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ARAŞTIRMA / RESEARCH

Effect of distal locking type on radiological results of proximal femoral nails used in the surgical treatment of hip fractures

Kalça kırıklarının cerrahi tedavisinde kullanılan proksimal femoral çivilerinin distal kilitlenme tipinin radyolojik sonuçlarına etkisi

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Abstract

Purpose: The aim of our study is to obtain data that will shed light on the effect of the distal locking type of proximal femoral nails (PFN) on fracture healing, causes of general complications, especially those in the distal of the nails, and reduction of possible complication rates.

Materials and Methods: Patients who underwent surgery with the diagnosis of trochanteric hip fracture between 01.01.2015 and 01.01.2020 and completed the second year follow-up time were examined from the medical records. Patients were grouped first according to AO/OTA sub-types (Three groups as AO A1, A2 and A3), then grouped according to distal locking type (Two groups as group 1: dynamic, group 2: static distal locking with 2 screws). The fracture type, healing status, fracture healing time, complication rates and reoperation because of complication development data were evaluated.

Results: 339 patients enrolled in the study [189 women, 150 men, mean age: 76.24 (60-102) years]. The overall complication rate was 15.6%. AO A3 type fractures had long fracture healing times in each distal locking group compared to the other fracture sub-types. AO A3 type fractures had more frequent complication rates than the other subtype groups. AO A3 type fractures in group 2 had higher overall complication rates than in group 1. There was a significant correlation between group 1 and lag screw cut-out complication occurrence in females and between group 2 and pseudoarthrosis occurrence in males. In addition, there was a statistically significant relationship between the AO fracture sub-type and total rate of complication occurrence, AO A2 fracture type and lag screw cut-out complication occurrence and AO A3

Öz

Amaç: Çalışmamızın amacı proksimal femoral çivilerin (PFN) distal kilitlenme tipinin kırık iyileşmesine etkisi, çivi distalinde olanlar başta olmak üzere genel komplikasyonların nedenleri ve olası komplikasyon oranlarının azaltılmasına ışık tutacak veriler elde etmektir.

Gereç ve Yöntem: 01.01.2015-01.01.2020 tarihleri arasında trokanterik kalça kırığı tanısı ile ameliyat edilen ve ikinci yıl takip süresini dolduran hastalar tıbbi kayıtlarından incelendi. Hastalar önce AO/OTA alt tiplerine göre (AO A1, A2 ve A3 olmak üzere üç grup) daha sonra distal kilitleme tipine göre gruplandırıldı (Grup 1: dinamik, grup 2: 2 vida ile statik distal kilitleme yapılan hastalar olarak iki grup). Kırık tipi, iyileşme durumu, kırık kaynama süresi, komplikasyon oranları ve komplikasyon gelişimi nedeniyle tekrar ameliyat verileri değerlendirildi.

Bulgular: 339 hasta çalışmaya dahil edildi [189 kadın, 150 erkek, ortalama yaş: 76.24 (60-102) yıl]. Genel komplikasyon oranı %15.6 idi. AO A3 tipi kırıkların her bir distal kilitleme grubunda diğer kırık alt tiplerine kıyasla daha uzun kırık kaynama süreleri vardı. AO A3 tipi kırıklar diğer tip gruplara göre daha sık komplikasyon oranlarına sahipti. Grup 2'deki AO A3 tip kırıkların genel komplikasyon oranları grup 1'e göre daha yüksekti. Grup 1 ile kadınlarda lag vidası sıyrılma komplikasyonu arasında ve grup 2 ile erkeklerde psödoartroz komplikasyonu gelişimi arasında anlamlı bir korelasyon vardı. Ayrıca, AO kırık alt tipi ile toplam komplikasyon görülme oranı, AO A2 kırık tipi ve lag vidası sıyrılması komplikasyonu gelişimi ve AO A3 kırık tipi ve psödoartroz komplikasyon oluşumu arasında istatistiksel olarak anlamlı bir ilişki vardı.

