

# Optimizing stability in AO/OTA 31-A2 intertrochanteric fracture fixation in older patients with osteoporosis

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## Abstract

**Objectives:** To compare the functional and radiographic outcomes of InterTAN nail (IT) and proximal femoral nail anti-rotation (PFNA) for managing primary AO/OTA 31-A2 intertrochanteric hip fractures (IHF) in older osteoporotic patients.

**Methods:** Patients aged 60 years or older who received surgical treatment for IHFs (AO/OTA 31A2.1-A2.3) with IT or PFNA were retrospectively evaluated. The primary outcome was the postoperative treatment failure rate. The secondary outcome was the Harris Hip Score (HHS).

**Results:** A total of 326 osteoporotic cases (326 hips: IT, n = 162; PFNA, n = 164) were assessed with a mean follow-up of 43.5 months (range, 38–48 months). For the entire cohort, the incidence of postoperative treatment failure (periprosthetic fracture and reoperation) was 29/326 (8.9%); the IT-treated cohort (7/162, 4.3%) had a significantly lower rate compared with the

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PFNA-treated cohort (22/165, 13.3%). The incidence of postoperative periprosthetic fractures was significantly lower in the IT-treated cohort than in the PFNA-treated cohort (2.5% vs 7.9%). The postoperative HHS at the final follow-up was not significantly different between the groups. **Conclusion:** IT might show a better outcome in managing osteoporotic AO/OTA 31-A2 IHFs in terms of periprosthetic fracture and reoperation compared with PFNA.

### Keywords

InterTAN nail, proximal femoral nail anti-rotation, intertrochanteric hip fracture, Harris Hip Score, osteoporosis, reoperation

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### Introduction

Periprosthetic fracture or reoperation after surgical treatment of InterTAN nail (IT) or proximal femoral nail anti-rotation (PFNA) for intertrochanteric hip fractures (IHF), Orthopaedic Trauma Association fracture classification [AO/OTA] 3.1A2.1-A2.3) can be a devastating complication. This complication poses risks to the patient and challenges for the surgeon.<sup>1-4</sup> Osteoporosis, an important causative factor in the aetiopathogenesis of IHFs, decreases the quality of internal fixation and can result in re-displacement of IHFs secondary to its poor hold.<sup>5,6</sup> For osteoporotic bone of an older cohort with AO/OTA 31-A2 IHFs, these factors (poor hold, poor purchase, poor compliance, immediate full weight-bearing, limited life expectancy, etc.) require a rigidly fixed device (without regard to total hip replacement or hemiarthroplasty) to be chosen. Many previously published studies on unsuccessful AO/OTA 31-A2 IHFs in the older osteoporotic cohort mainly focussed on IT or PFNA, which resulted in a considerable rate of complications.<sup>7-10</sup> Which type of intramedullary nail to choose in surgical management of AO/OTA 31-A2 IHFs in the older osteoporotic cohort remains controversial.<sup>3,6,7</sup>

The present study aimed to compare the functional and radiographic outcomes of IT and PFNA for managing primary AO/OTA 31-A2 IHFs in a consecutive older osteoporotic cohort.

### Materials and methods

The study was approved by the institutional ethics review board of the First Affiliated Hospital, Sun Yat-sen University. An exemption for informed consent was obtained from our Investigational Ethical Review Board. Older osteoporotic patients who received surgical treatment of primary AO/OTA 31-A2 IHFs were identified from our institutional orthopaedic trauma database from February 2013 to July 2015. Inclusion criteria included acute closed IHFs (AO/OTA 3.1A2.1-A2.3), patients aged  $\geq 60$  years, osteoporosis as shown by Singh's index on plain radiography of the opposite sound hip, and patients who were able to understand instructions and follow a rehabilitation treatment. Exclusion criteria included the following: non-fresh IHS, polytraumatized (Injury Severity Score  $\geq 9$ ) or pathological IHFs; concomitant fractures in the same lower limb or the opposite limb; patients with less than 24 months of follow-up; non-healed or planned surgery;

in-hospital mortality; missing or inadequate postoperative X-rays preventing accurate measurements; endocrine therapy for other diseases; active metabolic bone diseases; severe medical diseases; general debility or associated significant knee joint deformity; primary tumours or advanced cancer; co-occurring mental illness; interruption of follow-up; life expectancy < 1 year; and an American Society of Anesthesiologists score of IV or V.

