

Outcomes of U-Blade Lag Screw for Cephalomedullary Fixation of Unstable Trochanteric Femur Fractures: A Case Control Study

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Joon Soon Kang, MD, PhD¹, Yong Tak Kwon, MD¹,
Young Ju Suh, PhD², Tong Joo Lee, MD, PhD¹,
and Dong Jin Ryu, MD, MS¹ 

Abstract

Background: Unstable trochanteric femur fractures in elderly patients with osteoporosis are still challenging. Gamma3 nail with the U-blade lag screw (U-blade gamma nail) has been developed to improve mechanical stability of proximal femoral fragment. This study aimed to compare the clinical and radiologic outcomes of U-blade gamma nail to proximal femoral nail antirotation (PFNA), and standard Gamma3 nail (gamma nail) for unstable trochanteric femur fractures. **Methods:** A retrospective matched-pair case study was performed with U-blade gamma nail, PFNA, and gamma nail. During 2012-2018, 970 patients with unstable trochanteric femur fractures were reviewed. Matching criteria were set as follows: 1) sex; 2) age (± 3 years); 3) body mass index (± 2 kg/m²); 4) bone mineral density (± 1 T-score in femur neck). Finally, a total of 159 patients were enrolled. We assessed the tip-apex distance (TAD), neck shaft angle, and hip screw sliding distance using plain radiographs. Also, we evaluated the clinical outcomes with Koval's grade and fixation failure during 2 years. **Results:** The mean postoperative TAD was not significantly different among the 3 groups ($p = 0.519$). However, the change in the TAD at 1 year ($p = 0.027$) and 2 years ($p = 0.008$) after surgery was significantly smaller in U-blade gamma nail group compared with PFNA and gamma nail group. The hip screw sliding distance at 1 year ($p = 0.004$) and 2 years ($p = 0.001$) after surgery was significantly smaller in U-blade gamma nail group compared with PFNA and gamma nail group. However, there was no significant difference of Koval's grade and fixation failure among the 3 groups ($p = 0.535$). **Conclusion:** U-blade gamma nail showed favorable radiologic results in terms of the change in the hip screw position. However, U-blade gamma nail was not superior to PFNA and gamma nail in clinical outcomes.

Keywords

gamma nail, U blade, PFNA, trochanteric fracture, stability

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Introduction

Hip fracture is one of the most common fractures in elderly patients. In particular, the incidence of trochanteric femur fractures have been increasing due to improving life expectancy.¹ Despite advances in surgical fixation implants, the management of unstable trochanteric femur fractures in elderly patients with osteoporosis remains challenging.²⁻⁴

It is important to know which internal fixation device would provide maximum mechanical stability. Intramedullary nails and compression hip screws have been used for the surgical treatment of trochanteric femur fractures. In comparison with compression hip screw, it is widely accepted that

the intramedullary nails have superior biomechanical stability.⁵ InterTrochanteric/SubTrochanteric nail (ITST nail; Zimmer Biomet, Warsaw, IN, USA), Proximal Femoral Nail

¹ Department of Orthopaedic Surgery, Inha University Hospital, Incheon, Republic of Korea

² Department of Biomedical Sciences, College of Medicine, Inha University, Incheon, South Korea

Corresponding Author:

Dong Jin Ryu, MD, MS, Department of Orthopaedic Surgery, Inha University Hospital, 27 Inhang-ro, Jung-gu, Incheon 22332, Republic of Korea.
Email: mdryu24@naver.com



