



Should the diameter of the proximal femoral nail be large enough to fill the canal in the treatment of intertrochanteric femoral fracture in patients over fifty?

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Abstract

Purpose Many studies have been conducted to evaluate the effects of nail shape, design, or length on the treatment of intertrochanteric fractures. However, the clinical implications of the nail diameter remain unclear.

Methods This study was conducted with 191 patients aged ≥ 50 years with unilateral intertrochanteric fractures treated with the same type of short cephalomedullary nail and followed for at least one year. We recorded the reduction type, tip–apex distance, cortical contact of the nail, and nail/canal diameter ratio (NCR) just distal to the locking screw. The effects of nail diameter on the clinical results were evaluated.

Results The average NCR was 68.7. The average union time was 4.78 months. Delayed union or nonunion was seen in 17 patients. Eight patients underwent additional surgery. The mean change in the modified Koval activity score was -0.84 . The NCR did not significantly affect the clinical results. Comparisons of cases with NCRs above and below the average and the average $- 1$ standard deviation revealed no significant difference. The clinical outcome was not related to any variable associated with the nail diameter.

Conclusion With this specific proximal femoral nail, a small diameter relative to that of the femoral canal had no adverse effect on the union of osteoporotic intertrochanteric fractures, even in patients with unstable fractures and those who had unsatisfactory reductions.

Keywords Hip · Femur · Trochanter · Nailing · Diameter

Introduction

Various fixation devices have been designed for the treatment of intertrochanteric fractures, for which fixation using cephalomedullary nails is most widely preferred. Cephalomedullary nail fixation enables safe immediate weight bearing [1, 2] and has been used successfully for stable and unstable fractures [3]. The effects of various cephalomedullary nail shapes, designs, and lengths on the fixation of intertrochanteric fractures and the effects of distal interlocking

screws have been studied [4–7]. These results have been applied to the development of clinical devices. However, the clinical implications of the nail diameter, for the treatment of geriatric intertrochanteric fractures, remain unclear.

Thus, this study was conducted to investigate the importance of the cephalomedullary nail diameter in the fixation of intertrochanteric fractures. The primary goal was to investigate whether the nail should fill the femoral canal, to test the hypothesis that the group in which fractures were treated with nails with the greatest possible diameters would have better postoperative stability and clinical outcomes.

Level of evidence: Level III, comparative study

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Materials and methods

Patient selection

For this study, the medical records and radiographs of 259 consecutive patients aged ≥ 50 years who were diagnosed

with unilateral intertrochanteric fractures (AO classification 31.A1-3) between January 2015 and April 2019 were retrospectively reviewed. All cases underwent internal fixation with single implants [Proximal Femoral Nail Antirotation II (PFNA-II), DePuy-Synthes, USA] by a single surgeon. Of the 259 patients, 48 died within one year and 14 were lost to follow-up. Six patients were excluded because they were treated with long PFNA-IIs. Finally, 191 patients who were followed for at least one year were enrolled in the study. The Institutional Review Board approved the study design and protocol.

Variables and clinical and radiological outcomes

Patient information obtained from the medical records included age, sex, weight, height, body mass index (BMI), and treatment details, including the surgical delay, implant details, and procedures. Activity levels before surgery and at the final follow-up were evaluated using the Koval activity score [8].

