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ORIGINAL ARTICLE • HIP - TRAUMA

The impact of proximal femoral nail type on clinical and radiological outcomes in the treatment of intertrochanteric femur fractures: a comparative study

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Abstract

Purpose The aim of the study was to compare three different proximal femoral nails in terms of functional and radiological outcomes in patients treated with closed reduction and internal fixation for intertrochanteric femur fractures (IFFs).
Methods Between February 2010 and March 2016, 303 consecutive patients (132 male, 171 female) were included in the study. The groups were compared in terms of age, gender, body mass index, duration of surgery and duration of fluoroscopy, blood loss, type of fracture and quality of the reduction, complication rate, and functional and radiological results. Harris hip score (HHS), Barthel index, and full weight bearing time were used for functional evaluation. The quality of the reduction, collodiaphyseal angle (CDA), tip–apex distance (TAD), and fracture union were used for radiological results evaluation.
Results There was no significant difference between groups in terms of fracture type, reduction quality, and complication rates. The mean operation time, duration of scopy, blood loss, and TAD was higher for InterTan, whereas the mean postoperative CDA was higher for PFNA-II. Operation time, postoperative CDA, and full weight bearing duration were higher for Profin than for InterTan. The mean HHS and Barthel Index were higher for PFNA-II, while the mean duration of operation and fluoroscopy, blood loss, TAD, and full weight bearing time were higher for Profin.
Conclusion PFNA-II is a better option than Profin and InterTAN in the treatment of IFFs when the surgical parameters and functional and radiological results were evaluated as a whole.

Keywords Intertrochanteric femur fractures · Proximal femoral nail · Nail design · Clinical and radiological outcomes

Introduction

Intertrochanteric femur fractures (IFFs) are one of the most common lower extremity fractures that occur after minor trauma due to osteoporosis in the elderly and high-energy injuries in younger patients [1]. Surgical treatment remains a difficult and complex effort, while the incidence of IFFs has increased significantly in recent decades due to the increasing age of the population [2]. Currently, IFFs are usually treated with intramedullary fixation or extramedullary fixation [3]. However, the higher failure rate of dynamic hip screws (DHS), which provide extramedullary fixation in unstable IFFs, led to the preference for intramedullary fixation of proximal femoral nails (PFN). In addition, biomechanical studies have shown that PFN provides greater stability compared to DHS due to the shorter lever arm [4].

PFNs have advantages such as a minimally invasive surgical technique, easy administration, short surgical time, postoperative full weight bearing, and low complication rate [4, 5]. Thus, PFNs are the preferred method of osteosynthesis especially in the elderly, because of stable fixation and early postoperative mobilization [5]. Most of the PFNs provide interfragmentary linear compression at the fracture line with a lag screw, which is a significant effect on bone healing. A variety of PFN designs are available, such as one or two lag screws, integrated or locked lag screws, and a single helical blade [6]. The purpose of this retrospective study was to compare three different PFNs in terms of functional and radiological outcomes in patients treated with closed

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reduction and internal fixation using PFN. In the treatment of IFFs, PFN with a single helical blade was assumed to provide better functional and radiological results than two interlocking integrated lag screws PFNs and two separate lag screws PFNs.

Materials and methods

Patients who underwent surgery due to IFFs between February 2010 and March 2016 were investigated after approval of the local ethics committee (Bakırköy Dr. Sadi Konuk Education and Research Hospital Ethics Committee, protocol code: 2018/141, application ID: 2018-7). Patients with unilateral isolated IFF, ambulatory enough to perform daily activities before the fracture, at least 18 years of age, and at least 2 years of follow-up were included in the study. Patients with developmental hip dysplasia, femur fractures other than the trochanteric region, pathologic fractures, bilateral fractures, comorbidities affecting muscle strength and walking, cognitive dysfunctions, and inadequate follow-up were excluded from the study. Three hundred and three consecutive patients (132 male, 171 female) who met the inclusion criteria were included in the study. Informed consent was obtained from all individual participants included in the study. Fractures were classified according to AO (Arbeitsgemeinschaft für Osteosynthesefragen) classification using preoperative pelvis or hip radiographies. Surgeons have used Trigen InterTan (Smith & Nephew, Memphis, TN, USA) to 86 patients, PFNA-II (Synthes, Solothurn, Switzerland) to 100 patients, and Profin (TST SAN, Istanbul, Turkey) to 117 patients (Fig. 1). The groups were compared in terms of age, gender, body mass index (BMI), duration of surgery and duration of fluoroscopy, amount of blood loss, type of fracture and quality of the reduction, complication rate, and functional and radiological results. All patients were evaluated clinically and radiologically at postoperative second week, sixth week, third month, and sixth month and then evaluated annually. Harris hip score (HHS), Barthel index and full weight bearing time were used for functional evaluation. The Barthel index is a simple and understandable scale that includes all parameters of daily living activities. Turkish validity and reliability study was performed. Barthel index consists of 10 subheadings: eating, bathing, self-care, dressing, bladder control, bowel control, toilet use, chair/bed transfer, mobility, and staircase use. Barthel index score ranges from 0 to 100 [7]. Radiological results including the quality of the reduction, collodiaphyseal angle (CDA),