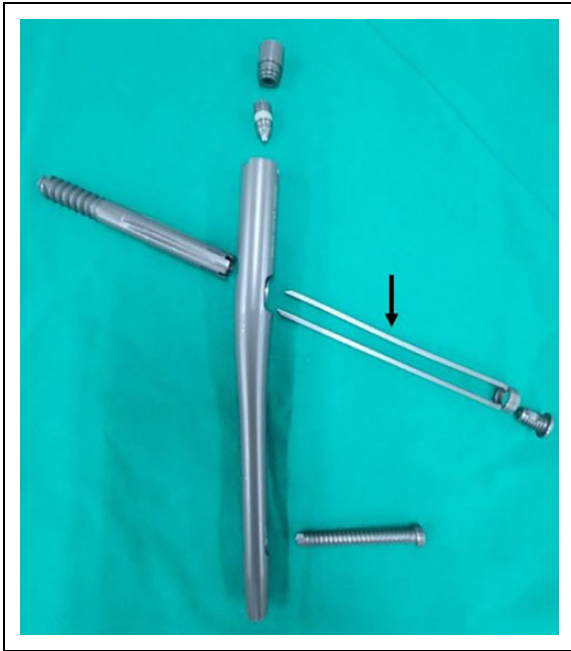


Figure 1. Photograph of U-blade gamma nail. (Black arrow: U-blade).

Antirotation (PFNA; Synthes, Paoli, Switzerland) and Gamma3 nail (Gamma Nail; Stryker Trauma GmbH, Schoenkirchen, Germany) are commonly used for intramedullary nailing.⁶ Although trochanteric femur fractures have been treated successfully using PFNA and gamma nail, various studies have reported rotational instability of the neck fragment, cut-out, and the migration of the neck screw.⁷⁻⁹ Therefore, there are still concerns regarding the stable fixation of unstable trochanteric femur fractures.

Gamma3 nail with U-blade lag screw (U-blade gamma nail, Stryker Trauma GmbH, Schoenkirchen, Germany) has been developed to improve the mechanical stability of unstable trochanteric femur fractures. This device was approved by FDA (K043431). U-blade gamma nail is combination of standard gamma lag screw with a spreading U-shape clip (Figure 1). The U-blade lag screw, which has a U-shape clip that expands the diameter of the lag screw, increases the contact surface in the cranio-caudal direction and provides better mechanical stability against rotation between the femoral head and neck.¹⁰ It has been introduced as a more ideal device for osteoporotic patients.¹¹ Unlike PFNA having a helical blade type of the femoral head fixation, U-blade gamma nail has a screw-blade hybrid type. The rotational change of the proximal fragment may be different depending on the fixation type of the femoral head.¹²

However, the clinical and radiologic benefits of Gamma3 nail with U-blade lag screw are unclear in previous studies.^{11,13} Previous studies had a short-term follow-up period of less than 1 year and lacked a direct comparison of clinical and radiologic outcomes between PFNA, gamma nail, and U-blade gamma nail.

Therefore, the aim of this study was to compare the clinical and radiologic outcomes of PFNA, gamma nail, and U-blade

gamma nail for unstable trochanteric femur fractures (AO/OTA [Arbeitsgemeinschaft für Osteosynthesefragen / Orthopaedic Trauma Association] 31A2 and 31A3) with a minimum follow-up of 2 years.

Materials and Methods

Patient Selection and Demographics

This retrospective matched-pair case control study reviewed 970 patients with unstable trochanteric femur fractures (AO/OTA classification 31A2 and 31A3) between March 2012 and March 2018.

Exclusion criteria included 1) pathologic fractures; 2) bilateral femur fractures; 3) and a follow-up of less than 2 years. Matching criteria were set as follows: 1) sex; 2) age (± 3 years); 3) body mass index (BMI) (± 2 kg/m²); 4) bone mineral density (BMD) (± 1 T-score in femur neck). The patient selection and matching process is presented in Figure 2. A total of 53 patients with U-blade gamma nail were matched to 53 patients of PFNA and 53 patients of gamma nail according to matching criteria. Finally, total of 159 patients with unstable trochanteric femur fractures were included.

All patients provided informed consent prior to treatment. The design and protocol of this study was reviewed and approved by Inha University Hospital Institutional Review Board (approval number: INHAUH 2020-03-022).

