RESEARCH

A six-year retrospective analysis of cut-out risk predictors in cephalomedullary nailing for pertrochanteric fractures

CAN THE TIP-APEX DISTANCE (TAD) STILL BE CONSIDERED THE BEST PARAMETER?

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Objectives

Intramedullary fixation is considered the most stable treatment for pertrochanteric fractures of the proximal femur and cut-out is one of the most frequent mechanical complications. In order to determine the role of clinical variables and radiological parameters in predicting the risk of this complication, we analysed the data pertaining to a group of patients recruited over the course of six years.

Methods

A total of 571 patients were included in this study, which analysed the incidence of cut-out in relation to several clinical variables: age; gender; the AO Foundation and Orthopaedic Trauma Association classification system (AO/OTA); type of nail; cervical-diaphyseal angle; surgical wait times; anti-osteoporotic medication; complete post-operative weight bearing; and radiological parameters (namely the lag-screw position with respect to the femoral head, the Cleveland system, the tip-apex distance (TAD), and the calcar-referenced tip-apex distance (CaTAD)).

Results

The incidence of cut-out across the sample was 5.6%, with a higher incidence in female patients. A significantly higher risk of this complication was correlated with lag-screw tip positioning in the upper part of the femoral head in the anteroposterior radiological view, posterior in the latero-lateral radiological view, and in the Cleveland peripheral zones. The tip-apex distance and the calcar-referenced tip-apex distance were found to be highly significant predictors of the risk of cut-out at cut-offs of 30.7 mm and 37.3 mm, respectively, but the former appeared more reliable than the latter in predicting the occurrence of this complication.

Conclusion

The tip-apex distance remains the most accurate predictor of cut-out, which is significantly greater above a cut-off of 30.7 mm.

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Keywords: Pertrochanteric fractures, Cut-out, Tip-apex distance, Calcar-referenced tip-apex distance

Article focus

- To provide the incidence of cut-out in a consecutive series of 571 patients treated via cephalomedullary nailing of proximal femoral fractures.
- To provide the reliability of predictors for screw cut-out in intertrochanteric hip fractures.

Key messages

- The incidence of cut-out across the sample was 5.6%, women having a higher risk of incurring the complication.
- A significantly higher risk of cut-out was correlated with lag-screw tip positioning in the upper part of the femoral head in the anteroposterior (AP) radiological view, posterior in the latero-lateral (LL) radiological view, and in the Cleveland peripheral zones.
- The tip-apex distance (TAD) and the calcar-referenced tip-apex distance (CaTAD) were found to be highly significant predictors of the risk of cut-out at cut-offs of 30.7 mm and 37.3 mm, respectively, but the
former appeared more reliable than the latter in predicting the occurrence of this complication.

**Strengths and limitations**

- **Strengths**: To our knowledge, this is the largest consecutive series available in the literature concerning this topic.
- **Limitations**: The study is limited by the systematic bias associated with retrospective studies.

**Introduction**

Fractures of the proximal femur place a heavy burden on orthopaedic departments worldwide, and the annual incidence of this type of injury is growing every year.1 Nevertheless, there is considerable controversy regarding the optimal implant for fixing these fractures. Extramedullary and intramedullary fixation are among the treatment options, with the preferred option for stable trochanteric fractures being a sliding or dynamic hip screw, rather than intramedullary nailing. A sliding or dynamic hip screw has an advantageous cost-benefit ratio in addition to comparable functional outcomes.2,3 The management of unstable proximal femoral fractures is still the subject of some debate, but intramedullary devices have become the benchmark in recent times as the minimally invasive surgery, the dynamic femoral neck screw, and the early post-operative weight-bearing involved lead to more rapid functional recovery.4

That being said, mechanical complications of this intervention are not uncommon, and cut-out failure after intramedullary and extramedullary treatment has an incidence of between 1.4% and 19%, depending on fracture type and implants used.5,6 Although the biomechanical principles of intramedullary devices suggest that the reduction in lever arm moment in unstable fractures should be associated with lower cut-out rates, this has been experimentally proven not to be the case.7

Early research showed that the risk of cut-out after internal fixation of intertrochanteric hip fractures can be raised by several variables, including fracture type, fracture reduction and lag-screw position in the femoral head.8,9 As far back as 1959, Cleveland et al10 introduced a system that divided the femoral head into nine zones, and others have since reported screw cut-out in relation to the screw position in the femoral head and the reliability of the Cleveland dividing system in this regard.

