

ORIGINAL ARTICLE

The Effect of Subchondral Claw-Deploying Lag Screw on Lateral Sliding Distance and Cut-Out in Treating Intertrochanteric Fractures

İntertrokanterik Kırıkların Tedavisinde Subkondral Pençe Yerleştirme Gecikmeli Vidanın Yanal Kayma Mesafesine ve Kesmeye Etkisi

¹Levent Horoz , ¹Mehmet Fevzi Cakmak 

¹Kırşehir Ahi Evran University Faculty of Medicine Orthopedics and Traumatology Clinic, Kırşehir/TURKEY

Correspondence

Kırşehir Ahi Evran University Faculty of Medicine Orthopedics and Traumatology Clinic, Kırşehir/TURKEY

E-Mail: lhoroz@yaani.com

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ABSTRACT

Introduction: The incidence of intertrochanteric fractures has increased in recent years due to the growing elderly population at risk of hip fractures, primarily attributed to osteoporosis. Among hip fractures, the prevalence of intertrochanteric fractures is progressively rising.

Aim: To evaluate clinical and radiological results of the lag screw that deploys the claw in the subchondral area of the femoral head in the treatment of advanced age unstable intertrochanteric fractures.

Methods: We retrospectively reviewed patients with intertrochanteric fractures treated with proximal femoral nails between 2019 and 2021. A total of 107 patients were examined under two groups according to the choice of the nail (Interclaw lag screw(n=52), Proximal femoral nail anti-rotation (n=55) used in the treatment. The radiological parameters in the post-operative 1st-day radiographs of the patients were evaluated. The changes in the first, three, six months, and one-year control radiographs of the patients were evaluated. Changes in tip apex distance and lateral sliding of the lag screw were compared between the two groups.

Result: There was no statistically significant difference between the two groups regarding operation time, post-operative femoral neck/shaft angle, post-operative Calcar gap (mm), and tip-apex distance (TAD) (mm). In the last clinical follow-up, the two groups had a statistically significant difference in the femoral neck/shaft angle and TAD change. There was a significant difference in sliding distance between the two groups at the last follow-up.

Conclusion: Using a subchondral claw-deploying lag screw is a reliable implant choice in the surgical treatment of geriatric intertrochanteric fractures. The claw mechanism increases fixation strength and restricts the movements of the lag screw in the femoral head.

Keywords: İntertrokanterik kırık, Proximal femoral nailing, Lag screw sliding, lag screw.

ÖZ

Giriş: İntertrokanterik kırıkların insidansı, özellikle osteoporozla atfedilen kalça kırığı riski taşıyan yaşlı nüfusun artması nedeniyle son yıllarda artmıştır. Kalça kırıkları arasında intertrokanterik kırıkların prevalansı giderek artmaktadır.

Amaç: İleri yaş instabil intertrokanterik kırıkların tedavisinde, femur başında subkondral pençe açan lag vidanın klinik ve radyolojik sonuçlarını değerlendirmek.

Metod: 2019-2021 yılları arasında proximal femur çivisi ile tedavi edilen intertrokanterik kırıklı hastaları retrospektif olarak inceledik. Toplam 107 hasta çivi seçimine göre iki grup altında incelendi (Interclaw lag screw(n=52), Proximal femoral çivi anti-rötasyon (n=55)) Hastaların post-operatif 1. gün radyografileri değerlendirildi. Hastaların 1, 3, 6 ay ve 1. yıl kontrol graflerindeki değişiklikler değerlendirildi. Lag vidasının uç apeks mesafesindeki değişiklikler ve lag vidasının yanall kayması iki grup arasında karşılaştırıldı.

Bulgular: Ameliyat süresi, ameliyat sonrası femur boyun/şaft açısı, ameliyat sonrası Calcar açıklığı (mm) ve TAD (mm) açısından iki grup arasında istatistiksel olarak anlamlı fark yoktu. Son klinik takipte femur boyun/şaft açısı ve TAD değişikliği açısından iki grup arasında istatistiksel olarak anlamlı bir fark bulundu. Son takipte iki grup arasında yanall kayma mesafesinde anlamlı bir fark gözlemlendi.