Surgical Procedure

All operations were performed under general or spinal anesthesia with the patients in the supine position on a fracture-reduction table. Manual reduction was achieved under C-arm fluoroscopy through traction and internal rotation and adduction. When manual reduction was unsatisfactory, a retractor or bone hook was used for compressing the lateral or anterior cortex. We made a hole in the middle-inner 1/3 point of the greater trochanter and inserted the guide pin in the medullary cavity. The intramedullary nail was inserted manually after standard reaming. Then, the lag screw was inserted in the caudal third of the antero-posterior (AP) plane and in the middle of the lateral plane of the femoral head. All patients were fixed with short nail (170-180 mm) and distal locking screw. Weight-bearing training and gait training were conducted approximately 2-3 days postoperatively, when the patients could tolerate the pain in a sitting position.⁶ Walking was allowed when the pain became tolerable.

Clinical Evaluation

Ambulatory ability at the preoperative and final follow-up was compared in each group. Ambulatory ability was assessed according to Koval's grade (grade I: independent community ambulator; grade II: community ambulator with cane; grade III: community ambulator with walker/crutches; grade IV: independent household ambulatory; grade V: household ambulator with cane; grade VI: household ambulator with

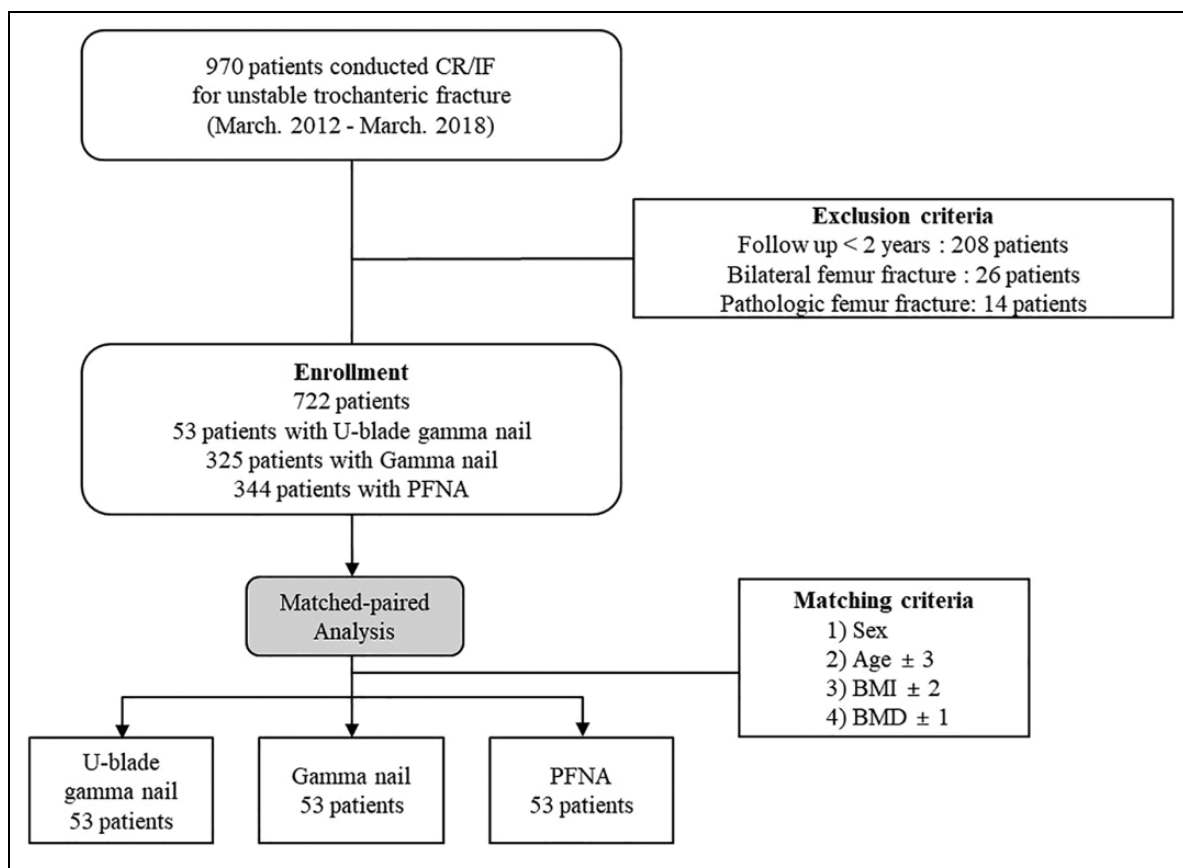


Figure 2. Patient flow diagram (CR/IF, closed reduction and internal fixation; PFNA, proximal femoral nail antirotation; BMI, body mass index; BMD, bone mineral density).

walker/crutches; grade VII: nonfunctional ambulator).^{6,14} The recovery rate was calculated as the percentage of patients who returned to ambulatory status prior to injury.

Radiologic Evaluation

All fractures were diagnosed based on plain radiographs and 3-dimensional computed tomography (3D-CT). The fractures were classified by 2 authors using the AO/OTA system.¹⁵ The presence of comminution of the anterior cortex was confirmed by 3D-CT.

Postoperative radiographs were taken immediately, 1 year, and 2 years after surgery. We assessed the tip-apex distance (TAD), neck shaft angle, and hip screw sliding distance using the plain radiographs. The TAD was measured as the sum of the distance from the tip of the screw to the apex of the femoral head in the AP (Xap) and lateral (Xlat) views (Figure 3).¹⁶ The neck shaft angle was measured as the angle between the midline of the femoral neck and the midline of the femoral shaft. The hip screw sliding distance was measured as the change in the distance from the tip of the screw to the point where the extension line meets the femoral head.

