Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v4i3.1010
Original Article

COMPARATIVE ANALYSIS OF FUNCTIONAL AND RADIOLOGICAL OUTCOMES BETWEEN PROXIMAL FEMORAL NAIL ANTI-ROTATION 2 AND CONVENTIONAL PROXIMAL FEMORAL NAIL AT SCHOOL OF MEDICAL SCIENCE AND RESEARCH, SHARDA UNIVERSITY GREATER NOIDA: A PROSPECTIVE OBSERVATIONAL STUDY.

Dr Faizan Khalid shah[1], Dr Ujjwal Sourav[2]*
[1]Assistant professor, Department of Orthopedics, School of Medical Science and Research, Sharda University and Medical College, Greater Noida.
[2]Associate professor, Department of Community Medicine, Amrita School of Medicine, Faridabad

Abstract

Introduction

The PFNA (Proximal Femoral Nail Antirotation) was developed to achieve improved stabilization of the femoral head and neck. The PFN (Proximal Femoral Nail) is a well-established treatment approach for proximal femoral fractures. A more recent alternative in the management of such fractures is the PFNA2 (Proximal Femoral Nail Anti-rotation 2), which incorporates a helical blade for improved bone compaction.

Aim and objectives

To evaluate the surgical and functional outcomes associated with the use of PFN and PFNA2 for the treatment of these fractures.

Material and methods

Following ethical clearance from the Ethical Committee of Sharda University, we conducted a prospective observational study involving 50 patients who were admitted to the School of Medical Science and Research, Sharda University and Medical College Greater Noida, India. The inclusion and exclusion criteria were applied to select eligible patients between Sept 2022 and Sept 2023.

Result

in the PFN group, out of the 25 study subjects 11 cases had fair modified Harris hip scores, 9 cases had good Harris hip scores, and 5 subjects had excellent modified Harris hip scores. In the PFNA2 group, out of 25 study subjects, 14 had a good modified Harris hip score, 6 had an excellent modified Harris hip score and 5 had a fair modified Harris hip score.

Conclusions

PFNA2 emerges as the preferred implant choice for elderly patients with osteoporotic bone, as it offers several advantages. Its shorter operative time is particularly beneficial for patients who may have medical comorbidities, making it a marginally superior option over PFN.

Recommendation

A larger sample size with a longer follow-up period and a multicentric approach would have provided a more comprehensive assessment of the long-term outcomes of this clinical issue

Keywords: *Proximal Femoral Nail, Proximal Femoral Nail Anti-Rotation 2, Intertrochanteric Fracture, Nail*
Submitted: *2024-01-26* ***Accepted****: 2024-01-31*

*Corresponding author: Dr Ujjwal Sourav**
Email: ujjwalsourav3@gmail.com
Associate professor, Department of Community Medicine, Amrita School of Medicine, Faridabad

Introduction

Pertrochanteric femoral fractures are prevalent among the elderly population, with their incidence on the rise due to increasing life expectancy worldwide. These fractures typically result from minor traumas and are categorized into three groups based on the AO/OTA classification system: 31.A1 for simple pertrochanteric fractures, 31.A2 for multifragmentary pertrochanteric fractures, and 31.A3 for intertrochanteric fractures. The primary treatment objective is early mobilization to prevent the potential complications associated with immobilization. In the case of pertrochanteric fractures, complications are primarily linked to the type of implant used rather than the bone union process, as cancellous bone in the intertrochanteric region, has a robust healing capacity. (1)

Fractures of this nature are commonly categorized into two groups based on their patterns: stable and unstable fractures. Stable fractures encompass those that are undisplaced or have an intact posteromedial cortex. In contrast, unstable fractures include those with posteromedial comminution, loss of the lateral wall, reverse obliquity fractures, and fractures consisting of four or more parts. Unstable fractures make up approximately 50%-60% of all intertrochanteric fractures. Employing surgical treatment involving internal fixation for these fractures offers several advantages, such as enhancing patient comfort, simplifying nursing care,

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reducing the length of hospitalization, and minimizing the complications associated with prolonged bed rest. (2)

Unstable femoral intertrochanteric fractures (classified as AO 31A2 and AO 31A3) remain a complex issue for orthopedic surgeons. Despite achieving high rates of bone union, these fractures often result in suboptimal functional outcomes. The presence of an intact lateral wall is crucial in stabilizing these unstable intertrochanteric fractures, as it serves as a lateral support for the upper fragment. In cases where the lateral wall is compromised, there is a tendency for excessive collapse and varus malalignment to occur. (3)