Sonuç: İleri yaş intertrokanterik kırıklı hastaların cerrahi tedavisinde subkondral pençe açılan lag vidası kullanımı güvenilirdir. Pençe mekanizması, lag vidasının tespit gücünü arttırmakta femur başı içindeki hareketlerini kısıtlamaktadır.

Anahtar Kelimeler: İntertrokanterik kırık, Proximal femur çivileme, lag vidası kayması, çekirtilme vidası

Introduction

The incidence of intertrochanteric fractures has increased in recent years due to the growing elderly population at risk of hip fractures, primarily attributed to osteoporosis (1–3). Among hip fractures, the prevalence of intertrochanteric fractures is progressively rising (4,5). Consequently, patients undergoing surgery for intertrochanteric fractures belong to more advanced age groups and generally suffer from severe osteoporosis (6). In order to achieve better outcomes with improved biomechanical advantages and surgical ease, intramedullary fixation is preferred in managing intertrochanteric fractures

(7). The popularity of proximal femoral nails (PFN) for intramedullary fixation in treating intertrochanteric fractures has increased in recent years (7). Despite its growing popularity, failure rates range between 2% and 14% (8,9). Factors contributing to failure include insufficient bone quality, absence of lateral wall integrity, posteromedial cortical discontinuity, poor surgical technique and excessive displacement of the lag screw (10–13). Failures of PFN are commonly observed as varus collapse and cut-out (14). Postoperative follow-ups have demonstrated that lateral displacement of the lag screw by 10 mm or more leads to mechanical failure

(15). Various implant designs are available to enhance the stability of the lag screw (16,17). Limited studies are available regarding the clinical and radiological outcomes of different claw mechanism lag screws (18,19).

The lag screw utilized in the Zimed proximal femoral nail system (Zimed Medical, Türkiye) represents a novel design. The screw incorporates a claw mechanism at its proximal end, and the claws are engaged into the subchondral bone for improved anchorage in the femoral head. Publications regarding the clinical outcomes of the Interclaw LAG screw (ILS) (Zimed Medical, Türkiye) in intertrochanteric fractures are limited. Therefore, this study aims to elucidate the clinical and radiological outcomes of using this newly designed lag screw in cases of intertrochanteric fractures in elderly patients.

Material and Method

Study Population

A total of 142 patients were evaluated in the study. We included patients with an intertrochanteric fracture due to low-energy trauma with a minimum follow-up of 12 months. A total of 107 patients met the inclusion criteria.

Study Design and Participants

This retrospective study was conducted at a tertiary education and research hospital in Türkiye. We retrospectively reviewed patients with intertrochanteric fractures treated with cephalomedullary nail fixation between 2019 and 2021. Treatment details and complications were identified by review of the electronic medical record. Fracture classification was made according to the AO/OTA classification used in previous studies (20). Patients with A1 and A2 type fractures were included in the study according to the AO/OTA classification. A review of surgical reports and radiograph analysis confirmed the intertrochanteric femur fracture diagnosis. Plain anterior-posterior (AP) and lateral hip radiographs were obtained on the immediate post-operative day one to analyze the reduction quality, TAD, lateral sliding, calcar fracture gap and lag screw placement according to Cleveland-Bosworth quadrants, femur neck/shaft angle. Calcar fracture gapping was measured as described by Ciuffo et al. (21) (Fig 1). The measurement was corrected according to the actual length and width of the lag screw. Lateral sliding was recorded as the change in the distance between the outer border of the lag screw and the lateral border of the nail in the immediate post-operative and final follow-up radiograph. The measurement was corrected according to the known actual width of the lag screw. The quality of reduction assessed on post-operative plain radiography according to Baumgaertner et al. described before (22). The reduction quality is determined by evaluating cortical translation and anteversion on both AP and axial plain radiography. As a result, it was evaluated as optimal, acceptable and unacceptable. Post-operative follow-ups were performed at six weeks, three months, six months,

one year, and per year after that. AP and axial plain radiographs obtained during routine controls were evaluated regarding lag screw sliding and femoral neck-shaft angle changes. Mechanical complications that developed during the routine controls were also evaluated.