The position of the lag screw in the femoral head was measured in the AP and lateral views. The position of the lag screw was determined using Cleveland zones,¹⁶ which were divided

into 9 zones in the AP and lateral x-ray views. The centric position was considered to be at the center position of the femoral head and corresponded to zone 5 of the Cleveland zone system. The eccentric position was defined as the screw deviating from the center of the femoral head.

Different types of fixation failure requiring hip revision surgery, such as cut-out, implant breakage, and peri-implant fracture, were evaluated.

Statistical Analysis

We calculated the required sample size per group by power analysis using G*Power (Version 3.1.). According to the guidelines of Cohen,¹⁷ the effect size may be described as small (0.10), medium (0.25), and large (0.40). We selected “medium” as the standardized effect size ($f = 0.25$). Following the detection of an effect size of $f = 0.25$ with a practical power value of 0.80 in 1-way ANOVA test (Analysis Of Variance, 3 groups, $\alpha = 0.05$), G*power suggested an appropriate sample size of 53 per group (total sample size = 159). Quantitative data were compared among the 3 groups or within each group (U-blade gamma nail, PFNA and gamma nail) by 1-way ANOVA using Scheffe’s post-hoc test. Radiologic findings and complications were compared by Pearson’s chi-squared test or Fisher’s exact test. Statistical significance was considered as



Figure 3. Evaluation of postoperative radiography through the (A) anteroposterior, and (B) axial view. The tip-apex distance (TAD, white arrow) and the hip screw sliding distance (Δ black arrow) were assessed. TAD = $X_{ap} + X_{lat}$; hip screw sliding distance = change in the distance from the tip of the screw to the point where the extension line meets the femoral head. (White arrow, X_{ap} : distance from the tip of the screw to the apex of the femoral head in the AP view; White arrow, X_{lat} : distance from the tip of the screw to the apex of the femoral head in the lateral view; Black arrow, distance from the tip of the screw to the point where the extension line meets the femoral head; Black dotted line, a line parallel to the axis of the lag screw and passing through the apex of the femoral head; Black dashed line, a line to along the axis of the lag screw).