Baumgaertner et al11 were the first to indicate that the tip-apex distance (TAD), the distance between the femoral head apex and the lag-screw tip, was a predictor of cut-out. They concluded that the TAD should be less than 25 mm, and that the lag-screw should be placed centrally in both latero-lateral (LL) and anteroposterior (AP) radiographs. This was followed by Kuzyk et al’s12 introduction of the calcar-referenced tip-apex distance (CaTAD) and their recommendation of inferior placement of the lag-screw on the anteroposterior radiograph and central placement on the lateral view. Indeed, they showed that anterior and posterior lag-screw positions produce the lowest stiffness and load-to-failure rates, while the inferior position yielded the highest axial and torsional stiffness. However, the reliability of these measures has recently been questioned,13-16 and at this point there is no conclusive evidence as to the reliability of predictors for screw cut-out in intertrochanteric hip fractures.

Hence, the aim of this study was to evaluate the association between cut-out, and TAD, CaTAD, and several other technical and clinical factors in patients treated via intramedullary nailing for proximal femoral fractures.

**Patients and Methods**

This retrospective observational cohort study was conducted on consecutive patients treated via cephalomedullary nailing of proximal femoral fractures at our hospital’s Department of Orthopaedics and Traumatology in the period between January 2009 and August 2015. Data pertaining to 1065 trochanteric and subtrochanteric fracture patients were collected and the following patients were excluded: those without complete follow-up three months after surgery; those under the age of 70 years; those who sustained pathological fractures; and those who died within three months of surgery without evidence of cut-out. After the exclusion of patients with poor quality post-operative radiographs precluding accurate radiograph assessment, a total of 571 patients were reviewed in the study (Fig. 1).

These 571 patients were subdivided by age at surgery, gender, laterality, fracture classification according to the AO/OTA system without the application of subgroups (the fractures were grouped into classes 31-A1, 31-A2 and 31-A3), surgical waiting times, type of implant, neck
angle for lag-screw entry, medication prior to trauma (vitamin D, bisphosphonates, corticosteroids), and weight-bearing after osteosynthesis. The TAD, CalTAD and lag-screw position according to the Cleveland femoral head dividing system were evaluated on post-operative standard anteroposterior radiographs of the hip (with the leg positioned at an internal rotation of 15°) and lateral radiographs (taken with the contralateral hip flexed and abducted). For the purposes of this study, the nine Cleveland zones were reduced to three, specifically a central area, taken as a reference category, and two peripherals, denoted “+” (in green) and “x” (in yellow) (Fig. 2). Post-operative radiographs were obtained within 24 hours of surgery, and full weight-bearing was allowed in cases in which good reduction and fixation had been achieved. The post-operative quality of fracture reduction was classified as good, acceptable or poor, according to the three-grade system proposed by Baumgaertner et al. A good reduction was taken as normal or slight valgus alignment on the anteroposterior radiograph, < 20° of angulation on the lateral radiograph, and ≤ 4 mm of displacement. All patients were routinely evaluated for clinical and radiological parameters a minimum of one month and three months after surgery, and data pertaining to these and the last follow-up available were analysed. Cut-out complications were identified through radiological and clinical evaluation, and radiographs and the relevant measures were evaluated with the aid of software Carestream Vue Picture Archiving and Communication System (PACS, version 11.4.1.1102) as highlighted in Johnson et al. Fracture reduction quality, TAD, CalTAD, and lag-screw position were assessed on immediate post-operative radiographs in anteroposterior (AP) and latero-lateral (LL) views. A single observer – a consultant trauma surgeon (M.B.) – measured the TAD and the CalTAD (Fig. 3), the screw position according to Cleveland et al., and the fracture reduction, in order to eliminate inter-observer variability.

