




Which is Superior in the Treatment of Femoral Shaft Fracture? A Comparison of Talon Intramedullary Nailing and Conventional Locked Intramedullary Nailing

Femur Cisim Kırığının Tedavisinde Hangisi Daha Üstündür? Talon İntramedüller Çivileme ile Konvansiyonel Kilitli İntramedüller Çivilemenin Karşılaştırılması

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ABSTRACT

Objective: This study compared the clinical and radiological outcomes of screw and talon locking systems, which are distal nail locking systems, in adult femoral shaft fractures treated with intramedullary nails.

Methods: The data of patients who received intramedullary nails were retrospectively analyzed. The patients were divided into two groups: patients treated with conventional intramedullary nails (group 1) and those with a talon distal locking system (group 2). Both groups were assessed according to age, sex, fracture side, type of implant, length of surgery, fluoroscopy shot number of intraoperative fluoroscopy, length of postoperative follow-up, time to union, smoking, AO classification of fractures, and presence of malunion and nonunion. Additionally, patients were compared using the Knee Society score and Harris Hip score as clinical functional scores.

Results: Among 102 study patients, were 21 (20.5%) females and 81 (79.5%) males, with a mean age of 39.34 (18-65) years. When the time to union, fluoroscopy shots number and length of surgery were compared between the groups, the results were statistically significant ($p < 0.05$). There was no statistically significant difference in malunion and nonunion rates between the groups ($p > 0.05$). Results of clinical scores were similar in both groups and there was no statistically significant difference ($p > 0.05$). Additionally, smoking, age, sex and subtype of fracture did not have a statistically significant association with time to union, and malunion and nonunion rates ($p > 0.05$).

Conclusion: The talon system is a reliable method that provides an advantage in terms of radiation exposure and length of surgery compared to the conventional locking system. The union time was observed to be longer in patients using the talon system compared with the conventional method, and a joint decision should be made by the surgeon and the patient on the treatment method, by informing the patients about the advantages and disadvantages of this system before the operation.

Keywords: Femur shaft fracture, talon femoral nail, conventional femoral nail, distal locking

ÖZ

Amaç: Bu çalışmadaki amaç tedavide intramedüller çivi kullanılan erişkin femur diyafiz kırıklarında çivi distalindeki kilitleme sistemleri olan vidalı ve talonlu kilitleme sistemlerinin klinik ve radyolojik sonuçlarını karşılaştırmaktır.

Gereç ve Yöntem: İntramedüller çivi kullanılan hastaların verileri retrospektif olarak incelenmiştir. Hastalar konvansiyonel intramedüller çivi yapılanlar (grup 1) ve talonlu distal kilitleme yapılanlar (grup 2) olarak iki gruba ayrılmıştır. Her iki grup yaş, cinsiyet, taraf, implant tipi, ameliyat süresi, intraoperatif skopi sayısı, postoperatif takip süresi, union sağlama süresi, sigara kullanımı, AO kırık sınıflaması, malunion ve nonunion varlığına göre değerlendirilmiştir. Ayrıca hastalar klinik fonksiyonel skorlamalar olan Knee Society skoru ve Harris Hip skorlaması ile kıyaslanmıştır.

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Bulgular: Çalışma kapsamında değerlendirilen 102 hastanın 21'i (%20,5) kadın 781'i (%79,5) erkek olup yaş ortalaması 39,34 (18-65) idi. Gruplar arasında kaynama zamanı, radyasyona maruziyet süresi ve ameliyat süresi kıyaslandığında sonuçlar istatistiksel olarak anlamlıydı ($p < 0,05$). Gruplar arasında malunion, nonunion gelişimi arasındaki ilişki istatistiksel olarak anlamlı değildi ($p > 0,05$). Gruplar arasındaki klinik skorlamaların sonuçları benzerdi ve istatistiksel olarak anlamlı fark yoktu ($p > 0,05$). Ayrıca sigara içimi, yaş, cinsiyet, kırık alt tipi ile kaynama zamanı, malunion ve nonunion gelişimi arasındaki ilişki istatistiksel olarak anlamlı değildi ($p > 0,05$).