$p < 0.05$. Statistical analyses were performed using SPSS software (Version 25; IBM, Chicago, IL, USA).

Results

Patient Demographics

Each group included 16 male and 37 female patients. There was no significant difference of demographics among the 3 groups. The statistically compared detailed data of the 3 groups are presented in Table 1.

Clinical Results

There was no significant difference in recovery of walking ability according to Koval's grade among the 3 groups ($p = 0.881$). (Table 2)

Radiologic Results

The identified AO/OTA classification (31 A2: 31 A3) in the groups with U-blade gamma nail, PFNA, and gamma nail was 18:35, 16:37 and 19:34, respectively ($p = 0.833$). The presence of comminution of the anterior cortex on preoperative 3D-CT and the position of the lag screw located in the centric position

Table 1. Patient Demographics of Each Study Group.

	U-blade gamma nail (n = 53)	PFNA (n = 53)	Gamma nail (n = 53)	p-value
Age (years)	79.7 \pm 10.7	80.0 \pm 10.8	81.3 \pm 9.4	0.719
Sex (M: F)	16:37	16:37	16:37	1.000
BMI (kg/m ²)	22.5 \pm 3.9	22.3 \pm 3.9	22.7 \pm 3.7	0.862
BMD (T-score)	-3.1 \pm 1.4	-3.2 \pm 1.0	-3.0 \pm 1.1	0.475

Values are presented as the mean \pm standard deviation (range).

PFNA, proximal femoral nail antirotation; M, male; F, female; BMI, body mass index; BMD, bone mineral density.

Table 2. Clinical Analysis and Complications of Each Study Group.

	U-blade gamma nail (n = 53)	PFNA (n = 53)	Gamma nail (n = 53)	p-value
Preoperative Koval's grade	2.7 \pm 1.8	2.8 \pm 1.7	2.6 \pm 1.9	0.859
Walking ability recovery (Koval's grade, %)	31 (58.4%)	29 (54.7%)	32 (60.4%)	0.881
Fixation failure (n, %)	2 (3.8%)	4 (7.5%)	3 (5.7%)	0.535
Implant breakage	0	1	0	
Cut-out	1	1	1	
Peri-implant fracture	1	2	2	

Values are presented as the mean \pm standard deviation (range).

PFNA, proximal femoral nail antirotation.

(Cleveland zone 5) was not significantly different among the 3 groups. (Table 3)

Although the mean immediate postoperative TAD value was not differ among the 3 groups, the change in the TAD at 1 year ($p = 0.027$) and at 2 years ($p = 0.008$) after surgery were significantly smaller in U-blade gamma nail. The significant differences were identified between U-blade gamma nail and PFNA group.

The hip screw sliding distance at 1 year ($p = 0.004$) and 2 years ($p = 0.001$) after surgery among the 3 groups showed significant differences. The differences were identified between U-blade gamma nail and PFNA group at 1 year. At 2 years, U-blade gamma nail showed smaller hip screw sliding distances than PFNA and gamma nail. The change in the neck shaft angle at 1 year and 2 years showed no significant difference ($p = 0.527$ at 1 year, $p = 0.430$ at 2 years). Detailed information on the radiologic analysis of the 3 groups is presented in Table 3.

A case of cut-out with U-blade gamma nail occurred 6 months after surgery (Figure 4). Despite the optimal lag screw position, poor bone quality (BMD: 3.4) and suboptimal reduction contributed to the cut-out. The patient underwent hip revision surgery, which involved proximal femoral nail removal and total hip arthroplasty. A case of peri-implant fracture was also observed in the group with U-blade gamma nail 22 months after surgery (Figure 5). The patient underwent

Table 3. Radiologic Analysis of Each Study Group.

