

Lag Screw Design Is a Predictor for Cut-Out Complication After Intertrochanteric Femur Fracture Treatment in Elderly. A Comparative Analysis

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Abstract

Background: Hip fractures are common in older adults and are associated with significant morbidity and mortality. Surgical fixation with intramedullary devices, such as proximal femoral nails (PFN), is a common treatment method. However, complications such as implant cut-out remain a challenge despite advancements in implant designs. The objective of this study was to evaluate the clinical experience with different PFN designs and lag screws and to compare implant cut-out rates. Additionally, the study aimed to identify the most important factors that could prevent complications and predict cut-out.

Methods: This retrospective study included 145 patients with trochanteric fractures who had undergone surgical treatment with PFN devices between January 2015 and December 2018. Patients younger than 65 years, those with pathological fractures, ipsilateral pelvic and knee fractures, subtrochanteric fractures, and multiple traumas were excluded. Radiographs were evaluated to determine osteoporosis, fracture type, implant type, fracture reduction quality, early and late neck shaft angle (NSA), lag screw position in the femoral head, tip-apex distance (TAD), and cut-out. Fractures were classified according to the AO/OTA classification system, and the quality of fracture reduction was assessed using the Baumgaertner classification. The Cleveland method was used to record the location of the screw/blade within the head.

Results: The study compared the implant features of four different PFN devices, including Double lag screw PFN, Wedge wing lag screw PFN nail, Helical blade PFN, and Integrated Dual Screw PFN. The statistical analysis indicated that early and late NSA, TAD, Reduction quality of fracture, Cleveland index, and the difference between PFN types were risk factors for Cut-out. ($P \leq .001$). Patients with helical blade PFN had a significantly higher rate of cut-out compared to other PFN devices. Univariate and multivariate regression analyses identified the Cleveland Index, fracture reduction quality ($P \leq .001$), TAD, and early and late NSA as significant predictors for cut-out complications ($P \leq .001$). Patients with poor Cleveland Index, poor fracture reduction quality, low TAD, and low NSA had a higher risk of cut-out ($P \leq .001$).

Conclusion: In conclusion, careful consideration of patient and surgical factors, including implant design and placement, is crucial in minimizing the risk of complications such as cut-out.

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Keywords

trochanteric fracture, proximal femoral nail, predictive factor, tip apex distance, cut-out, helical blade

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Introduction

Hip fractures are an important public health problem and can cause a reduced quality of life and increased mortality.¹ Hip fractures commonly occur among people over the age of 65 and, as the number of elderly people increases. In 2019, the number of people living with a disability is reached 2.9 million, and this number is expected to increase significantly over the years.² Trochanteric fractures accounted for 42% of all hip fracture types and 44% of the total orthopedic healthcare costs.³

Currently, surgical fixation is the standard treatment for trochanteric fractures as it allows early mobilization, weight bearing, and functional recovery. Fixation devices for trochanteric fractures include extramedullary devices, and more recently, intramedullary devices.⁴⁻⁶

Although many different intramedullary devices have been developed for use in trochanteric fractures, osteosynthesis complications are still seen. The most common complication is cut-out, which is the screw/blade cutting through the femoral head.⁷⁻⁹ Risk factors for cut-out complications have been determined as tip-apex distance, reduction of quality, osteoporosis, Neck-Shaft angle, lag-screw positioning in the femoral head, and implant designs.¹⁰⁻¹² The cut-out can be caused by modifiable factors, which includes tip-apex distance, Cleveland index, reduction quality, Neck-shaft angle (NSA), and implant types, and also non-modifiable variables such as osteoporosis, fracture type, and gender.¹³ Schmitz et al suggests that there are differences in the likelihood of complications based on the lag screw designs and implantation techniques.¹²

The aim of this study was to review our clinical experience with four proximal femoral nail fixation of trochanteric fractures to compare rates of implant cut-out between double lag screw PFN, wedge wing lag screw PFN, Helical blade PFN, and Integrated Dual Screw PFN.

The second aim of this study was to evaluate the most important predictive factors for cut-out such as age, sex, osteoporosis, NSA, TAD, the Cleveland Index and reduction reduction quality of Fracture.

We hypothesized that lag screw design will be associated with a high risk of cut-out as the some type of screws changes between the bone implant through the femoral neck and head during implantation.

Patients and Methods

Local Ethics Committee approval and informed consent from all the patients were obtained. A total 145 patients

with trochanteric fractures who were treated with proximal femoral nails at between January 2015 and December 2018 were included in the study. The assessment of patients eligibility is presented in Figure 1. The study was conducted over a period of 12 months from January 2018 to January 2019.

The operations were performed with the patients under general or spinal anesthesia in the supine position on a standard surgical table by four experienced surgeons. The proximal femoral nail had always been applied after anatomical reduction of trochanteric fractures under fluoroscopy intraoperatively.