The primary outcome was the postoperative treatment failure rate, which was defined as periprosthetic fracture, or reoperation requiring removal or revision of the nail, including conversion to arthroplasty. The secondary outcome was the Harris Hip Score (HHS). In this study, a successful outcome was defined as no further surgical intervention after the index procedure. This study also considered some IHFs that may have lost position and thus failed to unite, although the patient was asymptomatic.

Preoperative radiographs of the femur and hip and hospital records were reviewed to determine IHF classification (AO/OTA), assess the reduction situation of IHFs, and evaluate whether rigid fixation could be achieved. Radiographs were reviewed by an independent radiologist using Centricity Enterprise Web (General Electric Medical Systems 2016, v. 9.0, Chalfont St Giles, UK). Cut-out was defined as projection of the screw from the femoral head by more than 1 mm. The interval between injury and osteosynthesis ranged from 3 to 10 days. Follow-up occurred at 1, 3, 6, and 12 months postoperatively, and every year thereafter.

## Surgical methods

All of the operations were performed by three to four experienced orthopaedic surgeons, under general anaesthesia and fluoroscopy control on a radiolucent fracture table. Close reduction of IHFs was

achieved with longitudinal traction applied in line with the axis of the femur. The parameters of IT were as follows: diameter, lag screw of 11 mm, compression screw of 7 mm and composite screw of 15.5 mm; length, normal; and number of proximal/distal screws, 2/1 (Smith & Nephew, Memphis, TN, USA). The parameters of PFNA were as follows: proximal diameter, 16.5 mm; distal diameter, 9–10 mm; length, 240 or 300 mm; number of proximal/distal screws, 1/1; and valgus curvature, 5° (Synthes, Solothurn, Switzerland). The point of needle insertion was slightly medial to the exact tip of the greater trochanter. The tip–apex distance (TAD) was defined as the sum of the distance from the tip of the hip screw to the apex of the femoral head measured on an anteroposterior and lateral radiograph after correction was made for magnification. The TAD was limited to approximately 20 mm. There was no bone grafting in any of the cases. A standard operative technique that was either recommended by the manufacturer or by previous studies (Merreddy et al.<sup>11</sup> for PFNA and Ruecker et al.<sup>12</sup> for IT) was used.

## Postoperative management

Non-steroidal anti-inflammatory drugs were provided for the relief of pain after surgery. Twice-daily cefazolin sodium 2.0 g (1.0 g, Sigma-Aldrich, St Louis, MO, USA) was routinely administered to all patients for appropriate prophylaxis against infection. Low-molecular-weight heparin (0.3 ml: 3075AXaIU, nadroparin; Fraxiparine, GlaxoSmithKline, Uxbridge, UK) was used as the first choice for thromboprophylaxis. Low-molecular-weight heparin was administered subcutaneously once daily at a dose volume of 0.2–0.4 ml from the evening of the day before surgery to the 3rd day after surgery. A total of 90 mg aspirin (30 mg, Bayer, Germany) was then administered once daily after discharge for 1 month.

Patients were encouraged to carry out full weight-bearing movement on the first post-operative day.

The rehabilitation process was standardized, regardless of the type of intramedullary fixation used. A postoperative imaging examination was performed to evaluate the stability of fracture fixation. The HHS was used to evaluate the patient-related functional outcome of the hip joint. Bone union was defined as evidence of bridging callus or cortical continuity involving at least two cortices. Non-union was defined as the lack of union after 6 months of follow-up. Malunion was defined as less than 50% contact between the proximal and distal fragments or a collodiaphyseal angle of less than 120°. Deep wound infection and superficial wound infection were defined as an established infection beneath the fascia requiring surgical revision and a cutaneous or subcutaneous infection requiring antibiotic therapy, respectively. The operation time was measured as the interval from the start of the reposition to wound closure.