To address unstable fractures, the preferred method of fixation involves the utilization of an intramedullary nail along with a dynamic stabilization implant for the femoral head and neck. Over time, various nail designs have emerged, incorporating either a single compression screw or a combination of a compression screw and an anti-rotation screw, as seen in the case of the PFN implant. These designs have gained popularity in the treatment of unstable fractures. While the PFN implant has demonstrated its superiority over extramedullary devices for managing unstable intertrochanteric fractures, it is important to note that postoperative complications, including screw cut-out, screw migration, varus collapse, and rotational instability, have remained significant concerns, with reported complication rates of up to 31% in the literature. (4)

The PFNA (Proximal Femoral Nail Antirotation) was developed to achieve improved stabilization of the femoral head and neck. It accomplishes this by using a single helical blade for fixation, as opposed to a conventional screw system. The unique design of the helical blade is intended to enhance the connection between the implant and the bone, leading to the compaction of cancellous bone and, consequently, providing robust fixation stability. What makes the blade particularly advantageous is that it can be inserted without the need for extensive bone reaming in the head and neck fragment, making it especially effective in anchoring within the osteoporotic bone. Biomechanical studies have confirmed that the helical blade, through its compaction of cancellous bone, offers superior resistance to rotation and Varus collapse. (5)

The PFN (Proximal Femoral Nail) is a well-established treatment approach for proximal femoral fractures. A more recent alternative in the management of such fractures is the PFNA2 (Proximal Femoral Nail Anti-rotation 2), which incorporates a helical blade for improved bone compaction. In the PFN, two screws are employed for fixation, with the larger femoral neck screw bearing the majority of the load and the smaller hip screw contributing to rotational stability. In contrast, the PFNA2 utilizes a single proximal blade to compact the cancellous bone. Both nail designs, PFN and PFNA2, are available in varying lengths, including short and long versions. There are limited studies that have compared the treatment outcomes of intertrochanteric femur fractures using both nail designs, and none of them have examined the results of fracture geometry, design, and length with either of the two nail types. In our research. (6)

we aimed to evaluate the surgical and functional outcomes associated with the use of PFN and PFNA2 for the treatment of these fractures.

Material and methods

Following ethical clearance from the Ethical Committee of Sharda University, we conducted a prospective observational study involving 50 patients who were admitted to Sharda Institute of Medical Sciences in Greater Noida, India. These patients had sustained intertrochanteric (IT) femur fractures and provided written informed consent to participate in the study.

Study design

Prospective observational study

Study setting

Department of Orthopedics, Sharda Institute of Medical Sciences in Greater Noida, India.

Participants

50 patients who were admitted to Sharda Institute of Medical Sciences in Greater Noida, India. These patients had sustained intertrochanteric (IT) femur fractures and provided written informed consent to participate in the study.

Bis

selection bias maybe there

Study size

We determined the sample size using the following formula: $S = Z^2 \times P \times (1-P) / M^2$, where S represents the sample size, Z corresponds to the Z-score (1.96), P signifies the assumed population proportion (set at 50% or 0.5), and M represents the margin of error.

The inclusion and exclusion criteria were applied to select eligible patients between Sept 2022 and Sept 2023. Data collection and management were carried out using Microsoft Excel, a product of Microsoft Corporation in the United States. We presented all quantitative data in terms of means and suitable tables, and graphical methods were employed for data visualization and presentation

For qualitative data, we utilized numbers and percentages, and we employed appropriate graphs to visually represent the data. In this study, we included all cases of intertrochanteric (IT) femur fractures in individuals aged 18 years and older, with closed injuries, who provided their informed consent for participation. Exclusions comprised open injuries, patients who declined participation, those with associated injuries (such as head or abdominal injuries or other bone fractures), individuals with subtrochanteric femur fractures, and patients with less than six months of follow-up.

Our study was conducted in a tertiary care hospital with a medical college setup, consisting of three units within the department. Each unit had assigned days for emergency and outpatient department (OPD) services. We included

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all eligible patients during the study period, admitting them to the respective units based on their hospital arrival day, thereby avoiding selection bias.