The patients started to walk with a walking aid approximately 48 hours after surgery, firstly with toe-touch weight-bearing and then 6 weeks later with full weight-bearing. The patients were assessed clinically and radiographically at 1, 3, 6, and 12 months.

Inclusion criteria consisted of patients aged 65 years or older who underwent proximal femoral nail (PFN), due to intertrochanteric hip fracture. The exclusion criteria included patients younger than 65 years, those with pathological fracture, ipsilateral pelvic or knee fractures, subtrochanteric fractures, and multiple trauma cases. Additionally, demographic data, including patient gender, age and comorbidities, were collected and analyzed.

Radiographs were examined to assess osteoporosis, the fracture type, NSA, fracture reduction quality, the position of the screw within the head, TAD. Cut-out and union were assessed with the use of preoperative and postoperative A-P and lateral radiographs and, in some cases of multi-fragmentary fracture, for an understanding of the subtrochanteric extension fracture, computer tomography (CT) was used.

Fractures were classified according to the AO/OTA classification system as trochanteric (31A); stable (A1), unstable (A2), and transverse or reverse oblique (A3).¹⁴ NSA was measured on the AP pelvis radiograph as the angle between a line bisecting the femoral neck/head and a line down the center of the femoral shaft.¹⁰

BMD scores were recorded for all patients using DEXA and classified as severe, mild, or normal for osteoporosis.¹⁵ Patients who had been screened for osteoporosis within 1 year prior to surgery did not undergo DEXA, while those who had not been screened within 1 year prior to surgery underwent DEXA.

The quality of the reduction of the fracture that was achieved intraoperatively was assessed on the basis of the

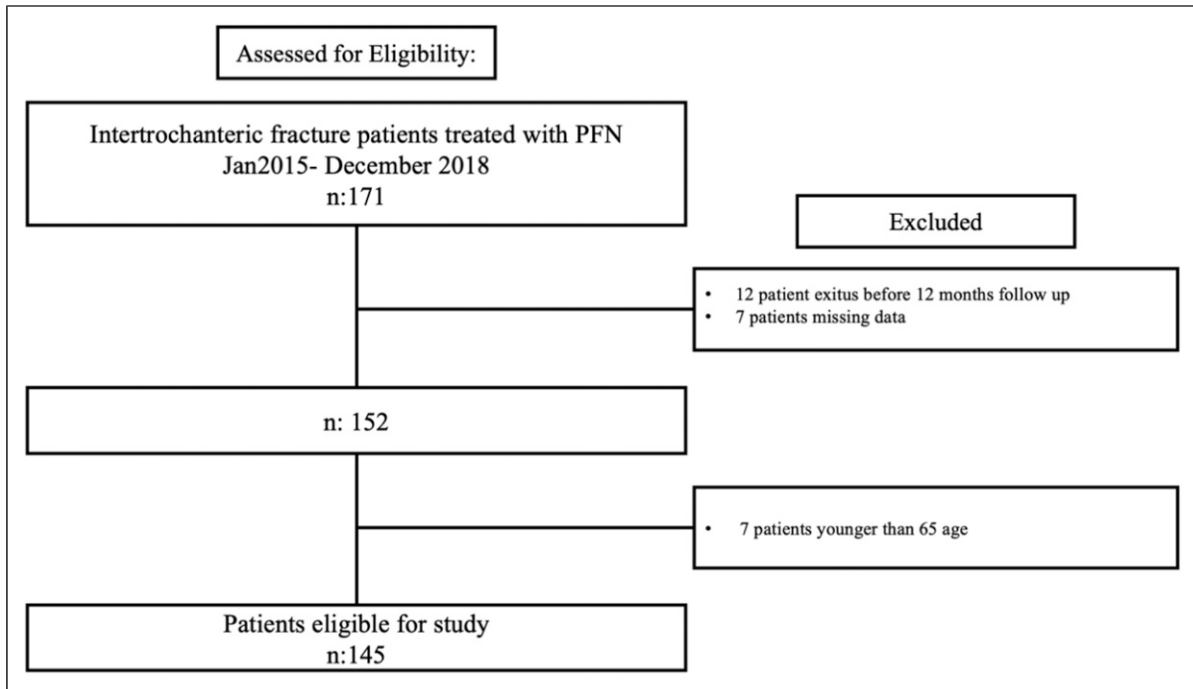


Figure 1. Patients Selection.

displacement and alignment of the fracture as seen on the postoperative radiographs. The quality of the reduction of the fracture was categorized as good, acceptable, or poor according to the definitions of the three-grade classification system proposed by Baumgaertner et al.¹⁶ The displacement criteria was satisfied if there was less than a 4-mm -displacement of the fracture fragments on the AP and lateral radiographs. The angulation criteria was met if the neck shaft angle was normal or slightly valgus (130° - 150°) and there was less than a 20° angulation on the lateral radiograph. The quality of the reduction of the fracture was considered as good if both criteria were met, acceptable if only 1 was met, and poor if neither was met.¹⁶