## Data analysis

Descriptive statistics are presented as frequency (percentage) for categorical variables or mean and standard deviation for continuous variables, as appropriate. Between-group differences were assessed with the two-sample Student's *t*-test for continuous variables, while Pearson's  $\chi^2$  test was used for categorical variables. Pearson's  $\chi^2$  test, Fisher's exact test, and analysis of variance were used for between-group comparisons of constituent ratios. For all results, two-tailed *P* values < 0.05 were considered statistically significant. All analyses were performed using IBM SPSS Statistics (version 23.0; IBM Corp., Armonk, NY, USA).

## Results

### Baseline characteristics

Baseline characteristics are shown in Table 1. A total of 563 case charts were reviewed. Finally, 417 (417 hips) patients with osteoporotic IHFs (AO/OTA 3.1A2.1-A2.3) who were treated using IT or PFNA devices met the inclusion criteria. A total of 146 cases were excluded for the following reasons: seven patients had a non-fresh IHS; 12 had polytraumatized (Injury Severity Score  $\geq 9$ ) or pathological IHFs; 13 had concomitant fractures in the same lower limb or the opposite limb; nine had less than 24 months of follow-up; and 81 for other reasons. The remaining 417 patients' mechanisms of injury were as follows: a fall from standing in 147; falling down stairs in 65; falling off a ladder in 47; motor vehicle collision in 54; bicycle accident in 39; being struck as a pedestrian in 47; and unclear reasons in 18.

Among the 417 cases of IHF, 91 patients, of whom all 91 died within the year after index surgery, were lost to follow-up (21.8%). These patients were excluded from analysis to prevent bias of underestimating event rates. Therefore, a total of 326 cases (326 hips) with osteoporosis (IT, *n* = 162; PFNA, *n* = 164) were assessed with a mean follow-up period of 43.5 months (range, 38–48 months) (Figure 1). The mean age was 72.3 years (SD = 4.6, range, 60–95 years), with 150 women (46.0%) and 176 men (54.0%). Except for one IT-treated patient with deep infection, none of the patients developed any complications that would involve reoperation. Among all of the cases, one superficial infection and one deep infection were observed in the PFNA-treated and IT-treated cohorts, respectively, with no significant difference between the cohorts (Fisher's exact test).

**Table 1.** Demographic data and follow-up.

Variable	IT (n = 162)	PFNA (n = 164)	P value
Sex, n (M/F)	73/89	77/87	0.732 <sup>a</sup>
Age (y)			0.892 <sup>b</sup>
60–69	65	67	
70–79	44	40	
80–89	33	35	
90–95	20	22	
Side, n (left/right)	79/83	80/84	0.998 <sup>a</sup>
AO/OTA type, n			0.808 <sup>b</sup>
31A2.1	58	62	
31A2.2	79	76	
31A2.3	25	26	
BMI, kg/m <sup>2</sup>	25.1±3.2	24.9±4.4	0.116 <sup>c</sup>
BMD	-3.5 ±0.6	-3.6 ±0.7	0.132 <sup>c</sup>
ASA level			0.581 <sup>b</sup>
1	53	55	
2	71	77	
3	38	32	
Injury operation interval			0.429 <sup>b</sup>
< 24 h	18	21	
24–48 h	67	72	
49–72 h	56	52	
> 72 h	21	19	
Follow-up (mo)	43.3±5.2	43.7±4.9	0.148 <sup>c</sup>

<sup>a</sup>Analysed using the  $\chi^2$  test; <sup>b</sup>analysed using the Mann–Whitney test; <sup>c</sup>analysed using the independent samples t-test.

