

Tip-apex distance as a risk factor for cut-out in cephalic double-screw nailing of intertrochanteric femur fractures

a retrospective study

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Aims

Proximal femur fractures treatment can involve anterograde nailing with a single or double cephalic screw. An undesirable failure for this fixation is screw cut-out. In a single-screw nail, a tip-apex distance (TAD) greater than 25 mm has been associated with an increased risk of cut-out. The aim of the study was to examine the role of TAD as a risk factor in a cephalic double-screw nail.

Methods

A retrospective study was conducted on 112 patients treated for intertrochanteric femur fracture with a double proximal screw nail (Endovis BA2; EBA2) from January to September 2021. The analyzed variables were age, sex, BMI, comorbidities, fracture type, side, time of surgery, quality of reduction, pre-existing therapy with bisphosphonate for osteoporosis, screw placement in two different views, and TAD. The last follow-up was at 12 months. Logistic regression was used to study the potential factors of screw cut-out, and receiver operating characteristic curve to identify the threshold value.

Results

A total of 98 of the 112 patients met the inclusion criteria. Overall, 65 patients were female (66.3%), the mean age was 83.23 years (SD 7.07), and the mean follow-up was 378 days (SD 36). Cut-out was observed in five patients (5.10%). The variables identified by univariate analysis with $p < 0.05$ were included in the multivariate logistic regression model were screw placement and TAD. The TAD was significant with an odds ratio (OR) 5.03 ($p = 0.012$) as the screw placement with an OR 4.35 ($p = 0.043$) in the anteroposterior view, and OR 10.61 ($p = 0.037$) in the lateral view. The TAD threshold value identified was 29.50 mm.

Conclusion

Our study confirmed the risk factors for cut-out in the double-screw nail are comparable to those in the single screw. We found a TAD value of 29.50 mm to be associated with a risk of cut-out in double-screw nails, when good fracture reduction is granted. This value is higher than the one reported with single-screw nails. Therefore, we suggest the role of TAD should be reconsidered in well-reduced fractures treated with double-screw intramedullary nail.

Take home message

- Risk factors for cut-out in the double-screw nail are comparable to those in the single-screw device, with a larger tip-apex distance when good reduction is granted.

Introduction

Intertrochanteric femur fractures are a significant concern, particularly among the elderly osteoporotic population, frequently occurring due to low-energy trauma such as falls. Surgical interventions, including anterograde nailing or dynamic hip screws (DHSs), are crucial in the management of these fractures.¹

There are various types of intramedullary nails available, utilizing either one or two cephalic lag screws, depending on the implant design. These implants are specifically designed to provide stability and facilitate the healing process in cases of intertrochanteric femur fractures.²

However, despite advances in surgical and design techniques, complications such as cut-out and union failure continue to present challenges in the management of intertrochanteric femur fractures. These complications can result in increased morbidity and unfavourable patient outcomes.^{3,4}

Cut-out is described as the extrusion of the cephalic screw, which occurs as a result of a varus collapse of the neck-shaft angle.⁵ The prevalence of cut-out is estimated to range between 1.85% and 16.5%. Several factors are believed to be related to this complication, including bone stock quality, positioning and length of the cephalic screw, tip-apex distance (TAD), and fracture reduction.^{3,6,7} Baumgaertner et al³ demonstrated that a TAD exceeding 25 mm was associated with an increased risk of cut-out in single-screw device. Currently, some authors have identified a TAD shorter than 25 mm as correlating with a low risk of cut-out.^{8,9} Yet, the significance of TAD in the context of cephalic double-screw nailing, which involves distinct mechanical principles, remains to be fully understood.

This study aims to bridge this knowledge gap by investigating the role of TAD as a potential risk factor for cut-out in patients treated with the dual-lag screw cephalic nail. The research seeks to provide valuable insights that can guide surgical decision-making, optimize patient outcomes, and contribute to the refinement of surgical protocols in the management of intertrochanteric femur fractures.

Methods

This was a retrospective cross-sectional study on consecutive patients with intertrochanteric fractures who underwent closed reduction and internal fixation with short intramedullary nails. The study included patients admitted to our orthopaedic and traumatology unit at Bari Di Venere Hospital, Italy, between January and September 2021. Patients who underwent surgery with a double-screw nail were identified from our hospital database.

The study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the Local Ethics Committee.