Sonuç: Statik distal kilitleme yapılmış AO/OTA 31 A3 tip kırıklı hastaların, dinamik kilitlemeye göre daha uzun kırık

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fracture type and pseudoarthrosis complication occurrence.
Conclusion: Patients with AO/OTA 31 A3 type fractures with static distal locking have a longer fracture healing time and a higher complication rate compared to dynamic locking. However, dynamic or static distal locking is not associated with other implant-related complications, especially those in the distal to the tip of PFN's.
Keywords: Hip fracture, proximal femoral nail, distal locking, complications

kaynama süresine ve daha yüksek komplikasyon oranına sahip olduğunu göstermektedir. Bununla birlikte, bulgularımız dinamik veya statik distal kilitlemenin özellikle PFN'lerin distalinde olanlar da dahil olmak üzere implant nedenli diğer komplikasyonlarla ilişkili olmadığını göstermektedir.

Anahtar kelimeler: Kalça kırığı, proksimal femur çivisi, distal kilitleme, komplikasyonlar

INTRODUCTION

Hip fractures usually occur in ageing people caused by low-energy trauma. According to the 2021 World Health Organization Report, an estimated 684,000 people die from falls each year, and the highest incidence of mortality is in adults over 60 years of age. Trochanteric and subtrochanteric hip fractures in the elderly have an increased risk of mortality[1]. Proximal femoral nails have become the most preferred implants in the treatment of these fractures[2]. Although it is a generally accepted concept that distal locking is necessary for the stability of proximal femoral nail (PFN) type implants used, in recent studies, it has been reported that dynamic locking is sufficient in stable type fractures and even locking is not required[3]. The issue of whether static distal locking with a single screw is safe has been investigated by some authors before. Hapa et al. declared that it is safe to lock the intramedullary nail with a single distal screw; nevertheless, one distal screw failed more often than two distal screws. However, the clinical results did not change significantly in this study and, as a result, there is no consensus on the use of single or twin-screw for static distal locking[4].

Apart from its contribution to fracture healing, another issue that should be considered is that multiple drilling attempts and related damage to the bone cortex and muscle-soft tissue injuries can also be seen frequently in the distal locking step[5]. When the literature is examined, there are a few studies evaluating the self-locking implants without using screws[3]. Also, a small number of studies state that safe fracture fixation can be made without distal locking[6,7]. Thus, it has been suggested that complications that may arise from the distal locking step can be prevented. In addition, the frequency of implant-related complications because of distal locking screws is still not precise, apart from the prolongation of the surgical time and the risks that the patient and surgical team are exposed to due to ionizing radiation.

The aim of our study is to obtain data that will shed light on the effect of distal locking on fracture healing and complication development in patients with PFN nailing and the reduction of possible complication rates.

MATERIALS AND METHODS

Participants

All patients who had surgery in Hatay Mustafa Kemal University Department of Orthopedics and Traumatology between 01.01.2015 and 01.01.2020 and completed the second-year follow-up after surgery was scanned from the archives. The information of 867 trochanteric hip fracture patients was obtained and evaluated for eligibility. 108 patients died before 2 years of follow-up time finished. 144 patients were excluded because their regular follow-ups or data were not sufficient. 276 patients were excluded because they did not meet the inclusion criteria. 339 patients (189 women; 150 men) who had a trochanteric hip fracture and were treated with a PFN device enrolled in the study (Fig. 1). Fracture classification made in accordance with the Arbeitsgemeinschaft für Osteosynthesefragen /Orthopedic Trauma Association (AO/OTA) classification. Patients were evaluated in detail as subtype group classification as two-part fractures (31A1), multi-fragmentary pertrochanteric fractures (31A2) and reverse oblique trochanteric or subtrochanteric fractures (31A3).

