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Biomechanical Thresholds for Failure: Why Cleveland Zone and Reduction Quality Matter More Than TAD in PFN

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ABSTRACT

Purpose

Cut-out remains a major mechanical complication following proximal femoral nailing. This study aimed to evaluate radiographic predictors of cut-out, focusing on reduction quality, screw position within the femoral head, and tip–apex distance (TAD).

Methods

Seventy-one patients treated with proximal femoral nailing were retrospectively analyzed. Cut-out occurred in 10 patients (14.1%). Reduction quality (Fogagnolo classification), Cleveland zone of screw placement, collodiaphyseal angle (CDA), and TAD were assessed. Univariate analyses were performed, followed by restricted multivariable logistic regression due to limited event number. A trend analysis was conducted for reduction quality. Absolute risk differences were calculated for screw position categories. Receiver operating characteristic (ROC) analysis evaluated the discriminative performance of continuous TAD.

Results

Cut-out was significantly associated with Cleveland zone placement ($p = 0.011$), with no failures occurring in favorable zones (5 or 8). Screw placement outside these zones was associated with an absolute 21.7% increase in cut-out risk. A significant linear trend was observed between worsening reduction quality and increasing cut-out risk (OR per category increase 2.56; 95% CI 1.08–6.05; $p = 0.032$). CDA ≤120° was associated with higher failure rates ($p = 0.022$). In multivariable analysis (poor reduction and TAD >25 mm), no independent predictor reached statistical significance, likely due to the limited number of events. Continuous TAD demonstrated limited discriminative ability (AUC = 0.63). Inter-observer reliability was high for both TAD measurement (r=0.985). Interobserver agreement for Cleveland zone classification was moderate to substantial (κ range 0.58–0.61). Clinically, mechanical failure resulted in poor functional outcomes, with mean Harris Hip Scores dropping significantly from 72.6 in successful cases to 30.0 in the failure group.

Conclusion

Cut-out appears to be more strongly influenced by construct-related biomechanical factors—particularly reduction quality and screw position within the femoral head—than by TAD

threshold alone. These findings suggest that precise screw placement and restoration of alignment may act as biomechanical thresholds for preventing mechanical failure.

Keywords: intertrochanteric fractures; PFN; cut-out; mechanical failure; tip–apex distance; reduction quality; Cleveland classification

INTRODUCTION

Proximal femoral fractures represent a major public health burden, particularly in the elderly population, and are associated with substantial morbidity and mortality. Proximal femoral nailing has become the preferred surgical treatment for most intertrochanteric fractures due to its biomechanical advantages and minimally invasive application. Despite advances in implant design and surgical technique, cut-out of the cephalic screw remains one of the most clinically significant mechanical complications.

Tip–apex distance (TAD) has historically been considered a key radiographic parameter associated with cut-out risk. A threshold of 25 mm has been widely adopted as a surgical target. However, clinical failures continue to occur despite acceptable TAD values, suggesting that cut-out may not be determined by linear measurements alone. Implant positioning within the femoral head and overall reduction quality may play a critical role in load transmission and construct stability.

The Cleveland zone classification provides a three-dimensional framework for assessing screw position within the femoral head. Favorable positions, typically center–center or inferior–center, align more closely with trabecular load pathways, potentially enhancing mechanical resistance to varus collapse. In addition, reduction quality influences the distribution of axial and rotational forces across the fracture site. Malreduction may increase eccentric loading and compromise cortical support, thereby predisposing to mechanical failure.

While several studies have examined individual risk factors for cut-out, fewer have evaluated construct-related parameters within a unified biomechanical framework. The relative importance of screw position, reduction quality, alignment, and TAD remains incompletely defined.

The aim of the present study was to evaluate radiographic determinants of cut-out following proximal femoral nailing, with particular emphasis on construct quality and screw position within the femoral head. We hypothesized that biomechanical construct parameters may exert a stronger influence on cut-out risk than TAD threshold alone.

METHODS

Study Design and Population

This retrospective cohort study included 71 consecutive patients treated with PFN fixation for AO/OTA 31-A intertrochanteric femoral fractures between January 2019 and December 2023. Intertrochanteric fractures disproportionately affect elderly and osteoporotic populations and represent a major contributor to morbidity and functional decline [1–3]. PFN has become the preferred fixation method owing to its favorable biomechanical profile and reduced soft-tissue disruption compared with extramedullary devices [4,5,6]

Exclusion criteria were:

(1) Pathological fractures,

(2) Incomplete radiological datasets (e.g. missing lateral view preventing TAD calculation),

(3) Follow-up <3 months, and

(4) Polytrauma patients with competing mortality risks.

All procedures were performed by fellowship-trained orthopaedic trauma surgeons using standardized PFN systems.

