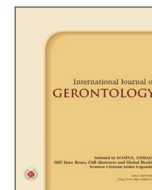




International Journal of Gerontology

journal homepage: <http://www.sgecm.org.tw/ijge/>

Original Article

Cephalomedullary Nail and Cement Augmentation Outcome Analysis in Geriatric Intertrochanteric Fractures

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ARTICLE INFO

Accepted 25 September 2025

Keywords:

bone cements,
fracture fixation,
hip fractures,
osteoporosis,
prosthesis failure

SUMMARY

Background: Intertrochanteric (IT) fractures account for nearly half of hip fractures, mainly in elderly patients with osteoporosis. Although cephalomedullary nails are widely used for fixation, few studies have directly compared Proximal Femoral Nail Antirotation-II (PFNA-II) and Trochanteric Femoral Nail Advanced (TFNA). In this study, we aimed to compare the functional outcomes and mechanical complication rates of PFNA-II and TFNA, and to assess the impact of TFNA cement augmentation in geriatric patients with osteoporotic IT fractures.

Methods: Between 2019 and 2023, 469 patients were retrospectively classified into three groups: PFNA-II (n = 224), TFNA without cement (n = 104), and TFNA with cement augmentation (n = 141). Perioperative evaluation included AO/OTA classification, reduction quality, Cleveland Index, and tip-apex distance. Functional outcomes were evaluated using the Harris Hip Score (HHS), EQ-5D, and Koval score. Mechanical complications were compared between PFNA-II and TFNA groups, and further analyses were performed between the non-cemented and cemented TFNA groups.

Results: No statistically significant differences were observed among the three groups regarding perioperative characteristics. Lateral migration was the predominant complication, with no significant differences in individual complication rates between the two implants. The absence of cut-out in the cemented TFNA group was statistically significant in comparison to the non-cemented group ($p = 0.031$).

Conclusion: Lateral migration is the most common complication following PFNA-II or TFNA fixation. Although the functional outcomes are comparable, cement augmentation with TFNA is recommended to minimize cut-out risk.

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1. Introduction

Globally, hip fracture incidence is projected to increase with population aging, from 1.66 million cases in 1990 to 6.3 million by 2050.¹ Intertrochanteric (IT) fractures account for approximately half of all hip fractures, with risk factors such as advanced age, female sex, and osteoporosis.² Although surgical fixation with cephalomedullary (CM) nail is the standard treatment due to less blood loss and higher Harris Hip Scores,^{3,4} the optimal implant remains debated.

The Proximal Femoral Nail Antirotation-II (PFNA-II; DePuy Synthes, Oberdorf, Basel-Landschaft, Switzerland) and Trochanteric Fixation Nail-Advanced (TFNA; DePuy Synthes, Oberdorf, Basel-Landschaft, Switzerland) are widely used implants for osteoporotic IT fractures, particularly in Asian patients due to better anatomical compatibility.⁵ PFNA-II features an antirotation helical blade that re-

duces cut-out and malrotation risk by compacting the surrounding bone. TFNA, introduced to the market in 2015, incorporates a high-strength titanium-molybdenum alloy to increase fatigue strength and advanced locking options for fixation stability.⁶ While a previous meta-analysis suggested that cement augmentation had no significant role in trochanteric fractures,⁷ cement augmentation of TFNA in osteoporotic bone can reduce fixation failure rates and implant micromotion,⁸ thereby accelerating rehabilitation.⁹ Therefore, TFNA has been increasingly used because its design allows cement augmentation.

Postoperative mechanical complications may lead to the need for revision surgery, functional decline, prolonged hospitalization, and increased costs. Given TFNA's novelty with limited literature, we aimed to compare functional outcomes and mechanical complication rates between PFNA-II and TFNA, and to evaluate the impact of cement augmentation in geriatric patients with osteoporotic IT fractures.