Inclusion and exclusion criteria

The inclusion criteria were patients older than 75 years, and intertrochanteric femur fracture (AO classification 31-A1 or

31-A2) treated with a standard EBA2 nail. The exclusion criteria were pathological fracture, open fracture, requirement for open reduction, and absence of imaging follow-up for at least six months after surgery.

Preoperative radiographs were evaluated to determine fracture type. Fractures were categorized into classes 31 (31.A1, 31.A2, and 31.A3) based on the Orthopaedic Trauma Association (AO/OTA) classification.¹⁰ Fractures were also classified as stable (A1) or unstable (A2, A3).¹¹

The patients underwent surgery within two days of admission. All patients received prophylactic low-molecular-weight heparin treatment. Patients were queried regarding the use of bisphosphonates as osteoporosis therapy prior to their admission for femur fracture.

A single dose of antibiotics was administered within 30 minutes before surgery. Surgeons with more than five years of experience and familiarity with the type of nail performed the procedures. Reduction and internal fixation were carried out in the supine position on a fracture table, utilizing an image intensifier for guidance. From the first postoperative day, patients were encouraged to walking with the assistance of crutches.

The Endovis BA2

The Endovis BA2 (EBA2) nail (Citieffe, Italy) was used in this study. The nail is 180 mm long, constructed of titanium alloy, and features a metaphyseal angle of 5°. Its proximal and distal diameters are 13.5 mm and 10 mm, respectively. The nail is equipped with two self-drilling parallel screws with a cervico-cephalic angle of 130° for proximal locking, which prevents rotation of the femoral head and neck. Additionally, the nail includes a four-ray, 30 mm “diapason” at its distal end, allowing for a gradual reduction in stiffness and decrease in stress-shielding. The distal screw, if required, could be inserted as static or dynamic locking.¹²

Data collection

Demographic information, including age, sex, BMI, and side of fracture was collected for each participant. Comorbidities were classified using the American Society of Anesthesiologists (ASA) grading system.¹³ Patients with mild (ASA grade 1 to 2) or severe (ASA grade 3 to 5) systemic diseases were grouped accordingly. Diagnosis of pre-existing osteoporosis and therapy with bisphosphonates were also investigated. Surgical variables, such as the time of surgery (expressed in minutes), type of distal locking, and quality of reduction, were documented.

Immediate postoperative radiographs were used to measure the quality of the reduction and measure the TAD using a Picture Archiving and Communication System (PACS) (Centricity; General Electric Health Systems, USA).

To assess TAD of the two screws in the anteroposterior (AP) view, we positioned a point midway between the tips of the two screws and measured the distance to the apex of the femoral head in both proximal fixation configurations. In lateral view, TAD was determined as the distance between apex of the femoral head and tip of the proximal lag screw. The apex of the femoral head is defined as the intersection between the subchondral bone and a line in the centre of and parallel to the femoral neck, as illustrated in [Figure 1](#).¹⁴

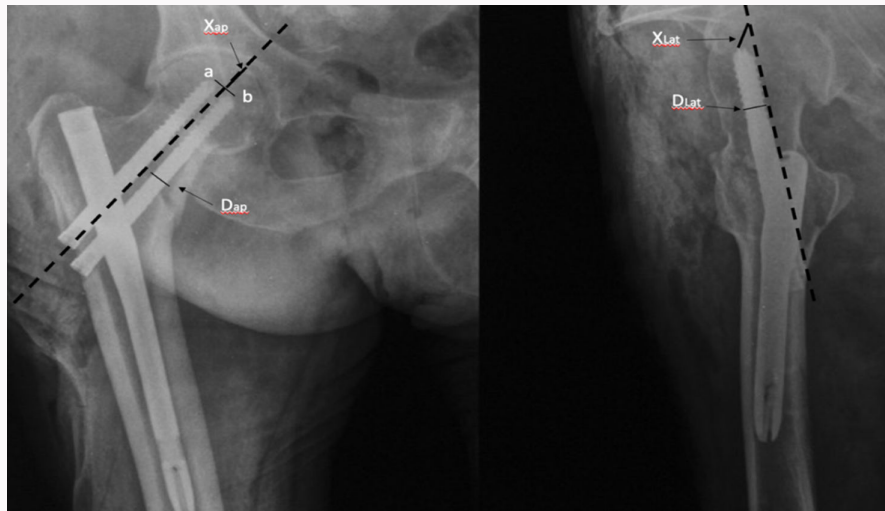


Fig. 1

Tip-apex distance in anterior-posterior and lateral views of intertrochanteric femur nailing. “Xap” was measured as the distance from the apex of the femoral head to a midpoint between the tips of the two screws, “Xlat” was the distance between the tips in lateral view and the femoral head, and “Dap” and “Dlat” were the diameter of the screws, respectively, in the two views.