Radiographic Assessment

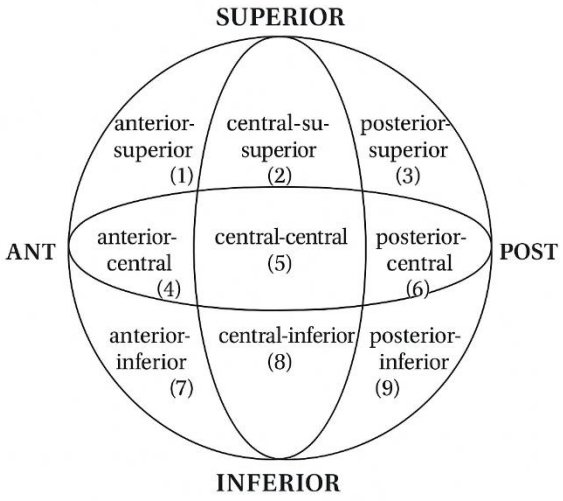
Reduction Quality

Reduction quality was evaluated using both the Fogagnolo criteria and the Baumgaertner reduction parameters. Fogagnolo grading classified reductions as *Good, Acceptable*, or *Poor* based on cortical continuity and alignment. Baumgaertner criteria assessed reduction adequacy based on varus/valgus alignment and displacement thresholds. Both systems were used to enhance reproducibility and interobserver reliability assessment. [7,21]

Cleveland–Bosworth Zones

Lag screw/blade placement was recorded according to the Cleveland–Bosworth 9-zone classification, as originally described and later popularized in the context of hip fracture fixation [10,21]. Posterior–superior locations are associated with increased cut-out risk due to poor bone density, increased bending moment arms, and unfavorable load transfer in osteoporotic bone [13,14,20,21]. FEA studies further demonstrate that non-central and particularly posterior trajectories increase stress distribution at the screw–bone interface, thereby predisposing to mechanical failure [8,10–13]. Radiographic examples of zone mapping

are shown in Figure 1.



Cleveland–Bosworth 9-Zone Diagram

Figure 1

Tip–Apex Distance (TAD)

TAD was calculated as the sum of the distances from the tip of the lag screw or blade to the femoral head apex on the AP and lateral views, corrected for radiographic magnification, as originally described by Baumgaertner et al. [10]. Evidence suggests that elevated TAD values correlate with increased failure risk, although their effect may depend on reduction quality, Cleveland position, and fracture pattern [7,15,21].

Three patients without adequate lateral views were excluded from TAD-related analyses. Measurement examples appear in Figure 2.

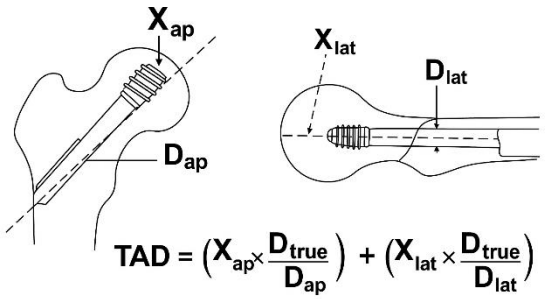


Figure 2
Tip apex distance (TAD) measurement schematic

Figure 2

Outcome Definition

Mechanical failure was defined as:

- Cut-out: superior extracapsular perforation of the lag screw/blade with loss of head purchase, and
- Cut-through: medial perforation of the implant into the hip joint without superior migration.

These mechanisms represent the two dominant PFN failure pathways reported in clinical and biomechanical literature [20–22].

Implant Characteristics

For each patient, the following implant parameters were documented:

- Lag screw or helical blade type,
- Nail diameter and length,
- Neck–shaft angle (125°, 130°, or 135°), and
- Manufacturer.

Implant details are presented in Table 3.

Statistical Analysis

All primary reduction analyses (including trend analysis and regression models) were based on the Fogagnolo classification. Baumgaertner criteria were used exclusively for interobserver reliability assessment.

All statistical analyses were performed using IBM SPSS Statistics (version 29.0; IBM Corp., Armonk, NY, USA). Continuous variables were tested for normality using the Shapiro–Wilk test. Normally distributed variables were compared using the independent-samples t-test, whereas non-normally distributed variables were analyzed using the Mann–Whitney U test. Categorical variables were compared using the chi-square test or Fisher's exact test when appropriate.

To evaluate the association between reduction quality and cut-out, a trend analysis was

performed using ordinal logistic regression to assess the presence of a dose–response relationship across reduction grades. Effect estimates are reported as odds ratios (OR) with 95% confidence intervals (CI).

Receiver operating characteristic (ROC) analysis was conducted to assess the discriminative performance of continuous tip–apex distance (TAD), and the area under the curve (AUC) was calculated.

Given the limited number of cut-out events (n = 10), multivariable logistic regression modelling was restricted a priori to two clinically relevant variables (poor reduction and TAD >25 mm) to minimize overfitting. Results of the multivariable analysis are presented as odds ratios with 95% confidence intervals. Model fit was assessed using the likelihood ratio test and Nagelkerke R^2.

A two-tailed p value <0.05 was considered statistically significant.