The location of the screw/blade within the head was recorded as per the Cleveland method. This method divides the femoral head into nine separate zones, with three zones on the anteroposterior radiograph (superior, central, and inferior) and three zones on the lateral radiograph (anterior, central, and posterior). The screw/blade can be located in any of these zones.^{17,18}

The TAD was used to describe the position of the screw. The TAD is defined as the sum of the distance in millimeters from the tip of the screw/blade to the apex of the femoral head on AP and lateral views.¹⁸ All measurements was performed by the first author, experienced surgeon.

All postoperative radiographs of the patients were reviewed to identify implant cut-out. A Cut-out is defined as the protrusion of the implant outside the femoral head on any radiographic view.¹⁹

Radiographs and the relevant measurements were evaluated with the aid of the Picture Archiving and Communication System (PACS).

Features of the Different Implants and Selection

A double lag screw PFN (the parallel lag screw 6.5 mm diameter, 127°), A wedge wing lag screw PFN nail,²⁰ A helical blade PFN,²¹ An integrated Dual Screw PFN²² was selected. All types of implants are presented in Figure 2. Implant selection was not based on predefined criteria such as fracture type or patient characteristics. In the early years of the study, helical blade PFNs and integrated double screw PFNs were randomly used, whereas in later years, double lag screw and wedge-wing PFNs were utilized. This variation was influenced by implant availability rather than a standardized institutional protocol.

Statistical Analysis

All statistical analyses were performed using SPSS software (version 21.0, IBM Corp, Armonk, NY, USA). The normality of continuous variables was assessed using histograms, probability plots, and the Kolmogorov-Smirnov/Shapiro-Wilk tests. Descriptive statistics were presented as mean \pm standard deviation (SD) for normally



Figure 2. (A) Wedge-Wing PFN: Preoperative, Postoperative, and 3-Month Follow-Up Radiographs. (B) Integrated Dual Screw PFN: Preoperative, Postoperative, and 3-Month Follow-Up Radiographs. (C) Double-Lag Screw PFN: Preoperative, Postoperative, and 3-Month Follow-Up Radiographs. (D) Helical Blade PFN: Preoperative, Postoperative, and Final Radiograph Demonstrating Cut-Out Complication.

distributed data and median (min-max) for non-normally distributed data.

Comparisons of categorical variables were conducted using the Chi-Square test. For comparisons of non-normally distributed continuous variables between two groups, the Mann-Whitney U test was used. Receiver Operating Characteristic (ROC) analysis was performed to determine the predictive value of numerical variables such as Tip-Apex Distance (TAD) and Neck-Shaft Angle (NSA) for implant cut-out. To identify independent risk factors for cut-out, logistic regression analysis was performed, including univariate and multivariate models.

A post-hoc power analysis was conducted using G*Power software (version 3.1.9.7, Heinrich Heine University, Düsseldorf, Germany) to evaluate the statistical power of the study. The achieved power values were as follows: Chi-Square test: 0.9999, Mann-Whitney U test: 0.49, and Logistic Regression: 1.0.

Results

The mean follow-up period was 29,6 months. Age, gender, osteoporosis, and AO classification did not show statistical significance among these parameters, whereas early-late NSA, Cleveland Index, reduction quality of fracture and PFN types were statistically significant for the risk of cut-out (Table 1).

The percentage of those with poor fracture reduction quality was determined to be statistically substantially higher in the helical blade group, at 42.9%, compared to 5.7% in the double lag PFN group, 6.9% in the wedge wing nail group, and 6.5% in the Integrated dual lag PFN group. Cut-out was observed to have occurred in 8.6% of those with double lag PFN, 38.1% of those with a helical blade PFN, and 5.2% of those with a wedge wing PFN ($P = .0001$).

The risk analysis of variables that may lead to cut-out formation was performed by univariate and multivariate regression analyses. The Cleveland Index, fracture reduction, TAD total, and early and late NSA cut-out were considered to be predictive factors. Patients who had a poor Cleveland Index were 5.396 (95% CI: 1.437-20.270) times more likely to develop cut-out than those with an acceptable Cleveland Index. The risk of cut-out was 177 600 (95% CI 19 059-1 654 944) times higher in individuals with poor fracture reduction quality compared to those with good fracture reduction quality. It was discovered that a one-unit increase in total TAD multiplied cut-out development by 1.21 times (95% CI: 1.105-1.306). Those with early NSA of $<130^\circ$ were 13 609 (95% CI 1.730-107.057) times more likely to develop cut-out than those with early NSA of $\geq 130^\circ$. Those with a late NSA of $<130^\circ$ had 14.468 (95% CI 1.839-113.816) times higher risk of developing a cut-out than those with a late NSA of $\geq 130^\circ$. The Cleveland Index, TAD, NSA early, and NSA late variables were included in the