The inclusion criteria were as follows: patients over 60 years of age who were diagnosed with trochanteric hip fracture, fracture fixation with a proximal femoral nail, anatomic radiological bone reduction described by Ito et al.[8] (medial cortical continuity, displacement of the fracture < 4 mm, the neck-shaft angle >130°–150°< on anterior- posterior radiograph and < 20° of angulation on the lateral radiograph) and adequate lag

screw position [9,10] (middle-middle or inferior middle lag screw position, tip apex distance <25 mm), at least 2 years of follow-up, and sufficient medical records. The exclusion criteria were as follows: Patients below 60 years of age, treated using a fracture fixation implant other than PFN, patients with a follow-up period of fewer than 2 years, inadequate radiological bone reduction (medial cortical incontinuity, displacement of the fracture > 4 mm, the neck-shaft angle <130°–150°> on anterior-posterior radiograph and > 20° of angulation on the lateral radiograph) and lag screw position (not in the middle-middle or inferior middle lag screw position, tip apex distance >25 mm), patients with inadequate medical records, patients with endocrine diseases affecting fracture union, patients with pathological hip fractures and patients who did not comply with the committees to be applied in the treatment of fractures due to their diseases (Schizophrenia, Alzheimer's disease and other mental-behavioural disorders).

Study design

The study was performed in accordance with the Declaration of Helsinki after approval by the Ethics Committee of Hatay Mustafa Kemal University (Decision No. 36, dated 26.08.2021). Demographic data and information about preoperative diagnosis, distal locking type, complication rate and type, reoperation surgery type (if a complication occurred) and the presence of fracture healing and also fracture healing time data of the patients were obtained from the medical archive records. Patients were grouped first according to AO/OTA sub-types (Three groups as AO A1, AO A2 and AO A3), then grouped according to distal locking type as group 1: patients who had dynamically distal locked with one locking screw and as group 2: patients which had statically distal locked with two locking screws.