Upon X-ray scans, we explained the treatment plan and prognosis to the patients, and ankle skin traction was applied to the affected limb. Preoperative investigations and anesthesia assessments were conducted. The choice of implant size (long or short) and design (PFN or PFNA2) was made randomly without any bias, following the decision of the unit head. An initial assessment of the nail angle was made based on the relative positions of the center of the femoral head and the tip of the greater trochanter on the unaffected side. If the tip of the greater trochanter was higher (indicating a coxa vara), an angle of 130° was selected. All surgical procedures were performed by the respective unit heads

Stringent aseptic and antiseptic measures were rigorously followed throughout the surgical procedures. Patients were positioned in the supine position on an orthopedic fracture table. In all cases, distal femur Steinmann pins (ST) with Bohler's stir-up were used for skeletal traction.

The implants used in this study were sourced from Nebula Surgical Pvt. Ltd. Long nails, whether PFN or PFNA2, were specific to the side of the fracture. These nails were available in diameters of 9, 10, and 11 mm. Long nail options ranged from 340 to 420 mm in length, while short nails were available in lengths of 180 and 250 mm. Helical blades came in lengths spanning from 70 mm to 120 mm. To achieve proper reduction, ST pins and guide wires were inserted into the anterosuperior quadrant of the femoral head and neck, taking into consideration the intended path of the future nail placement. Additionally, adduction was performed at the hip joint (rather than at the fracture site), specifically to enhance the prominence and palpability of the greater trochanter. This was particularly useful in obese patients, facilitating the entry of the nail, and the alignment was confirmed using fluoroscopy (C-arm).

Result

Of the total 74 patients operated on for IT femur fracture, as per the sample size and criteria satisfying inclusion and exclusion criteria we selected 50 study subjects. we found that the maximum number of patients were in the age group of 51-70 years in both PFN and PFNA2. The overall mean age was 62.84 years; 59 and 66.66 years for PFN and PFNA2, respectively. Age groups were defined as young age (18-30 years), middle age (31-50 years), elderly (51-70 years), and old age (>70 years) groups.

Tab 1: Distribution of study subjects as per age group

Age group	PFN	PFNA2
18-30	5	2
31-50	6	6
51-70	10	11
>70	4	6
Total	25	25

Tab 1 shows the Distribution of study subjects as per age group, In the age group 18-30 years, 5 subjects were in the PFN group whereas 2 subjects were in the PFNA2 group, In the age group 31-50 years, 6 subjects were from both group, In the age group 51-70 year, 10 subjects were from PFN group whereas 11 subjects were from PFNA2 group.

Table 2: Distribution of study subjects as per gender

gender	PFN	PFNA2
Male	10	17
Female	15	8
Total	25	25

Table 2 shows the Distribution of study subjects as per gender, In the PFN group out of 25 study subjects 15 were female whereas out of 25 study subjects in the PFNA2 group, 8 subjects were female.

Tab 3: Distribution of study subjects as per type of implant

Type of Implant	Short nail	Long Nail
PFN	15	10
PFNA2	18	7
Total	33	17

Tab 3 shows the Distribution of study subjects as per the type of implant, out of 25 PFN study subjects 15 subjects had short nails and 10 had long nails, whereas out of 25 PFNA2, 18 subjects had short nails whereas 7 subjects had long nails.

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Fig 1: Distribution of study subjects as per duration of Implant used

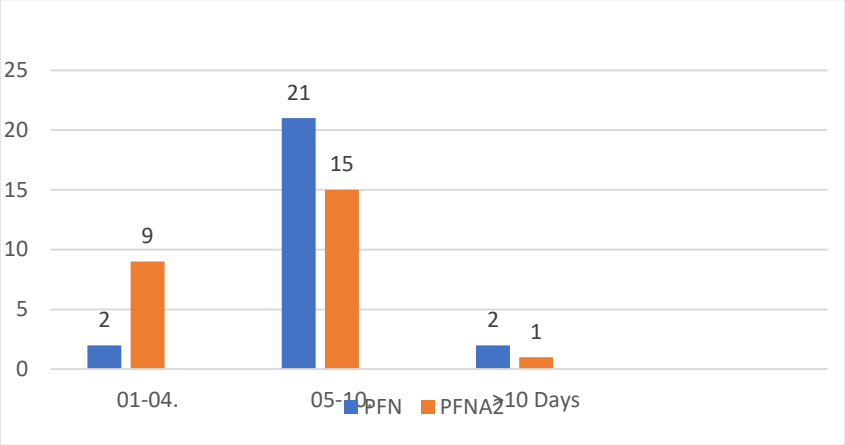

Fig 1 shows the Distribution of study subjects as per the duration of Implant used, In the PFN group out of 25 study subjects 2 subjects had an implant duration of 1-4 days, 21 subjects had a duration of implant of 5-10 days, 2 subjects had a duration of more than 10 days, In PFNA2 group 9 subjects had a duration of the implant 1-4 days, 15 subjects were had duration 5-10 days, whereas 1 subject had a duration of implant >10 days.