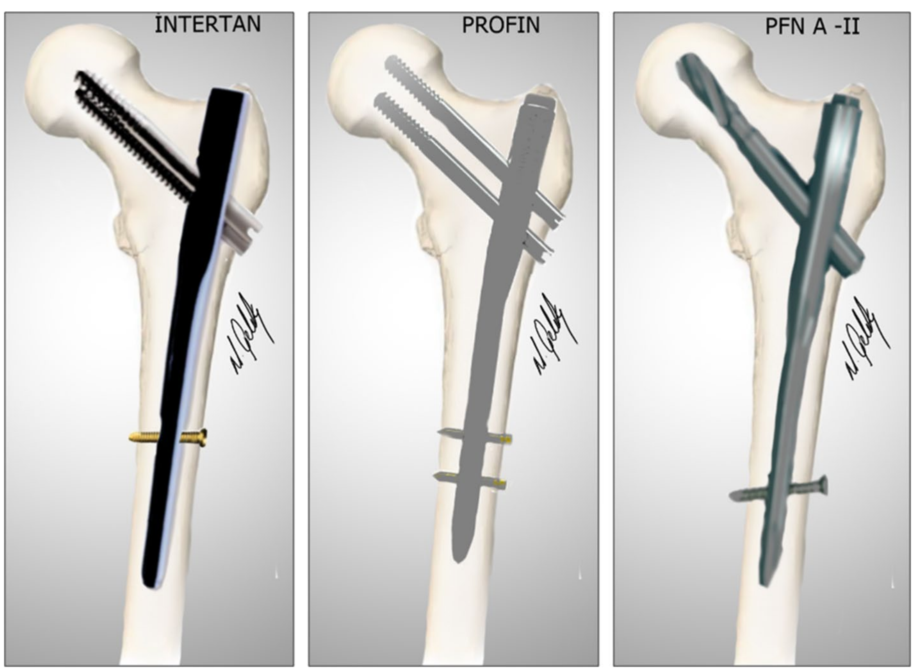

Fig. 1 Medical illustrations show the mechanical design of all three proximal femoral nails. InterTan includes two screws: 11-mm lag screw and 7-mm compression screw (total diameter: 15.5 mm) that has the potential to perform interfragmentary compression up to 15 mm. Profin is applied with two 8.5-mm lag screws with 135° CDA and has the proximal portion that is 16 mm in diameter. Interfragmentary fracture compression was also possible intraoperatively with Profin. PFNA is fixed with one proximal helical blade and one distal locking screw. The proximal screw is inserted in place by driving, and it has the potential to compress up to 5 mm by screwing. PFNA has a 16.5 mm proximal diameter and 9 and 10 mm distal diameters

tip–apex distance (TAD), and fracture union were evaluated by an independent senior orthopedic surgeon. Reduction measures of Baumgaertner, modified by Fogagnolo et al. [8], were used to evaluate postoperative reduction quality. CDA was measured on the first anterior–posterior radiographs postoperatively. TAD was measured on postoperative anteroposterior and lateral graphs of patients as described by Baumgaertner et al. [9]. Since two separate lag screws were used in the Profin, TAD was measured from the tip of the proximal screw [10].

Proximal femoral nail design

InterTan (intertrochanteric antegrade nail)

InterTan PFN is manufactured from a titanium alloy and has a proximal 4° valgus offset. The nail has a trapezoidal cross section with a proximal diameter of 17 mm and a grooved distal tip diameter of 10 and 11.5 mm. Intertan PFNs have two types with 125° or 130° CDA. It includes two screws: 11-mm lag screw and 7-mm compression screw (total diameter: 15.5 mm). The nail is fixed at the distal with a single screw that can be locked as dynamic or static. It has the potential to perform interfragmentary compression up to 15 mm as a result of the integrated proximal screw system (Fig. 2).