	U-blade gamma nail (n = 53)	PFNA (n = 53)	Gamma nail (n = 53)	p value			
				Over-all significance	U-blade vs. PFNA	U-blade vs. gamma nail	PFNA vs. gamma nail
AO/OTA classification				0.833			
31 A2	18	16	19				
31 A3	35	37	34				
Communion of anterior cortex	9	10	7	0.800			
Position of lag screw				0.333			
Centric (zone 5)	39	35	42				
Eccentric	14	18	11				
TAD of lag screw (postoperative, mm)	19.3 ± 6.24	20.6 ± 7.26	19.1 ± 4.59	0.253	0.519	0.197	0.014
TAD change (postop to 1 year, mm)	0.98 ± 1.29	1.98 ± 3.10	1.12 ± 1.26	0.027	0.045	0.937	0.102
TAD change (postop to 2 years, mm)	1.84 ± 2.11	2.41 ± 4.04	2.70 ± 2.60	0.008	0.011	0.764	0.073
Hip screw sliding distance (1 year, mm)	0.60 ± 0.67	1.17 ± 1.00	0.79 ± 0.92	0.004	0.005	0.522	0.095
Hip screw sliding distance (2 years, mm)	1.15 ± 1.07	2.38 ± 1.58	1.93 ± 1.47	0.001	0.001	0.013	0.207
Neck shaft angle change (postop to 1 year, °)	1.80 ± 1.71	2.13 ± 1.95	2.23 ± 2.44	0.527	0.705	0.558	0.970
Neck shaft angle change (postop to 2 years, °)	3.62 ± 2.68	4.13 ± 3.54	4.59 ± 4.97	0.430	0.786	0.430	0.831

Values are presented as the mean ± standard deviation (range).

Statistical significance was determined by 1-way ANOVA followed by Scheffe's post hoc analysis.

PFNA, proximal femoral nail antirotation; TAD, tip-apex distance; postop, postoperative.

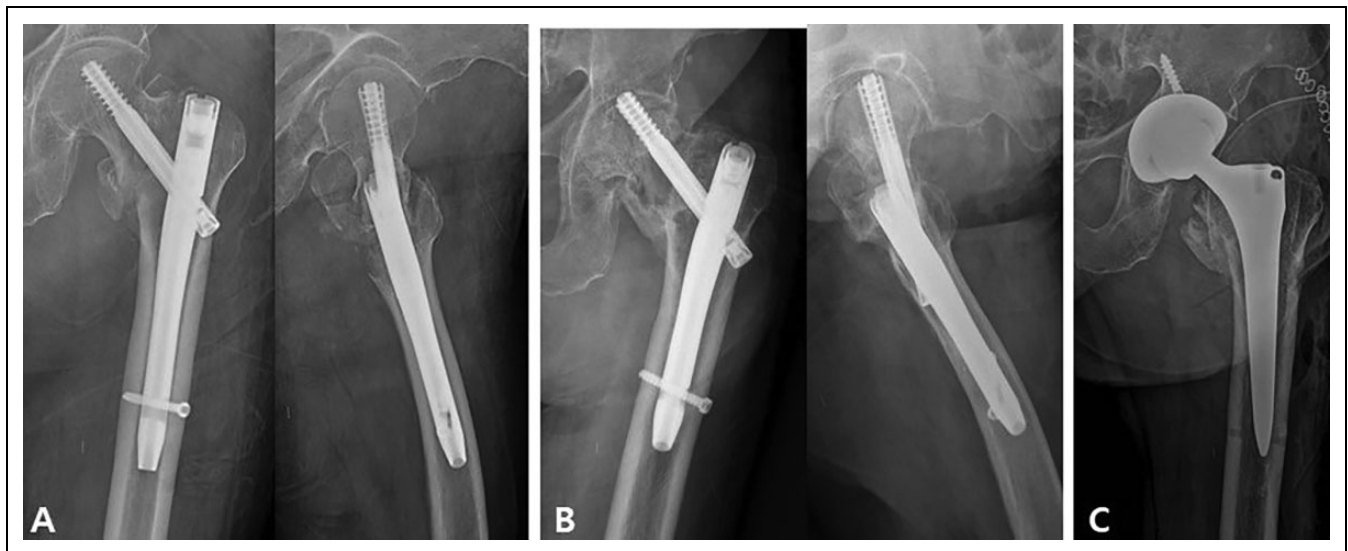


Figure 4. A 80-year-old woman with U-blade gamma nail who showed fixation failure and cut-out of a lag screw. (A) 2 weeks after surgery, (B) Fixation failure was occurred at 6 months after surgery, (C) Conversion surgery to total hip arthroplasty was done.