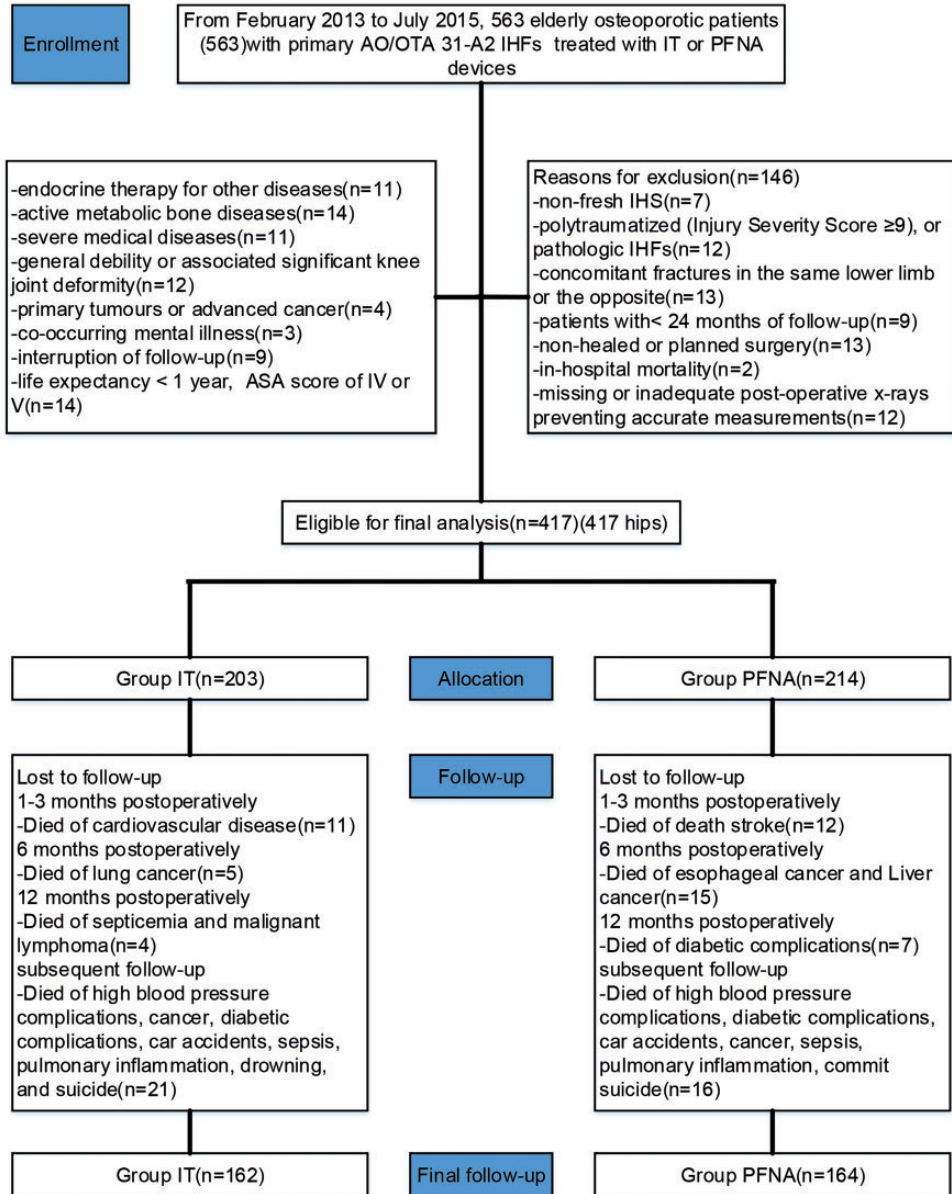
M: male; F: female; IT: InterTAN nail; PFNA: proximal femoral nail anti-rotation; HHS: Harris Hip Score; ASA: American Society of Anesthesiologists; BMI: body mass index; BMD: bone mineral density.

### Radiographic outcomes

The total incidence of postoperative treatment failure (periprosthetic fracture and reoperation) was 29 of 326 (8.9%) patients (Table 2). The IT-treated cohort (7/162, 4.3%) had a significantly lower rate of periprosthetic fracture and reoperation compared with the PFNA-treated cohort (22/165, 13.3%;  $P=0.004$ ). The incidence of postoperative periprosthetic fracture was significantly lower in the IT-treated cohort than in the PFNA-treated cohort (2.5% [4/162] vs 7.9% [13/165],  $P=0.028$ ). Four patients with anatomical reduction who suffered from postoperative periprosthetic

fractures in the IT-treated cohort were older than 80 years (mean, 83.3 years). A total of 13 patients with anatomical reduction who suffered from postoperative periprosthetic fractures in the PFNA-treated cohort had a mean age of 72 years (range, 60–75 years).