multivariate regression analysis. It was established that a 1-unit increase in the TAD value increased the cut-out risk by 1.334 times (95% confidence interval: 1.156-1.538) in model 1, and 1.345 times (95% confidence interval: 1.160-1.560) in model 2. In Model 1, those with early NSA ≤ 130 had a 93 912-fold (95% CI 3.767-2341.022) risk of developing cut-out compared to those with ≥ 130 . In Model 2, those with a late NSA ≤ 130 had the cut-out risk of 107 506-fold (95% CI 4.039-2861 822) compared to those with ≥ 130 .

A univariate logistic regression analysis, excluding confounders, showed a statistical difference between helical blade type and double-lag and wedge wing. This is a two categorical data comparison between PFN types and section, and there is not enough homogeneity (Table 2).

The most dangerous combination parameters are that bad fracture reduction quality + TAD (≥ 30). The risk of cut-out 236.5 times higher than other parameters (35.562-1568.844 OR 95%, $P = .0001$), (Table 3).

The ROC curve analysis was used to investigate the diagnostic decision-making possibilities of the TAD total value in predicting cut-out development. The TAD total value cut-out value for predicting the risk of developing cut-out was determined to be 28.70 mm, with a sensitivity of 85.7% and a specificity of 77.8%.

The ROC curve analysis shows that early NSA has a cut-out predictive angle. The cut-off value of the early NSA for predicting the risk of developing cut-out, with a sensitivity of 85.7% and a specificity of 68.8%, was determined to be 126.50° .

The ROC curve analysis for late NSA determined a cut-out predictive angle. The cut-off value of late NSA for predicting the risk of developing cut-out, with a sensitivity of 85.7% and a specificity of 87.0%, was determined to be 120.5° .

Discussion

The study's most significant finding is that the most dangerous combination of cut-out is poor fracture reduction quality with high TAD. Among risk factors, fracture reduction quality was the most critical, followed by TAD, late NSA, early NSA and the Cleveland index, respectively. While previous studies have identified TAD, reduction quality, the Cleveland index and NSA as predictors for cut-out complications,²³ they have not established a ranking of risk factors or emphasized the most hazardous combination.

The helical blade PFN had a significantly higher rate of cutout complications among the four PFNs studied (double lag PFN, wedge wing lag PFN, integrated double lag PFN, and helical blade PFN). Cut-out was observed in 14 of 145 patients (9.6%), experienced cut-out, with 8 patients specifically linked to poor fracture reduction quality and increased TAD in helical blades. Although some may consider this surgical technique inadequate, experienced trauma surgeons at our clinic performed these procedures.

Table 1. Demographic and Clinical Assessment of Cut-Out.

		Cut out				P
		No		Yes		
		n	%	n	%	
Age mean (min-max)		131	84.0 (55.0-99.0)	14	83.0 (69.0-83.0)	.286
Sex	Male	73	85.9	12	14.1	.030
	Female	58	96.7	2	3.3	
NSA early	<130	64	83.1	13	16.9	.002
	≥130	67	98.5	1	1.5	
NSA late	<130	62	82.7	13	17.3	.001
	≥130	69	98.6	1	1.4	
AO classification	A1	34	94.4	2	5.6	.319
	A2	88	88.0	12	12.0	
	A3	9	100.0	0	.0	
TAD	≤30	120	97.6	3	2.4	.001
	>30	11	50.0	11	50.0	
Osteoporosis	Normal	32	23.1	5	35.7	.653
	Mild	76	58.1	5	35.7	
	Severe	23	17.9	4	28.6	
Cleveland zone	Acceptable	78	96.3	3	3.7	.006
	Poor	53	82.8	11	17.2	
Reduction quality	Good	74	98.7	1	1.3	.001
	Acceptable	52	98.1	1	1.9	
	Poor	5	29.4	12	70.6	
PFN type	Double lag PFN	32	91.4	3	8.6	.001
	Wedge wing nail	55	94.8	3	5.2	
	Integrated dual lag PFN	31	100.0	0	.0	
	Helical blade	13	61.9	8	38.1	

p<0.05 statistically significant.

We observed loss of reduction during implantation and high TAD in procedures performed after anatomical reduction was achieved. Additionally, the reduction loss observed during the follow-up period highlights the importance of implant-related problems (rotational movement of the helical blade during implantation).

However, it is difficult to determine which PFN type is the most hazardous in terms of causing cut-out due to the presence of numerous confounding factors and lack of homogeneity between PFN types.