PFNA-II (proximal femoral nail-antirotation II)

PFNA-II PFN is a straight tubular section made of titanium alloy. Proximal diameter is 16.5 mm, and distal diameter is 9 and 10 mm. The proximal tip has a 5° valgus offset, and the CDA is 130°. It is fixed with one proximal helical blade and one distal locking screw. The proximal screw is inserted in place by driving, and it has the potential to compress up to 5 mm by screwing. The single screw at the distal end allows dynamic or static fixation (Fig. 3).

Profin (proximal femoral intramedullary nail)

Profin PFN is a cannulated and flat tube, made of titanium alloy. It has a proximal 6° valgus offset and a distal grooved design and is applied with two 8.5-mm lag screws with 135°

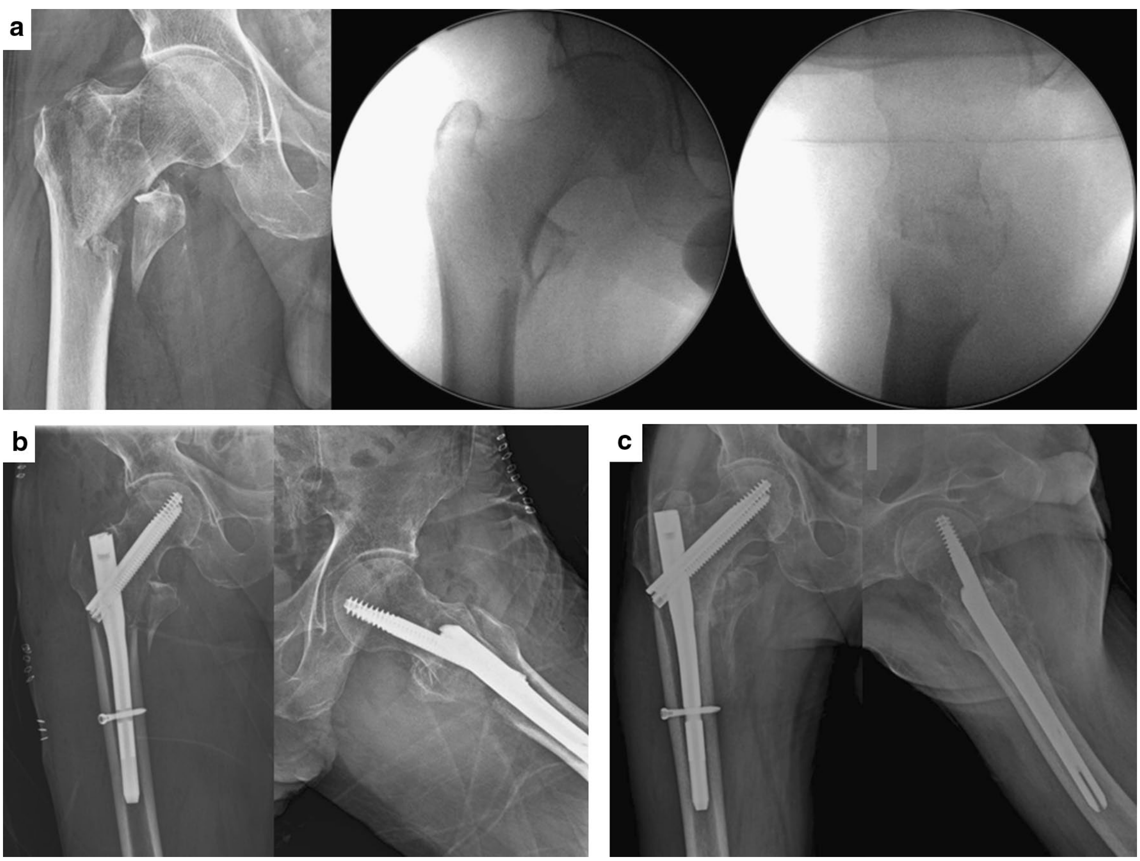

Fig. 2 58-year-old male patient who has AO type 31-A2.2 femur fracture. **a** preoperative anteroposterior hip radiography, anteroposterior, and lateral fluoroscopy images, **b** early postoperative plain radiographs show fracture reduction and fixation using InterTan PFN and **c** anteroposterior and lateral hip radiographs show the IFF union 28th month after the surgery