gamma nail removal and revision using long gamma nail with U-blade. In the group of PFNA, implant breakage was observed in 1 patient, cut-out in 1 patient, and peri-implant fracture in 2 patients. In the group of gamma nail, cut-out was observed in 1 patient, and peri-implant fracture in 2 patients.

Overall, fixation failure, including cut-out, implant breakage, and peri-implant fracture, was observed in 2 patients (3.8%) with U-blade gamma nail, 4 patients (7.5%) with PFNA, and 3 patients (5.7%) with gamma nail; however, there was no significant difference in fixation failure ($p = 0.535$).

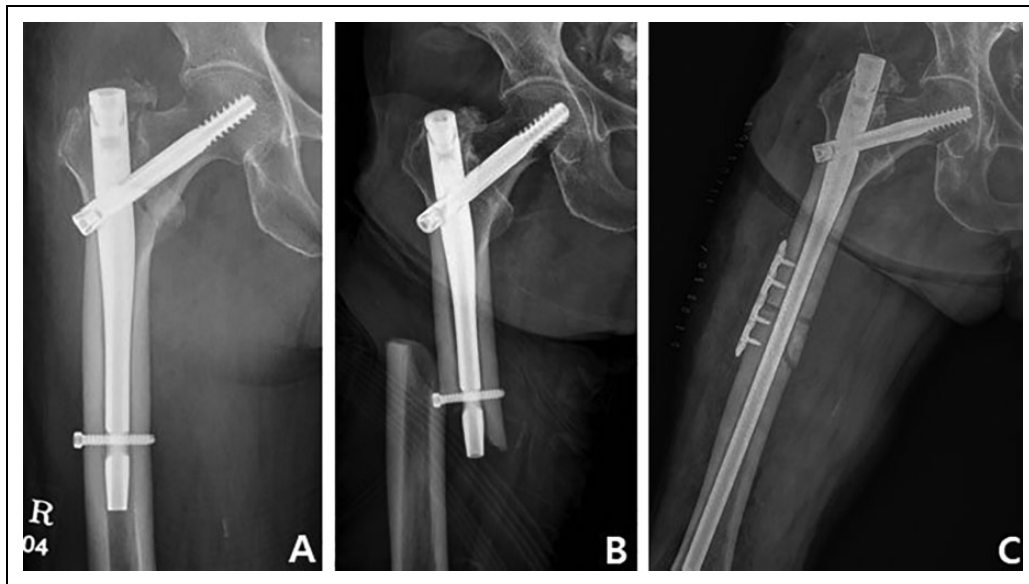


Figure 5. A 91-year-old woman with U-blade gamma nail who showed fixation failure of peri-implant fracture. (A) 2 weeks after surgery, (B) Peri-prosthetic fracture was occurred at 22 months after surgery, (C) Conversion surgery to long gamma nail with U-blade was done.

Detailed information on the clinical analysis of the 3 groups is presented in Table 2.

Discussion

The most important finding of this study was that U-blade gamma nail showed better radiologic results in terms of the change in the hip screw position compared with PFNA or gamma nail in unstable trochanteric femur fractures over 2 years follow up. In comparison with the PFNA or gamma nail, the U-blade gamma nail showed significantly smaller change in the TAD ($p = 0.008$) and hip screw sliding distance ($p = 0.001$) during the 2 years after surgery. However, these changes did not affect clinical outcomes and fixation failure.