The study was approved by the local University Hospital Human Subject Research Ethics Committee, and data collection and analysis were performed in compliance with the Declaration of Helsinki.

**Statistical analysis**

The Shapiro-Wilk test was used to assess the assumption of normality, and data were expressed as mean and SD or as median (interquartile range, IQR), according to their distribution. Categorical data are presented as numbers (%). Percentages were compared using the chi-square test, and continuous data via the Student t-test or Mann-Whitney test, as appropriate. A receiver operating characteristic (ROC) curve was used to investigate the diagnostic accuracy of TAD and CalTAD in predicting screw cut-out, and to identify the optimal cut-off point of these parameters for distinguishing between patients with and without screw cut-out. Odds ratios (OR) and 95% confidence intervals (95% CI) were estimated using an unadjusted logistic regression model which considered the lag-screw cut-out to be a dependent variable and the demographic, surgical, pharmacological and radiological parameters to be independent variables. Odds ratios and 95% confidence interval (CI) were also calculated for an adjusted logistic regression analysis to assess the strength of associations between the dependent variable screw cut-out and several potential predictors (the independent variables: gender; age; anti-osteoporotic therapy; weight-bearing; Cleveland classification and TAD). Multivariate logistic regression analysis was conducted on the female
Table I. Demographic data and baseline characteristics of all patients with trochanteric fractures

| Without cut-out (n = 539) | With cut-out (n = 32) | Total (n = 571) | p-value |
|--------------------------|----------------------|----------------|---------|
| Gender, (n, %): M/F      | 81 (15.0)/458 (85.0)| 11 (34.4)/21 (65.6)| 92 (16.1)/479 (83.9)| 0.004 |
| Age, mean (Standard deviation) | 84.1 (6.3) | 84.9 (7.1) | 84.1 (6.3) | 0.4832 |
| AO/OTA Classification, (n, %) | 88 (16.3) | 6 (18.8) | 94 (16.3) | 0.719 |
| A1                      | 306 (56.8) | 20 (62.5) | 326 (57.1) | 0.525 |
| A2                      | 145 (26.9) | 6 (18.8) | 151 (26.4) | 0.310 |
| Device, (n, %)           | 34 (6.3) | 2 (6.3) | 36 (6.3) | 0.990 |
| CaltAD, median (IQR, Q1 to Q3) | 29.6 (25.0 to 33.7) | 29.6 (25.0 to 34.0) | 0.002 |
| CaltAD, n (%): < 30.7 mm/higher than 30.7 mm | 244 (45.6) | 344 (45.6) | 588 (50.0) | 0.136 |
| Gamma3                  | 434 (80.5) | 29 (90.6) | 463 (81.1) | 0.156 |
| Gamma3 Long             | 71 (13.2) | 1 (3.1) | 72 (12.6) | 0.096 |
| Peripheral area          | 205 (38.4) | 61 (18.8) | 266 (46.8) | 0.001 |
| Central                  | 326 (60.5) | 10 (31.3) | 336 (58.8) | 0.001 |
| Central                  | 733 (65.5) | 16 (50.0) | 749 (65.4) | 0.075 |
| Anterior                 | 111 (20.4) | 6 (18.8) | 117 (20.3) | 0.821 |
| Posterior                | 76 (13.9) | 10 (31.3) | 86 (15.1) | 0.008 |
| Waiting times, (n, %): less than 48 hours/more than 48 hours | 251 (46.6)/288 (53.4) | 16 (50.0)/16 (50.0) | 267 (46.8)/304 (53.2) | 0.705 |
| Anti-osteoporotic therapy, (n, %): yes/no | 77 (15.2)/431 (84.8) | 6 (19.4)/25 (80.7) | 83 (15.4)/456 (84.6) | 0.530 |
| Weight bearing, (n, %): yes/no | 351 (69.4)/155 (30.6) | 21 (67.7)/10 (32.3) | 372 (65.3)/165 (34.7) | 0.849 |
| Screw position on the anteroposterior radiograph, (n, %) | 326 (60.5) | 10 (31.3) | 336 (58.8) | 0.001 |
| Screw position on the lateral radiograph, (n, %) | 353 (65.5) | 16 (50.0) | 369 (64.6) | 0.075 |
| Modified Cleveland system, (n, %) | 76 (13.9) | 10 (31.3) | 86 (15.1) | 0.008 |
| Central                  | 237 (44.0) | 6 (18.6) | 243 (42.6) | 0.005 |
| Peripheral area +        | 205 (38.0) | 14 (43.8) | 219 (38.4) | 0.518 |
| Central                  | 353 (65.5) | 16 (50.0) | 369 (64.6) | 0.075 |
| Peripheral area x        | 97 (18.0) | 12 (37.5) | 109 (19.1) | 0.022 |
| TAD, median (IQR, Q1 to Q3) | 27.92 (22.5 to 33.5) | 35.53 (29.45 to 43.54) | 28.14 (22.8 to 33.9) | < 0.001 |
| TAD, n (%)               | 344 (63.8)/195 (36.2) | 9 (28.1)/23 (71.9) | 353 (61.8)/218 (38.2) | < 0.001 |
| CalTAD, median (IQR, Q1 to Q3) | 29.6 (25.0 to 33.7) | 37.79 (25.5 to 46.6) | 29.7 (25 to 34) | 0.002 |
| CalTAD, n (%)            | 456 (86.8)/83 (13.4) | 17 (53.1)/15 (46.9) | 473 (82.8)/98 (17.2) | < 0.001 |