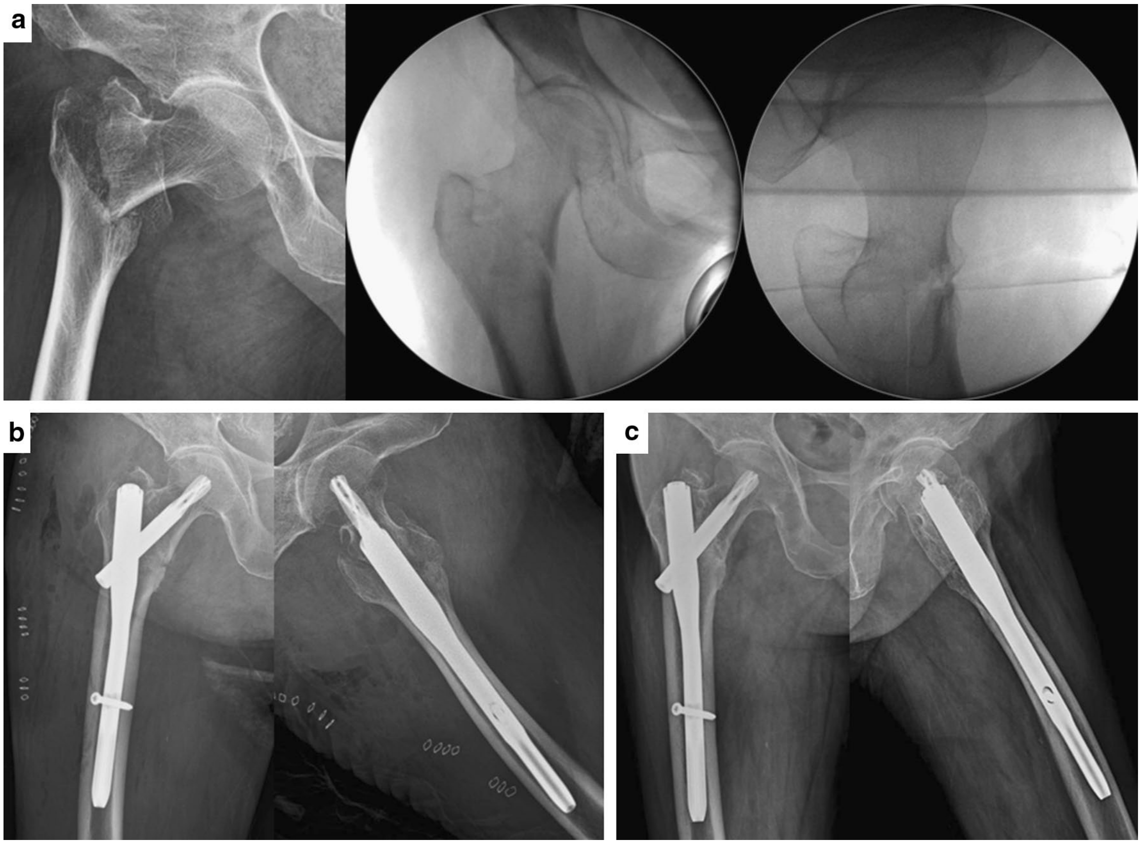

Fig. 3 67-year-old female patient who has AO type 31-A1.2 femur fracture. **a** preoperative anteroposterior hip radiography, anteroposterior and lateral fluoroscopy images, **b** early postoperative plain radiographs show fracture reduction and fixation using PFNA-II and **c** anteroposterior and lateral hip radiographs show the IFF union 29th month after the surgery

CDA. Interfragmentary fracture compression was also possible intraoperatively with this design. The proximal portion of the nail was 16 mm in diameter and the distal diameters were of three different types, 10, 11 and 12 mm. There are two distal holes that allow dynamic or static fixation using 4.5-mm locking screws (Fig. 4).