The quality of the reduction was assessed based on the Baumgartner et al³ and Sembro et al¹⁵ criteria. Reduction was deemed good when there was alignment with the neck-shaft angle between 125° and 145° in the AP view and under 20° of angulation on the lateral view, and when the displacement of any fragment was 4 mm or less on either view. A reduction was categorized as good if both criteria were met, as moderate if only one criterion was met, and as poor if neither criterion was met.^{15,16}

The assessment of reduction quality and TAD measurements was conducted using the radiograph on the PACS obtained immediately after the operation by experienced surgeons who were not involved in the study, and were blinded to each other's measurements. The diagram of the Cleveland system, originally developed for single-screw nails, was used for the analysis, as described by several authors.^{6,17–19}

AP and lateral radiographs were used to divide the femoral head into three equal portions for each view.²⁰ The midpoint between the two screws was calculated and indicated within the femoral head section. Patients with fractures categorized as type 31A3 and those with poor reduction were excluded from the study. A total of 98 patients met the inclusion criteria and were thus included in the study cohort.

The primary endpoint of the study was the assessment of cut-out risk factors in the double lag system. The secondary endpoint was the determination of the TAD threshold predictive of cut-out.

Statistical analysis

Statistical analyses were conducted using SPSS for Windows software (v. 17.0; SPSS, USA). For the entire sample, descriptive statistics were calculated. Categorical variables were presented as percentages and numbers, while continuous variables were expressed as mean and standard deviation (SD). Non-parametric tests were conducted due to the non-homogeneous distribution of the values, confirmed using the Kolmogorov-Smirnov test ($p > 0.05$).

The categorical and continuous parameters were analyzed using the chi-squared test and univariate binary logistic regression, respectively. The occurrence of cut-out was set as the dependent variable in a multivariate analysis, and independent factors from the univariate analysis with a $p < 0.05$ were included. Any factor in the multivariate model with a corresponding $p \leq 0.05$ was considered significant. The likelihood ratio backward test was used to determine the best-fit model, with entry probability fixed at $p < 0.05$ and removal likelihood at $p > 0.100$. The Hosmer and Lemeshow goodness-of-fit test was performed to assess if the logistic regression model adequately fit the data.

The cutoff value of TAD for the diagnosis of cut-out was established using receiver operating characteristic (ROC) analysis. According to Youden's J statistic, the TAD thresholds were determined as a desirable cutoff that maximized the distance to the identity (diagonal) line on the ROC curve.

Results

Between January and September 2021, 112 patients underwent intertrochanteric hip fracture and fixation with an EBA2 nail. However, six patients died within 12 months after surgery, one patient had a reported pathological hip fracture, and seven patients were lost to follow-up. Therefore, these patients were excluded from the study, resulting in a total of 98 patients with hip fractures included in our investigation, analyzed as cut-out and non-cut-out subjects (Table I). Among them, 65 patients were female (66.3%) and 33 male (33.7%). The mean age was 83.23 years (SD 7.07). Overall, 30 patients (30.6%) were taking bisphosphonates before hospital admission for a pre-existing diagnosis of osteoporosis. The mean follow-up period was 378 days (SD 36). During the study, cut-out occurred in five patients (5.10%), with four cases occurring within three months after surgery and one case occurring after the third month. There were no statistically significant differences in age ($p = 0.125$), sex ($p = 0.669$), BMI ($p = 0.742$), side ($p = 0.361$), duration of operation ($p = 0.524$), type of distal locking ($p =$

Table 1. Univariate analysis.