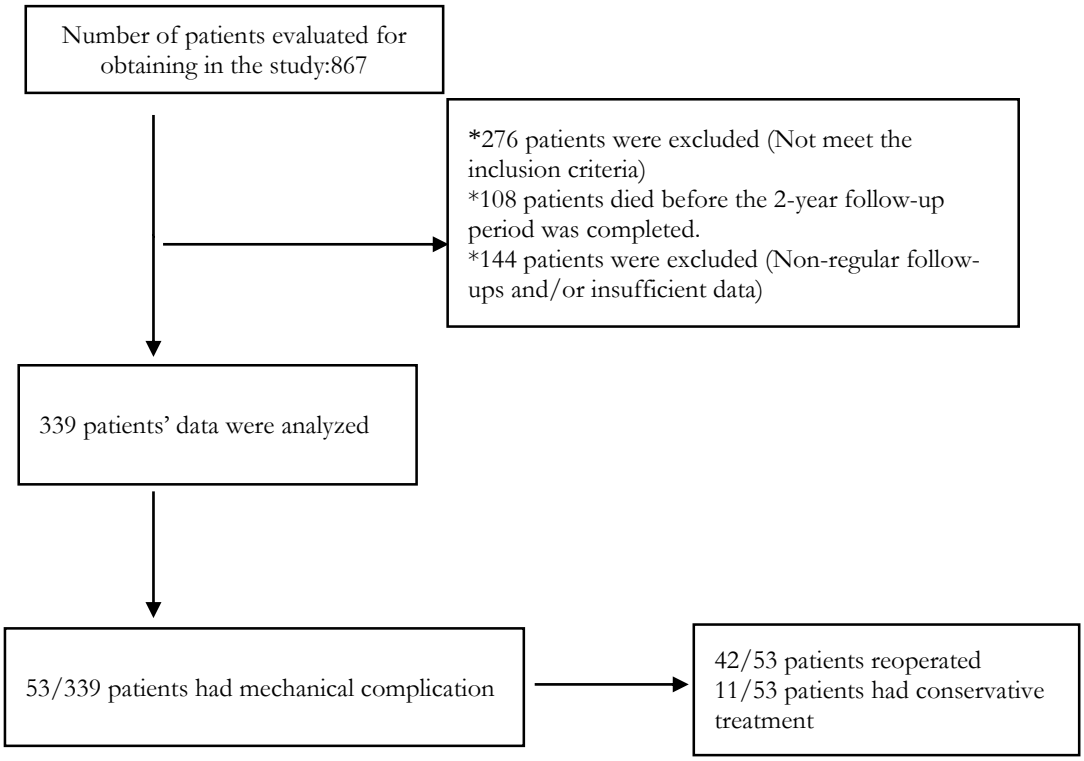

Figure 1. Flow chart of the study

Statistical analysis

Statistical analysis was performed with the Windows-based SPSS 22 (IBM Corp. Armonk, New York, USA) programme. The conformity of the variables to the normal distribution was examined using the visual (histogram and probability graphs) and analytical method Kolmogorov-Smirnov. Mean and standard deviation values were given for normally distributed variables, counts(n) and percentages (%) for nominal variables.

Relationships between nominal variables were analyzed with the Chi-square test and Fisher's exact test when necessary. Normally distributed continuous variables were analyzed with Student's t-test and ANOVA test, and abnormally distributed variables were evaluated with Kruskal-Wallis and Mann-Whitney U test. A p-value of 0.05 was accepted.

RESULTS

339 patients (189 women, 150 men, mean age: 76.24±10.292 year minimum: 60 maximum: 102 years). According to AO/OTA fracture classification 153 (45.1%) patients were A1 sub-type, 116 (34.2%) patients were A2 sub-type and 70 (20.6%) patients were A3 sub-type trochanteric fractures. In group 1, distal locking was made with one screw as dynamic in 155 (45.7%) patients and in group 2, with two screws as static in 184 (54.3 %) patients. The overall complication rate was 15.6 %. General information about the patients were shown in table 1. AO fracture subtype distribution in study groups was shown in table 2. Fracture healing times compared to fracture sub-types and distal locking groups' data were shown in table 3. The complication rates of AO fracture sub-type groups compared to study groups data were shown in table 4. The rates of complication sub-types that occurred in study groups were shown in table 5.

Table. 1. General information of the patients

Variable	Fracture sub-type			Total n:339 (%) /std	P value
	AO A1 n:153 (45.1%) /std	AO A2 n:116 (34.2%) /std	AO A3 n:70 (20.6%) /std		
Female	88 (26%)	60 (17.7%)	41 (12.1%)	189 (55.8%)	.554
Male	65 (19.2%)	56 (16.5%)	29 (8.6 %)	150 (44.2%)	
Age	76.34±10.791	78.34±9.744	72.54 ±9.101	76.24±10.292	.001
Fracture side					.227
Right hip	71 (20.9%)	65 (19.2%)	32 (9.4%)	168 (49.6%)	
Left hip	82 (24.2%)	51 (15%)	38 (11.2%)	171 (504%)	

Table 2. AO fracture subtype distribution in study groups

Fracture sub-type	Distal locking type		Total (%)	P value
	Group 1/n (%)	Group 2/ n (%)		
AO A1	67 (19.8%)	86 (25.4%)	153 (45.1%)	.164
AO A2	49 (14.5%)	67 (19.8%)	116 (34.2%)	
AO A3	39 (11.5%)	31 (9.1%)	70 (20.6%)	
Total	155 (45.7%)	184 (54.3%)	339 (100%)	

Table 3. Fracture healing times compared between AO fracture sub-type groups and study groups (weeks)

Fracture sub-type	Fracture healing time					
	Distal locking type					
	Group 1			Group 2		
	Mean	Min-max	P value	Mean	Min-max	P value
AO A1	12.0596	6-45	.017	13.3024	6-49	.000
AO A2	11.3876	8-27		12.0896	8-19	
AO A3	14.718	8-48		21.226	8-68	
Total	12.516	6-48		14.1956	6-68	

Table 4. The complication rates of AO fracture sub-type groups compared to study groups