Surgical technique

All patients were infused 1.5-g intravenous cefuroxime sodium 60 min before skin incision. All patients were operated under general or regional anesthesia on a traction table in the supine position. The closed reduction under fluoroscopic guidance and minimally invasive nailing were performed. All three PFN types were placed with trochanter major entry. Interfragmentary compression was obtained using the integrated compression screw after placing the lag screw in InterTan. In Profin, interfragmentary compression was achieved using two separate lag screws positioned through the nail. While applying PFNA-II, compression of the helical blade was used to obtain interfragmentary compression. The distal hole was also statically locked in all three groups. After hospitalizing of all patients, low molecular weight heparin (enoxaparin sodium 0.4 mL, Clexane®; Sanofi-Aventis Ltd, Istanbul, Turkey) was used for venous thromboembolism (VTE) prophylaxis. Twelve hours before the operation, the VTE prophylaxis was interrupted, resumed after 6 h from the operation. Postoperative treatment was the same in all patients. Subcutaneous enoxaparin injection was administered once daily for 3 weeks to prevent VTE. After the surgery, 3 g/day first-generation cephalosporin sodium (Sefazol®; MN Pharmaceutics, Istanbul, Turkey) were infused intravenously for 2 days. Two days after the operation, the patients were allowed out-of-bed activities with the help of a walker. Three weeks after the operation, the patients were encouraged to partial weight bearing. Patients were allowed to full weight bearing after radiographic fracture healing was demonstrated. The duration of operation was measured as the interval from the onset of fracture reduction until wound closure. The duration of fluoroscopy was determined as the number of exposures on the fluoroscopy device at the end of the operation. Blood loss during or after the operation was recorded

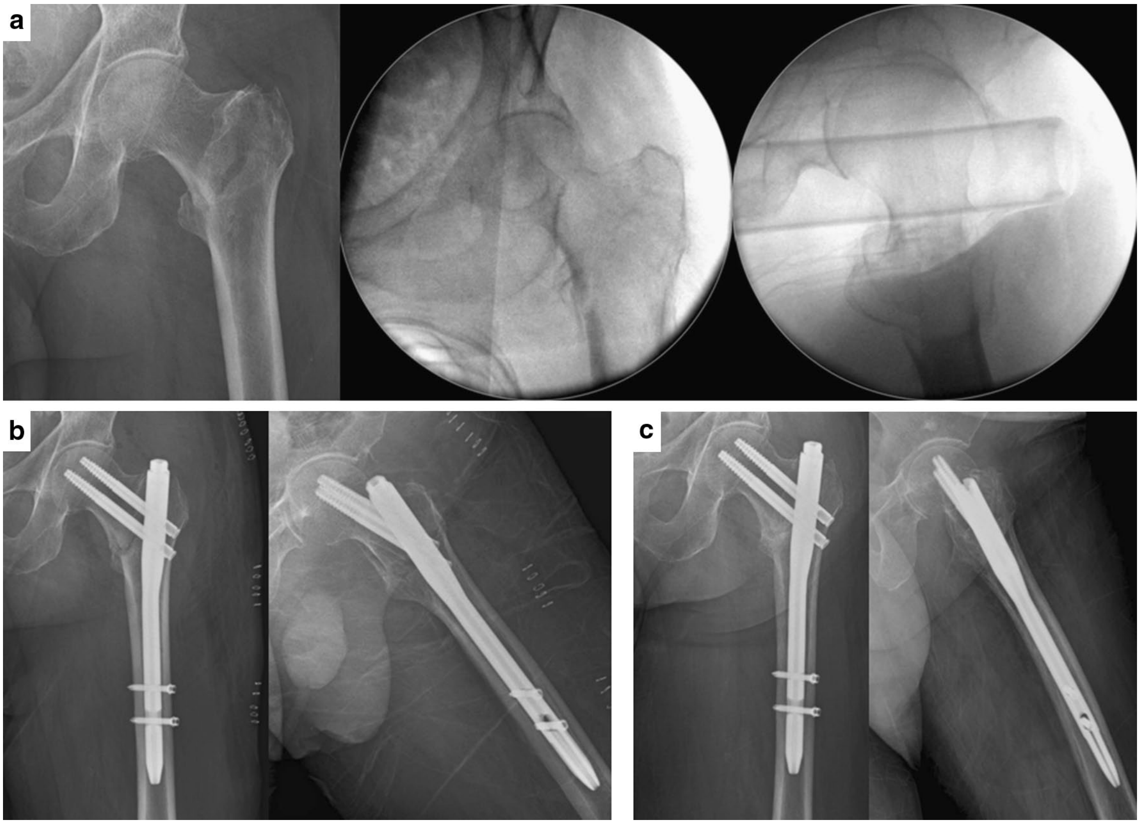

Fig. 4 63-year-old male patient who has AO type 31-A2.2 femur fracture. **a** preoperative anteroposterior hip radiography, anteroposterior and lateral fluoroscopy images, **b** early postoperative plain radiographs show fracture reduction and fixation using Profin PFN and **c** anteroposterior and lateral hip radiographs show the IFF union 24th month after the surgery

in milliliters (mL). Bone healing was defined as the formation of cortical continuity in at least three cortex or bridged callus.