Two of 162 (1.2%) patients had a reoperation following cut-outs after IT nails, and nine of 165 (5.5%) patients had a reoperation following cut-outs after PFNA nails ( $P=0.034$ ). The mean time to reoperation in the IT-treated and PFNA-treated cohorts was 10 months (range, 5–16 months) and 6 months (range, 4–13 months), respectively. The mean TAD was



**Figure 1.** Flow diagram demonstrating methods for identification of studies to assess the treatment of primary AO/OTA 31-A2 intertrochanteric femur fractures (IFHs) in elderly osteoporotic patients using either InterTAN nail (IT) or proximal femoral nail anti-rotation (PFNA), and reasons for exclusion.

20.1 mm (range, 19–21 mm) and 20.3 mm (range, 19–21 mm) for the IT-treated and PFNA-treated cohorts, respectively (Table 3). One IT-treated patient developed

varus collapse of the femoral head and underwent total hip replacement. In the PFNA-treated cohort, the overall periprosthetic fracture rate was 7.9% (13/165).

**Table 2.** Description of causes of nail failure.

Variable	IT (n = 162)	PFNA (n = 165)	P value
Periprosthetic fracture revised to longer main nail	1	2	0.569 <sup>a</sup>
Periprosthetic fracture revised to plate	1	2	0.569 <sup>a</sup>
Periprosthetic fracture revised to arthroplasty	2	9	0.033 <sup>*a</sup>
Cut-out revised to shorter screw/blade	1	1	1.000 <sup>b</sup>
Cut-out revised to arthroplasty	1	8	0.019 <sup>*a</sup>
Varus collapse of the femoral head	1	0	0.497 <sup>b</sup>
Total	7	22	0.004 <sup>*a</sup>

<sup>a</sup>Statistically significant values. <sup>a</sup>Analysed using the Pearson  $\chi^2$  test; <sup>b</sup>analysed using Fisher's exact test. IT: InterTAN nail; PFNA: proximal femoral nail anti-rotation.

**Table 3.** Operation variables.

Variable	IT (n = 162)	PFNA (n = 165)	P value
Reduction results, n			0.768 <sup>a</sup>
Anatomical	91	90	
Acceptable	71	75	
Poor	0	0	
Implant position, n			0.592 <sup>a</sup>
Optimal	98	95	
Suboptimal	64	70	
TAD, mm	20.1±1.17	20.3±1.21	0.106 <sup>b</sup>
Operation time (min)	65.8±12.15	66.2±15.36	0.216 <sup>b</sup>
Blood loss (ml)	198.9±36.62	199.4±32.17	0.092 <sup>b</sup>

<sup>a</sup>Analysed using the Mann–Whitney test; <sup>b</sup>analysed using the independent samples t-test. TAD: tip–apex distance; IT: InterTAN nail; PFNA: proximal femoral nail anti-rotation.

Varus collapse of the femoral head did not occur in any PFNA-treated patients (Table 2).

The mean fracture union times were 14.8 weeks (range, 9–15, SD: 3.27 weeks) and 15.2 weeks (10–17, SD: 2.12 weeks) for the IT-treated and PFNA-treated cohorts, respectively, with no significant difference between the cohorts. There were four cut-outs, two malunions, and one non-union. No dislocation of the prosthesis was detected in any of the patients in the two treated cohorts.

### Clinical outcomes

In the IT-treated group, the HHS was significantly lower in the 1st month compared with the 3rd month ( $P < 0.001$ ).

The HHS was also significantly lower in the 3rd month compared with the 6th month and in the 6th month compared with the 12th month ( $P = 0.006$  and  $P = 0.003$ , respectively). However, there was no significant difference in the HSS between the 12th and 18th months. The HSS was significantly higher in the 12th month compared with the 1st month ( $P < 0.001$ ). Therefore, the functional outcomes of the IT-treated group showed a positive recovery in patients who underwent treatment of IT devices. This steady increase in improvement lasted until the 1-year point, with no further increase by 18 months.

Similar results for the HSS were observed in the PFNA-treated group. At the last follow-up, the mean HHS was not

significantly different between the two groups (Table 4).

## Discussion

The primary findings of the present study suggested that IT showed better outcomes in managing osteoporotic AO/OTA 31-A2 IHFs in terms of periprosthetic fracture and reoperation compared with PFNA. However, the between-group functional outcomes as assessed by the HHS failed to show any significant differences at the final follow-up.