Fracture sub-type	Distal locking type		Total n:339	P value
	Group 1 n:155 (%)	Group 2 n:184 (%)		
AO A1	5 (9.4%)	5 (9.4%)	10 (18.9%)	.623
AO A2	11 (20.8%)	12 (22.6%)	23 (43.4%)	.621
AO A3	7 (13.2%)	13 (24.5)	20 (37.8)	.027
Total	23 (43.4%)	30 (56.6%)	53 (100%)	.137

Table 5. The rates of complication sub-types that occurred in study groups

Complication type	Distal locking type		Total (%)	P value
	Group 1 n (%)	Group 2 n (%)		
Lag screw cut-out	17 (32.1%)	9 (17%)	26 (49.1)	.052
Femoral fracture distal to implant	3(5.7%)	8 (15.1%)	11 (20.8)	.174
Pseudoarthrosis	1 (1.9%)	7 (13.2%)	8 (15.1%)	.056
Avasculary necrosis	1 (1.9%)	2 (3.8%)	3 (5.7%)	.081
Secondary hip osteoarthritis	1(1.9%)	3 (5.7%)	4 (7.6%)	.513
Fracture of lag screw	0 (0%)	1 (1.9%)	1 (1.9%)	n.c.*
Total:	23 (43.4%)	30 (56.6%)	53 (100)	.094

*n.c: not calculated

There was no statistically significant relationship between the AO fracture sub-type and fracture side (p: 0.227) and study group distribution (p: 0.164). However, there was a statistically significant relationship between the AO fracture sub-type and total rate of complication occurrence (p:0.000), AO A2 fracture sub-type and lag screw cut-out complication occurrence (p:0.002) and AO A3 fracture sub-type and pseudoarthrosis complication occurrence (p:0.011).In addition, there was no statistically significant relationship between the variables analyzed to determine whether there were sex differences in AO subtype distribution (p:0.554), fracture side (p: 0.109), sex distribution within study groups (p: 0.728), and total rate of complication occurrence (p: 0.358). In detailed analyses, there was a correlation between group 1 and lag screw cut-out complication occurrence in females (p:0.023) and between group 2 and pseudoarthrosis occurrence in males (p:0.049). Treatments applied in patients with complications were; revision fracture surgery with PFN in 29 patients, partial hip arthroplasty in 1 patient, total hip arthroplasty in 7 patients, and PFN removal in 5 patients. No surgical procedure was applied to 11 of 53 patients who developed complications.

DISCUSSION

In this study, the radiological outcomes of proximal femoral nails utilized in the surgical treatment of hip fractures were studied in relation to the distal locking type. There was no statistically significant difference between groups 1 and 2 in the occurrence rates of each implant-related complication type. Nevertheless, when the gender differences were taken into consideration, there was a significant association between group 1 and the occurrence of lag screw cut-out in females and between group 2 and the occurrence of pseudoarthrosis in males..

When previous studies are examined, it is seen that there is a difference in the declared data about the timing of fracture union among different subtype fracture patterns. Ozkan et al reported the fracture healing time as 14 weeks (range: 9-28) in all patients[6]. Erturer et al declared complete union in all types of fractures in an average of 17.6 (range: 15-22) weeks[11]. In addition, some authors compared the fracture healing time between locking or unlocking the nails. In a prospective comparative randomized study by Lil NA et al, the average fracture healing time was 8.8± 2.2 weeks in the locking group and (8.5±2.4 weeks) was in the unlocking group. There was no significant difference in the results[3]. Xing Li et al found the healing time as 14-16 weeks for patients having fracture pattern AO/OTA 31- A1 both in distal locked and unlocked patients[7]. However, in fracture pattern AO/OTA 31-A2, the average union time was 16-18 weeks in locking and 15-16 weeks in unlocking patients and this was significant.

According to the study results of Ciaffa et al., fracture union time was 9.6±1.1 weeks in the unlocked group, 10±0.6 weeks in the dynamic locked group and 10±0.2 weeks in the static locked group[12]. In our study, fracture healing time results were as 12.5 weeks in group 1 and 14.2 weeks in group 2, however, in AO/OTA 31- A3 type fracture group, it was longer as 14.7 weeks in group 1 and 21.2 weeks in group 2. This difference was significant.