| Variable | Total | No cut-out group (n = 93) | Cut-out group (n = 5) | p-value* | OR (95% CI) |
|---------------------------------------|--------------|---------------------------|-----------------------|--------------|----------------------|
| Mean age, yrs (SD) | 83.23 (7.07) | 83.24 (7.15) | 88.13 (6.57) | 0.125 | 1.125 (0.96 to 1.31) |
| Sex, n (%) | | | | 0.669 | 0.48 (0.05 to 4.44) |
| Male | 33 (33.7) | 32 (34.4) | 1 (20.0) | | |
| Female | 65 (66.3) | 46 (49.5) | 4 (80.0) | | |
| Mean BMI, kg/m ² (SD) | 26.27 (4.99) | 26.22 (4.91) | 27.00 (6.96) | 0.742 | 1.03 (0.86 to 1.24) |
| Side, n (%) | | | | 0.361 | 4.00 (0.44 to 37.95) |
| Left | 48 (49.0) | 47 (50.5) | 1 (20.0) | | |
| Right | 50 (51.0) | 46 (49.5) | 4 (80.0) | | |
| Mean surgical time, mins (SD) | 29.00 (9.82) | 29.15 (9.98) | 26.20 (6.06) | 0.524 | 0.96 (0.87 to 1-07) |
| Fracture classification, n (%) | | | | 0.074 | 6.94 (0.75 to 64.65) |
| 31-A1 | 60 (61.2) | 59 (63.4) | 1 (20.0) | | |
| 31-A2 | 38 (38.8) | 34 (36.6) | 4 (80.0) | | |
| Distal locking, n (%) | | | | 0.393 | 1.55 (0.57 to 4.16) |
| No | 52 (53.1) | 49 (52.7) | 1 (20.0) | | |
| Dynamic | 33 (33.7) | 33 (35.5) | 2 (40.0) | | |
| Static | 13 (13.3) | 11 (11.8) | 2 (40.0) | | |
| ASA grade, n (%) | | | | 0.667 | 0.57 (0.09 to 3.59) |
| > II | 52 (53.1) | 50 (53.8) | 2 (40.0) | | |
| ≤ II | 46 (46.9) | 43 (46.2) | 3 (60.0) | | |
| Reduction, n (%) | | | | 0.082 | 0.15 (0.02 to 1.41) |
| Good | 59 (60.2) | 58 (62.4%) | 1 (20.0) | | |
| Acceptable | 39 (39.8) | 35 (37.6%) | 4 (80.0) | | |
| Mean tip-apex distance, mm (SD) | 25.58 (3.21) | 25.32 (3.08) | 30.40 (0.89) | 0.024 | 3.49 (1.17 to 10.34) |
| Screw placement (AP), n (%) | | | | 0.025 | 3.01 (1.16 to 7.82) |
| Central | 80 (81.6) | 78 (83.9) | 2 (40.0) | | |
| Inferior | 2 (2.0) | 2 (2.1) | 0 (0.00) | | |
| Superior | 16 (16.3) | 13 (14.0) | 3 (60.0) | | |
| Screw placement (LL), n (%) | | | | 0.041 | 3.02 (1.06 to 8.58) |
| Central | 75 (76.5) | 74 (79.6) | 1 (20.0) | | |
| Anterior | 13 (13.3) | 10 (10.7) | 3 (60.0) | | |
| Posterior | 10 (10.2) | 9 (9.7) | 1 (20.0) | | |
| Osteoporosis therapy, (%) | | | | 0.649 | 1.55 (0.25 to 9.77) |
| No | 68 (69.4) | 65 (69.9) | 3 (60.0) | | |
| Yes | 30 (30.6) | 28 (30.1) | 2 (40.0) | | |

*Chi-squared test and binary logistic regression were used for univariate analyses of the categorical and continuous parameters. Any p-values in bold demonstrate significance.

AP, anteroposterior view; ASA, American Society of Anesthesiologists; CI, confidence interval; LL, lateral view; OR, odds ratio; SD, standard deviation.

0.393), or osteoporosis therapy ($p = 0.649$) between the two groups. Cut-out was more common in unstable fractures with unsatisfactory reduction, although there were no significant differences between groups according to AO fracture grading ($p = 0.074$) and reduction quality ($p = 0.082$). A higher TAD represented the main risk factor for cut-out ($p = 0.024$), and superior and anterior screw placement, as indicated by the Cleveland diagram, were also associated with a higher risk of cut-out ($p = 0.025$ and $p = 0.041$, respectively) using

univariate analysis. [Table 1](#) presents all p-values, along with their confidence intervals and odds ratios.