2. Patients and methods

This retrospective study included 613 patients with IT fractures

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treated between March 2019 and June 2023 at our medical center. It was approved by the Institutional Review Board of MacKay Memorial Hospital and conducted in accordance with the Declaration of Helsinki (number: 22MMHIS365e). The inclusion criteria for participants with IT fractures included: (1) age over 65 years with bone mineral density (BMD) via dual-energy X-ray absorptiometry of less than -2.5; (2) primary reduction and internal fixation with PFNA-II or TFNA with a helical blade; and (3) at least six months of postoperative follow-up. The exclusion criteria included: (1) concomitant ipsilateral femoral fractures (e.g., neck, subtrochanter, shaft); (2) non-ambulatory prior to fracture; and (3) pathological features. After excluding 144 patients, a total of 469 patients (males: 182, females: 287) with a mean follow-up of 40.2 ± 10.4 weeks were included. All procedures were performed by experienced orthopedic surgeons at our Level I Trauma Center using standardized techniques and perioperative protocols.

Short nails (PFNA-II: 200 and 240 mm; TFNA: 200 and 235 mm) were used via the standard reduction technique on a fracture table in supine position. All selected implants had the same caput-collum-diaphyseal angle of 130° . To enhance stability, polymethylmethacrylate cement augmentation (DePuy Synthes, Oberdorf, Basel-Landschaft, Switzerland) was used in the femoral head for the TFNA cement group but not in the PFNA-II group due to design limitations. PFNA-II is an earlier-developed and widely utilized implant; however, since the introduction of TFNA, it has also been commonly adopted for the treatment of patients with osteoporosis owing to its favorable clinical outcomes. Nevertheless, some surgeons remain cautious regarding the use of cement augmentation in primary fracture fixation. Therefore, patients were categorized into three groups: (1) PFNA-II, (2) TFNA without cementation, and (3) TFNA with cement augmentation.

2.1. Clinical evaluations

Demographic data including age, sex, body mass index (BMI), BMD (T-score), and American Society of Anesthesiologists (ASA) classification were collected from electronic medical records. Fracture patterns were classified using the AO Foundation/Orthopedic Trauma Association (AO/OTA) classification. Perioperative radiographic evaluations included reduction quality, Cleveland zones,¹⁰ and tip-apex distance (TAD) to evaluate fixation stability (detailed definitions are listed below).^{11,12} Surgical time, blood loss, and length of hospital stay were also recorded. All assessments were independently reviewed by two authors to minimize interpretation bias.

Table 1
Comparison of baseline characteristics among participants in three fixation groups.

	Total (n = 469)	PFNA-II (n = 224)	TFNA without cement (n = 104)	TFNA with cement (n = 141)	p value
Age, years	82.2 ± 8.5	82.4 ± 8.6	80.0 ± 8.9	83.6 ± 7.8	0.007 ^a
Female, n	287 (61.2%)	123 (54.9%)	66 (63.5%)	98 (69.5%)	0.018 ^{a,b}
BMI, kg/m ²	22.7 ± 3.7	22.4 ± 3.7	23.1 ± 4.2	22.7 ± 3.4	0.329 ^a
BMD (T-score)	-3.2 ± 0.7	-3.2 ± 0.7	-3.2 ± 0.8	-3.2 ± 0.7	0.704 ^a
AO/OTA classification					0.180 ^b
31-A1	167 (35.6%)	86 (38.4%)	40 (38.5%)	41 (29.1%)	
31-A2	233 (49.7%)	105 (46.9%)	46 (44.2%)	82 (58.2%)	
31-A3	69 (14.7%)	33 (14.7%)	18 (17.3%)	18 (12.7%)	
ASA classification					0.411 ^b
ASA II	143 (30.5%)	69 (30.8%)	35 (33.7%)	39 (27.7%)	
ASA III	316 (67.4%)	152 (67.9%)	67 (64.4%)	97 (68.8%)	
ASA IV	10 (2.1%)	3 (1.3%)	2 (1.9%)	5 (3.5%)	

Abbreviations: AO/OTA, AO Foundation/Orthopedic Trauma Association; ASA, American Society of Anesthesiologist; BMD, bone mineral density; BMI, body mass index; kg/m², kilogram per square meter; PFNA-II, Proximal Femoral Nail Antirotation-II; TFNA, Trochanteric Fixation Nail-Advanced.

^a Kruskal-Wallis test. ^b Chi-squared test.

