Predictors of Cut-Out after Fixation of Intertrochanteric Fractures with Two Cephalocervical Screwed Proximal Femur Nails

İki Sefaloservikal Vidalı Proksimal Femur Çivisi ile Intertrokanterik Kırıkların Fiksasyonundan Sonra Implant Sıyrılmasının Öngördürücüleri

Mehmet Ali Tokgöz[1], Ömer Faruk Kılıçaslan[2]

ABSTRACT

Objective: To identify the factors of predicting cut-out development about implant position after fixation of proximal femoral fractures with two cephalocervical screwed femoral nails and to calculate the position-related failure risk.

Methods: Retrospective analysis of clinical and radiographic data were performed on hospital records and 20 cases with implant cut-out were included in the study group. 31 cases from a similar epidemiological group who completed the second year without failure were included as a control group. Tip-apex distance (TADAP-TADL), calcar tip apex distance (CalTAD) were measured using radiographs, and Parker ratio was calculated for anteroposterior (ParkerAP) and lateral (ParkerLat) views. Advanced analysis was performed for each statistically significant variable to determine the cut-off point of the predictors for implant cut-out.

Results: TADAP-L (p:<0.001), CalTAD (p:0.001) and ParkerLat ratio (p:0.001) calculated were found to have prognostic significance to estimate implant cut-out. ParkerLat was found to be the most significant to estimate implant cut-out (p:0.001). The risk of implant cut-out development increased by 7.3 fold in TADAP, 5.7 in TADLat, and 8.6 in CalTAD, and the greatest risk was calculated in ParkerLat, and this increase was 11.5 fold (Cut-off:≥0.58, p:<0,001)

Conclusion: Current study confirmed the significant relationship between implant cut-out and inadequate TAD and ParkerLat. The importance of predictors identified to prevent the development of this phenomenon has been demonstrated in this study for two cephalocervical screwed proximal femur nails. It has been shown that the central positioning of the proximal screw inserted while providing osteosynthesis in both anterior-posterior and lateral views was important in preventing cut-out development.

Keywords: Proximal femur nail, Implant cut-out predictors, Parker ratio, Tip-apex distance, Intertrochanteric fracture, Cephalocervical screw

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ÖZET

Amaç: Proksimal femur kırıklarının iki sefaloservikal vidalı femoral çivi ile fiksasyonu sonrası implant pozisyonu ile ilgili implant sıyrılma gelişimini öngördürücü faktörleri belirlemek ve pozisyona bağlı başarısızlık riskini hesaplamak

Yöntem: Hastane kayıtlarında klinik ve radyografik verilerin retrospektif analizi yapıldı ve implant sıyrılması olan 20 vaka çalışma grubuna alındı. İkinci yılı başarısızlık olmadan tamamlayan benzer bir epidemiyolojik gruptan 31 vaka kontrol grubu olarak dahil edildi. Tip-apeks mesafesi (TADAP-TADL), kalkar tip-apeks mesafesi (CalTAD) radyografiler kullanılarak ölçüldü. Parker oranı ön-arka (ParkerAP) ve yan (ParkerLat) grafiler için hesaplandı. İmplant sıyrılması için öngördürücülerin kesme noktasını belirlemek amacıyla, istatistiksel olarak anlamlı her değişken için ileri analiz yapıldı.

Bulgular: Hesaplanan TADAP-L (p: <0.001), CalTAD (p: 0.001) ve ParkerLat oranının (p: 0.001) implant sıyrılmasını tahmin etmede prognostik önemi olduğu bulundu. ParkerLat'ın implant sıyrılmasını tahmin etmek için en önemli olduğu bulundu (p: 0.001). İmplant sıyrılma gelişme riski TADAP'ta 7,3 kat, TADLat'ta 5,7 ve CalTAD'de 8,6 arttı ve en büyük risk ParkerLat'ta hesaplandı ve bu artış 11,5 kat oldu (Kesme noktası: ≥0,58, p: < 0,001)

Sonuç: Mevcut çalışma, implant sıyrılması ile yetersiz TAD ve ParkerLat arasındaki önemli ilişkiyi doğruladı. Bu fenomenin gelişimini önlemek için belirlenen öngördürücülerin önemi, bu çalışmada iki sefaloservikal vidalı proksimal femur çivisi için gösterilmiştir. Hem anterior-posterior hem de lateral görünümlerde osteosentez sağlarken yerleştirilen proksimal vidanın merkezi konumlandırılmasının, implant sıyrılmasının gelişimini önlemede önemli olduğu gösterilmiştir.