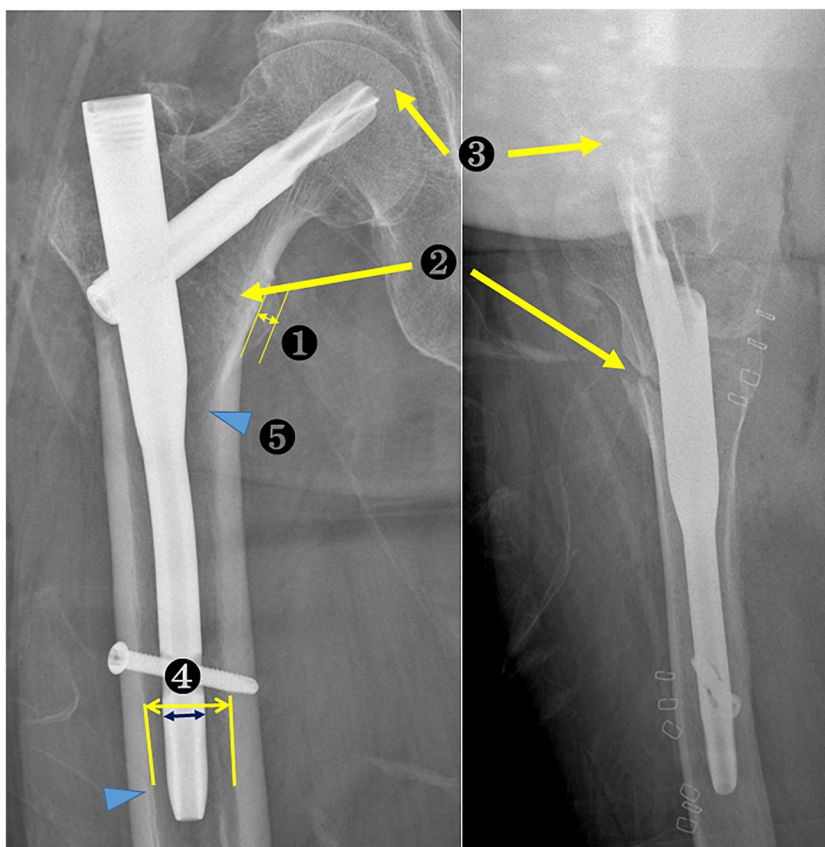
The pattern of fracture according to the AO/OTA fracture classification system [9], the quality of reduction according to Chang's modified criteria [10], and the tip–apex distance (TAD) [11, 12] were evaluated using true anteroposterior (AP) and lateral femur radiographs obtained before and after surgery. The nail/canal ratio (NCR) was defined as the ratio

between the nail diameter and the inner diameter of the femoral canal measured just distal to the interference screw. The occurrence of contact between the nail and femoral endocortex at any place was checked on the x-rays. To minimize measurement errors created by differences in proximal femoral rotation, we matched the known length of the PFNA-II blade to select suitable AP radiographs (Fig. 1).

The reductions were graded in three ways. They were defined as “in” when the cortices (medial on AP and anterior on lateral views) of the proximal fragment were located inside those of the distal fragment and as “out” when they were outside of this fragment. Cases in which the cortices were parallel were designated “neutral.” When “in” was observed on either the AP or lateral view, the case was designated “One In,” and when it was observed on both views, the case was designated “In-In”; both cases were defined as unsatisfactory reductions. Otherwise, cases were designated “No In” and reductions were deemed satisfactory.

Follow-up visits were scheduled two and six weeks, three and six months, and one year after surgery. Union time was evaluated using serial AP and lateral femur radiographs taken at the regular outpatient follow-ups. When a patient could not visit the outpatient clinic, s/he or a caregiver was interviewed via telephone. In these cases, the union time was represented by the time at which the patient could endure full weight bearing without pain. Delayed union was defined

Fig. 1 Five parameters assessed in this study. 1) The width of the lesser trochanter (to verify that the radiograph was truly AP). 2) The relative positions of the proximal and distal cortices (to evaluate the reduction quality; this case depicted was graded as “neutral” on the AP view and “inside” on the lateral view). 3) The tip–apex distance. 4) The nail/canal ratio. 5) Possible areas of nail contact with the femoral endocortex (arrowheads)



as that delayed by more than the average plus two standard deviations. Nonunion was defined by the failure of union to proceed thereafter or the observation of fixation loss at any time. Orthopaedic complications, such as fixation failure and the occurrence of a second hip fracture, general complications after discharge, readmission within 90 days, and re-operation were also recorded.

The variables described above were analyzed by comparing low and high NCR groups defined by the average NCR. For the worst-case scenario, the same investigation was repeated between the group with NCRs below the mean minus one standard deviation and the higher NCR group. The effect of the nails' contact with the femoral endocortex was also analyzed.