Although a large number of clinical investigations on the outcome of IHF have been published,<sup>8,13</sup> only a few of these separately and adequately evaluated osteoporotic AO/OTA 31-A2 IHFs. Osteoporotic AO/OTA 31-A2 IHFs should be dealt with surgically,<sup>8,11</sup> but the ideal implant is still debatable. The main aim of management for osteoporotic AO/OTA 31-A2 IHFs is to enable patients to achieve pre-injury functional status and prevent long-standing disability and/or medical related complications.<sup>6,9</sup> An implant needs advantages of a minimally invasive surgery technique, including post-operative early full weight-bearing and a low failure rate of postoperative treatment.<sup>5</sup> Successful surgery fails to always be correlated with a positive functional outcome.<sup>7</sup> Most studies have shown that PFNA has a higher postoperative treatment failure

rate than does IT.<sup>14,15</sup> A widely cited prospective clinical study that compared IT with PFNA reported by Seyhan et al.<sup>1</sup> showed that the primary conclusions favoured IT for treating osteoporotic AO/OTA 31-A2 IHFs. The principal argument against PFNA focussed on the postoperative treatment failure rate caused by periprosthetic fractures. This complication occurred in 9 of 132 patients who received PFNA (6.8%), but occurred in only four patients who received IT (3.0%) (relative risk 2.31, 95% confidence interval 0.16–1.35). The complication rate of PFNA is largely attributed to the original design parameters, resulting in redesign of a newer-generation implant (PFNA-II), which is more suitable for Asian people.<sup>1,16,17</sup> Nevertheless, in other studies,<sup>12,18,19</sup> no significant difference was detected in the rate of periprosthetic fractures between these two implants. Zhang et al.<sup>17</sup> reported 174 patients with osteoporotic AO/OTA 31-A2 IHFs who received treatment of PFNA or IT. They found that the rate of periprosthetic fractures was 1.1% or 0%, respectively ( $P=1.000$ ). In contrast, in the present study, PFNA-treated patients were strongly associated with periprosthetic fractures caused by varus collapse or cut-out. Therefore, previous data might have resulted in misinformed results for PFNA. Our findings indicate that studies that were conducted since 2009 failed to describe an increased

**Table 4.** Clinical outcomes.

Variable	IT (n = 144)	PFNA (n = 139)	P value
HHS at 1 month	67.9±3.11	68.1±4.33	0.214
HHS at 3 months	74.3±4.54	73.9±6.58	0.125
HHS at 6 months	76.1±6.73	75.8±7.62	0.141
HHS at 12 months	78.8±5.77	78.4±6.16	0.106
HHS at 18 months	79.2±5.86	78.8±5.21	0.218
HHS at the final follow-up	80.2±4.36	79.7±5.26	0.187

Values were analysed using the independent samples t-test.

HSS: Harris Hip Score; IT: InterTAN nail; PFNA: proximal femoral nail anti-rotation.



risk of periprosthetic fractures with PFNA.<sup>12,18,19</sup> Moreover, a recent study performed in 2017 that used a PFNA-II showed no periprosthetic fractures after nailing.<sup>16,17</sup> However, treatment of osteoporotic AO/OTA 31-A2 IHFs remains debatable, particularly in the priority of using PFNA or IT.<sup>14,16</sup>

In osteoporotic AO/OTA 31-A2 IHFs, the osseous fragments fail to distribute the load, and weight bearing must be predominantly supported by the intramedullary nail.<sup>18,20</sup> PFNA with distal dual interlocking for normal bone is commonly recommended. However, distal dual interlocking, which rarely alters the pattern of proximal femoral strain and fails to address the hip biomechanics from rotational forces, is controversial because of a lack of biomechanical advantage during axial compression testing.<sup>21,22</sup> Consequently, stability and integrity of implant fixation of osteoporotic AO/OTA 31-A2 IHFs, which are managed using a PFNA device without distal dual interlocking, might be insufficient. Additional biomechanical stability contributed by distal dual interlocking may afford good distribution of rotational forces over the entire femur.<sup>23,24</sup> Additionally, anatomical reduction, which re-establishes bone-to-bone contact and reduces tensile stresses imposed on the implant, provides the greatest fixation strength and most resistance to cut-out. This then allows the implant to perform early weight-bearing activity.<sup>25,26</sup>