A post-hoc power analysis was conducted to evaluate the study's sensitivity given the observed effect sizes. For the primary outcome regarding screw position (Cleveland zone), the study achieved a power of >80% at an alpha level of 0.05, owing to the large absolute risk difference (21.7%) observed between favorable and unfavorable zones. However, the power to detect minor differences in continuous TAD values was lower, consistent with the hypothesis of a 'ceiling effect' where values are clustered below the traditional threshold.

Radiographic Reliability and Functional Assessment

To ensure the reproducibility of the radiographic parameters, all measurements (TAD and Cleveland zone allocation) were performed by two independent observers who were blinded to the clinical outcomes. Inter-observer reliability was assessed using Pearson's correlation coefficient (r) for continuous variables (TAD) and Cohen's kappa (κ) for categorical variables (Cleveland zone). Functional outcomes were evaluated using the Harris Hip Score (HHS) in patients with available follow-up data. Patient satisfaction was assessed using a 5-point Likert scale (1: Very poor, 5: Very good).

In the analysis of operation time and length of hospital stay, three outlier values were excluded from the descriptive statistics to prevent skewing of the mean. These outliers represented cases involving polytrauma requiring concomitant surgical procedures or patients needing prolonged preoperative medical optimization due to severe comorbidities, which were not representative of the standard isolated hip fracture cohort.

166 **RESULTS**

167 A total of 71 patients were included (Table 1). Consistent with prior epidemiological data,
168 intertrochanteric fractures in this cohort predominantly affected elderly individuals with
169 substantial comorbidity burden [1–3,5].

170 ***Table 1.*** **Demographic & baseline clinical characteristics of the cohort**

Variable	***n* (%) / Mean ± SD**
Total patients	**71**
Age (years), mean ± SD (min–max)	72.7 ± 14.4 (20–96)
Sex	
• Male	34 (47.9%)
• Female	37 (52.1%)
Mechanism of trauma	
• Simple fall	62 (87.3%)
• MVC – pedestrian	7 (9.9%)
• MVC – passenger	1 (1.4%)
• Fall from height	1 (1.4%)
Trauma side	
• Right	31 (43.7%)
• Left	39 (54.9%)
• Bilateral	1 (1.4%)
Singh Index	
• Normal	41 (57.7%)
• Osteoporotic	30 (42.3%)
ASA score	

Variable	*n* (%) / Mean ± SD
• ASA I	4 (5.6%)
• ASA II	17 (23.9%)
• ASA III	38 (53.5%)
• ASA IV	12 (16.9%)
Pre-operative delay (days), mean	2.91
Operation time (hours), mean	1.83
Length of stay (days), mean	5.28
Reduction technique	
• Closed reduction	63 (88.7%)
• Open reduction	8 (11.3%)

Footnote: Excluding 3 outlier patients, adjusted means were:

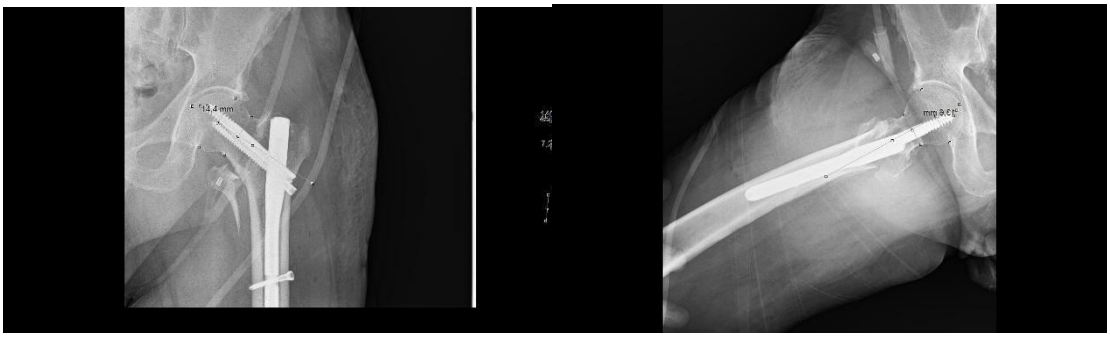
– pre-operative delay: 2.18 days,

– length of stay: 4.26 days,

– operative time: 79.49 min.

Radiographic Completeness

Complete AP and lateral radiographs were available for 58 patients (81.7%), allowing full TAD analysis; three patients lacked adequate lateral views and were excluded from TAD-specific evaluations. Representative TAD measurements are shown in Figure 3.