Mechanical instability of the lag screw could contribute to screw migration and consequent fixation failure. Each intramedullary nail has been designed for increasing holding power for the proximal fragment and decreasing rotational instability through different types of femoral head fixation. The PFNA has a helical blade type device, the gamma nail has a hip screw type device, and the U-blade gamma nail has a screw-blade hybrid type device. Kwak et al. reported that the rotational stability of the proximal fragment was greater with the hip screw type than with the blade type and hybrid type in a biomechanical study.¹² Strauss et al. reported the superior biomechanical design of the helical blade type compared with the standard hip screw type.¹⁸ However, Knoke et al. reported that there was no significant difference in biomechanical properties between the helical blade type and hip screw type.¹⁹ Theoretically, U-blade gamma nail, which has a U-shape clip that expands the diameter of the lag screw, can increase the contact surface area, by around 15% and achieve better mechanical stability against rotation and cut-out.¹¹ In this study, compared with PFNA and gamma nail, U-blade gamma nail showed

better radiologic results based on the change in the TAD and hip screw sliding distance.

Despite radiological improvements, there was no significant difference in clinical outcomes among the 3 groups. In the literature, cut-out rates have been reported as 0-6.2% for PFNA and 1.85-6.7% for gamma nail.^{20,21} In the current study, the rate of fixation failure in the groups with U-blade gamma nail, PFNA, and gamma nail was 3.8%, 7.5%, and 5.7% respectively. The overall rate of fixation failure was 5.7%, which was consistent with that of previous literature. Although there were some radiologic differences, they did not significantly affect the patients clinical symptoms.

The cut-out rate may be representative of non-anatomical reduction or a non-optimal screw position.²² Yoo et al. reported that fixation failure is more likely to occur in cases of trochanteric fractures with comminution of the anterior cortex.⁶ In patients with comminution of the anterior cortex, cortical contact and reduction may be obtained only in the medial cortex. Therefore, the risk of rotational instability and fixation failure may increase. In the current study, the position of the lag screw and comminution of the anterior cortex were not statistically different among the 3 groups. Therefore, U-blade gamma nail was not superior to PFNA and gamma nail in reducing fixation failure.

The strength of our study is the comparison of clinical and radiologic outcomes through matched analysis (not randomized study) based on sex, age, BMI, and BMD. The control of these variables allowed a more comprehensive comparison of outcomes. To the best of our knowledge, previous studies had a shorter follow-up period; however the follow-up period was a minimum of 2 years in our study. Furthermore, we used an appropriate sample size, which was calculated by power analysis.

There are several limitations in this study. First, we could not rule out selection bias entirely even through matched-pair analysis. Second, we did not consider the patients general condition and medical comorbidity, which can influence the results. Third, a large number of patients with U-blade gamma nail could not be obtained because U-blade gamma nail is the relatively latest model. However, we determined the appropriate sample size through power analysis. Fourth, the values from plain radiographs, especially the TAD, hip screw sliding distance, and neck shaft angle, may vary depending on the observers.

Conclusion

In comparison with PFNA and gamma nail, U-blade gamma nail showed better favorable radiologic results in terms of the change in the hip screw position in unstable trochanteric femur fractures at the 2-years follow-up. However, there was no significant difference in clinical outcomes and fixation failure.

Author's Note

All contributors meet the criteria for authorship of International Committee of Medical Journal Editors. The protocol for this study was approved by the Institutional Review Board of Inha University Hospital, Incheon, Korea (IRB No. INHAUH 2020-03-022).

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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. The protocol for this study was approved by the Institutional Review Board of Inha University Hospital, Incheon, Korea (IRB No. INHAUH 2020-03-022). All patients provided informed consent prior to treatment.

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ORCID iD

Dong Jin Ryu, MD, MS  <https://orcid.org/0000-0003-2455-5230>

Level of Evidence

Therapeutic level III.

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