Age, sex, osteoporosis and fracture classification were not found to be a predictor of cut-out, verifying previous reports.²⁴

Fuse et al²⁵ claimed that PFN types for severely osteoporotic bones were crucial and that performing the rotating movement with a helical blade PFN might have resulted in reduction loss, and thus this type of PFN should not be recommended for severely osteoporotic trochanteric fractures. However, our study highlights that even in patients with normal bone density, helical blade PFNs exhibit a higher complication rate. This may be attributed to rotational and compression movement during lag screw advancement, which reduces bone contact in the femoral head and neck, ultimately causing reduction loss.

According to certain recent studies, the rate of cut-out using helical blades has increased in comparison to integrated dual lag PFNs.^{26,27} Several cohort studies have considered that the cause for the increase was not connected to the helical blade, but due to technical errors.^{9,28} Schmitz et al¹² showed that mechanical failure was not related to the learning curve but was connected to the implant design. Our clinical observations in treating trochanteric fractures align with these findings. Specifically, the helical blade's impaction and rotational movement may result in compromised bone-implant integration, resulting in micro-instability and the formation of a gap around the implant, which could predispose it to mechanical failure.

Wang et al²⁹ determined a case of implantation failure of a helical blade that had caused a compression issue, which is another disadvantage of the use of helical blades. A similarity was reported in Chapman et al³⁰ that emphasized the problem of inadequate technical ability.

Another study that investigated the radiological differences between helical blades and lg-screw devices reported that helical blades were at fault.²⁷ Stern et al²⁶ did not investigate reduction quality and did not mention any reduction loss after helical blade application. However, in our study, we

Table 2. Predictive Factors for Cutout.

	Univariate				Multivariate (Model 1)				Multivariate (Model 2)			
	OR	95% GA		P	OR	95% GA		P	OR	95% GA		P
		Lower limit	Upper limit			Lower limit	Upper limit			Lower limit	Upper limit	
Age	0.988	0.931	1.048	.683								
Cleveland (referans grup = acceptable)	10.057	2.649	38.178	.001	1.084	0.126	9.302	.941	1.140	0.133	9.764	.905
AO Classification	1.192	0.414	3.432	.745								
Fracture reduction quality	34.410	8.162	145.059	.000	14.862	2.852	77.451	.001	15.261	2.940	79.221	.001
Good-acceptable (Reference Group = good)	1.423	.087	23.271	.805								
Good-poor (Reference group = good)	177.600	19.059	1654.948	.000								
Tip apex distance total (TAD)	1.201	1.105	1.306	.000	1.168	0.975	1.400	.092	1.167	0.972	1.400	0.097
NSA early (Reference group = ≥ 130)	13.609	1.730	107.057	.013	0.245	0.018	3.275	.288				
NSA late (Reference group = ≥ 130)	14.468	1.839	113.816	.011					0.245	0.018	3.291	.289
PFN type	2.123	1.189	3.790	.011	0.988	0.388	2.517	0.980	0.945	0.373	2.392	.905
Double lag—wedge wing	.582	.111	3.056	0.522								
Double lag—integrated double lag	-	-	-	0.998								
Double lag—helical blade	6.564	1.501	28.698	.012								
Wedge wing—integrated double lag	-	-	-	0.998								
Wedge wing—helical blade	11.282	2.625	48.487	.001								
Integrated double lag—helical blade	-	-	-	0.998								

p<0.05 statistically significant.

have stated that sometimes the blade type is to blame for cut-out complications. Stern et al²⁶ identified a critical TAD cut-off range <20 mm or >30 mm for cut-out risk. Our study refined this threshold to 28.7 mm, demonstrating that each

1 mm increase beyond this value elevates the risk of cut-out by 1.21-fold. Two prior meta-analyses compared helical blade extramedullary implants^{31,32} and Kim et al³³ discussed lag-screw and helical blades. All three studies show clinical

Table 3. Risk Factor Combinations of Cut-Out.

Combinations	Cut out				OR (95%CA)	P
	No		Yes			
	n	%	n	%		
1 ^a	2	20.0	8	80.0	86.000 (14.909-496.089)	.0001
	129	95.6	6	4.4		
2 ^b	1	11.1	8	88.9	173.333 (18.561-1618.683)	.0001
	130	95.6	6	4.4		
3 ^c	2	15.4	11	84.6	236.500 (35.652-1568.844)	.0001
	129	97.7	3	2.3		

^a1 Helical blade + TAD.

^b2 Helical blade + Reduction Quality (BAD).

^c3 Reduction quality (BAD) + TAD.

p<0.05 statistically significant.

Table 4. Tip-Apex ROC Curve for Predictive Cut-Out.