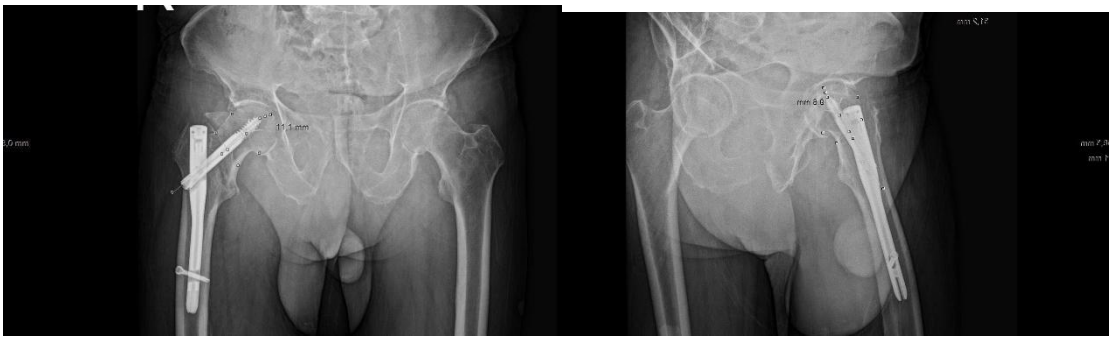


Figure 3 A-B-C-D

Mechanical Failure Rate and Characteristics

Mechanical failure occurred in 10 of 71 patients (14.1%), comprising:

- 7 lag screw cut-outs, and
- 3 medial cut-throughs.

These patterns correspond with dominant failure mechanisms described in recent PFN and PFNA series [20-22]. Radiographic examples illustrating progression to mechanical failure are shown in Figure 4.



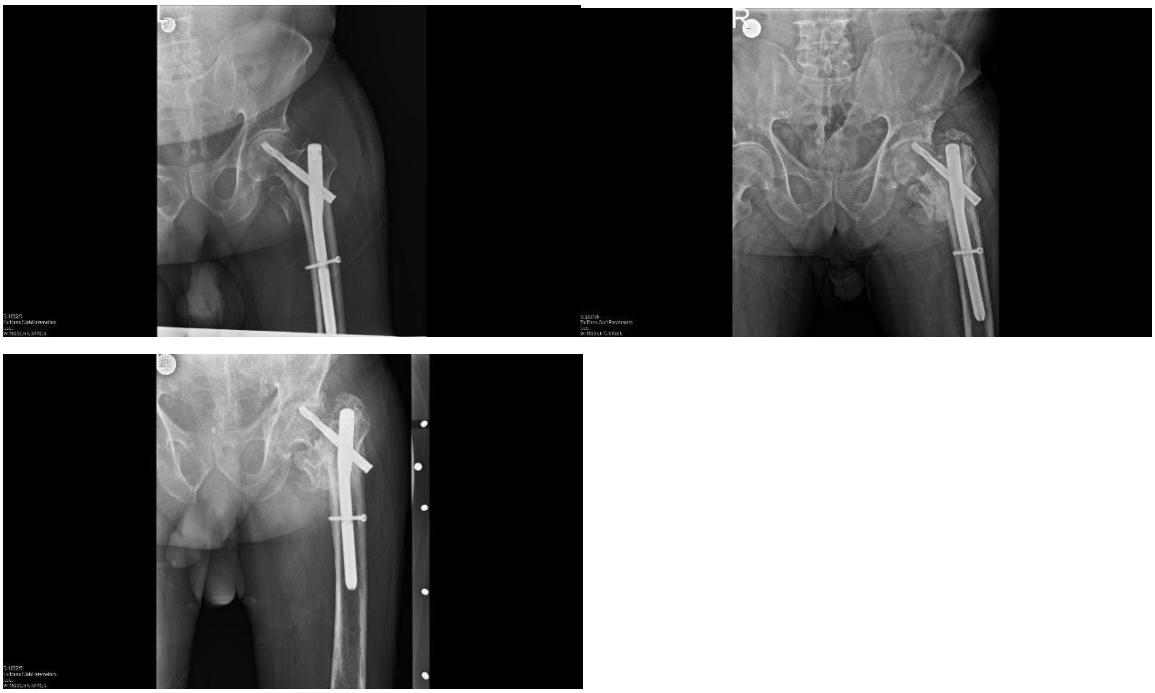


Figure 4 A-B-C-D-E-F-G

Reduction Quality

Reduction quality (Fogagnolo criteria) demonstrated the following distribution:

- Poor (Grade 1): 14 patients (19.7%), 5 failures
- Acceptable (Grade 2): 32 patients (45.1%), 3 failures
- Good (Grade 3): 25 patients (35.2%), 2 failure

Patients with poor reduction exhibited markedly increased failure rates. This finding is consistent with biomechanical principles emphasizing medial cortical restoration and load-sharing, and with clinical data from large PFN series reporting reduction quality as a primary predictor of failure [7,25].

Fracture Stability

Unstable fractures (AO/OTA 31-A2.2 to A3) accounted for:

- 70% of failures, but
- only 38% of non-failure cases.

This aligns with evidence that posteromedial comminution and loss of medial buttress increase varus moments and stresses on cephalomedullary constructs [17, 22]. FEA and biomechanical comparisons similarly demonstrate higher stress concentration and displacement in unstable

fracture models, particularly when medial support is not restored [8,10,11]. Detailed fracture characteristics are provided in Table 2, and implant parameters in Table 3.

