 demonstrated significantly shorter operative time, lower blood loss, and reduced hospital stay. However, the time to full weight-bearing and callus formation were comparable between the two groups.

Table 2: Intra-Operative and Post-Operative Parameters

Variables	PFN (Mean ± SD)	PFNA2 (Mean ± SD)	P-value
Operative Time (mins)	112.3 ± 8.4	56.4 ± 5.7	< 0.01
Amount of Blood Loss (ml)	190.6 ± 25.9	82.1 ± 10.4	< 0.01
Duration of Hospital Stay (days)	6.6 ± 0.9	5.9 ± 1.3	0.021
Time to Full Weight Bearing (weeks)	7.46 ± 1.44	7.22 ± 0.79	0.47
Callus Formation (weeks)	6.98 ± 1.03	6.54 ± 0.70	0.09

Table 3 shows the early and late complications observed in PFN and PFNA2 groups. PFNA2 had significantly fewer complications, with no cases of implant loosening, implant failure, or mal-union. The majority of patients in both groups did not experience any complications, with 91.4% in the PFNA2 group and 77.1% in the PFN group.

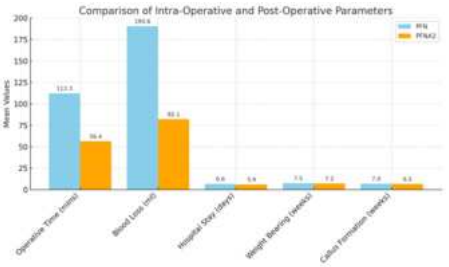


Table 3: Early and Late Complications in Study Groups

	Complications	PFN (N=35)	PFNA2 (N=35)	Total (N=70)	PFN (%)	PFNA2 (%)	Total (%)
Early Complications	Implant Loosening	4	0	4	11.4%	0.0%	5.7%
	Pulmonary	3	1	4	8.6%	2.9%	5.7%
	Surgical Site Infection (SSI)	2	1	3	5.7%	2.9%	4.3%
	None	26	33	59	74.3%	94.3%	84.3%
Late Complications	Deep Vein Thrombosis (DVT)	1	1	2	2.9%	2.9%	2.9%
	Implant Failure / Re-operation	3	0	3	8.6%	0.0%	4.3%
	Mal-union	1	0	1	2.9%	0.0%	1.4%
	Pressure Sores	3	2	5	8.6%	5.7%	7.1%
	None	27	32	59	77.1%	91.4%	84.3%

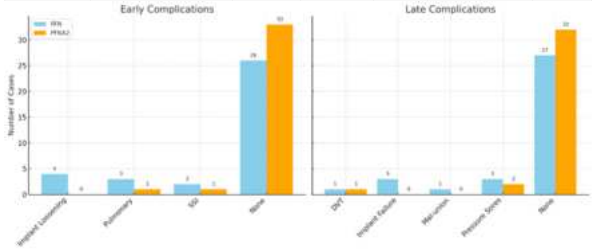


Table 4 shows comparable functional scores between PFN and PFNA2 groups at all follow-up intervals. At 6 months, scores were 78.51 ± 5.07 for PFN and 79.56 ± 5.62 for PFNA2 (p=0.42), indicating similar functional recovery for both implants.

Table 4: Lower Extremity Functional Scores

Follow-Up Period	PFN (Mean ± SD)	PFNA2 (Mean ± SD)	P-value
1 Week	23.81 ± 2.45	24.46 ± 2.42	0.27
3 Weeks	49.94 ± 3.69	50.43 ± 4.29	0.61
3 Months	65.57 ± 4.27	66.46 ± 4.64	0.41
6 Months	78.51 ± 5.07	79.56 ± 5.62	0.42

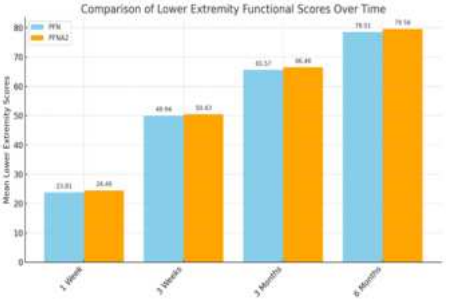
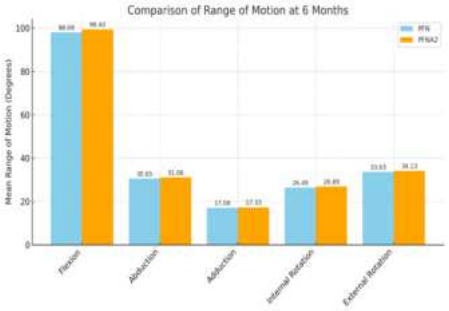


Table 5 presents the mean range of motion at 6 months for PFN and PFNA2 groups. Both groups exhibited comparable outcomes across all movements, with no statistically significant differences noted.