Sonuç: Talonlu sistem konvansiyonel kilitleme sistemine göre radyasyona maruziyet ve ameliyat süresi açısından avantaj sağlayan güvenilir bir yöntemdir. Talonlu sistem kullanılan hastalarda kaynama zamanı konvansiyonel yöntemle göre daha uzun olarak görülmüş olup, ameliyat öncesi hastaların bu sistemin avantaj ve dezavantajları hakkında bilgilendirilerek, cerrah ve hasta tarafından tedavi yöntemi konusunda ortak karar alınmalıdır.

Anahtar Kelimeler: Femur shaft kırığı, talonlu femur çivisi, geleneksel femur çivisi, distal kilitleme

INTRODUCTION

Femoral shaft fracture is a common condition in adults that is caused by high-energy trauma and represents 4.6% of all adult fractures (1). Intramedullary nailing is accepted and used as a gold standard for treating adult femoral shaft fractures by several trauma surgeons since it allows early limb movement with stable fracture reduction (2-5). Although intramedullary nails are the gold standard treatment, the reported rate of nonunion after intramedullary nailing ranges from 0.5% to 12.5% in the literature (6-9). This rate, of course, may change due to reasons such as the mechanism of injury, the location of the fracture, and the amount of soft tissue affected (10-12). Additionally, intramedullary nails have changed in design along with the development of today's technology. A quick, safe and practical distal locking mechanism is of importance both in terms of saving time in surgery and stabilization of fracture fixation. The talon distal locking mechanism, in turn, is a new locking system that has become popular recently. With this system, stabilization is achieved via distal talon locks that can be deployed through the intramedullary nail.

Our aim in this study was to compare the clinical and functional results of two different locking systems (talon distal locking and conventional distal locking) in patients with femoral shaft fractures treated with a femoral nail.

METHODS

The study included 102 patients who were treated and followed up for femoral shaft fractures between 2017 and 2020. The data of the patients were analyzed retrospectively, and the data were collected by the Declaration of Helsinki. Adult patients who were aged ≥ 18 years, who had an isolated femoral shaft fracture, who were treated with antegrade nailing, and who had accessible 12-month follow-up data were included in the study. Patients with pathological fractures, open fractures according to the Gustilo-Anderson classification, an additional injury or a fracture involving a different extremity, who were treated with retrograde nailing, aged ≥ 65 years, previously operated for the same

fracture, pregnant, using immunosuppressive drugs, and patients with a body mass index of ≥ 35 , and chronic renal failure were excluded. The patients were divided into two groups according to the implants used in the treatment. Additionally, no specific criteria were used to determine which implant design should be used in which patient. Patient and implant design choices were made randomized. Based on two different distal locking designs, patients who were treated with intramedullary nails (Zimed Medical Türkiye, ZFN Multi-Purpose Femoral Nail Systems) were assigned to group 1 (Figure 1), and those who were treated with Talon distal locked IMN (Zimed Medical Türkiye, ZFN-Talon Lock Femoral Nail Systems) to group 2 (Figure 2). Patients' age, sex, length of follow-up, mechanism of injury, type of fractures according to AO classification, smoking, length of surgery, the number of intraoperative fluoroscopy shots, time to the union after treatment, postoperative infections, malunion and nonunion were recorded and the statistical difference between the groups was examined. Functional outcomes of the study group patients were assessed by the



Figure 1. Intramedullary antegrade conventional locking nail preferred in group 1 patients



Figure 2. Femoral cannulated intramedullary talon distal fixation nail preferred in group 2 patients

Knee Society score and Harris Hip score. For all patients, radiographic data on months 1, 3, 6, 9, and 12 at follow-up were used. Union was considered to be achieved in patients with no pain on weight-bearing and with callus formation on three of four cortices on radiographs at the follow-up (Figure 3, 4). An angulation of >5 degrees, a shortness of more than 2 cm, and a rotational deformity of >15 degrees in any plane were considered malunion (13). Patients were also evaluated in terms of limb length difference and the distance between spina iliaca anterior superior and medial malleolus was considered. The study was approved by the Gaziantep University Clinical Research Ethics Committee (decision no: 2021/53, date: 24.02.2021).