Exclusion Criteria

- Pathologic fractures (n=2),
- Previous ipsilateral extremity surgeries (n=3),
- Inability to walk before surgery (n=11),
- Intertrochanteric fracture with subtrochanteric extension (n=5),
- Lateral wall involvement (n=7),
- Advanced hip osteoarthritis (n=7),
- Cases with lateral wall fractures extending to the lag screw in which the lag screw was left in static mode.

Groups

- First group proximal femur anti-rotation (PFN-A, IMN group, Türkiye) (n=55),
- Second group PFN-A with ILS (n=52).

Examined Variables

- Demographic characteristics of the patients
 - o Sex n (%)
 - o Age
 - o AO/OTA n (%)
 - o Follow-up time (month)
- Intra and post operative variables
 - o Time of operation (min)
 - o Femur neck/shaft angle Postop 1
 - o Femur neck/shaft angle change at last follow-up
 - o Postoperative Calcar gap (mm)
 - o TAD (mm)
 - o TAD change at last follow-up (mm)
 - o Sliding distance (mm)
 - o Reduction quality
 - o Lag Screw Placement according to
 - o Mini open reduction requirement
 - o Time to Healing
 - o Non-union (Cut-out)
- Complications
 - o Distal locking difficulties
 - o Loss of reduction during a nail application
 - o Trochanteric Fracture

Surgical Technique

A single surgeon performed all surgeries. All surgeries

were performed in the supine position on the traction table. The mini-open or closed technique achieved fracture reduction according to the need. All nails were applied according to the manufacturer's guidelines; for all nails, a set screw was used to prevent lag screw rotation. The proximal set screw was rotated one-quarter counterclockwise to allow the lag screw to slide after being tightened for all cases. The standard 200 mm nail size was used for all cases, and all nails were distally locked statically with one screw. Intraoperative difficulties and complications were evaluated. All patients were allowed weight bearing as tolerated using a walker on the first postoperative day and underwent the same rehabilitation program.

Zimed PFN with Interclaw Lag Screw

200 mm length Zimed proximal femoral nail used for all cases. The nail lateral bend angle measures 6° . One lag screw with three deployable/retractable claws can be inserted through the nail with a 130° angle option. After the interclaw lag screw application, the claws deploy from the distal part of the lag screw to the subchondral area. Claws can be opened up to the screw tip. Compression is done through the system. Finally, as stated above, the set screw is locked in the dynamic position (Fig 2).

Ethics

The research obtained ethical committee approval, as evidenced by the ethical committee approval (2023-05/32). The principle of voluntary participation was strictly adhered to, ensuring no coercion was involved in recruiting participants for the study. The principles of the Helsinki Declaration conducted our research.

Statistical Analysis

The data obtained in the study were analyzed with the IBM SPSS 25.0 (Statistical Package for the Social Sciences) program. While evaluating the study data, the normal distribution of the data was evaluated with the Shapiro-Wilk test. Within our study, descriptive statistics, including frequency (%), mean and standard deviation (SD), as well as minimum, median, and maximum values have been provided. Chi-square or Fisher exact test was used for categorical data, independent t-test for parametric data with normal distribution, and Mann Whitney U test was used for non-parametric data to compare two groups. The Spearman test was used for correlation evaluations. Significance was evaluated at the $p < 0.05$ level.