According to the literature, the prevalence of mechanical complication occurrence rate after hip fracture surgery with using proximal femoral nail implants varies to 23.4%. Pascarella et al. reported a total complication rate of 2144 patients treated with any kind of gamma nails as 5.4%[13]. Suckel et al. reported the overall complication rate as 7.8% [14]. Koyuncu et al reported an overall complication rate of 7.7%[15]. Fogagnolo et al. reported the overall rate of mechanical failures at 23.4%[16]. In our study, the 15.6% overall complication rate was in the range defined in the previous studies.

The possibility of developing complications is less common after the treatment of AO A1 subtype fractures compared to AO A2 and AO A3 sub-types[13,14]. Recent recommendations of some publications for distal locking of the AO/OTA A1 sub-type fractures are 'not required'. However, distal locking is strongly recommended for unstable trochanteric fractures, especially in patients with AO A3 sub-type fractures. Suckel et al. reported that no complications developed in AO A1 subtype fractures. Regarding the distribution of complication rates, considering the fracture types, the study results of Suckel et al were 0/67 (0 %) in sub-type AO A1, 22/204 (10.8 %) in sub-type AO A2 and 4/64 (6.2 %) in sub-type AO A3 fractures[14]. In our study, these rates were higher compared to the previous study as 10/153 (6.5%) in sub-type AO A1, 23/116 (18.8 %) in sub-type AO A2 and 20/70 (28.6%) in sub-type AO A3. When the complication rate of the AO A3 sub-type fracture group was examined, it is seen that static distal locking causes a higher complication rate than dynamic locking and this difference is also statistically significant. Nevertheless, there was no difference in A1 subtype patients. When we analyzed the complication sub-types separately, no correlation was found between the distal locking type and the rate of complication development. However, there was a significant difference between the AO sub-type fracture groups and complication sub-type occurrence. The relationship between AO fracture sub-type and total rate of complication occurrence, AO A2 fracture type and lag screw cut-out complication occurrence and AO A3 fracture type and pseudoarthrosis complication occurrence were statistically significant. In addition, in locking group 2 the AO A3 sub-type fractures had more frequent overall complication rates than that in group 1. Despite the high rate of complications in the AO A3 group, it was consistent with the literature.

Lag screw cut-out is considered to be the most common major complication in proximal nailing procedures. Moreover, lag screw breakage, nail breakage, locking screw breakage, delayed union, non-union, avascular necrosis, peri-implant or distal to implant fractures etc. are the other common complications. There are various complication occurrence rates in previous studies. Even so, it is seen that the results are not compatible with each other[3,15,18,19]. We did not have nail or locking screw breakage and the other results were similar to the previous studies. Lag screw cut-out rate was higher in Group 1 and in detailed analysis, AO A2 fracture subtype and female gender were determined as predisposing factors. However, there was no difference in other fracture sub-types or male gender. Therefore, this situation was attributed to the sex-related bone quality and the biomechanical behaviour of the fracture sub-type rather than the distal locking type.

In our study, the nonunion rate was higher in group 2 compared to group 1. According to the analysis results, AO A3 fracture sub-type and male sex were defined as predisposing factors for nonunion. In addition, with a similar hypothesis to Hapa et al., we thought that the reason for this higher rate might be due to the distal load transfer by the contact of the two locking screws with 4 different cortices, and this situation clearly prevents dynamization and leads to a disadvantage. No distal screw breakage was observed in our study, and auto-dynamization was not observed in patients who underwent distal locking with a single screw, as described previously[4].