Surgical Technique

All patients were taken into the operating room after preoperative preparation. The same surgical procedure was performed in both the groups of patients. For prophylaxis, a second-generation cephalosporin (1 g was administered intravenously 45 min before the surgery and continued for one postoperative day. The patients included in the study were closed-reduced and the fracture line did not need to be opened. In all patients, a nail with the apex entrance of the trochanter major was preferred and a nail of appropriate thickness was placed in the medulla of each patient after femur reamerization. For distal locking with screws, the nail was locked manually with two screws under fluoroscopy and no dynamization was performed during follow-up. For the talon system, locking was completed by deploying the talons with the guide advanced into the nail. All patients



Figure 3. 19-year-old male patient. X-ray images at 6th and 12th months of post-traumatic treatment



Figure 4. 55-year-old male patient. X-ray images at 4th and 12th months of post-traumatic treatment

were postoperatively administered low-molecular-weight heparin. In the postoperative rehabilitation, weight-bearing was initiated at a tolerable level with early postoperative movement in both groups.

Statistical Analysis

The descriptive statistics of the variables analyzed in the study were expressed as mean \pm standard deviation, median (minimum-maximum), and nominal variables as n (%), represented with appropriate charts. A comparison of two independent groups was analyzed by Mann-Whitney U test and t-test in accordance with Shapiro-Wilk normality test. In all statistical analyses, the level of significance was set at $p < 0.05$. IBM SPSS version 22.0 (IBM Corp, Armonk, NY, USA) software was used for data analysis.

RESULTS

Among 102 study patients, were 21 (20.5%) females and 81 (79.5%) males, with a mean age of 39.34 (18-65) years. Additionally, the fracture was on the right side in 41 (40%) and left side in 61 (60%) patients. There were 37 (36.2%) non-smoker patients, while 65 (63.7%) patients were smokers independent of dose assessment. According to the AO classification of femoral shaft fractures, 62 (60.7%) patients had type A, 35 (34.4%) patients had type B, and 5 (4.9%) patients had type C fractures. The etiology of the fracture was a traffic accident in 51 (50%) patients and a fall in 51 (50%) patients. As the fracture fixation method, implants with a distal locking screw were used in 65 (63.7%) patients who received intramedullary femoral nailing and with a talon distal locking system in the remaining 37 (36.3%) patients. Mean follow-up time was 16.7 (12-44) months. During the follow-up of 102 patients, 6 (5.8%) patients were diagnosed with malunion and 3 (2.9%) patients with nonunion. No patient showed signs of infection during follow-up. Additionally, the demographic data of the study group patients are presented in Table 1.

There was a statistically significant difference between implant design and time to union ($p < 0.05$). The implant design was also significantly difference with the length of surgery and duration of intraoperative fluoroscopy shots number ($p < 0.05$). Regarding nonunion and malunion, the results were similar in both groups, to no statistical significance ($p > 0.05$). The use of talon or screws for distal locking as implant design had similar effects on functional

outcomes and there was no statistically significant difference ($p > 0.05$) The mean values according to the groups are given in Table 2.

Fracture subtype did not have a statistically significant difference with nonunion, malunion and time to union ($p > 0.05$). Our study could not establish any statistically significant difference in smoking, sex, age, and etiology of injury with time to union, malunion and nonunion ($p > 0.05$) (Table 3).

DISCUSSION

The most important finding of this study is that the talon locking system provides the advantage of faster surgery and less radiation exposure compared to the conventional locking system.