Tab 4: Distribution of study subjects as per the mode of Injury

Mode of Injury	PFN	PFNA2
Road traffic accident	8	7
Slippage/domestic fall	17	18
Total	25	25

Tab 4 shows the Distribution of study subjects as per the mode of Injury. Out of the 25 study subjects in the PFN group, 17 subjects had domestic falls, whereas in the PFNA2 group out of 25 study subjects, 18 subjects had a history of domestic falls.

Tab 5: Distribution of study subjects as per complications

Complications	PFN	PFNA2
Reverse Z-effect/screw back-out	2	1
Superior screw cut-out	1	1
Deep vein thrombosis	1	1
Fat Embolism	2	1
Total	6	4

Tab 5 shows the Distribution of study subjects as per complications, In the PFN group there are 6 cases of complications in which 2 subjects had reverse z effect, 2 had a fat embolism, 1 had deep vein thrombosis, and 1 case had superior screw cut out. In the PFNA2 group, a total of 4 cases had complications, 1 subject had reverse z effect, 1 had a superior screw cut out, 1 had deep vein thrombosis, and 1 had a fat embolism.

Tab 6: Distribution of study subjects as per modified Harris hip score at the final follow-up

modified Harris hip score	PFN	PFNA2
Excellent	5	6
Good	9	14
Fair	11	5
Total	25	25

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Tab 6 shows the distribution of study subjects as per modified Harris hip score at the final follow-up, in the PFN group, out of the 25 study subjects 11 cases had a fair modified Harris hip score, 9 cases had a good Harris hip score, and 5 subjects had excellent modified harris hip score. In the PFNA2 group, out of 25 study subjects, 14 had a good modified Harris hip score, 6 had an excellent modified Harris hip score and 5 had a fair modified Harris hip score.

Discussion

In the current investigation, the age distribution revealed that among individuals aged 18-30 years, 5 participants were assigned to the PFN group, while 2 were assigned to the PFNA2 group. For the 31-50 age group, 6 subjects were included in both the PFN and PFNA2 groups. In the 51-70 age bracket, 10 subjects belonged to the PFN group, while 11 were part of the PFNA2 group. Notably, Harish Mahesan et al (7) discovered that 2 out of 43 patients studied succumbed during the follow-up period, with an average patient age of 72 years.

Manish R Shah et al (8) reported a mean age of 62.84 years in their study, with 59 years for PFN and 66.66 years for PFNA2. They categorized age groups as young (18-30 years), middle-aged (31-50 years), elderly (51-70 years), and old age (>70 years).

Regarding gender distribution, in the PFN group, out of 25 subjects, 15 were female, while in the PFNA2 group, 8 out of 25 subjects were female. In contrast, Manish R Shah et al (8) noted a male preponderance in their study, where PFNA2 was predominantly used for males, and PFN for females, emphasizing the randomization process. Siddharth Singh et al (9**)** reported a male-to-female ratio of 1:0.8, while Ajay Rajput et al found a mean age of 59.03 ± 16.10 years in their Group 1 (range 41 to 85 years)

In the present study, among the 25 study subjects in the PFN group, 15 had short nails and 10 had long nails. In the PFNA2 group, 18 subjects had short nails, while 7 had long nails. Manish R Shah et al (8) study indicated that the majority of patients, specifically 19 out of 30, underwent surgery with short nails, encompassing both PFN and PFNA2.

Regarding the duration of implant in the PFN group, 2 subjects had an implant duration of 1-4 days, 21 had a duration of 5-10 days, and 2 had a duration exceeding 10 days. In the PFNA2 group, 9 subjects had an implant duration of 1-4 days, 15 had a duration of 5-10 days, and 1 had a duration exceeding 10 days.