Anahtar Sözcükler: Proksimal femur çivisi, İmplant sıyrılması öngördürücüleri, Parker oranı, Tip-apeks mesafesi, İntertrokanterik kırık, Sefaloservikal vida

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ORCID IDs: M.A.T. 0000-0002-4056-3743,Ö.F.K.0000-0001-6716-4542

Address for Correspondence / Yazışma Adresi: Mehmet Ali Tokgöz, Dr Nafiz Korez Sincan State Hospital - Department of Orthopaedics and Traumatology, Ankara, Turkey E-mail: m.alitokgoz@gmail.com

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INTRODUCTION

Proximal femoral fractures are occurred more frequently due to the increase in the elderly population and their prevalence and incidence are expected to increase in the near future. (1, 2) Due to the special population hip fractures are caused a high level of morbidity and mortality. In case of treatment failure, both the cost and these rates increase furtherly. (3-6) It has been reported that the incidence of dynamic hip screw cut-out rate varies between 1% and 17% (7), plus the rate of cutting development after using intramedullary systems is 8%.(8) If treatment failure was prevented, these undesirable results for both the patient and the health system could occur less frequently.

The most common cause of fixation failure of intertrochanteric fractures is due to the cut-out of the screw in the femoral head. (9-11) The predictors of the screw cut-out have been extensively studied and evidence of screw position has been demonstrated in intertrochanteric fractures. But recommendations regarding the lag screw position in the femoral head are based on studies involving fixation using the dynamic hip screw, including the tip apex distance on true anteroposterior and lateral views (TADAP+TADL<25 mm). (12, 13)

It is also reported that these suggestions could not be valid to the fixation of intertrochanteric fractures with intramedullary systems due to the improvements in implant design and biomechanical differences.(14)

Although the use of proximal femur nails (PFN) is increasing especially in unstable fractures (15), there is relative information's about predictors of PFN cut-outs. The most important predictors emphasized in the literature are fracture type, implant position, and success in surgical technique.(16)

Implant technology is developing rapidly and studies on new implants developed are often insufficient. The aim of this study was to identify the factors of predicting cut-out development about implant position after the fixation of proximal femoral fractures with two cephalocervical screwed proximal femoral nails and to calculate the position-related failure risk.

METHODS

All patients treated with intramedullary nailing with two cephalocervical screws with an indication of intertrochanteric fracture in our institute between January 2014 and December 2018 were retrospectively reviewed. This study protocol was approved by the Local Ethics Committee of the University of Health Sciences, Antalya Training, and Research Hospital (Date: 07.05.2020, Decision Number: 6/22). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Retrospective analysis of clinical and radiographic data was performed on hospital clinical records and cases (9 men, 11 women) with implant cut-out was detected and included in the study group. Cases from a similar epidemiological group (11 men, 20 women) who completed their second year without failure were included as a control group. Patients with pathological, delayed, and stress fractures; patients without perioperative conventional radiography were not included in the study.

The sample size was calculated based on a 20% difference in complication rate between the two groups with an alpha level of 5% and a power of 80%. As a result of the sample size analysis, it was found that at least 6 participants should be included in each group.(17) However, the current study was conducted on more than the suggested number of patients in order to obtain stronger results.

Preoperative radiographs were examined to determine the type of fracture; perioperative radiographs to evaluate the reduction quality and to make measurements regarding implant position; and follow-up radiographs to determine the status of implant cut-out development during follow-up. Patients were evaluated for age, sex, fracture type (AO/OTA type-31-A, for intertrochanteric fractures), and the quality of reduction according to Baumgartner's scale (12) (poor/good or acceptable). Tip-apex distance (TAD_{AP}-TAD_{L}), calcar tip apex distance (CalTAD) were measured using conventional radiographs and Parker ratio was calculated for both anteroposterior ($Parker_{AP}$) and lateral ($Parker_{Lat}$) views. The methods in which the measurements were made was demonstrated schematically on radiographs in Figure 1, separately for each.