Results

There was no statistically significant difference between the two groups in demographic data (Table 1). There was no statistically significant difference between two groups regarding operation time, post-operative femoral neck/shaft angle, post-operative Calcar gap (mm), and TAD (mm). The two groups had a statistically significant difference in the femoral neck/shaft angle and TAD change in the last clinical follow-up (Fig 4). Sliding distance (mm) and recovery times were statistically different between the two groups ($p < 0.05$) (Table 2). The position of the lag screw

in the femoral head according to the Cleveland index is given in Figure 3 for both groups. A statistically significant difference was observed between the two groups regarding union times. Union time was shorter than six months in 43 patients in the ICL group and 31 in the PFNA group. Considering the intraoperative complications and difficulties, two distal locking problems, two trochanteric fractures, and reduction loss during nail application were observed in one patient in the ILS nail group. In the PFN-A group, one distal locking problem, two trochanteric fractures, and reduction loss were observed in two patients during nail application (Table 3). No statistically significant difference was observed in cut-out rates in the ILS nail ($n=2$) and PFN-A ($n=4$) groups in the clinical follow-up of the patients. Arthroplasty was applied for these cases. Nail breakage was observed in one patient in the ILS nail group. An exchange nail was applied. As a result of the correlation analysis of TAD change (mm) and the other data, it was observed that the sliding distance increased in cases where the post-operative calcar gap distance increased ($r=0,567$, $p < 0,001$). There was a significant negative correlation between TAD change and femoral neck/shaft angle on postoperative day one ($r=-0,338$, $p < 0,001$). As a result of the correlation analysis of the sliding distance and other parameters, a significant positive correlation was found between age ($r=0,532$, $p < 0,001$) and fracture gap (mm) ($r=0,507$, $p < 0,001$). A significant negative correlation was found between the sliding distance and the femoral neck/shaft angle on postoperative day one ($r=-0,272$, $p=0,005$).

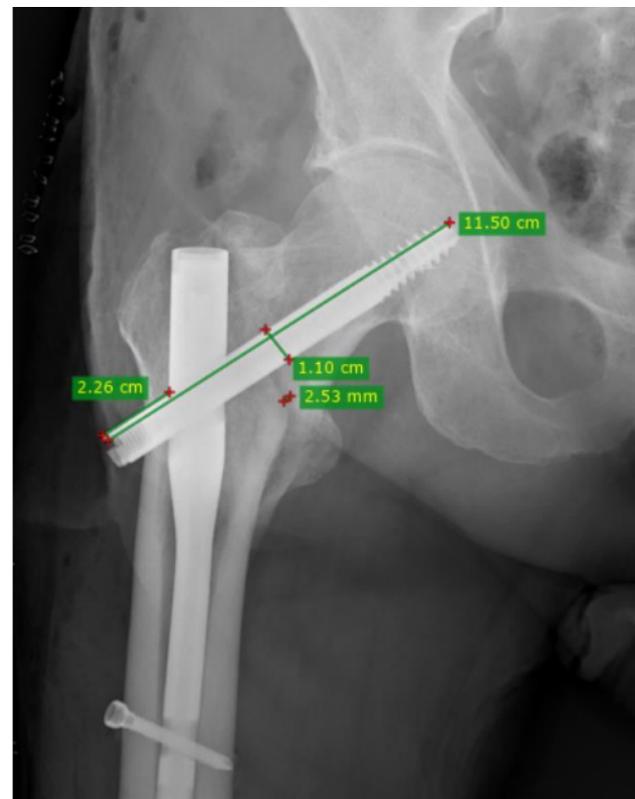


Figure 1. Fracture gap; Maximum distance between two fragments in the calcar region. Lag screw protrusion; distance between the lateral border of the nail and the lateral border of the lag screw. All measurements were verified and corrected using the known length and width of the lag screw.