AO/OTA AO Foundation and Orthopaedic Trauma Association classification system; A1, A2, A3, Type of fracture according to AO/OTA classification; TAD, tip-apex distance; CalTAD, calcar-referenced tip-apex distance; IQR, Interquartile range

chi-squared test was used for all p-values

Among the 571 patients with pertrochanteric fracture of the proximal femur who were reviewed in this study, lag-screw cut-out was observed in 32 cases (an incidence of 5.6%), in line with the range reported in the literature,20-22

As shown in the demographic data and patient characteristics presented in Table I, there was a prevalence of female subjects among those affected (83.9%), and a greater percentage of AO/OTA type 31-A2 fractures (57.1% of the total) than types A3 (26%) and A1 (17%).

As for the surgical device, the Gamma 3 trochanteric nail (Stryker Trauma GmbH Schönkirchen, Germany) was used in 81% of cases, the Gamma 3 Long nail (Stryker Trauma GmbH) in 12.6%, and the Elos nail (Intrauma S.r.l, Turin, Italy) in 6.3%; the cervical-diaphyseal angle most commonly employed was 125°, in 55.7% of cases.

Fig. 4

Diagram showing the number of cut-outs observed out of the total number of lag-screw positions in Cleveland’s10 nine areas.

population data as we found a statistically gender-related difference. This was stratified by age range (< 85 and ≥ 85 years). All analyses were performed using Stata 12.1 SE software. (Stata Statistical Software: Release 12. College Station, Texas), and all tests were two-sided. Statistical significance was set at a p-value of < 0.05.

Results

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As shown in Figure 4, according to the classical Cleveland system, lag-screws were positioned most frequently in the centro-central area (42.5% of cases), followed by the infero-central area (17.5%). However, the Cleveland areas in which the highest incidence of cut-out was observed were the postero-superior (50%) and the antero-superior (12.5%). Figures 5a and 5b show the respective box plots created for the TAD and CalTAD measurements in relation to the presence or absence of cut-out. Calculation of the ROC curves, specifically the area under the curve (AUC), showed the accuracy of TAD and CalTAD in predicting the risk of cut-out as AUC = 0.72 and AUC = 0.67, respectively (Figs 6a and 6b). Thus, according to the AUC measurements calculated for our sample, TAD is a more reliable predictor of cut-out risk than CalTAD, albeit with only moderate and poor levels of accuracy, respectively. Application of the Youden test, which balances the highest values of sensitivity and specificity, showed that the best cut-offs were 30.7 mm for TAD and 37.3 mm for CalTAD. The results of the unadjusted and adjusted logistic regression analyses shown in Table II indicate a statistically significant gender-related difference, with the likelihood of cut-out being almost three times higher in females than in males. Furthermore, the probability of cut-out was statistically linked to the position of the lag-screw on the two radiological views, with significant differences between both the superior position in AP view (OR 8.58; 95% CI 3.36 to 21.93) and the posterior position in LL view (OR 2.90; 95% CI 1.27 to 6.64) with the centro-central position chosen as reference category.17