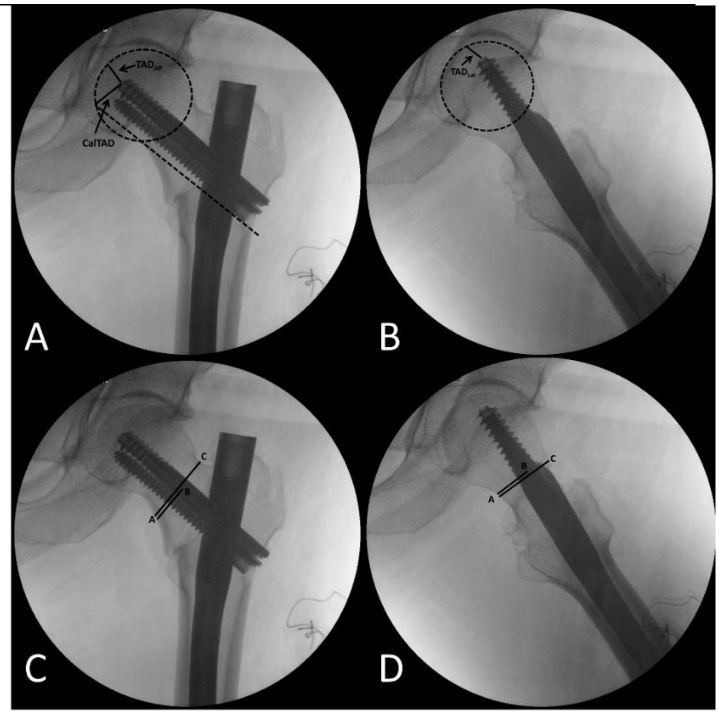

Figure 1: Radiographs demonstrated how the measurements were made. TADAP and CalTAD measurement (A) on the anterior-posterior view, TAPLat measurement (B) on the lateral view, ParkerAP (AB/AC) (C), and ParkerLat (AB/AC) (D) measurement on the anteroposterior and lateral views.

Radiological measurement results were corrected using known real diameters of the nail and analyses were performed on the corrected results. (9) To ensure the interobserver reliability of the measurements and to minimize technical errors, the assessments were performed twice (two weeks apart) by two different orthopedic surgeons. The mean of these measurements was used in the statistical analyzes. Besides the measurements and ratios, the placement of the cephalocervical screws on the femoral neck was also categorically evaluated (superior, inferior, or central) on the anteroposterior view.

Statistical Analysis

All statistical analyzes were performed using IBM SPSS version 23.0 software (IBM Corp., Armonk, NY, USA) and p <0.05 was considered statistically significant. In statistical analysis, categorical variables were given as numbers and percentages, and continuous variables were presented as mean ± standard deviation (SD). Pearson chi-square test, Fisher's chi-square test, and Continuity Correction Chi-square test was used to compare categorical variables in independent groups. The suitability of continuous variables to normal distribution was evaluated using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov / Shapiro-Wilk tests). The normality analysis revealed that all data sets were normally distributed. Student's t-test (independent groups) was used for group comparison analysis on normal distribution data.

The ROC analysis was performed to determine whether the measurements had an optimum cut-out value to distinguish the implant cut-out. The sensitivity, specificity, and positive-negative predictive value of limit values were estimated. These data were presented as Odds Ratio (OR) with 95% confidence intervals (95% CIs). The power of the study results was rechecked after statistical analysis on an open-source online application (http://www.openepi.com/). The result of power analysis was considered significant when the power was >0.80 for all tests.

RESULTS

The mean age of 51 cases included in the study was calculated as 75 (44-93). There was no difference between the demographic data of the study and control groups in terms of implant cut-out development. There was no relationship between the type of fracture and the development of implant cut-out, whereas the reduction quality was found to be statistically significant (p: 0.043, power: 52.7%).