Distal fractures close to the implant are complications that challenge surgeons. Some authors have reported that they have not seen any complications related to distal locking[3,11] , but there are also publications stating that implant-related complications occur, especially in the distal of the nail tips. Even so, no one examined this issue in detail. Bone quality, fracture type, implant designs, fixation type etc is considered to be the major factors

affecting the treatment success. Also, as stated before, similar factors such as implant design, stress transfer concentration near the distal portion of the implant, presence of an additional locking hole drilled in the wrong location, the diameter and location of this hole and how much damage it causes to the cortex of the bone or cortical thermal damage during drilling are blamed for the formation of additional implant-related fractures[20-23]. There was a fracture rate distal to implants of 1.7 % stated in a systemic review study reported by Norris et al which evaluated the occurrence of secondary fracture around intramedullary nails on 13,568 patients[24]. Bojan evaluated 3066 patients and reported that 19 (0.6%) patients had femur fractures distal to the nail[16]. Lang et al observed fractures distal to nails in 2 (0.8%) patients[19]. Ciaffa et al reported the incidence of femoral fractures distal to the implants as 2 (2.7 %) in the unlocked group, 3 (4,4 %) in the dynamic locked group and 2 (2.8 %) in the static locked group[12]. Although we did not examine these factors, we found a complication rate of 3.3% (1.9% in group 1 and 4.4% in group 2) and, there was no statistically significant relationship between locking groups. Nevertheless, as the reason for this increased risk, it was thought that the incidence of fracture might be higher due to the possibility of more drilling attempts for static locking with twin screws and the possibility of multiple cortical bone damage.

The treatment of patients with implant failure (Frequently in patients with cut-out complications) is made taking into account the remaining bone stock and the condition of the femoral head. Zhong et al treated 16 cases (mean age: 67.3 years) of internal fixation failure of intertrochanteric and subtrochanteric fractures. They treated 8 of them with revision internal fixation, 4 of them with partial arthroplasty and 6 of them with total arthroplasty. According to their results, they recommend revision of the internal fixation for youngers and arthroplasty surgery for elderly patients to treat a failed internal fixation treatment[25]. D'Arrigo et al. treated 21 patients (mean age: 75.8) with failure of trochanteric fracture fixation with partial (n:2) or total hip arthroplasty (n:19). There was no difference between the functional results of the patients in the last control. They stated that arthroplasty can be a good treatment choice for failed internal fixation in old patients[26]. In our study 29 patients had fracture fixation revision with a PFN, 8 patients had arthroplasty surgery; partial hip arthroplasty in 1 patient, and total hip arthroplasty in 7 patients.

Our recommendation is that dynamic distal locking may be sufficient to provide adequate fracture healing in AO A1 and A2 sub-type trochanteric fractures. However, the results suggest that the distal locking made with two screws to achieve a static distal locking leads to higher complication rates in patients with AO A3 subtype fractures. To the best of our knowledge, this is a rare study that assesses the effect of distal locking screw type and screw number on treatment results and complication rates. In order to increase the success of fracture treatment, a PFN distal locking strategy specific to each fracture type should be developed. In addition, comprehensive studies should be planned to evaluate the success of a stable fracture fixation with single screw static locking and to compare the results including these findings with the results of dynamic locking and static locking with 2 screws in order to reduce the complication rates. In order to prevent complications that may occur due to technique or devices, new studies focusing on the aetiology of refracture or implant-related complications in elderly individuals should be organized especially which take the implant designs, bone quality and locking types into concern.

There are some limitations of our study. Although, distal locking attempt numbers or wrong drill hole presence and bone quality affected by osteoporosis and the effects of co-morbidities of the patients are thought to be some of the main factors affecting the surgery results, we did not take them into account. Single lag screw-type PFN implants with similar designs produced by different companies were used so that this may influence the results. Complication occurrence time or the reasons like falling injury after surgery leading to a complication has not been examined. In addition, the functional results are not questioned, thus possible related complications were not noted.

Yazar Katkıları: Çalışma konsepti/Tasarımı: SD; Veri toplama: SD; Veri analizi ve yorumlama: SD; Yazı taslağı: SD; İçeriğin eleştirel incelenmesi: SD; Son onay ve sorumluluk: SD; Teknik ve malzeme desteği: SD; Süpervizyon: SD; Fon sağlama (mevcut ise): yok.
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