Operative techniques and postoperative care

A single surgeon performed all surgeries on an orthopaedic fracture table with the patients in the supine position using PFNA II implants. The procedures were performed under general or spinal anaesthesia. The nail diameters were determined roughly, not directly, just before skin incision (i.e., without measurement of the inner diameter of the femoral canal). A short (200-mm-long) stem was used when the lesser trochanter was detached as a long triangular fragment. Otherwise, an ultra-short (170-mm-long) nail was used. Closed reduction was performed before nail insertion, with every effort made to reduce the anterior and medial cortices.

From the first postoperative day, patients performed isometric quadriceps femoris exercises. Standing and walking with assistance were started using a high walker. The patients were allowed to bear tolerable weight with no limit as soon as possible. They were encouraged to discard the walker or crutches by six weeks postoperatively if possible. However, cane use was recommended to avoid subsequent falls.

Statistical analysis

The statistical analyses were performed using IBM SPSS Statistics for Windows (ver. 22.0; SPSS, IBM, Chicago, IL, USA). The Shapiro–Wilk test was used to examine the normality of data distributions. Normally distributed continuous data were reported as means and standard deviations, and non-normal continuous data were reported as medians and ranges. Continuous data were compared using the two-tailed Student's *t* test and analysis of variance. Categorical data were analyzed using Fisher's exact test. Significant variables were entered into binary logistic regression analyses to identify significant associations between variables with 95% confidence intervals (CIs). Continuous variables such as the NCR, union time, and recovery (difference in Koval score) were analyzed using Pearson's correlation analysis.

Results

Patient demographics and fracture and treatment characteristics

The average patient age was 79 (50–95) years, and the patients were predominantly female (125 vs. 66 males). The patients' demographic and clinical (fracture, reduction, and operative implant) characteristics are summarized in Table 1. Surgeries were performed an average of 2.5 days after fracture. Of the 191 fractures, 78 were unstable. Unsatisfactory reduction (“One In” or “In-In”) was identified on at least one radiographic view in 95 cases. The average TAD was 18.8 mm. Ultra-short (170-mm-long) nails were used in 129 patients. The average NCR was $68.7\% \pm 10.43\%$ (range 45.50–99.60%). Of the nails, 144 (75.3%) were in contact with the femoral endocortex. The average preoperative

Table 1 Patient demographics, fracture information, and operation details

Patient Demographics	
Patients, <i>n</i>	191
Mean age (years)	79 (50–95)
Sex, male/female	66/125
Height (cm)	158.2 ± 9.3
Weight (kg)	56.1 ± 12.1
BMI (kg/m ²)	22.3 ± 3.8
BMD (spine / femur)	-2.59 ± 1.61 / -2.35 ± 1.47
Assessment of Fracture and Reduction	
Surgical delay (day)	2.5 ± 3.1
Stable/unstable	113/78
Type of reduction (number of cases)	No'In' 96 One'In' 70 In-In 25
TAD* (mm)	18.8 ± 4.9
TAD* > 25 (number of cases)	14
Operative Implant Details	
Nail diameter	
- 9 mm	68
- 10 mm	106
- 11 mm	16
- 12 mm	1
Nail length	
- 170 mm	129
- 200 mm	62
Nail/canal ratio (%)	68.7 ± 10.43
- Below the average (<i>n</i>)	101 (52.9%)
- Above the average (<i>n</i>)	90 (47.1%)
Nail contact to cortex (<i>n</i>)	144 (75.3%)

*TAD: Tip-Apex Distance

spinal and femoral bone mineral densities were -2.59 ± 1.61 and -2.35 ± 1.47 , respectively.

Clinical outcomes

The average time required for union was 4.78 months. The time defining delayed union was ten months (average plus two standard deviations). Seventeen (8.9%) cases had delayed union or nonunion, fixation failure occurred in six (3.1%) cases, and eight (4.2%) cases required re-operation. The average pre-injury activity level (Koval score), for the 148 patients who were able to walk independently, was 2.33 ± 1.77 . In 100 (52.4%) cases, the Koval score was lower at the final follow-up, with an average decrease of 0.84 ± 1.8 . The average final Koval score was 3.18 ± 2.13 .