Table 1: Patient Characteristics and Results of Analysis

	Cut-out (+)	Cut-out (-)	p value
Age, year			
Mean + SD	77±8.45	73.71±11.78	0.285
Gender			
Male (n)	9	11	
Female (n)	11	20	0.565
Fracture Type (AO/OTA 31A1/A2/A3)	7/10/3	16/7/8	0.126
Quality of Reduction (poor/good or acceptable)	10/10	7/24	0.043
TAD_{AP}			
Mean + SD	17.92±5.42	11.73±4.88	<0.001
TAD_{Lat}			
Mean + SD	15.36±4.90	10.01±3.70	<0.001
CalTAD			
Mean + SD	25.16±5.27	20.10±4.2	<0.001
Parker Ratio AP			
Mean + SD	0.60±0.10	0.55±0.12	0.169
Parker Ratio Lat			
Mean + SD	0.63±0.1	0.52±0.1	<0.001

TAD: Tip-apex distance; CalTAD: Calcar tip apex distance
AP: Anteroposterior; Lat: Lateral; SD: Standard deviation

When the variables related to implant placement were evaluated, it was seen that the mean values of TADAP (p:<0.001), TADLat (p:<0.001), and CalTAD (p:<0.001) were statistically significantly different in the study group compared to the control group. On the other hand, Parker ratio results, which allow the evaluation of the position of the implant in both directions on the radiographs, were statistically significant in the lateral (p:<0.001) plane, but there was no same result in the anteroposterior (p: 0.169). For all statistically significant analyzes, post hoc power analysis values were over 90%.

Detailed information about the demographic characteristics of the cases included in the study and the results of the analysis made from the perioperative radiographs are presented in Table 1. There was a statistically significant difference in categorical variables for cephalocervical screw position (p:0.004) on the anteroposterior radiograph that was not detected with continuous variable evaluation. Screws were in superior placement in 65% of cases with implant cut-out.

Table 2: Area under the curve, 95% confidence interval and p value for measurements

			%95 CI	
	AUC	p value	Lower	Upper
TAD_{AP}	0.80	<0.001	0.674	0.930
TAD_{Lat}	0.80	<0.001	0.67	0.927
CalTAD	0.78	0.001	0.640	0.924
Parker Ratio AP	0.62	0.171	0.458	0.771
Parker Ratio Lat	0.79	0.001	0.650	0.927

TAD: Tip-apex distance; CalTAD: Calcar tip apex distance
AP: Anteroposterior; Lat: Lateral;
SD: Standard deviation; ROC: Receiver operating characteristic;
AUC: Area Under the Curve; CI: Confidence Interval

The ROC analysis was performed to determine a cut-off value for the measurements and ratios to determine implant cut-out risk. According to the results, the AUC was found to be statistically significant (p<0.001) for whole variables except ParkerAP. As a result of ROC analysis, TADAP, TADLat, CalTAD, and ParkerLat were observed to be diagnostic in predicting implant cut-out (Figure 2, Table 2). The cut-off values and accuracy of measurements were presented in detail in Table 3.

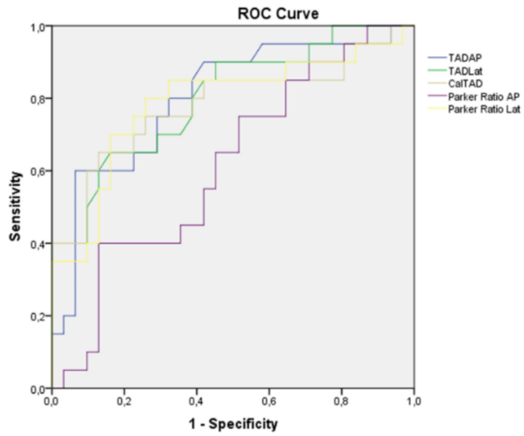

Figure 2: Receiver operating characteristic curve of a total of 51 individuals included in the study for TAD_{AP} (Blue), TAD_{Lat} (Green), CalTAD (Brown), Parker $Ratio_{AP}$ (Purple) and Parker $Ratio_{Lat}$ (Yellow)

Table 3: Statistical parameters of various diagnostic approaches for predicting implant cut-out

	Cut-off value	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
TAD_{AP}	≥14.1 mm	75	71	62.5	81.48
TAD_{Lat}	≥11.75 mm	70	71	60.87	78.57
CalTAD	≥22.7 mm	75	75	65.22	82.14
Parker Ratio AP	≥0.58	55	55	43.48	64.29
Parker Ratio Lat	≥0.58	80	75	66.67	85.19

TAD: Tip-apex distance; CalTAD: Calcar tip apex distance AP: Anteroposterior; Lat: Lateral
PPV: Positivenegative predictive value; NPV: Negative predictive value

The cases included in the study were re-grouped using cut-off values obtained by ROC analysis. In the reassessment, the risk of implant cut-out development increased by 7.3 fold in TAD_{AP}, 5.7 fold in TAD_{Lat}, and 8.6 fold in CalTAD in patients exceeding the cut-off value stated in Table 3, and the greatest risk was calculated in $Parker_{Lat}$, and this increase was 11.5 fold (Cut-off: ≥0.58, 95% CI: 3-44.8, p:<0,001) (Table 4).