2.2. Outcomes

Primary outcomes were functional assessments: Harris Hip Score (HHS), EuroQol 5-Dimension (EQ-5D), and Koval scores at six months postoperatively. The HHS evaluates hip-specific functions, including pain, functional activities, deformity, and range of motion.¹³ EQ-5D measures general geriatric health status, and the Koval score assesses ambulatory ability across seven levels. Both EQ-5D and Koval score are known predictors of mortality after hip fracture.^{14,15}

Secondary outcomes included mechanical complication rates: cut-out, cut-through, lateral migration, periprosthetic fracture, and implant breakage.¹⁶ Cut-out was defined as varus collapse of the neck-shaft angle with superior extrusion of the cephalic element, while cut-through was defined as cephalic element protrusion through the femoral head along the head-neck axis. Lateral migration was defined as a proximal shift of the implant exceeding 10 mm toward the lateral thigh.¹⁷ Periprosthetic fracture was diagnosed at least three months postoperatively. Implant breakage was observed within 10 months postoperatively, which typically occurs before fracture healing is complete.¹⁸ To assess both implant type and the impact of cement augmentation, complication rates were analyzed through pairwise comparisons: PFNA-II versus TFNA, and non-augmented TFNA versus augmented TFNA.

2.3. Statistical analysis

Statistical analyses were performed using SPSS Statistics version 29 (IBM Corp., Armonk, NY, USA), with *p* values less than 0.05 considered statistically significant. Categorical variables are presented as numbers (frequency %) and continuous variables as mean ± standard deviation (SD). Non-parametric methods were employed: the Kruskal-Wallis test for continuous variables across the three groups, the chi-squared test for categorical variables, and the Fisher's exact test for comparing complication rates.

3. Results

Demographic and clinical characteristics of the fixation groups are shown in Table 1. The overall mean age was 82.2 ± 8.5 years, 61.2% were female, the mean BMD T-score was -3.2 ± 0.7 , and the mean BMI was 22.7 ± 3.7 kg/m². Based on the AO/OTA classification, 167 (35.6%) cases were 31-A1, 233 (49.7%) were 31-A2, and 69 (14.7%) were 31-A3 fractures. The TFNA with cement group had the highest mean age (83.6 ± 7.8 years), followed by the PFNA-II ($82.4 \pm$

8.6 years) and TFNA without cement (80.0 ± 8.9 years) groups ($p = 0.007$). The TFNA with cement group also had the highest proportion of females (69.5%), while the PFNA-II group had the lowest (54.9%), with a significant difference ($p = 0.018$). No statistically significant differences were found among the groups in BMI, BMD, AO/OTA classification, or ASA classification.

Comparison of radiographic and perioperative outcomes among the participants in the three groups is summarized in Table 2.

3.1. Reduction quality

Reduction quality was assessed based on alignment and displacement.¹¹

Acceptable trabecular alignment was defined as $\leq 10^\circ$ valgus on the anteroposterior (AP) view and $< 20^\circ$ angulation on the lateral view. The displacement criterion was defined as ≤ 4 mm for any fracture fragment. Cases meeting both criteria were classified as “good”, one as “acceptable”, and neither as “poor”. Among 469 patients, 338 (72.1%) had good reduction quality, 99 (21.1%) had acceptable quality, and 32 (6.8%) had poor reduction quality. Reduction quality was comparable among the fixation groups ($p = 0.906$).

3.2. Cleveland zones

The blade tip position was divided into three regions in the AP (superior, central, and inferior) and lateral views (anterior, central, and posterior). A total of 382 center-to-center positions (81.4%) were reported without statistical difference across the groups ($p = 0.328$).

3.3. TAD

TAD was the sum of the distances from the blade tip to the femoral head apex on AP and lateral radiographs after adjustment. TAD < 25 mm was considered optimal.¹² Our findings showed the average TAD was 16.7 mm, with no statistical difference across the groups ($p = 0.947$).

Table 2
Comparison of operative evaluation among participants in three fixation groups.