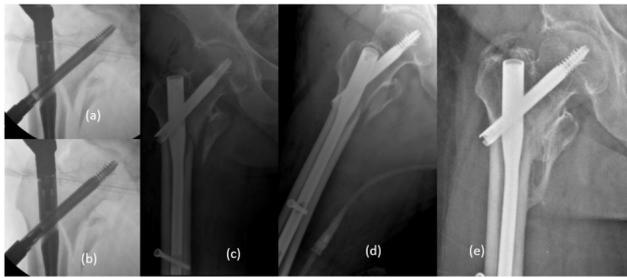


Figure 2. (a,b) Intraoperative fluoroscopy of claw deployment and fracture compression. Anterior-posterior (c) and lateral (d) postoperative radiographs of the Zimed proximal femoral nail with interclaw lag screw. (e) The complete union was observed at three months in clinical follow-ups.

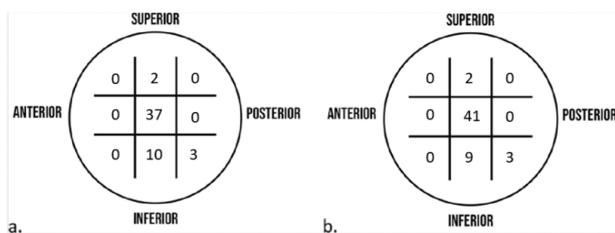


Fig 3. a Position of the lag screw in the head of the femur (ILS Nail). b Position of the lag screw in the head of the femur (PFN-A)

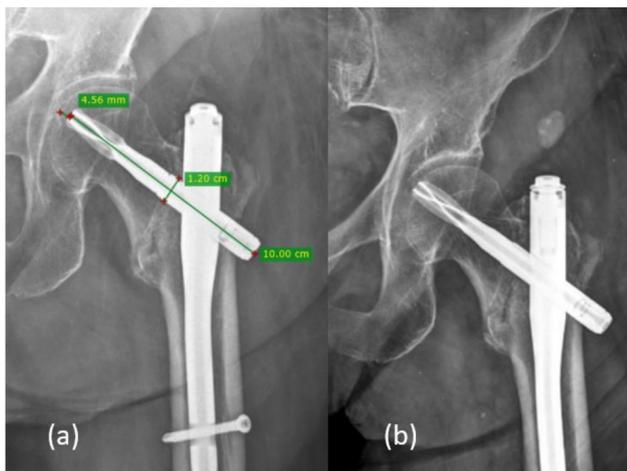


Fig 4. (a) Early postoperative anterior-posterior radiograph of the patient who underwent PFNA. (b) TAD change and cut-out on the 6th-week follow-up radiograph

Discussion

Our study's most important finding was that the ILS's lateral sliding was significantly lower when compared to the PFN-A group. Considering the lateral sliding of the lag screw in both groups, the clawed lag screw group was superior. Similar cut-out ratios were observed. When the factors affecting the union's delay were examined, it was observed that lateral sliding and calcar fracture had a significant effect. The change in the femoral neck shaft angle at the last follow-up was significantly lower in the ILS group.

Because of their unstable nature, intertrochanteric fractures should be treated with stable, load-bearing implants (23). Considering the re-operation and

mechanical complication rates, intramedullary nail applications give more successful results in unstable intertrochanteric fractures (24,25). As intramedullary fixation methods have become more popular, complication rates have increased (26,27). Mechanical complication rates after fixation of unstable intertrochanteric fractures with intramedullary nails vary between 3-13% (9). Excessive blade sliding (>5mm) is one of the causes of mechanical failures (28,29). Complications such as lateral sliding and varus collapse are frequently encountered in clinical follow-ups, especially in elderly patients with osteoporotic intertrochanteric fractures (30). It has been shown that single-lag screw CMNs are prone to both varus collapse and lateral regression in osteoporotic intertrochanteric fractures (31). In geriatric intertrochanteric fractures without medial support, excessive lateral sliding and high non-union rates have been observed after single-lag intramedullary nail application (32). Gavaskar et al. (33) reported that the lateral sliding of the lag screw was found higher (6.9 ± 2.9 mm) in single-lag intramedullary nails than the dual lag intramedullary nails (1.9 ± 0.97 mm). In the current study, the average lateral sliding was 2.33 ± 1.48 mm in the ILS nail group and 3.94 ± 1.84 mm in the single lag group. Cut-out was observed after varus collapse in two claw deploying nail group patients. Arthroplasty was applied to these patients. In one patient, an exchange nail was applied due to nail breakage. Dual lag screw PFN was preferred in nail revision.