	AUC (95% GA)	Sensitivity	Specificity	P
Tip-apex distance (cut off = 28.70)	0.865 (0.736-0.993)	85.7	77.9	.001

AUC, area under the curve.
 $p < 0.05$ statistically significant.

differences but not a statistically significant difference. Ibrahim et al.⁹ had a large number of patients but this study did not apportion blame to the helical blade. Many more prospective randomized studies and meta-analyses are required to provide clearer findings on whether helical blade type PFN does a greater risk of complications.

In the univariate logistic regression analysis, modifiable factors such as TAD, the Cleveland Index, and a reduction of quality were found to be directly connected to mechanical complications.³⁴⁻³⁶ In addition, the helical blade had an increased risk of cut-out complications compared to the other three types of PFN.

The current study shows that the TAD cut-off value was determined as 28.7 mm, which is slightly higher than the values reported in the studies by Khanna et al.³⁷ and Lopes-

Coutinho et al.³⁸ The incidence of cut-out due to a higher TAD was determined by Yam et al.³⁹ to be 6.7% and by Geller et al.⁴⁰ Our multivariate analysis reinforces that each 1 mm increase in TAD beyond 28.7 raises cut-out risk by 1.21-fold (Table 4) (Figure 3).

In this study, the importance of reduction quality was demonstrated by the 177.000-fold increase in cut-out complication compared to those with poor reduction quality, Şişman et al.¹⁰ showed a 57.917-fold. This emphasizes the significance of assessment using intraoperative fluoroscopy and early postoperative X-rays. If an inadequate reduction is observed, a change in early surgical technique or even arthroplasty may be recommended over an intramedullary implant. 42% of patients with a helical blade showed poor reduction quality due to implantation failure

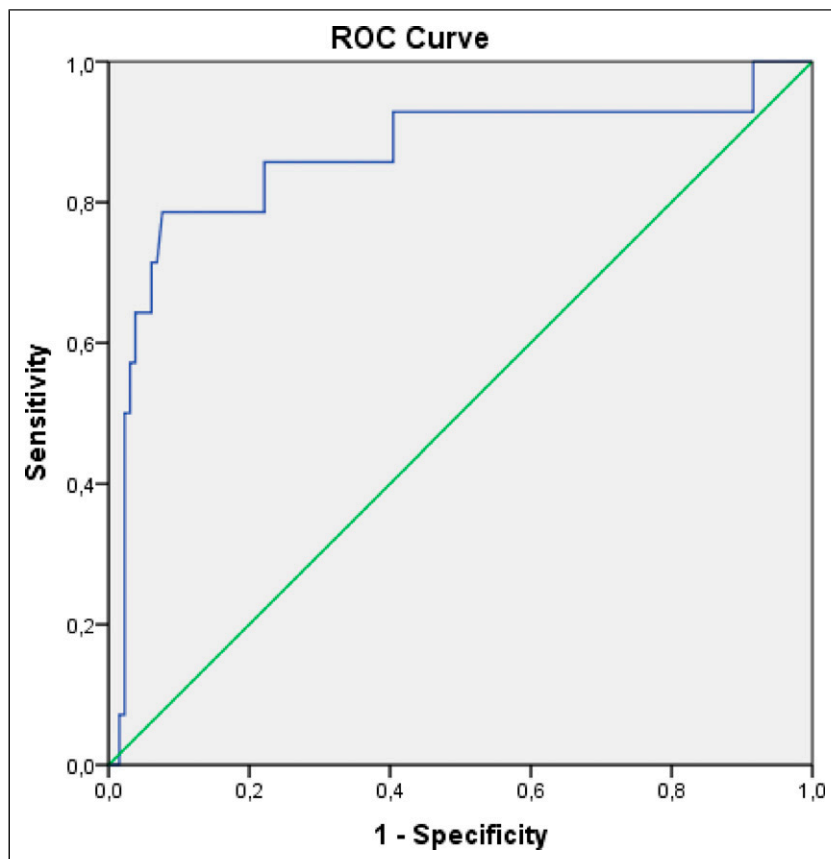


Figure 3. ROC Curve Demonstrating the Diagnostic Performance of the Model. The Area Under the Curve (AUC) is 0.865, Indicating Strong Discriminative Ability. The Optimal Cut-Off Value is Determined as 28.7 mm for TAD.

Table 5. Early NSA ROC Curve for Predictive Cut-Out.

	AUC (95% GA)	Sensitivity	Specificity	P
NSA early (cut off = 126,50)	0.696 (0.596-0.797)	85.7	68.7	.016

AUC, area under the curve.

p<0.05 statistically significant.

when the impaction blade to head fracture reduction was displaced. A couple prior studies have determined the poor reduction as an increase in cut-out complications.^{41,42}

Early and late NSA have a critical role in the assessment of cut-out complications. Below 130° predicted 13.609 and 14.468 times greater risk of cut-out complication for early NSA and late NSA, respectively. Lopes-Coutinho et al³⁸ showed the importance of the neck-shaft angle which was lower the mean angle of 126.50 that was found to increase complications. Gavaskar et al⁴³ emphasized a higher varus collapse with a helical blade without logistic regression analyses. The current study has determined that NSA is a predictive factor with univariate and multivariate logistic regression analysis and showed the cut-off value for

early NSA as 126.50 (Table 5) (Figure 4) and 120.50 for late NSA (Table 6) (Figure 5).