	PFNA-II (n = 224)	TFNA without cement (n = 104)	TFNA with cement (n = 141)	p value
Reduction quality				0.906 ^a
Good	166 (74.1%)	73 (70.2%)	99 (70.2%)	
Acceptable	44 (19.6%)	24 (23.1%)	31 (22.0%)	
Poor	14 (6.3%)	7 (6.7%)	11 (7.8%)	
Cleveland’s zone				0.328 ^a
Center-center	183 (81.7%)	80 (76.9%)	119 (84.4%)	
Others	41 (18.3%)	24 (23.1%)	22 (15.6%)	
TAD (millimeters)	16.7 \pm 4.3	16.7 \pm 3.7	16.7 \pm 3.7	0.947 ^b
Surgical times (minutes)	72.4 \pm 28.4	73.8 \pm 39.4	78.8 \pm 30.6	0.340 ^b
Blood loss (milliliters)	104.4 \pm 68.8	102.4 \pm 59.7	105.8 \pm 66.2	0.835 ^b
Length of hospital stay (days)	7.3 \pm 6.4	7.6 \pm 6.1	6.5 \pm 3.9	0.184 ^b

Abbreviations: PFNA-II, Proximal Femoral Nail Antirotation-II; TAD, tip apex distance; TFNA, Trochanteric Fixation Nail-Advanced.

^a Chi-squared test. ^b Kruskal-Wallis test.

Table 3
Comparison of primary outcomes among three fixation groups.

	PFNA-II (n = 224)	TFNA without cement (n = 104)	TFNA with cement (n = 141)	p value ^a
HHS (0–100)	83.0 \pm 4.5	84.99 \pm 3.9	85.1 \pm 4.9	< 0.001
EQ-5D (0–1)	0.7 \pm 0.1	0.7 \pm 0.1	0.7 \pm 0.1	0.300
Postoperative Koval score (1–7)	3.6 \pm 0.9	3.4 \pm 1.1	3.5 \pm 0.9	0.380

Abbreviations: EQ-5D, EuroQol 5-Dimension; HHS, Harris Hip Score; PFNA-II, Proximal Femoral Nail Antirotation-II; TFNA, Trochanteric Fixation Nail-Advanced.

^a Kruskal-Wallis test.

The 6-month functional outcomes among the three fixation groups are summarized in Table 3. The TFNA with cement group demonstrated the highest mean HHS (85.1 ± 4.9), followed by TFNA without cement (85.0 ± 3.9), and PFNA-II (83.0 ± 4.5), with a statistical difference ($p < 0.001$). No statistical differences were found in EQ-5D and Koval scores.

Table 4 summarizes the complication rates of the two implants. Overall, lateral migration was the most common complication, occurring in 10 patients (2.1%) after fixation (six in PFNA-II and four in TFNA). Cut-out (1.7%) and cut-through (0.9%) were the second and third most common complications, respectively, with no significant difference between the two groups ($p > 0.99$).

Complication rates for TFNA with and without cement are shown in Table 5. Lateral migration and cut-out were the major complications in the TFNA groups (1.6%). Cut-out occurred exclusively in the non-cemented group (n = 4), showing a statistically significant difference compared with the cemented group ($p = 0.031$). Binary logistic regression analysis revealed no significant interaction between sex ($p = 0.586$), age ($p = 0.113$), and TFNA type (cemented versus non-cemented) in predicting the risk of cut-out. No statistically significant differences were found in other complications.

3.4. Revision surgeries

One patient treated with PFNA-II experienced concurrent lateral migration, cut-out, and periprosthetic fracture at three months

Table 4
Comparison of secondary outcomes between two implants.

	PFNA-II (n = 224)	TFNA (n = 245)	p value ^a
Cut-out	4	4	> 0.99
Cut-through	2	2	> 0.99
Lateral migration	6	4	0.530
Periprosthetic fracture	2	1	0.608
Implant breakage	1	1	> 0.99

Abbreviations: PFNA-II, Proximal Femoral Nail Antirotation-II; TFNA, Trochanteric Fixation Nail-Advanced.

^a Fisher’s exact test.

postoperatively, subsequently requiring revisional cemented bipolar long-stem hemiarthroplasty (Figure 1). Two of the nine remaining lateral migration cases underwent cephalic element repositioning with cement fixation, while the others were managed conservatively. Among the other seven cut-out cases, five required secondary arthroplasty, while the others were treated non-operatively. Of the

four patients who experienced cut-through, two underwent implant removal, one underwent secondary fixation with a cement-augmented CM nail, and one was treated conservatively. Both implant breakage cases were revised by long cemented CM nailing.