Ruangsillapanan et al. (34) reported that leaving the lag screw in dynamic mode increased the complication rates (8.8%) in advanced-age osteoporotic intertrochanteric fractures. In our current study, the lag screw was used in dynamic mode, and the mechanical complication rate was low (5.7%) in the ILS group due to the claw mechanism increasing its grip within the femoral head. During the clinical follow-up of osteoporotic intertrochanteric fractures treated with intra-medullary nailing, changes in TAD and related complications were observed (35,36). Geller et al. (37) have reported that complication rates increase in cases where TAD changes more than 3 mm during follow-up. As a result of our study, the average TAD change in the last follow-up was 1.22 ± 1.09 mm in the claw mechanism lag group, while it was 2.33 ± 1.46 mm in the single lag group.

Many new-generation implants are designed and used today to prevent excessive lateral sliding of the lag screw. For this purpose, double lag systems, a U blade with a lag screw, cemented augmented lag screw are used to increase the grip of the lag screw at the femoral head (38-40). Claw mechanisms anchored through the lag screw were used to increase the fixation strength of the lag screw in the femoral head, and successful results were obtained in unstable and stable intertrochanteric fractures (18,19,41,42). Temiz et al. reported five greater trochanteric fractures while applying the DTL trochanteric nail (42). We observed two iatrogenic trochanteric fractures in the ICL group. Gunay et al. (41) reported the mechanical complication rate as 25% in unstable intertrochanteric

fractures. Reduction quality and lag screw placement are thought to affect this result. Lag screw placement and reduction quality are essential in determining intertrochanteric fracture prognoses (43). In our series mechanical complication rate was 5.8% in the ICL group. In the group with mechanical complications, varus collapse was observed in two patients, and one patient was re-operated with nail breakage after falling again. In the ICL group, the lag screw was placed in the inferior-center position in 10 patients and the center-center position in 37 patients. As a result of recent studies, it has been observed that similar results are obtained after the center or inferior application of the lag screw. We obtained similar results in our clinical study (44). While claw-deploying nails treat intertrochanteric fractures, cortex penetration can be observed, especially in nails that open claws on the femoral neck (18). In the nail we used, cortical or chondral penetration was not observed due to the opening of the claw mechanism into the femoral head, which is relatively more comprehensive. There is no biomechanical research on the subchondral claw deploying lag screw systems in the literature, but as a result of the research conducted with nails deploying the claw on the femoral neck, it was seen that it showed similar biomechanical properties with single lag screw system (45).

Our study had some limitations. Our study's first and foremost limitation was the retrospective design and the patients' non-randomization. Another limitation of our study is that the sample size was small because the nails used in the patient population could not be supplied periodically. The last limitation of our study is that the clinical scoring systems that allow us to compare the patients' daily activity and pain results were not analyzed.

Conclusion

Using a subchondral claw-deploying lag screw is a reliable implant choice in the surgical treatment of geriatric intertrochanteric fractures. The claw mechanism increases fixation strength and restricts the movements of the lag screw in the femoral head. Compared with PFNA, it was superior regarding TAD change and lateral sliding in clinical follow-ups. Since the study was retrospective, prospective studies with a more extensive series are needed to conclude a clear superiority between the two nails.

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Author contributions: LH. and MFC study design. LH and MFC data collection. LH wrote the manuscript. All the authors have agreed to be accountable for all aspects of the study and have approved the final version of the manuscript.

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