Variables with $p < 0.05$ in the univariate model were examined in a multivariate logistic regression ([Table II](#)). TAD (odds ratio (OR) 5.03; $p = 0.012$), anteroposterior screw placement (OR 4.35, $p = 0.044$), and lateral screw placement (OR 10.61; $p = 0.037$) demonstrated statistical significance using the multivariate model. The goodness-of-fit test

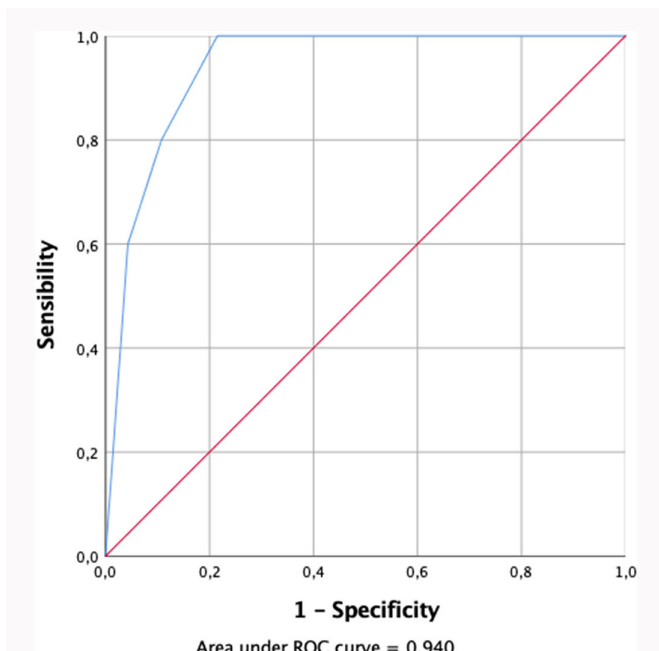


Fig. 2
Receiver operating characteristic curve of the tip-apex distance (TAD). The Youden's test describes the sensitive and specific value of TAD for predicting the risk of cut-out as 29.50 mm.

performed by Hosmer and Lemeshow indicated that these parameters adequately fit the data ($p = 0.791$).

In the ROC analysis, a cutoff value of 29.50 mm was determined, with a sensitivity of 0.800, a 1-specificity of 0.108, a standard error of 0.032, a $p = 0.001$, and an area under the curve (AUC) of 0.940. These values are reported in [Figure 2](#).

Discussion

Intertrochanteric femur fractures are a complex clinical challenge, particularly among the ageing population, necessitating effective surgical strategies for optimal outcomes.²¹ Factors such as fracture reduction, bone quality, and biomechanical conditions at the fracture site are crucial determinants that influence healing.²² This study specifically investigated intertrochanteric fractures treated with a double proximal screw nail (Endovis BA2) and aimed to assess the potential predictive role of TAD in the occurrence of cut-out with double-screw femoral nails.

Cut-out represents one of the most concerning complications of intramedullary nails in proximal femoral fractures, given its substantial impact on functional recovery and life expectancy, especially in elderly patients.^{5,23}

In 1995, Baumgaertner et al³ introduced the TAD as the sum of distances measured on AP and lateral radiographs, between the tip of the compression screw and the apex of the femoral head. They established the optimal cutoff for TAD as 25 mm.²⁴ While several authors have concurred with this ideal TAD limit of 25 mm,^{14,25-27} some studies have challenged this.²⁸⁻³⁰

Furthermore, Yam et al³¹ raised the traditional TAD failure cutoff from 25 mm to 27 mm; Caruso et al³² proposed a cutoff value > 34.8 mm in their cross-sectional study involving 604 patients.

Table II. Multivariate analysis.

| Factor | p-value* | OR (95% CI) |
|----------------------|----------|-----------------------|
| Tip-apex distance | 0.012 | 5.03 (1.36 to 18.48) |
| Screw placement (AP) | 0.044 | 4.35 (1.16 to 17.49) |
| Screw placement (LL) | 0.037 | 10.61 (1.27 to 88.71) |

*Multivariate analysis with likelihood ratio backward test.

AP, anteroposterior view; CI, confidence interval; LL, lateral view; OR, odds ratio.

This variation in cutoff values could be attributed to the fact that nearly 30 years later, there has been an increase in the number and types of fixation devices available, along with significant changes in material and device design. Despite the introduction of double-screw femoral nails, there has been limited research on the correlation between TAD values and the risk of cut-out in proximal femoral fractures.