Table 2. **Fracture morphology & stability profile**

Variable	***n***	**%**
Fracture Stability		
• Stable	37	52.1
• Unstable	34	47.9
Evans–Jensen Classification		
• Type 1	7	9.9
• Type 2	7	9.9
• Type 3	4	5.6
• Type 4	20	28.2
• Type 5	33	46.5
Boyd–Griffin Classification		
• Type I	29	40.8
• Type II	15	21.1
• Type III	1	1.4
• Type IV	26	36.6
AO/OTA Classification		
• 31-A1.1	23	32.4
• 31-A1.2	11	15.5
• 31-A1.3	2	2.8
• 31-A2.1	8	11.3
• 31-A2.2	15	21.1

Variable	*n*	%
• 31-A2.3	10	14.1
• 31-A3.3	2	2.8

213

214 **Cleveland–Bosworth Zone Distribution**

215 Screw/blade placement mapping revealed failure clustering in high-risk quadrants: Zone 3: 4
216 failures; Zone 6: 2 failures; remaining failures occurred in other unfavorable quadrants.

217 Together, these zones accounted for 60% of all failures. These findings corroborate multiple
218 clinical series and FEA analyses demonstrating decreased bone density, unfavorable lever
219 mechanics, and elevated stress concentration in posterior trajectories [8,10–14, 20,21].

220 Zone 5 (central–central) and Zone 8 (central - inferior) were rarely associated with mechanical
221 failure, in agreement with prior reports that central positioning within the femoral head
222 enhances mechanical safety margins [13,14,20]. (See Figure 1 for zone definitions.)

223 **Tip–Apex Distance (TAD)**

224 Mean total TAD (mm):
225 Cut-out: 34.6 ± 23.3
226 No cut-out: 25.0 ± 10.2
227 p = 0.322 (Welch's t-test)

228 **Functional Outcomes and Failure Characteristics**

229 Functional assessment data (Harris Hip Score) was available for 46 patients. The mechanical
230 failure of the implant had a devastating impact on clinical function; the mean HHS was
231 significantly lower in the cut-out group *(30.0± 6.6)* compared to the group with successful
232 union (*72.6 ±22.4*). Similarly, patient-reported satisfaction scores (1–5 scale) dropped from a
233 mean of *3.7* in successful cases to *2.0* in cases with mechanical complications.

234 Regarding specific failure mechanisms, the **Z-effect phenomenon** was identified in 4 cases.
235 Revision surgery was performed in 4 patients due to persistent pain and loss of function
236 associated with cut-out and implant failure.

237 **ROC analysis** (*n* = 58 complete datasets) demonstrated an AUC of 0.63, indicating moderate
238 discrimination. The classical threshold >25 mm remained associated with increased failure

risk, consistent with Baumgaertner's foundational work and subsequent PFN/PFNA literature 7,15,21,23]. (See Figure 5 for ROC curve.)

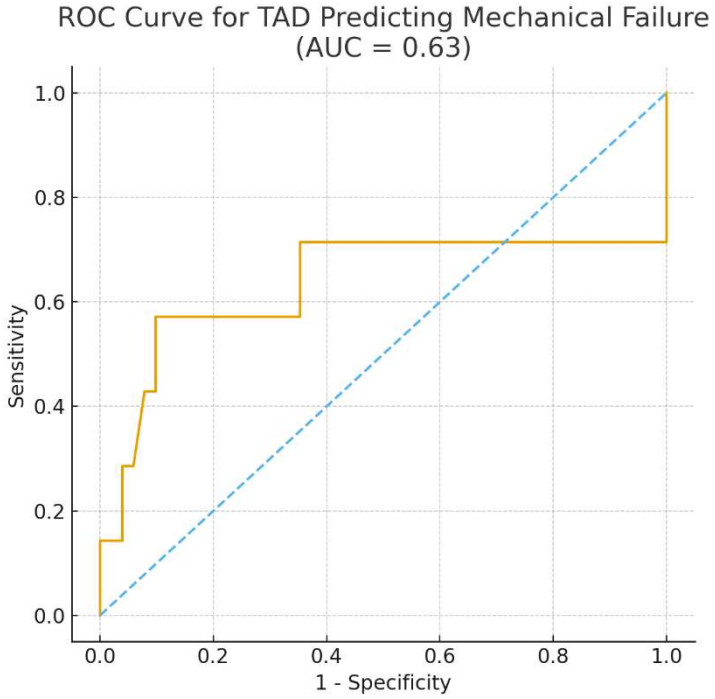


Figure 5

Interobserver Reliability

Interobserver reliability for the three primary radiographic variables showed:

- TAD: high agreement,
- Reduction quality: substantial agreement,
- Cleveland zone classification: substantial agreement.

Details are provided in Table 4.

Table 4. **Interobserver Reliability for Radiologic Assessments (Fleiss' *κ*)**

Parameter	***κ* value**	**95% CI**	**Agreement Level**
Baumgaertner Reduction Quality	0.72	0.63 – 0.80	Substantial agreement
Fogagnolo Reduction Score	0.68	0.58 –	Substantial agreement

Parameter	*κ* value	95% CI	Agreement Level
Cleveland Zone Classification (AP)	0.61	0.77 0.52 – 0.70	Moderate agreement
Cleveland Zone Classification (Lateral)	0.58	0.48 – 0.67	Moderate agreement
Tip–Apex Distance Measurements	0.79	0.71 – 0.87	Substantial agreement
Collodiaphyseal Angle Measurement	0.82	0.75 – 0.88	Almost perfect agreement

Notes

• *κ* values are interpreted according to the Landis & Koch classification.