Statistical analysis

Descriptive statistics (mean, standard deviation, minimum, median, maximum) are used to describe continuous variables. The Kruskal–Wallis test was used to compare two independent variables with no normal distribution. Mann–Whitney U test was used to compare two independent and non-normal distributive variables. Chi-square (or Fisher's exact test at appropriate locations) was used to examine the relationship between categorical variables. The statistical significance level was determined as $p < 0.05$. Analyses were performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013).

Results

The descriptive characteristics of the patients are presented in Table 1. The most common trauma mechanism in all groups is fall at home and simple fall. Among all complications, the frequency of hip and thigh pain is remarkable. Twenty-five patients in Profin, 21 patients in InterTan, and 20 patients in PFNA-II were found to have hip and thigh pain postoperatively. Superficial tissue infection was observed in five patients in Profin, four patients in InterTan, and four patients in PFNA-II, and all patients were treated with antibiotherapy. Lag screw cutout is the most common among the implant-related complications. Four patients in Profin, four patients in InterTan, and three patients in PFNA-II, all underwent revision surgery. Z-effect developed in seven of the patients who treated with Profin. The screw size was changed in three patients, while screws were removed in four patients. The PFN was broke in two patient with Profin, two patients with Intertan, and one patient with PFNA-II. All of these patients underwent revision surgery by replacing PFN. There was a statistically significant difference between the groups in terms of operation time, duration of fluoroscopy, amount of blood loss, postoperative CDA and TAD,

Table 1 Descriptive characteristics of patients

	N	%
Gender		
Male	132	43.6
Female	171	56.4
Fractured side		
Right	158	52.1
Left	145	47.9
Trauma mechanism		
Fall at home	114	37.6
Simple fall	110	36.3
Fall from height	20	6.6
Traffic accident	59	19.5
Anesthesia type		
General	99	32.7
Regional	204	67.3
ASA score		
1	60	19.8
2	86	28.4
3	98	32.3
4	59	19.5
General complications		
Superficial wound infection	15	4.9
Deep wound infection	4	1.3
Hip–thigh pain	66	21.8
Urinary tract infection	7	2.3
Implant-related complications		
Z-effect	7	2.3
Hardware breakage	4	1.3
Cutout	11	3.6
	Mean ± SD	Median (min–max)
Postoperative intensive care follow-up (days)	0.76 ± 0.9	0 (0–5)
Hospitalization (days)	5.48 ± 1.5	5 (3–12)
Overall follow-up (months)	25.9 ± 2.5	25 (24–41)

ASA American society of anesthesiologists

HHS, Barthel Index, and duration of full weight bearing ($p < 0.05$) (Table 2). There was no significant difference between groups in terms of fracture type, reduction quality, and complication rates. According to post hoc binary comparison results, there was a statistically significant difference between InterTan and PFNA-II in terms of operation time, duration of fluoroscopy, amount of blood loss, and postoperative CDA and TAD ($p < 0.05$). The mean operation time, duration of fluoroscopy, amount of hemorrhage and TAD was higher for InterTan, whereas the mean postoperative CDA was higher for PFNA-II ($p < 0.016$; Mann–Whitney U, Bonferroni correction). There was a statistically significant difference between InterTan and Profin in terms of operation time, postoperative CDA, and duration of full weight bearing ($p < 0.05$). Operation time, postoperative CDA, and full weight bearing duration were higher for Profin ($p < 0.016$; Mann–Whitney U, Bonferroni correction). There was a statistically significant difference between PFNA-II and Profin in terms of operation time, duration of fluoroscopy, amount of blood loss, TAD, HHS, Barthel Index, full weight bearing duration ($p < 0.05$). The mean HHS and Barthel Index was higher for PFNA-II, while the mean duration of operation and fluoroscopy, hemorrhage, TAD, and full weight bearing time were higher for Profin ($p < 0.016$, Mann–Whitney U, Bonferroni correction) (Table 3).