The first study conducted in 2016 on the Veronail Trochanteric System (Orthofix, Italy) double-screw femoral nail concluded that a TAD exceeding 25 mm remains a valid risk factor for this type of device. Additionally, the study suggested that the risk of cut-out can be minimized through optimal placement of femoral head screws.¹⁴

In 2022, Şişman et al¹⁹ identified TAD as a predictive risk factor for cut-out with the double proximal screw design nails (TST-PROFIN; proximal femur nail), along with factors such as the positioning of proximal screws, fracture type, and reduction quality. Their findings confirmed the TAD cutoff value proposed by Baumgaertner et al.¹⁶

Similar to other studies,^{16,19} we found that reduction quality and fracture type are important risk factors for cut-out. However, the main difference in our data, compared to the two previously mentioned studies about double lag femoral nails, is that our TAD cutoff was raised to 29 mm. We believe this could be explained by the fact that when good reduction is achieved and a double cephalic lag nail is used, the rate of failure decreases, and the relationship between TAD values and cut-out risk diminishes. Therefore, the traditional 25 mm TAD cutoff should not be strictly considered a predictive value in double-screw nail fixation when good reduction is ensured.

Although bisphosphonates are primarily used to reduce the risk of fragility fractures in patients with osteoporosis, there is still no consensus regarding their contribution to fracture healing, particularly in long-term treatment before a fracture occurs.³³ A larger number of patients enrolled in a prospective study is needed to investigate any correlation between long-term bisphosphonate therapy and the risk of fracture fixation failure.

In a study by Parker et al,³⁴ posterior screw placement was reported to increase the risk of cut-out, whereas Baumgaertner et al³ determined a higher risk with anteriorly placed screws. Similarly, in the study by Şişman et al,¹⁹ superior and anterior placement significantly increased the risk of cut-out when a double proximal screw nail was used. Our results are consistent with these findings. However, it is worth noting that other studies have reported that screw placement does not affect the risk of cut-out.³⁵

Strengths and limitations

This study is limited by its retrospective design, which may introduce selection bias and confounding variables. Additionally, the sample size is relatively small, which may limit the generalizability of the results to broader populations. Furthermore, some parameters are lacking, such as the evaluation of osteoporosis index and the assessment of screw positioning. These limitations should be considered when interpreting the findings, and further prospective studies with larger sample sizes and more comprehensive evaluations are warranted to confirm the results.

The strengths of this research lie in its methodological assessment of EBA2 patients, which has not been investigated previously. Our findings could be particularly attractive for surgeons who choose this type of implant. By providing insights into the risk factors for cut-out and proposing a revised TAD cutoff value specific to double-screw nail fixation, our study offers valuable information that can aid surgeons in making informed decisions, and potentially improve patient outcomes.

Surgeons may consider accepting a femoral head screw position farther from the medial cortex of the femoral head in double-screw proximal femur nail procedures, provided that it does not lead to an increased risk of cut-out (TAD > 25 mm). This approach could potentially reduce surgical time without compromising the fracture healing process. However, it is crucial to prioritize the quality of reduction and ensure adequate positioning of the screws, while avoiding superior and anterior placement, as these factors have been shown to reduce the incidence of fixation failure and fracture nonunion.

Further research is warranted to explore the correlation between TAD and the risk of cut-out in double-screw femoral nails. Comparative or trial studies comparing different types of single- or double-screw nails, involving a larger number of patients and longer follow-up periods, are necessary to provide more comprehensive insights into the optimal surgical strategies for managing proximal femur fractures. Such studies could help refine current guidelines and improve patient outcomes in the future.

In conclusion, this study aimed to investigate the role of TAD as a risk factor for cut-out in intertrochanteric femur fractures treated with a double-screw proximal femoral nail. By conducting a thorough analysis of patient characteristics, fracture parameters, and surgical variables, the study sought to clarify the relationship between TAD and the occurrence of cut-out. The findings suggest that if reduction parameters are adequately achieved, an increase in TAD cutoff does not appear to influence the risk of implant failure. These insights contribute to our understanding of optimal surgical approaches for managing intertrochanteric femur fractures, and may inform clinical decision-making in the future.

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Data sharing

The data supporting the findings of this study are available to other researchers from the corresponding author upon reasonable request. Access to the data will allow for further analysis, verification, and replication of the study findings, thereby contributing to the advancement of research in this field.

Ethical review statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Local Ethics Committee (Prot. No. 143/C.E. - 22/11/2020). Written consent was obtained from all participants prior to the surgical procedure in accordance with department protocol. Additionally, all participants provided signed written consent for the use and publication of all personal data, including personal X-rays. This ensured compliance with ethical standards and protected the privacy and confidentiality of the participants' information. Finally, all the authors confirm that all the research meets the ethical guidelines, including adherence to the legal requirements of the study country.

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