Findings of group analysis

Two NCR values were used as standards: the average (NCR) and the average minus one standard deviation (NCR'). After division into high and low NCR groups, patient factors (age, sex, BMI, and fracture type), operative details, and clinical outcomes were compared.

When the patients were divided into two groups based on the average NCR (68.7%), the frequency of nail contact with the endocortex and the postoperative decrease in the Koval activity score were significantly lower in the low NCR group ($p=0.019$ and 0.020 , respectively; Table 2). No other significant difference was observed between groups.

Similarly, the low NCR' group had significantly less cortical contact and a smaller decrease in the Koval activity score than did the high NCR' group ($p=0.046$ and 0.004 , respectively). The time required for union was shorter in the low NCR' group ($p=0.001$; Table 3).

The patients were divided into four groups based on the NCR and nail contact with the endocortex. The groups with low NCR/NCR's and cortical contact had shorter union times and smaller decreases in the Koval score than did the groups with high NCRs/NCR's and no cortical contact (Tables 4 and 5).

In the low NCR' group, Pearson's coefficient of correlation between the union time and NCR was 0.273 ($p=0.005$); no such correlation was observed in the high NCR' group. Recovery and the NCR were not correlated in either group (Fig. 2).

Delayed union and nonunion

Delayed union or nonunion occurred in 17 (8.9%) patients. The TAD was the only variable that was related to the incidence of delayed union or nonunion ($p=0.03$; odds ratio 1.12, $1.01 \leq 95\% \text{ CI} \leq 1.25$). No variable related to the nail diameter or length differed significantly with the occurrence of any orthopedic complication, re-operation, or readmission within 90 days, in the full sample or in the samples of patients with unstable fractures ($n=78$) and unsatisfactory reduction ($n=95$).

Table 2 Variables analyzed when an average of nail canal ratio (68.74%) was used as a standard

Variable	High NCR (N=90)	Low NCR (N=101)	P-Value
Patient factors			
Age (years)	77.83 ± 12.29	79.51 ± 11.43	0.347
Sex (M/F)	31/59	35/66	0.976
BMI (kg/m ²)	22.03 ± 5.03	21.98 ± 4.43	0.972
Type of fracture (stable/unstable)	59/31	54/47	0.105
Any result			
Nail contact at endo-cortex (Y/N)	75/15	69/32	0.019
Reduction type			
Any 'In'	41	54	0.311
No 'In'	49	47	
TAD	18.31 ± 4.67	19.23 ± 5.04	0.209
Union time (month)	5.07 ± 3.08	4.29 ± 2.52	0.056
Koval recovery	-1.12 ± 1.87	-0.56 ± 1.74	0.020
Delayed union (Y/N)	10/80	7/94	0.324
Re-operation (Y/N)	5/85	3/98	0.479
Orthopedic complications (Y/N)	7/83	4/97	0.354

SD, standard deviation; BMI, body mass index

Statistical significance was set at $P < .05$

Table 3 Variables analyzed when an average – 1 standard deviation of nail canal ratio (58.27%) was used as a standard

Variable	High NCR (N= 161)	Low NCR (N= 30)	P-Value
Patient factors			
Age (years)	78.26 ± 12.45	81.24 ± 7.66	0.075
Sex (M/F)	59/102	7/23	0.210
Body Mass Index (kg/m ²)	22.03 ± 4.54	21.82 ± 5.47	0.834
Type of Fracture (stable/unstable)	95/66	18/12	1.000
Any result			
Nail contact at endo-cortex (Y/N)	126/35	18/12	0.040
Reduction type			
Any 'In'	81	14	0.843
No'In'	80	16	
Tip Apex Distance	18.93 ± 4.73	18.24 ± 5.59	0.463
Union time (month)	4.85 ± 2.98	3.67 ± 1.41	0.026
Koval recovery	-1.02 ± 1.85	-0.00 ± 1.64	0.004
Delayed union (Y/N)	16/145	1/29	0.481
Re-operation (Y/N)	8/153	0/30	0.361
Orthopedic complications (Y/N)	10/151	1/29	1.000