Table 2 Comparison of the groups in terms of demographic features, surgical parameters, and functional and radiological features

	InterTan ($n=86$) Mean ± SD Median (min–max)	PFNA-II ($n=100$) Mean ± SD Median (min–max)	Profin ($n=117$) Mean ± SD Median (min–max)	p^{a}
Demographic features				
Age	61.5 ± 15.8	61.01 ± 16.6	59.1 ± 15.7	0.531
	64 (28–89)	64 (28–89)	60 (26–85)	
Body mass index (kg/m^2)	25.3 ± 3.7	25.5 ± 3.6	25.6 ± 3.4	0.858
	25 (19–34)	25 (20–35)	25 (20–35)	
Preoperative time (days)	3.4 ± 1.8	3.02 ± 1.5	3.2 ± 1.7	0.377
	3 (1–9)	3 (1–8)	3 (1–10)	
Surgical parameters				
Duration of surgery (min)	61.6 ± 6.5	52.5 ± 7	64.6 ± 8.2	**< 0.001**
	60 (52–75)	52 (41–65)	62 (51–81)	
Fluoroscopy time (s)	34.6 ± 5.6	29.9 ± 6.7	36.6 ± 7.6	**< 0.001**
	34 (27–49)	29 (19–45)	35 (24–54)	
Blood loss (mL)	204.2 ± 23.7	196.9 ± 23.7	207.8 ± 27.5	**0.012**
	200 (170–280)	195 (160–265)	200 (170–295)	
Radiological measurements				
Contralateral CDA (°)	136.6 ± 4.03	137.1 ± 3.5	137.2 ± 4.01	0.508
	136 (131–146)	137 (132–146)	137 (131–146)	
Postoperative CDA (°)	135.5 ± 1.9	136.5 ± 2.6	136.3 ± 2.4	**< 0.001**
	135 (133–144)	136 (133–145)	136 (132–144)	
TAD (mm)	26.7 ± 3.6	25.1 ± 3.1	27.1 ± 3.04	**< 0.001**
	26 (21–35)	25 (20–32)	27 (23–37)	
Functional outcomes				
Harris hip score	75.2 ± 13.1	76.8 ± 14.4	73.3 ± 11.9	**0.038**
	75 (36–97)	79 (36–98)	75 (37–92)	
Barthel index	88.3 ± 12.9	90.05 ± 10.7	86.5 ± 11.5	**0.028**
	95 (55–100)	95 (50–100)	95 (55–100)	
Full weight bearing (weeks)	13.2 ± 1.7	12.8 ± 1.4	13.6 ± 1.7	**0.001**
	13 (11–18)	13 (11–17)	13 (11–19)	
	InterTan ($n=86$) *N* (%)	PFNA-II ($n=100$) *N* (%)	Profin ($n=117$) *N* (%)	p^{b}
Fracture classification				
31-A1	34 (39.5)	28 (28)	44 (37.6)	0.419
31-A2	32 (37.2)	49 (49)	47 (40.2)	
31-A3	20 (23.3)	23 (23)	26 (22.2)	
Reduction type				
Closed	80 (93)	91 (91)	104 (88.9)	0.596
Open	6 (7)	9 (9)	13 (11.1)	
Reduction quality				
Anatomic	70 (81.4)	83 (83)	87 (74.4)	0.532
Acceptable	12 (14)	11 (11)	22 (18.8)	
Poor	4 (4.7)	6 (6)	8 (6.8)	
Complication				
No	63 (73.3)	83 (83)	83 (70.9)	0.089
Yes	23 (26.7)	17 (17)	34 (29.1)	

Statistically significant parameters were marked in bold

CDA collodiaphyseal angle, *TAD* tip-apex distance

[a]Kruskal–Wallis test (Mann–Whitney U test)

[b]Fisher's exact test

Table 3 Post hoc binary comparisons (*p*) of the groups in terms of functional outcomes, surgical parameters and radiological measurements

	InterTan versus PFNA-II	InterTan versus profin	Profin versus PFNA-II
Surgical parameters			
Duration of surgery (min)	**< 0.001**	**0.011**	**< 0.001**
Fluoroscopy time (s)	**< 0.001**	0.083	**< 0.001**
Blood loss (mL)	**0.035**	0.53	**0.004**
Radiological measurements			
Postoperative CDA (°)	**0.005**	**< 0.001**	0.234
TAD (mm)	**0.006**	0.086	**< 0.001**
Functional outcomes			
Harris hip score	0.186	0.306	**0.010**
Barthel index	0.631	0.082	**0.009**
Full weight bearing (weeks)	0.236	**0.039**	**< 0.001**