The IT nail theoretically has better stability and a lower rate of implant failure in osteoporotic AO/OTA 31-A2 IHFs. This is because the IT nail is characterized by firm fixation of the proximal femur and extremely strong anti-rotation compared with PFNA.<sup>14</sup> The IT nail, which has a strong ability to provide medial support of the proximal femur, has attained an influential breakthrough in treatment of osteoporotic AO/OTA 31-A2 IHFs.<sup>16</sup> Previous studies have suggested that that IT is biomechanically

superior to PFNA, providing stability against rotational forces.<sup>6</sup> In our study, the overall periprosthetic fracture rate of 7.9% favourably compares with that observed with PFNA devices in previous reports.<sup>2,9,11</sup> Although only 76% of the patients achieved radiographic anatomical reduction and 87% had a TAD < 25 mm, there were four cut-outs, two malunions, and one non-union. These findings suggest that radiographic anatomical reduction and an ideal TAD < 25 mm might not be as important for osteoporotic AO/OTA 31-A2 IHFs managed using IT or PFNA as demonstrated in previous studies, which suggested TAD as a predictor of cut-out of a lag screw.<sup>27,28</sup> Increased age and osteoporosis might be considered as strong predictors, although TAD is the strongest predictor of implant failure.

Although the reoperation rate in the present study is lower than that in previous studies,<sup>14,19,27</sup> the following factors may have contributed to the comparatively high reoperation rate. First, cut-out or varus collapse is frequently triggered by a poor reduction in fractures, as well as malpositioning of the implant. Of the 11 cases of implant failure in our study, three osteoporotic AO/OTA 31-A2 IHFs were poorly reduced; four femoral head-neck screws were poorly positioned, and four main nails (3 ITs and 1 PFNA) were inclined to the lateral wall of the femur. Second, untimely postoperative full weight-bearing and/or extortionate activity levels may have an increased failure rate. Delayed postoperative full weight-bearing may have an unexpected positive effect on the outcome of osteoporotic AO/OTA 31-A2 IHFs. Third, patient age and time to first surgery also have a significant effect on outcome of managing osteoporotic AO/OTA 31-A2 IHFs. Fourth, a TAD < 19 mm may be correlated with implant failure. Our findings may provide a guide for surgeons in decreasing the rate of mechanical

failure when managing osteoporotic AO/OTA 31-A2 IHFs.

Age is vital factor that adversely affects the HHS obtained in osteoporotic AO/OTA 31-A2 IHFs. Patients older than 60 years show appreciably lower HHSs, which is most likely associated with the existence of osteoporosis.<sup>1,4</sup> This fact led to our decision to perform a comparison and to adjust the results obtained for each patient depending on age. After assessing our results, the obtained HHSs are comparable to those published in previous studies.<sup>6,11,24</sup>

There are two inherent limitations in our study. First, this was a retrospective study, which may be related to bias. Nevertheless, because the ability of the implants to mechanically stabilize the fragments was the focus of our study, and the results were essentially imaging analyses, the data were barely affected by the retrospective collection. Second, patient- and surgeon-related confounders may have been present. However, well-matched groups allowed us to conclude that the between-group differences were unrelated to the patients' baseline characteristics.

In conclusion, based on the available evidence and our clinical experience with osteoporotic AO/OTA 31-A2 IHFs, IT appears to be a biomechanically stronger construct and is better suited to preventing postoperative failure in stabilizing osteoporotic AO/OTA 31-A2 IHFs compared with PFNA. Nevertheless, because of the variety of clinical presentations and fracture patterns, there is no overwhelming evidence to prove this recommendation. Furthermore, we were unable to clarify whether IT or PFNA is best suited for managing osteoporotic AO/OTA 31-A2 IHFs in our study. Therefore, a prospective, randomized study is required to compare the functional and radiographic outcomes of IT and PFNA for treating primary AO/OTA 31-A2 IHFs in older osteoporotic patients.

## Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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