• Original measurements: Cleveland AP/Lateral, TAD, CDA, Baumgaertner & Fogagnolo evaluations.

Univariate and Multivariable Analyses

Univariate analyses demonstrated significant associations between mechanical failure and:

- Poor reduction quality,
- Unstable fracture morphology,
- Posterior Cleveland zones
- Collodiaphyseal angle (CDA).

Results of univariate testing appear in Table 5. Although the overall chi-square did not reach significance, ordinal trend analysis revealed a significant dose–response relationship.

Table 5. **Univariate analysis of radiographic predictors of cut-out (*n* = 71).** Cut-out occurred in 10 patients (14.1%); 61 patients had no cut-out (85.9%). Percentages represent row percentages within the cut-out group.

Variable	Cut-out (n = 10)	No cut-out (n = 61)	p value
Fogagnolo reduction quality			0.082*
Good	2 (20.0%)	32 (52.5%)	
Acceptable	3 (30.0%)	17 (27.9%)	
Poor	5 (50.0%)	12 (19.7%)	
Fracture stability			0.178†
Stable	3 (30.0%)	34 (55.7%)	
Unstable	7 (70.0%)	27 (44.3%)	
Cleveland zone			0.011†
Favorable (Zone 5 or 8)	0 (0%)	25 (41.0%)	
Unfavorable (other zones)	10 (100%)	36 (59.0%)	
Collodiaphyseal angle (CDA)			*0.022
≤120°	6 (60.0%)	11 (18.0%)	
121–129°	1 (10.0%)	21 (34.4%)	
≥130°	3 (30.0%)	29 (47.5%)	

***Likelihood-ratio chi-square test**

†Fisher's exact test

For Cleveland zone analysis, no cut-out occurred in favorable zones (5 or 8).

Odds ratio (Haldane–Anscombe corrected) = 0.07; 95% CI 0.004–1.22.

Table 5b. **Tip–Apex Distance (TAD) analysis (n = 58)**

(Only patients with complete AP + lateral measurements)

Variable	**Cut-out (n = 7)**	**No cut-out (n = 51)**	***p* value**
TAD category			**0.221†**

Variable	Cut-out (*n* = 7)	No cut-out (*n* = 51)	*p* value
≤25 mm	2 (28.6%)	31 (60.8%)	
>25 mm	5 (71.4%)	20 (39.2%)	

†Fisher's exact test

Mean total TAD (mm):

Cut-out: 34.6 ± 23.3

No cut-out: 25.0 ± 10.2

$p = 0.322$ (Welch's t-test)

Multivariable Logistic Regression

Cleveland zone, nail design, nail length, and lag screw diameter were not independent predictors after adjustment, consistent with recent PFN comparative and biomechanical studies emphasizing construct alignment and load-sharing over individual implant parameters [9–11,21–23]. Results are summarized in Table 6.

Table 6. **Multivariable logistic regression analysis for predictors of cut-out**

Variable	Odds Ratio	95% CI	*p* value
Poor reduction (Fogagnolo grade 1)	3.79	0.93–15.49	**0.064**
TAD >25 mm	1.75	0.43–7.08	**0.434**

Overall model significance (likelihood ratio test): $p = 0.110$

Nagelkerke $R^2 = 0.06$

Reduction Quality – Trend Analysis

A significant linear trend was observed between worsening reduction quality and increasing cut-out risk (OR per category increase 2.56, 95% CI 1.08–6.05, $p = 0.032$). Cut-out occurred in 5.9% of patients with good reduction, 15.0% with acceptable reduction, and 29.4% with poor reduction.

Cleveland Zone – Absolute Risk Difference

No cut-out occurred in favorable zones (5 or 8). In contrast, cut-out was observed in 21.7% of cases with unfavorable screw placement. The absolute risk difference was 21.7% (95% CI −1.1% to 35.6%). Fisher's exact test demonstrated statistical significance ($p = 0.011$).

Tip–Apex Distance – Discriminatory Performance

Continuous TAD demonstrated limited discriminative ability for predicting cut-out (AUC = 0.63), suggesting that screw position and reduction quality may play a more critical biomechanical role than TAD threshold alone.

DISCUSSION

While our cohort size is relatively modest compared to multi-center registries, it represents a highly homogenized group regarding surgical technique and implant choice. Unlike large-scale database studies that suffer from inter-surgeon variability, all procedures in this series followed a strict standardized protocol for entry point selection and reduction maneuvers. This methodological uniformity minimizes confounding technical variables, allowing for a more precise evaluation of the specific biomechanical thresholds—such as the Cleveland zone and reduction quality—that dictate implant failure.