Table 4: Implant cut-out risk analysis in formed groups after new grouping according to cut-off values (n=51)

	Cut-out (+) N*	**Cut-out (-) (%)**	**Odds Ratio**	**%95 CI**	**p value**
TAD_{AP}	15/20	75	7.3	2.1-26.3	0.002
TAD_{Lat}	14/20	70	5.7	1.7-19.5	0.009
CalTAD	15/20	75	8.6	2.4-31.4	0.001
Parker Ratio AP	10/20	50	1.4	0.4-4.3	0.390
Parker Ratio Lat	16/20	80	11.5	3-44.8	<0.001

TAD: Tip-apex distance; CalTAD: Calcar tip apex distance
AP: Anteroposterior; Lat: Lateral; SD: Standard deviation
CI: Confidence Interval

DISCUSSION

The current study was the first article to determine the risk of implant cut-out in proximal femoral nails with cephalocervical two-screw, to the best of our knowledge. The results of the current study supported the hypothesis that the implant position affected the risk of developing cut-out, as shown in the literature earlier in other implant designs. (9, 16, 18)

Many variables have been evaluated as risk factors to determine the risk of implant cut-out after intramedullary fixation of intertrochanteric fracture. (17, 19) The unique finding of the current study was that eccentric screw placement on lateral view was shown to be highly related to implant cut-out. In a study about proximal femoral nails with another implant design, there was no statistically significant relationship between the implant position in the lateral view and the cut-out. But it was noticed that in 50% of patients with cut-out, the cephalocervical screws were not undergone to the center of the femoral neck. (20) It was thought that this situation could be caused as a result of the relatively low bone mineral density of the anterior and posterior region of the femoral head reported in previous studies. (21)

However, studies that investigated the relationship of the intramedullary position of the implant with cut-out are few and there are contradictions between the results of these studies.

Increased TAD and CalTAD measurements, which was important in the majority of previous studies, increase the cut-out risk in this design as in other implant designs. (12, 18) Previous studies have focused on TAD measurement in determining the risk of implant cut-out and reported that values over 20-25 mm increase the risk. In the current study, the mean of TADAP and TADLat cut-off values for implant cut-out was calculated as 25.9 mm and was found similar to previous studies. (22, 23)

In a study investigating the relationship between implant position and protrusion, a positive correlation was found between $Parker_{AP}$ and implant protrusion (24). In the current study, no statistically significant relationship was found between ParkerAP and implant cut-out. However, in the analysis made with categorical variables, it was shown that placing the screw in the superior half of the femoral head increased the risk of cut-out, similar to the literature.(20, 25) It was thought that the reason for not detecting the difference in continuous variables was because of the choice of reference point, which was the middle of the superior screw, for the measurements.

The strengths of this study were the use of clearly defined measurements of the implant position and the verification of the importance of the lateral position of the cephalocervical screws. The limitation of the present study was primarily its retrospective design. Another important limitation was the relatively limited number of cases in which the implant was cut-out, although the current study had high statistical power. Although it was paid attention to the patient's position when taking radiographs and selecting the patient for the study, positional differences could have occurred between the patients due to the nature of the fracture pathology.

CONCLUSIONS

As a result, the development of implant cut-out after detection of proximal femoral fractures causes a significant burden on both the patient and the health system. The importance of predictors identified to prevent the development of this phenomenon has been demonstrated in this study for two cephalocervical screwed proximal femur nails. It has been shown that the central positioning of the superior proximal screw inserted while providing osteosynthesis in both anterior-posterior and lateral views was important in preventing cut-out development.

Conflict of interest
No conflict of interest was declared by the authors.

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