4. Discussion

We observed significantly higher HHS at six months postoperatively in patients treated with TFNA, unlike previous studies which reported no difference.^{19,20} This may be attributed to TFNA's lateral relief cut and smaller proximal diameter (TFNA: 15.66 mm; PFNA-II: 16.5 mm) design.⁶ These features could potentially reduce irritation, lateral thigh pain, and the risk of gluteus medius tendon injury during nail insertion.^{21,22} Although a statistically significant difference was observed in HHS, it was far below the previously reported minimal clinically important difference (7.2–16.8 points) in a prior study, suggesting that the observed difference may not be clinically meaningful.²³

Our study revealed that lateral migration was the most common complication associated with both PFNA-II and TFNA. Cancellous bone failure has been proposed as a potential cause of implant mi-

Table 5
Comparison of secondary outcomes in the TFNA group with and without cement augmentation.

	TFNA without cement (n = 104)	TFNA with cement (n = 141)	p value ^a
Cut-out ^b	4	0	0.031
Cut-through	2	0	0.179
Lateral migration	2	2	> 0.99
Periprosthetic fracture	0	1	> 0.99
Implant breakage	0	1	> 0.99

Abbreviations: TFNA, Trochanteric Fixation Nail-Advanced.
^a Fisher's exact test. ^b Binary logistic regression showed no significant sex or age interaction with TFNA type in relation to cut-out risk ($p = 0.586$ and $p = 0.113$, respectively).

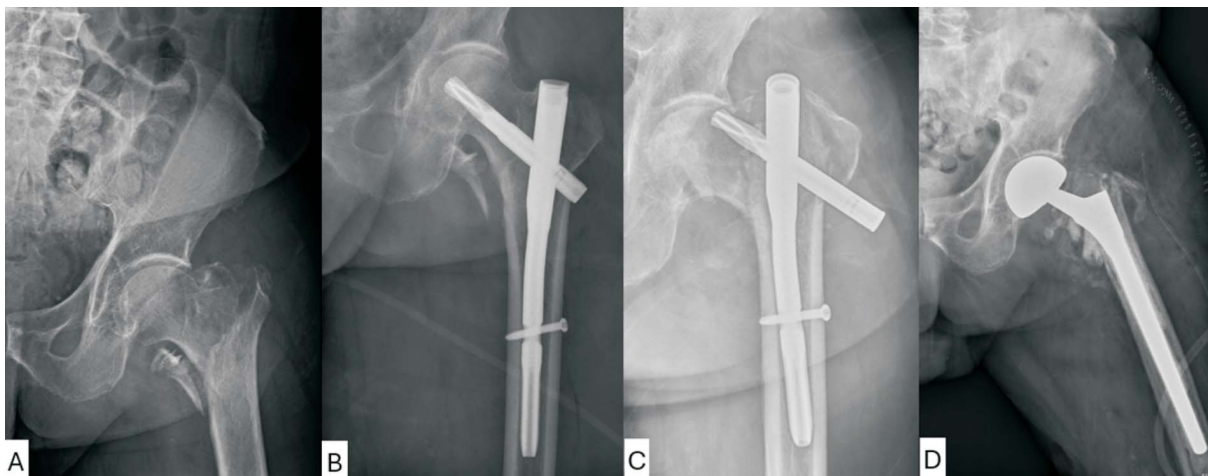


Figure 1. An 86-year-old male with a BMD T-score of -2.6 suffered from 31-A2 fracture and underwent PFNA-II fixation. (A) Preoperative X-ray; (B) Postoperative X-ray; (C) Radiograph postoperatively showed cut-out, lateral migration, and periprosthetic fracture; (D) Revision surgery with cemented bipolar hemiarthroplasty.