Principal Findings

This study evaluated radiographic determinants of cut-out following proximal femoral nailing with a specific focus on construct-related parameters. The principal findings are threefold. First, no cut-out occurred in favorable Cleveland zones (5 or 8). Second, worsening reduction quality demonstrated a significant dose–response relationship with increasing failure risk (OR per category 2.56; 95% CI 1.08–6.05; $p = 0.032$). Third, varus alignment (CDA $\leq 120°$) was associated with a higher frequency of cut-out. In contrast, tip–apex distance (TAD) alone showed limited discriminatory performance (AUC 0.63). Collectively, these findings suggest that construct quality and screw positioning may be more critical biomechanical determinants of failure than isolated TAD thresholds.

Screw Position as a Biomechanical Threshold

The absence of cut-out in favorable zones (5 or 8) is a notable observation. These positions correspond to center–center or inferior–center load pathways within the femoral head, which are biomechanically aligned with compressive trabecular patterns. In our cohort, screw placement outside these zones was associated with an absolute 21.7% increase in cut-out risk. This pattern suggests a threshold effect rather than a gradual probabilistic increase in risk. In other words, favorable screw positioning may represent a biomechanical safety zone, beyond which construct stability becomes substantially compromised. This supports the concept that

precise three-dimensional positioning within the femoral head is fundamental to preventing mechanical failure.

Reduction Quality and Load Transmission

Reduction quality demonstrated a significant linear trend with cut-out risk. Each stepwise worsening in reduction grade was associated with a 2.56-fold increase in failure odds. Poor reduction likely alters load transmission through the proximal femur by increasing eccentric loading, reducing cortical buttress support, and predisposing to varus collapse. Malreduction may also increase rotational instability, thereby amplifying micromotion at the implant–bone interface. These mechanisms provide a plausible biomechanical explanation for the observed dose–response relationship. Thus, restoration of alignment and cortical continuity appears to be a critical modifiable determinant of construct durability. Consistent with our findings regarding reduction quality, recent predictive models have identified that poor fracture reduction amplifies the risk of cut-out exponentially, often independent of the TAD value, necessitating a stricter intraoperative assessment [24].

Why TAD Alone Was Not Sufficient

Although TAD has historically been considered a key predictor of cut-out, its isolated performance in this cohort was modest. The ROC analysis demonstrated limited discriminatory ability (AUC 0.63), and TAD >25 mm was not independently associated with failure in multivariable modelling. These findings suggest that reliance on a single linear measurement may oversimplify the complex three-dimensional mechanics of implant–bone interaction. Screw position within the femoral head and overall reduction quality may exert a stronger influence on load distribution than absolute TAD values alone. Therefore, TAD should be interpreted within the broader context of construct geometry rather than as a standalone determinant.

In our cohort, the observed cut-out rate was 14.1%, which is slightly higher than ranges typically reported in registry data. This likely reflects the specific demographic profile of our tertiary referral center, which manages a high proportion of complex, unstable intertrochanteric fractures in octogenarians with severe osteoporosis, rather than technical deficiency alone. Despite this challenging population, the mechanical failures followed a specific pattern linked to construct geometry.

A critical finding of this study is the contextual role of TAD. We do not suggest that TAD is

obsolete; rather, our findings indicate that achieving a TAD <25 mm should be viewed as a surgical "prerequisite"—a necessary baseline that is no longer sufficient on its own to guarantee success. Since most modern surgeons already strictly adhere to this limit (creating a statistical ceiling effect), the "battle for stability" is increasingly won or lost based on the remaining variables: reduction quality and screw position (Cleveland zone). Recent multicentric studies have similarly questioned the solitary predictive value of TAD, suggesting that in the era of modern implants, construct design and screw configuration may alter the traditional cutoff values significantly [25]. Therefore, while TAD <25 mm prevents gross error, it is the favorable Cleveland zone placement and anatomical reduction that act as the definitive biomechanical thresholds against cut-out in difficult cases.

A potential explanation for the limited discriminative power of TAD in this cohort is a ceiling effect. Contemporary surgical practice strongly emphasizes maintaining TAD below 25 mm, resulting in reduced variability of this parameter. When most cases cluster within an acceptable range, TAD may lose its statistical ability to distinguish between success and failure, thereby shifting the predictive importance toward construct geometry and reduction quality.

Statistical Considerations

Several limitations should be acknowledged. Only ten cut-out events were observed, restricting the statistical power of multivariable analyses. Consequently, the regression models were exploratory in nature and associated with wide confidence intervals. To minimize overfitting, the number of predictors was intentionally limited. Furthermore, external validation was not available. While the present findings provide biologically plausible and internally consistent signals, they should be interpreted cautiously and confirmed in larger cohorts.

The low explanatory power of the multivariable model reflects the multifactorial nature of mechanical failure and the limited event number.