As is known, intramedullary nailing is the gold standard for treating femoral shaft fractures caused by high-energy traumas. Many surgeons use the advantages of the nail fixed with the conventional locking method implantation intramedullary along with reamerization in intramedullary nailing, such as high rates of union, early weight-bearing with axial and rotational stability, short hospital stay, and short duration of surgery (14,15).

Despite these advantages, the use of intramedullary nails in the femur also has disadvantages, such as difficulty in inserting distal locking screws, increased radiation exposure time, prolonged surgery, risk of neurovascular injury, and soft tissue injury (16,17). Similar complications were reported by

Table 1. Demographic data by groups

		Group 1	Group 2	p-value
Sex	Female	13 (20%)	8 (21.6%)	0.82
	Male	52 (80%)	29 (78.4%)	
Age		38.98 (18-65)	39.97 (18-65)	0.85
Type of injury	Traffic accident	32 (49.2%)	19 (51.4%)	0.78
	Fall	33 (50.8%)	18 (48.6%)	
Smoking	No	24 (36.9%)	13 (35.1%)	0.82
	Yes	41 (63.1%)	24 (64.9%)	
AO type of fracture	A	40 (61.5%)	22 (59.4%)	0.72
	B	22 (33.8%)	13 (35.13%)	
	C	3 (4.6%)	2 (5.4%)	
Length of follow-up (month)		18.46 (12-26)	13.62 (12-44)	0.35
Infection		No	No	-
Malunion		4 (6%)	2 (5.4%)	0.74
Nonunion		2 (3%)	1 (2.7%)	0.87

Table 2. Correlations of type of implant with time to union, malunion and nonunion

Variables	Group 1	Group 2	p-value
Time to union (week)	14.2 (9-24)	19.4 (10-28)	0.008
Length of surgery (minute)	54.2 (±10.1)	44.2 (±8.2)	0.02
Fluoroscopy shot (number)	52 (32-150)	32 (20-60)	0.01
Knee society score (points)	92 (85-100)	91 (83-96)	0.88
Harris hip score (points)	92.50 (86-95)	90.5 (83-93)	0.8

studies on the use of distal locking screws in intramedullary nailing of the tibia, another long bone of the lower extremity (18,19).

According to the results of this study, the talon system for intramedullary femoral nailing resulted in a shorter duration of surgery and decrease fluoroscopy shots number. Biomechanical studies have shown that it improves the interfragmentary torsional and compression strength (20). In their study on proximal femoral fractures, Zehir et al. (21) found this system reduced the length of surgery and resulted in low cut-out rates. Similarly, Yapici et al. (22) showed that the talon nailing could be an alternative in proximal femoral fractures. Additionally, Çamurcu et al. (19) compared intramedullary nailing using conventional locking and talons in tibial shaft fractures and concluded that talon nailing was technically easy and safe.

However, the time to union was longer compared to the conventional distal locked tibial nailing. Besides, both techniques yielded successful outcomes in clinical and radiological terms.

Literature data show that the time to union may range from 5.4 months to 24 months in patients treated with conventional locking (6,23-26). According to our study data, the meantime to union was 14.2 (9-24) weeks in group 1, which agrees with the literature. For the talon system, the meantime was 19.4 (10-28) weeks. Even if there was a difference in the time to union, when we evaluate it together with the complication rates and clinical outcomes, both systems can be considered successful. A meta-analysis on nonunion reviewed 2,829 cases and reported a nonunion rate of 2.9% (27). In line with the data in the literature, our study identified a nonunion rate of 3% in patients treated with the conventional method and 2.7% in patients treated with the talon design, and the difference between the two methods was statistically insignificant.