SD, standard deviation; BMI, body mass index

Statistical significance was set at $P < .05$

Table 4 Variables analysis with an average of NCR* (68.7%) & nail contact endo-cortex

Variable	High NCR + contact (N= 75)	High NCR—contact (N= 15)	Low NCR + contact (N= 69)	Low NCR—contact (N= 32)	P-Value
Patient factors					
Age	79.99 ± 9.98	68.40 ± 17.48	78.46 ± 11.74	81.24 ± 10.92	0.003
Sex (Male/Female)	24/52	7/7	26/44	9/22	0.358
Body Mass Index	22.44 ± 3.84	19.22 ± 8.40	22.27 ± 3.54	21.60 ± 6.08	0.092
Type of fracture (stable/unstable)	48/27	11/4	33/36	21/11	0.076
Any result					
Reduction type					
Any 'In'	37	4	39	15	0.271
No'In'	38	11	30	17	
Tip-Apex Distance	18.66 ± 3.29	17.22 ± 8.87	19.42 ± 4.86	18.57 ± 5.55	0.415
Union time (month)	4.86 ± 2.76	6.27 ± 4.28 ^a	4.08 ± 2.05 ^a	4.70 ± 3.30	0.039
Koval recovery	-1.13 ± 1.90 ^b	-1.47 ± 2.13	-0.33 ± 1.68 ^b	-1.03 ± 1.78	0.024
Delayed union	7	3	4	3	0.305
Re-operation	4	1	2	1	0.765
Orthopedic complications	6	1	3	1	0.692

*NCR: Nail Canal Ratio

a: only two groups significantly different by Bonferroni method

b: only two groups significantly different by Bonferroni method

Statistical significance was set at $P < .05$

Discussion

The goal of the surgical treatment of intertrochanteric femoral fractures is to return patients' conditions to the

pre-injury level as quickly as possible. Successful treatment requires immediate ambulation after stable fixation [13, 14]. So far, numerous surgical methods have been proposed [15]. Researchers have sought to identify the

Table 5 Variables analysis with NCR' (average -1 Standard deviation of NCR * (58.27%)) & nail contact endo-cortex

Variable	High NCR' + contact (N=126)	High NCR'—contact (N=35)	Low NCR' + contact (N=18)	Low NCR'—contact (N=12)	P-Value
Patient factors					
Age	79.17 ± 11.14	75.00 ± 16.06	80.65 ± 8.34	82.15 ± 6.69	0.146
Sex (Male/Female)	44/82	15/20	5/13	2/10	0.280
Body Mass Index (kg/m ²)	22.35 ± 3.65	20.88 ± 6.78	22.01 ± 3.67	21.52 ± 7.63	0.407
Type of fracture (stable/unstable)	70/56	25/10	10/8	8/4	0.331
Any result					
Reduction type					
Any 'In'	69	12	7	7	0.093
No 'In'	57	23	12	5	
Tip Apex Distance	19.15 ± 4.04	18.13 ± 6.63	18.61 ± 4.49	17.68 ± 7.13	0.560
Union time (month)	4.63 ± 2.57	5.64 ± 4.08 ^a	3.60 ± 1.50 ^a	3.77 ± 1.30	0.035
Koval recovery	-0.93 ± 1.80	-1.33 ± 2.00 ^b	0.40 ± 1.70 ^b	-0.62 ± 1.39	0.007
Delayed union	10	6	1	0	0.280
Re-operation	6	2	0	0	0.920
Orthopedic complications	8	2	1	0	1.000