Table 5: Range of Motion (6 Months)

Movement	PFN (Mean ± SD)	PFNA2 (Mean ± SD)	P-value

Flexion	98.09 ± 6.09	99.40 ± 6.17	0.37
Abduction	30.65 ± 1.90	31.06 ± 1.93	0.39
Adduction	17.08 ± 1.13	17.33 ± 1.09	0.31
Internal Rotation	26.49 ± 1.75	26.89 ± 1.69	0.37
External Rotation	33.63 ± 2.22	34.13 ± 2.14	0.38




Abduction


Extension


Flexion


Adduction


Squatting


Cross leg sitting


External Rotation


Internal Rotation

Functional outcome of postoperative case fracture right intertrochanteric after 6 months follow-up

DISCUSSION

Unstable intertrochanteric fractures, commonly seen in the elderly, pose significant challenges in treatment. This study compared the outcomes of Proximal Femoral Nailing (PFN) and Proximal Femoral Nailing Anti-rotation for Asia (PFNA2) in managing these fractures, with specific focus on surgical parameters, functional outcomes, and complications.

Demographic and Clinical Characteristics

The mean age in our study was 68.8 years, aligning with **Shetty et al. [10],** who reported 83.3% of patients with intertrochanteric fractures were over 50 years. Similarly, **Sinno et al. [11]** documented a mean age of 78.6 years, with a female predominance (64%), consistent with our findings (64.3% females). Trivial falls were the most common mode of injury in our study (47.1%), which is comparable to findings by **Patil SN [12]** (61.4%) and **Sinno et al. [11],** highlighting the role of osteoporosis and reduced bone strength in elderly patients.

Operative Parameters

In our study, PFNA2 was associated with significantly shorter operative time (56.4 vs. 112.3 mins; p<0.01), reduced blood loss (82.1 vs. 190.6 mL; p<0.01), and shorter hospital stays (5.9 vs. 6.6 days; p=0.021). These findings align with **Singh S et al. [13],** who demonstrated PFNA2's superiority in reducing operative time and intraoperative complications. **Meena BK [14]** reported similar trends, noting reduced blood loss and shorter operative durations with PFNA2. **Yadav S [15]** and **Bihari AM [16]** also highlighted PFNA2's efficiency in reducing intraoperative challenges and enhancing surgical outcomes.

Functional and Radiological Outcomes

Both groups in our study achieved comparable functional outcomes over six months. The mean time to full weight-bearing was 7.22 weeks for PFNA2 and 7.46 weeks for PFN (p=0.47). Callus formation occurred slightly earlier in the PFNA2 group (6.54 vs. 6.98 weeks; p=0.09). These findings are consistent with **Sharma A [17] and Singh S [13]**, who reported similar functional recovery in both groups. **Das PB [18] and Kim[19]** documented comparable timeframes for weight-bearing in PFN-treated patients, further supporting our findings. **Mallya S [20]** noted that while functional outcomes between the implants were similar, PFNA2 offered higher union rates, which correlates with our radiological findings.

Complications

The overall complication rate was significantly lower in the PFNA2 group (5.7%) compared to PFN (25.7%; p=0.045). Implant loosening and re-operations due to implant failure were observed only in the PFN group (11.4% and 8.6%, respectively). These findings are in agreement with studies by **Singh S [13] and Sharma A [17]**, who reported significantly lower complication rates with PFNA2. **Mallya S [20]** observed fewer implant-related complications in the PFNA2 group, including better implant positioning and reduced risk of implant failure. Similarly, **Bihari AM [16]** emphasized PFNA2's effectiveness in minimizing late complications and improving overall outcomes.

CONCLUSION

This study confirms that both PFN and PFNA2 are effective for managing unstable intertrochanteric fractures, but PFNA2 offers significant advantages, including reduced surgical time, blood loss, and hospital stay, with fewer complications. Functional and radiological outcomes were comparable, but PFNA2's superior safety profile makes it the preferred choice, especially for elderly osteoporotic patients.

Limitations

The study's small sample size and single-center design limit the generalizability of findings. The six-month follow-up may not capture long-term outcomes, and excluding patients with severe comorbidities restricts insights into high-risk populations.

Strengths

The randomized design minimized bias, and the direct comparison of PFN and PFNA2 provided valuable insights. Comprehensive evaluation of outcomes and a focus on elderly osteoporotic patients enhance the study's clinical relevance, reinforcing PFNA2 as a highly effective implant option.

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Ethical Approval: Obtained.
Consent: Written consent secured.

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