The current study has shown that poor Cleveland zone positioning had a 5.396 times greater risk for cut-out than placement in an acceptable Cleveland zone. Güven et al⁴⁴ determined anteriorly and superiorly positioning of the Cleveland zone with an acceptable reduction quality that had a risk of cut-out, but this was described with a Dynamic hip screw. Parker et al⁴⁵ determined the increased risk of cut-out with superiorly and posteriorly screw placement, while Turgut et al⁴⁶ demonstrated the decreased risk of cut-out with posterior inferior screw placement. Mao et al⁴⁷ emphasized that the position and direction were distinct concepts, and also described the axis-blade angle (ABA), between the helical blade axis and the

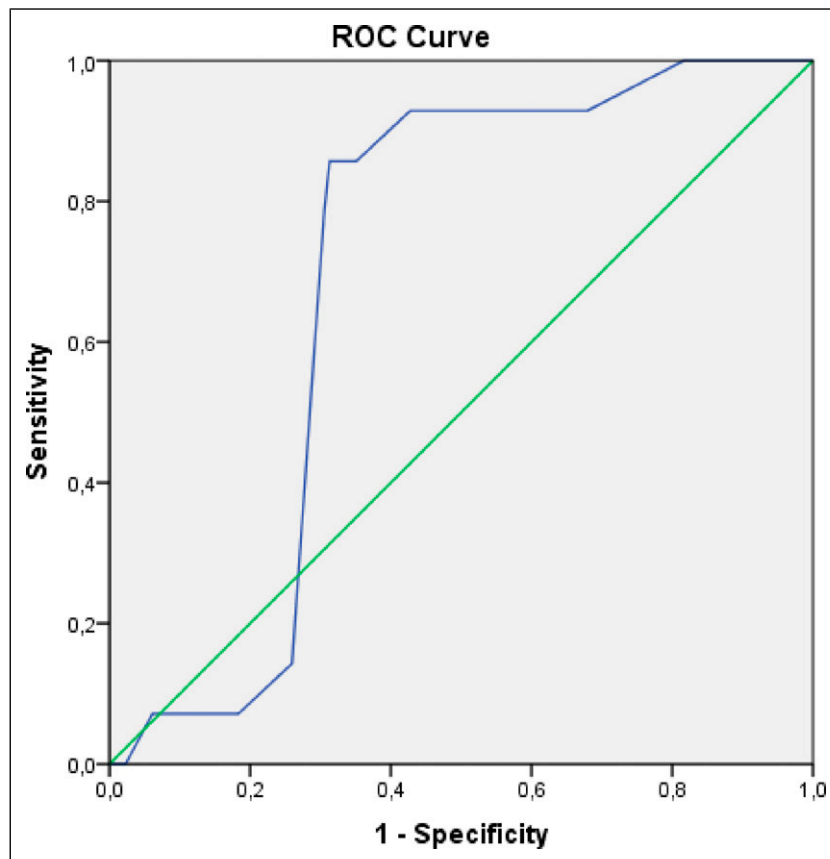


Figure 4. ROC Curve Demonstrating the Diagnostic Performance of NSA Early. The Area Under the Curve (AUC) is 0.696, Indicating Moderate Discriminative Ability. The Optimal Cut-Off Value for NSA Early is Determined as 126.5°.

Table 6. Roc Curve Late NSA for Predictive Cutout.

	AUC (95% GA)	Sensitivity	Specificity	P
NSA late (cut off = 120,50)	0.893 (0.756-1.000)	85.7	87.0	.001

AUC, area under the curve.

p<0.05 statistically significant.

femoral neck axis on anteroposterior and lateral views and reported that placing the helical blade towards the anterior or superior direction was a predictive factor for cut-out.

The objective of this study was to investigate the cause of the high cut-out rate in proximal femur fractures treated with PFN. However, in 8 out of 14 patients with cut-out, helical blade PFN was implanted. It is speculated that the minimal gap between the femoral head and the helical blade lag screw is the reason for the high cut-out rate in our study. Notably, these complications were observed in bones that did not have osteoporosis.

The study has limitations due to its retrospective design, which means that confounding is likely to be present. Notably, although fracture types were matched

for a subset of baseline characteristics, unmeasured co-variables may still differ. For instance, disparities in fracture types, implant selections and intra-surgeon differences cannot be ruled out. This potential source of bias seems to be restricted as it was reached by agreement among all orthopaedic surgeons during weekly trauma meetings throughout the entire study period, thereby preventing individual surgeon assessments.