Concerning the cause of injury, in the PFN group, 17 subjects experienced a domestic fall, while in the PFNA2 group, 18 subjects had a history of domestic falls. Ajay Rajput et al's (3) study revealed that slip and fall incidents accounted for injuries in 21 patients, while 6 patients sustained injuries due to road traffic accidents (RTA), and 3 patients suffered injuries from falling from a height. Similarly, Manish R Shah et al (8) reported that the majority of fractures resulted from falls or slipping on level ground (trivial trauma). Ahmad M. Radaideh et al (1) found that the primary mechanism of injury was a simple fall at home in 46 out of 50 subjects, while 4 subjects experienced injuries due to traffic accidents.

In the current investigation, the PFN group experienced 6 cases of complications, with 2 subjects encountering the reverse Z effect, 2 facing fat embolism, 1 developing deep vein thrombosis, and 1 exhibiting superior screw cut-out. In the PFNA2 group, a total of 4 complications were reported, including 1 case each of reverse Z effect, superior screw cut-out, deep vein thrombosis, and fat embolism. Manish R. Shah et al (8) highlighted that the reverse Z effect in two cases was attributed to the non-maintenance of the temporary anchorage device (TAD), but this was not considered a demerit of the implant. Other complications were explained, such as difficulties in passing the distal dynamic screw, leading to a superior screw cut-out, and deep vein thrombosis linked to surgery delay due to comorbidities. The cause of fat embolism in one case remained unidentified, although the patient survived.

In terms of hip scores, the PFN group exhibited 11 cases with fair modified Harris hip scores, 9 with good scores, and 5 with excellent scores. In the PFNA2 group, 14 subjects achieved good modified Harris hip scores, 6 had excellent scores, and 5 had fair scores. Manish R. Patil et al's (8) study similarly indicated positive outcomes with short PFNA2, reporting excellent results in seven patients and good results in 14 patients. Another study by Singh and Bhartiya (10) demonstrated comparable functional outcomes between PFNA and PFN, with no significant advantages of PFNA in terms of postoperative complications.

Conclusions

PFNA2 emerges as the preferred implant choice for elderly patients with osteoporotic bone, as it offers several advantages. Its shorter operative time is particularly beneficial for patients who may have medical comorbidities, making it a marginally superior option over PFN. The use of a short nail design further reduces operative time and minimizes blood loss. Additionally, complications are relatively less common with PFNA2. A systematic approach to following all surgical steps is crucial for avoiding complications in both groups of patients, whether PFN or PFNA2 is used. The utilization of only distal dynamic locking screws allows for fracture collapse, improved compliance, and faster union of the fracture. Importantly, there is no significant difference in the time it takes for the fracture to heal between short and long nail designs. Ultimately, the clinical and functional outcomes remain unchanged at the final follow-up when either PFN or PFNA2 is employed, underlining the effectiveness of both implant options in treating intertrochanteric fractures.

Generalizability

The results of this study hold generalizability to a broader context within the orthopedic community, as the outcomes are likely to apply to similar patient populations and surgical settings. The findings may inform orthopedic surgeons, researchers, and healthcare professionals worldwide, aiding in evidence-based decision-making when choosing between PFNA-2 and conventional PFN for treating proximal femoral fractures. However, it's

essential to consider specific patient demographics, fracture types, and surgical techniques to ensure the appropriate application of the study's conclusions in different clinical scenarios. Overall, the study contributes valuable information that can enhance the understanding of optimal treatment strategies for proximal femoral fractures, potentially influencing practices on a global scale

Limitation

Limitations such as a relatively small sample size, a shorter follow-up period, and a single-center approach were acknowledged. A larger sample size, an extended follow-up duration, and a multicentric approach would have enhanced the comprehensiveness of the assessment of long-term outcomes for this clinical matter.

Acknowledgment

We thank all our study subjects for participating in the study, we also thank all medical and paramedical staff who are directly or indirectly involved in the study

Conflict of interest

There was no conflict of interest

Funding

The study was not funded

Author Biography

Dr Faizan Khalid Shah is a very skilled orthopedic surgeon, with having keen interest in clinical practice and research. After working with other premier organizations he is currently working as an Assistant professor in orthopedic surgery at the School of Medicine and Research, Sharda University, Greater Noida.

Dr. Ujjwal Sourav is a known epidemiologist with having keen interest in clinical research, After working with many premier organizations he is currently working as an Associate professor at, the Department of Community Medicine, Amrita School of Medicine, Faridabad

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https://doi.org/10.51168/sjhrafrica.v4i3.1010
Original Article

Publisher details:

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org, info@sjpublisher.org or studentsjournal2020@gmail.com
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.