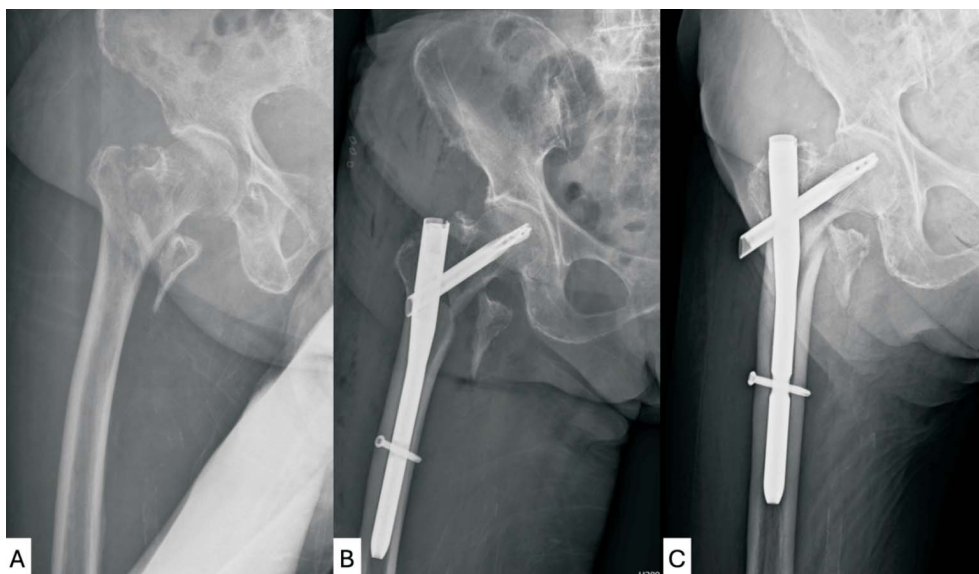


Figure 2. An 88-year-old female with a 31-A2 fracture and a BMD T-score of -2.8, underwent fixation with TFNA without cement augmentation. (A) Preoperative X-ray; (B) Postoperative X-ray; (C) 1 month postoperatively showing lateral migration.

gration. Patients with repetitive loading over time can also develop microcracks within the trabecular structure, compromising bone integrity and reducing implant stability. Furthermore, osteoporotic bone with diminished load-bearing capacity and stress shielding can lead to localized stress accumulation.²⁴ Previous research studies have suggested that unstable fractures, reduction quality, and bone fragility may exacerbate lateral migration.¹⁷ The biomechanics of the set-screw mechanism in TFNA allows controlled sliding of the head element, promoting fracture compression.²⁵ However, in osteoporotic bone, the weak purchase of the cephalic element can increase the probability of lateral migration.²⁶

Our findings demonstrated that cement augmentation lowered the cut-out rate in the TFNA group with no statistical differences in reduction quality and TAD.²⁷ Previous studies support the benefits of cement augmentation in geriatric patients with IT fracture.²⁸ Moreover, both clinical and biomechanical studies have concluded that augmented TFNA can strengthen osteosynthesis construct, increase cut-out resistance, and reduce fixation failure risk compared to non-augmented fixation.^{29,30} Although TFNA with cement is associated with higher cost, growing evidence, including biomechanical studies and our findings, supports its use in elderly patients with osteoporotic IT fractures.

Although previous studies have compared clinical outcomes between PFNA-II and TFNA,^{19,31} few have included comparisons with cement augmentation with a relatively large sample size. However, this study has several limitations. First, its retrospective nature and confounders such as sex and age may limit generalizability. Furthermore, implant use and cement augmentation were determined at the surgeon's discretion and decided by emerging evidence of cement augmentation. As a relatively new implant, TFNA may also influence surgeons' implant selection. However, no significant differences in perioperative outcomes, including reduction quality and TAD, were observed between the groups, thereby minimizing potential selection bias. Second, although blades are generally preferred in osteoporotic fractures for reduced cut-out rates and improved stability,³² TFNA cases using lag screws were not included in our study because of the small sample size, which limited the applicability of TFNA screws. Third, our study focused on mechanical complications and did not evaluate systemic issues, such as mortality, delirium, or infection, limiting the comprehensiveness of the results. In conclusion, lateral migration represents the most frequent complication after PFNA-II or TFNA fixation in elderly patients with osteoporotic IT fractures. While PFNA-II and non-augmented and augmented TFNA yield similar functional outcomes, TFNA with cement augmentation appears to reduce the risk of cut-out.

Acknowledgements

We sincerely acknowledge the Department of Orthopedics at MacKay Memorial Hospital for their valuable clinical expertise and support in patient recruitment. We also acknowledge Editage for their professional English language editing services.

Declarations of any potential financial and non-financial conflicts of interest

This research received no specific funding from public, commercial, or non-profit sectors. The authors declare no conflict of interest.

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