Second limitation of this study is that all measurements were performed by the first author, an experienced orthopedic surgeon. While efforts were made to standardize the measurements based on previously published methods, the lack of interobserver validation may introduce measurement bias.

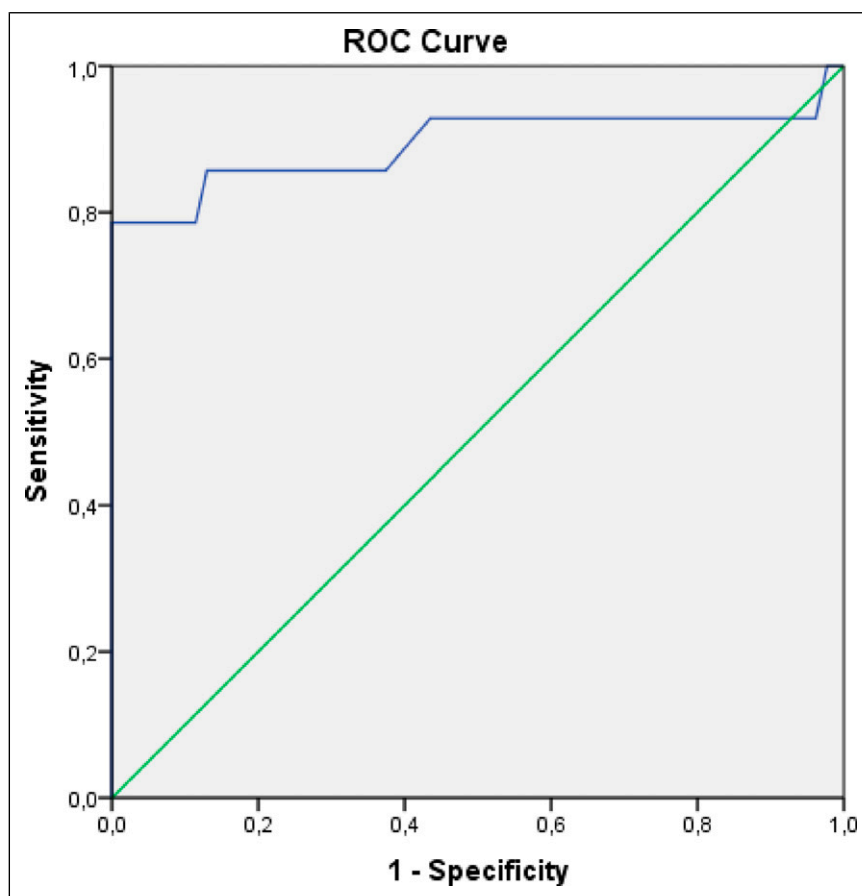


Figure 5. ROC Curve Demonstrating the Diagnostic Performance of the Model. The Area Under the Curve (AUC) is 0.893, Indicating Strong Discriminative Ability. The Optimal Cut-Off Value is Determined as 120.5 mm for NSA Late.

Third limitation of the study was for the Mann-Whitney U test, the power was 0.49, suggesting a lower sensitivity in detecting differences between specific groups. These results highlight that while the overall study design had sufficient power for categorical and nonparametric group comparisons, the ability to detect smaller differences in pairwise nonparametric analyses was more limited. This limitation has been acknowledged in the discussion section.

Conclusion

Whenever applying a proximal femoral nail with a helical blade to treat trochanteric fractures, I should pay particular attention to predicted factors such as TAD, NSA, fracture reduction, and the position of the Lag screw's head. If loss of fracture reduction or an unacceptable TAD is observed when using a helical blade, a correction must be done or an alternative proximal nail must be employed. Furthermore, anatomical reduction must be tried, and the TAD must be maintained below 28.7 mm.

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Statements and Declarations

Ethical Considerations

This study was approved by the Medical Ethics Committee of Eskişehir Osmangazi University Ethical Committee. Informed Consent was obtained from all individuals. The study was performed in accordance with the Declaration of Helsinki, as revised in 2008. All patients provided written informed consent prior to participation.

Author contributions

Aytek Hüseyin Çeliksöz and EroL Göktürk collaborate on article design and writing, Aytek Hüseyin Çeliksöz and Akın Turgut handles data collecting and analysis, Akın Turgut helps with all patients follow-up, Akın Turgut and Nusret Köse handles with article editing and proofreading. All authors have read and approved the final manuscript, and these four authors all contributed equally to this work.

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Conflicting interests

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

Data Availability Statement

The data and materials are available from the medical records Eskişehir Osmangazi University Orthopaedics and Traumatology Department. The datasets used and analyzed during the current study are available from corresponding author on reasonable request.

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