*NCR: Nail Canal Ratio

a: only two groups significantly different by Bonferroni method

b: only two groups significantly different by Bonferroni method

Statistical significance was set at $P < .05$

optimal methods for intramedullary nail use in the treatment of intertrochanteric fractures. Lindvall et al. [4] reported no difference in the union or failure rate between fixation with short and long intramedullary nails. Zhang et al. [5] also found no difference in clinical outcome according to nail length in a meta-analysis, and concluded that short nails were efficient because of the short operating time. The use of interlocking screws has also been discussed. Gallagher et al. [6] found that the routine use of distal interlocking screws with cephalomedullary nails in the treatment of unstable intertrochanteric fractures significantly increased the rotational load to failure. Nail design and shape have also been discussed, and the PFNA II implant was introduced for the Asian population. Even after this introduction, researchers have continued to identify ways in which to improve the implant's shape, lateral impingement, and anterior femoral curvature [16, 17]. The PFNA-II is equipped with distal interlocking screw holes available for dynamic screw insertion. However, in this study, all these holes were employed for static screws using an oblique insertion technique. This approach involves inserting the screw obliquely, engaging the proximal side of the dynamic hole. As a result, it can be inferred that this method not only provides resistance against rotation but also offers axial stability.

The clinical significance of the proximal femoral nail diameter has rarely been discussed. In 2020, Rinehart et al.

[18] compared the re-operation rate between groups with nail diameters of 10 mm and > 10 mm, found no difference. However, they did not consider the size of patients' femora. To our knowledge, this study is the first to examine the clinical implications of the cephalomedullary nail diameter. We sought to determine whether this diameter should be large enough to fill the femoral canal for stable fixation and sought evidence supporting a correlation between the femoral canal and nail diameters. The specific device in this study, maintains identical distal interlocking screw configurations in its two different length versions, 170 and 200 mm. This consistency in the placement of the distal interlocking screw renders it an appropriate landmark, allowing for the consistent measurement of femoral canal thickness at the same location in both device variations. The nail diameter was measured at the level of the distal locking screw to assess the need for complete filling of the distal femoral canal. If the chosen diameter was too small, should the nail contact or abut the femoral endocortex for mechanical support? We assessed nail diameter adequacy using the NCR. The NCR and NCR' (the average minus one standard deviation) were used to subdivide the patients and analyses. Variables such as the fracture pattern, reduction quality, and nail length were analyzed together to minimize the influence of other variables.

The nail contacted the endocortex more frequently in the high NCR and NCR' groups. This finding is easily explained because thicker implants easily catch the cortex anywhere