Statistically significant parameters were marked in bold

CDA collodiaphyseal angle, *TAD* tip–apex distance

Discussion

The most important finding of our study is that it shows the unique advantages and disadvantages of three different PFN designs. Early surgical fixation is recommended to prevent complications associated with prolonged immobility in IFFs [11]. However, the best PFN in the treatment of IFFs still remains controversial, despite the various implants suitable for fixation [12, 13]. There are many studies in the literature comparing two different PFNs [6, 11–13]. Clinical and radiological results of three different PFNs were compared in our study. In recent years, InterTan has become a standard treatment device. Yu et al. [14] found that the mean duration of operation, mean blood loss and mean fluoroscopy time was higher for Intertan than PFNA-II. In a study comparing four different PFN types, it was noted that the mean duration of operation and fluoroscopic time were the shortest in PFNA-II [15]. Similarly in our study, mean duration of operation, mean blood loss, and mean fluoroscopic time were the shortest in PFNA-II. This difference has been associated with the use of two lag screws in both InterTan and Profin PFN. The fact that PFNA-II is simple to use and easy to apply also contributes to this difference. Especially in unstable IFFs, intramedullary fixation is associated with mild pain on the affected limb. This is often due to lag screw cutout or lateral migration [16]. In literature, the incidence of lag screw cutout is between 3 and 10% [17]. The total cutout rate in the current study was 3.6% (11 patients; four in Profin, four in InterTan, and three in PFNA-II), and no significant difference was observed between the groups. Z-effect or reverse Z-effect are frequent complications of IFF treatment with PFN with two separate lag screws [15, 18]. In the present study, Z-effect was developed in all seven patients treated with Profin PFN, whereas reverse Z-effect was not observed in any patient. In the biomechanical study of Huang et al., femoral resistance, stability, and bearing capacity were found to be higher in InterTAN than in PFNA [19]. In a prospective cohort study by Zhang et al. [17], 1-year follow-up between InterTAN and PFNA group showed no significant differences in complications, walking ability, HHS, and range of motion of the hip. In a previous study, it was determined that there was no difference between InterTan and Profin in terms of functional and radiological results [6]. HHS, Barthel Index, and full weight bearing of PFNs differ significantly in our study. In post hoc binary comparisons, there was no difference in functional outcomes between InterTAN and PFNA-II ($p > 0.05$), whereas only full weight bearing time in InterTAN was better than that of Profin ($p = 0.039$). In PFNA-II, the HHS, Barthel Index, and full weight bearing duration were significantly superior to Profin ($p = 0.01$, $p = 0.009$ and $p < 0.001$, respectively).

Significantly higher rotation torques and increased fracture fixation stability have been demonstrated in biomechanical studies with the helical blade system [19, 20]. On the other hand, Gardenbroek et al. [21] reported that osteosynthesis with PFNA did not outweigh 2-lag screw apex systems in terms of femoral head/neck stabilization. For the implantation of PFN such as Profin and Intertan, drilling of the femoral head is necessary and results in loss of useful bone tissue. On the contrary, the helical blade is placed with less drilling or lower bone defect by drilling only the lateral cortex [15]. Fixation stability was assessed radiologically by postoperative TAD and CDA in the current study. Contralateral CDA was also similar in the three PFNs ($p = 0.508$). Postoperative CDA and TAD showed a significant difference between PFNs. In post hoc bilateral comparisons, PFNA-II was found to be better in terms of postoperative CDA and TAD than InterTAN. While Profin was superior to InterTAN only in terms of the postoperative CDA, PFNA-II outperformed Profin only in terms of TAD. Yaozeng et al. [22] showed that 90.1% of patients complained of hip and thigh pain, which is related to the gluteus medius muscle scraping during nail placement. On the other hand, Kumbaracı et al. [11] found that 72% of patients had thigh or hip pain but these pains did not affect functional outcomes. In our study, the rate of hip and thigh pain was 21.8% (66 patients; 23 Profin, 21 PFNA-II, and 22 InterTAN), and it was observed that it did not affect functional and radiological results. Our surgeons have identified some disadvantages associated with the PFNs. First, in patients with good bone quality, PFNA-II tends to disrupt the reduction by causing femoral head-neck distraction while inserting the blade. Second, Profin can cause a problem in terms of the placement of two separate lag screws, frequently in female patients who have narrow femur necks. Last, InterTan require frequent fluoroscopic control because it can make compression as much as the femur shortens. Limitations of our study are retrospective design, no randomization, and wide age range. On the other hand, the adequate number of patients, at least a 2-year follow-up and compliance in terms of the demographic characteristics of the patients in the three groups are the strengths of our study.

Conclusion

In conclusion, all three PFNs have several advantages and disadvantages. However, when the surgical parameters and functional and radiological results were evaluated as a whole, PFNA-II is a better option than Profin and InterTAN in the treatment of IFFs.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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