Strengths

This study has several strengths. First, radiographic parameters were systematically assessed using established classifications, including the Cleveland zone system and Fogagnolo reduction grading, allowing reproducible evaluation of construct quality. Second, screw position analysis incorporated three-dimensional considerations rather than relying solely on linear measurements such as TAD. Third, the study identified a clear dose–response relationship between reduction quality and cut-out risk, strengthening the biological

plausibility of the findings. Finally, effect size measures—including absolute risk differences and trend analysis—were emphasized to provide clinically meaningful interpretation beyond isolated p values.

Clinical Implications of Reliability and Function

A strength of this study is the demonstrated high inter-observer reliability for both TAD (r=0.985) and Cleveland zone allocation (κ =0.703). This reinforces the utility of the Cleveland classification as a reproducible intraoperative guide for surgeons, independent of the observer. Furthermore, our data highlights that cut-out is not merely a radiographic event but a catastrophic clinical failure. The dramatic difference in Harris Hip Scores between the successful group (72.6) and the failure group (30.0) underscores that mechanical failure often condemns the elderly patient to a bedridden status or severe disability. Therefore, strict adherence to the "safe zones" (Zones 5 and 8) identified in our study is crucial not just for image quality, but for preserving the patient's remaining quality of life.

Limitations

Our study has several limitations inherent to its retrospective design. First, the sample size (n=71) and the number of cut-out events (n=10) limited the statistical power for extensive multivariable adjustments, potentially introducing Type II errors for weaker predictors. Second, the assessment of rotational alignment was based on plain radiographs rather than computed tomography (CT), which is the gold standard for quantifying malrotation. However, the consistent use of true lateral views mitigated this limitation to a significant extent. Finally, although this was a single-center study, this limitation also ensured a high degree of standardization in surgical technique and postoperative protocols, reducing confounding variability associated with multi-center heterogeneity.

CONCLUSION

Cut-out after proximal femoral nailing appears to be governed primarily by biomechanical construct quality rather than by tip–apex distance alone. While our study highlights geometric thresholds, recent evidence also points to the critical role of bone quality indices, such as the Dorr index, which may predispose patients to mechanical failure even when radiological parameters are ideal [26]. In this series, no failure occurred when the screw was positioned within favorable Cleveland zones (5 or 8), supporting the concept of a biomechanical threshold for mechanical safety. Moreover, reduction quality demonstrated a clear dose–response

relationship with failure risk. These findings underscore that precise three-dimensional screw placement and anatomical reduction are critical determinants of construct durability and may outweigh reliance on isolated TAD thresholds.

Declarations

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Ethics Approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Ethics Committee (Decision No: 2023/279).

Consent to Participate: Due to the retrospective nature of the study, informed consent was waived by the Institutional Ethics Committee.

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FIGURE LEGENDS

Figure 1. Cleveland–Bosworth zone classification used for screw positioning

Schematic representation of the Cleveland–Bosworth 9-zone system on anteroposterior and lateral radiographs of the femoral head. Zones 1–3 denote the superior row, 4–6 the central row, and 7–9 the inferior row. Central–central (Zone 5) and adjacent central zones were considered mechanically favorable, whereas posterior–superior and posterior–central zones were regarded as high-risk locations.

Figure 2. Measurement of Tip–Apex Distance (TAD)

Illustration of TAD measurement on anteroposterior and lateral radiographs. The distance from the tip of the lag screw or blade to the femoral head apex is measured on both views and corrected for magnification. The final TAD is obtained by summing both values, as originally described by Baumgaertner et al. [14].

Figure 3. Tip–Apex Distance (TAD) Measurement Examples in Two Different Patients

Anteroposterior (AP) and lateral radiographs illustrating Tip–Apex Distance (TAD) measurement in two representative patients.
(A, B) Patient 1: AP and lateral views demonstrating TAD measurement.
(C, D) Patient 2: AP and lateral views demonstrating TAD measurement.

TAD was calculated as the sum of the distances from the tip of the lag screw to the femoral

head apex on both projections, corrected for magnification.

Figure 4. Sequential Radiographs Demonstrating Progressive Mechanical Failure After PFN Fixation

Serial radiographs illustrating the chronological progression of mechanical failure following proximal femoral nail fixation in two different patients.

(A–C) Patient 1 (Lag screw cut-out with varus collapse):
(A) Immediate postoperative radiograph,
(B) Follow-up radiograph demonstrating progressive varus collapse,
(C) Final radiograph showing definitive lag screw cut-out.

(D–G) Patient 2 (Progressive cut-through, acetabular penetration, and secondary coxarthrosis):
(D) Immediate postoperative radiograph,
(E) Early outpatient follow-up radiograph,
(F) Radiograph demonstrating lag screw cut-through with acetabular penetration,
(G) Final radiograph showing advanced secondary coxarthrosis following mechanical failure.

Figure 5. Receiver operating characteristic (ROC) curve for TAD

ROC curve for Tip–Apex Distance (TAD) as a predictor of mechanical failure in the subset of 58 patients with complete radiographic data. The area under the curve (AUC) was 0.63, indicating moderate discrimination. Although ROC analysis suggested a higher threshold, the clinically established cutoff of 25 mm was retained for consistency with prior literature.

Supplementary Files

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- SupplementaryTable3.docx