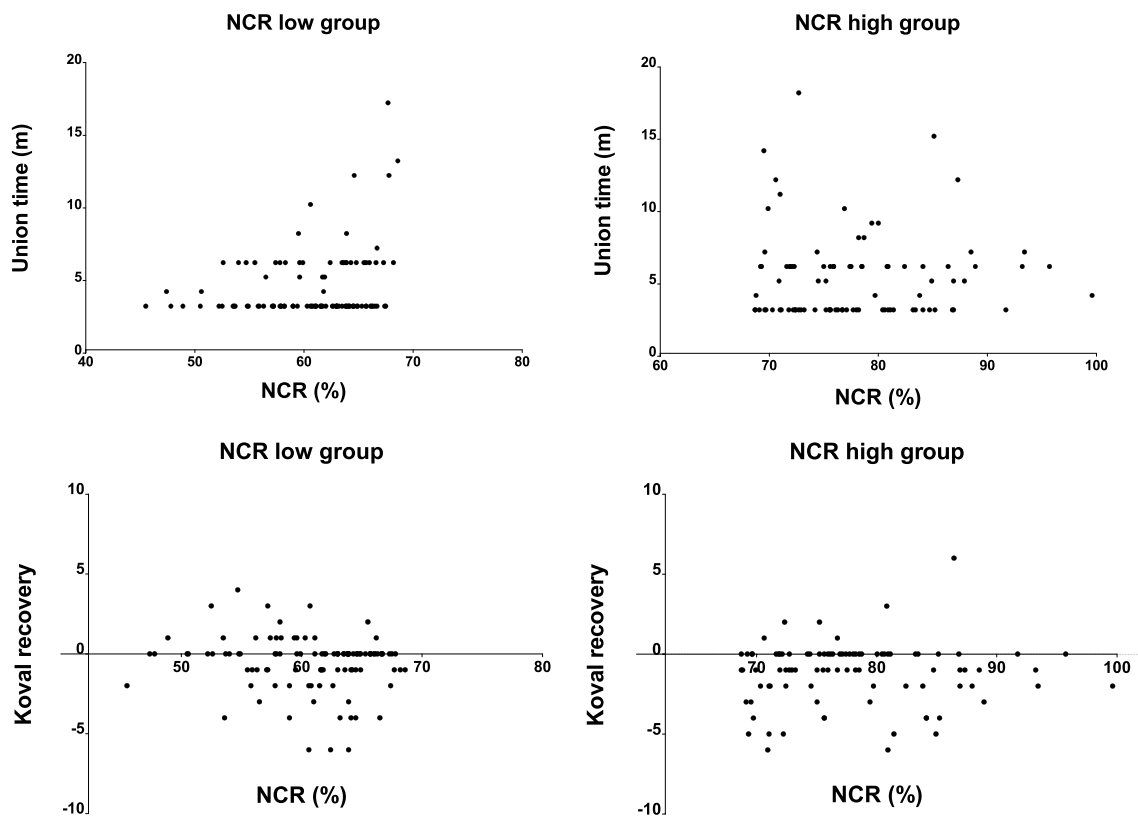


Fig. 2 Scatterplots of the NCR, union time, and recovery (difference in Koval score; all continuous variables) in the low and high NCR groups. In the low NCR group, Pearson's coefficient of correlation

between the NCR and union time was 0.273 ($p=0.005$; upper left). No other significant correlation was observed

along its length. Contrary to our hypothesis, however, nail contact with the endocortex was associated with shorter union times in patients with small NCRs and NCR's than no cortical contact. This finding implies that unintended three-point fixation at the blade entrance, a point of cortical contact, and the firm purchase of an interlocking screw enhance early construct stability. Because the number of cases was relatively small, however, we cannot conclude that a small nail diameter yields a better result. The same may be true for the change in the Koval score, for which the low NCR and NCR' with cortical contact groups had better results than at least one other group each. Thus, this study confirmed only that the use of this specific nail with a small diameter did not adversely affect fracture healing. The only factor related to any adverse results was the TAD.

This study has several limitations. First, it was retrospective. The patients' conditions were determined from medical records, and bias may have occurred due to inaccuracy therein. However, two orthopedic surgeons independently checked the medical record data to reduce this possibility. Second, this study was conducted with data on surgeries performed by a single surgeon using a single implant type, and the findings might not be generalizable. However, as the

same implant and procedure were used, they may be highly reproducible. Possible confounding of the nail length may also be a factor. Short and ultra-short nails were used in this study, and mechanical differences between the two may exist. However, the location of the interlocking screw used with this specific implant is the same for both nail types. Thus, the nails' working lengths do not differ and should not affect the study results. Finally, scores clearly reflecting clinical outcomes were not used in this study. Due to the nature of intertrochanteric fractures, the patients were elderly adults. Asking these patients complex questions and determining clinical scores may not be effective. Moreover, complete face-to-face follow-up was challenging. Thus, we attempted to evaluate the clinical results using the change in the Koval activity score from before the injury to the final follow-up. When patients could not attend the outpatient clinic, we contacted them or their caregivers by telephone to ask about their current status.

In conclusion, the results of this study do not support the hypothesis. The use of this specific proximal femoral nail with a small diameter relative to that of the femoral canal had no adverse effect on the union of intertrochanteric fractures in elderly patients, including those with unstable

fractures and unsatisfactory reduction. Canal reaming or the use of a nail with the largest diameter to fill the femoral canal space is unnecessary.

Author contributions The order of authors has been decided according to the degree of contribution. Surgery and study design were made by KH Rhyu and YJ Cho. Data collection and measurement were done by SH Choi and CJ Lee. Statistical assessment and draft-writing were done by YS Chun and YJ Cho. Manuscript editing and proofreading was done by SH Choi and KH Rhyu.

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Data Availability The data (both the image and numerical) that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval This study was approved by Kyung Hee University Hospital Institutional Review Board (KHUH 2021–04-022–005).

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

Consent to publish Not applicable.

Competing interest The authors have no relevant financial or non-financial interests to disclose.

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