Biomechanical studies report data indicating that new design expandable nails are weaker in resisting rotational

Table 3. Correlations of smoking, sex, type of fracture and etiology of injury with time to union, malunion and nonunion

Variables		Time to union	Malunion	Nonunion
Smoking	p-value	0.06	0.182	0.809
Sex	p-value	0.806	0.433	0.887
Age	p-value	0.975	0.982	0.943
Type of fracture	p-value	0.388	0.31	0.32
Etiology of injury	p-value	0.785	0.198	0.304

and axial forces compared to conventional locked nails (28,29). Concerning the number of distal locking screws, studies are reported that two screws are superior to one screw against axial and angular deformities (30). When we evaluated the patient's radiographs, we concluded that callus formation was more prominent in patients who used a talon design. This result showed that a more stable fracture fixation was achieved against axial and rotational forces in cases where distal locking was performed with two screws. It is also possible to suggest that the talon system provided weaker stabilization in the fracture line due to the prolonged time to union.

The development of minimally invasive techniques in orthopedic surgery and traumatology creates the necessity of using fluoroscopy for a longer time. Nevertheless, various techniques have been developed to reduce the length of surgery and fluoroscopy shots number, depending on the distal locking mechanism of the intramedullary femoral nails (31,32). In this study, we assessed the length of surgery and the number of fluoroscopy shots for two different designs. We found approximately two times shorter radiation exposure with the talon system compared to the conventional method. The main advantage of the talon intramedullary femoral nail seems to be the reduction in radiation exposure by both the orthopedic surgeon and the patient by providing distal locking with six talons deployed distally. Thus, the length of surgery is reduced, suggesting a positive effect on the comfort of the surgery. When we look at the literature, this advantage of the talon design has been emphasized in studies on different long bone fractures (33,34). This study highlights that these advantages of the talon system apply to femoral shaft fractures. When we look at the literature, Yapıcı et al. (35) evaluated the data of 85 patients with femoral shaft fractures retrospectively, and compared the talon system with the conventional locking system. According to the results of this study, the talon system shortened the operation time and intraoperative radiation exposure time, however, clinical and functional results were similar for both systems (35).

When we made an overall assessment of the designs used in the study, we did not establish any significant differences in both clinical outcomes or complications. In our study, 6 patients were evaluated as malunion. These patients had an angulation of >5 degrees, but the angulation were <10 degrees. The patients refuse revision surgery, thinking that they did not have any problems in their daily lives. A total of 3 patients with the diagnosis of nonunion underwent revision with nail exchange and iliac autogenous graft, and union was observed in their follow-up. Although we expected an increase in the complication rate due to the lower stability of the talon system in terms of resistance to rotational and axial forces compared to the conventional method, the results revealed no significant difference. Additionally, we did not observe any reduction in limb length at the post-fracture follow-up. The point to be paid attention here is to ensure the contact of the talons with the femoral cortex while ensuring the central placement of the nail in the intramedullary area. Because of the width of the metaphysis, the talon system may be incapable of providing adequate stabilization, leading to instability in extra-articular fractures of the distal metaphysis.

There are factors that limit our study. First all, our study was a retrospective assessment. The number of patients can be considered another limitation. However, we ensured homogeneous results by including similar groups in the study while examining the outcomes of implant designs. Another factor is that we did not evaluate the effects of nail diameter. Despite the known effect of nail diameter on union, it was excluded in the assessment in this study.

CONCLUSION

In conclusion, intramedullary femoral nailing with a talon system can be considered an easier and safer option for femoral diaphyseal fractures compared with conventional locking design because of the reduction in the length of surgery and radiation exposure. Radiographic outcomes showed that the time to union might be longer with the talon system than with the conventional method, which should be considered during patient follow-up. We believe that this study is the first in the literature to compare the outcomes of two different implant designs for femoral diaphyseal fractures. We further believe that the minimum 12-month follow-up of our patients was a sufficient period for clinical assessment.

ETHICS

Ethics Committee Approval: The study was approved by the Gaziantep University Clinical Research Ethics Committee (decision no: 2021/53, date: 24.02.2021).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: A.M., S.B.T., Concept: A.M., Design: S.B.T., Data Collection or Processing: B.B., Analysis or Interpretation: A.M., Literature Search: S.B.T., Writing: B.B.

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