Using our modified version of the Cleveland system, the probability of cut-out increased by roughly five-fold when the lag-screw tip was located in peripheral zone “x”. TAD and CalTAD values were also highly significant when considered as dichotomous variables. In fact, the risk of lag-screw cut-out was 4.51 times greater when the TAD was above 30.7 mm, and 4.85 times greater when
CaltAD was above 37.3 mm. As shown in Figure 7, the probability of cut-out increased with increasing tAD, and by considering tAD as a continuous variable it was therefore possible to estimate the increase in cut-out per unit increase in TAD. This analysis showed that for every millimetre of increase in TAD, the cut-out risk increased roughly 1.1-fold.

Finally, multivariate regression analysis on the female population stratified by age range showed that in women of less than 85 years of age, the risk of cut-out was increased 6.4-fold when the TAD was above 30.7 mm as shown in supplementary table i.

Discussion
Before discussing the results obtained in this study, it is necessary to point out its limitations, which could have influenced clinical outcomes. The first is that the analysis was carried out retrospectively, on patients recruited over a long period of time. The second involves the comparability of populations undergoing the two treatments, which may only be suggested by a retrospective study – i.e., weak evidence that would need to be confirmed by a specifically designed randomised clinical trial.
Unlike previous studies,\textsuperscript{23} in which no apparent influence of gender on the incidence of cut-out was found, in our sample there was a clear prevalence of complications in female patients, a disparity that, in our opinion, may be linked to the greater incidence and severity of osteoporosis in this patient category. However, our data are in line with some of the literature\textsuperscript{8,9,11,22} on the subject of cut-out incidence with respect to the Cleveland method of lag-screw positioning. Specifically, we observed that positioning the lag-screw tip in the supero-posterior sector was linked to a greater risk of cut-out. Moreover, when using our modified version of the Cleveland classification, we observed that the risk of cut-out increased almost five-fold if the lag-screw tip was positioned in the peripheral zone denoted “x”. Indeed, Baumgaertner et al\textsuperscript{11} found the highest rates of cut-out in the posteroinferior and antero-superior zones, and consequently recommended a deep central insertion of the lag-screw. De Bruijn et al\textsuperscript{23} also recommended centro-central or low-central lag-screw placement with minimal TAD. These conclusions, however, differ from those of Kaufers, Matthews and Sonstegard\textsuperscript{24} who argued in favour of lag-screw placement in the postero-inferior quadrant of the femoral head, as the crossing of tension and compression trabeculae in that area of the femoral head probably provides the best bone for screw placement, thus improving proximal fragment control. This theory was recently tested in a biomechanical study by Kane et al\textsuperscript{17} who found that the low central position with a TAD of greater than 25 mm provided equal if not superior stability to centro-central placement with the then optimal TAD of less than 25 mm.

Our results also showed that TAD is a better predictor of cut-out risk than CalTAD, with their respective AUCs generated by ROC analysis suggesting that TAD is more reliable than CalTAD in this regard. This, however, contrasts with findings by Kashigar et al\textsuperscript{20} that CalTAD is the only significant predictor of cut-out, which was not observed in patients with a CalTAD value lower than 20.98 mm. Our case series, on the other hand, showed much higher cut-offs, of 37.3 mm for CalTAD and 30.7 mm for TAD, with respective increases in cut-out risk of roughly 4.8- and 4.5-fold above these thresholds. There is therefore a considerable discrepancy between our values and those traditionally found in the literature,\textsuperscript{11,16} which identify 25 mm as the value above which the risk of cut-out is increased. However, this discrepancy may in part be explained, as recently suggested in a mathematical simulation by Li et al,\textsuperscript{16} by the fact that in order to be accurate the cut-off proposed by Baumgaertner et al\textsuperscript{11} should be corrected in relation to the diameter of the femoral head, which varies according to gender and anthropometric characteristics, and among individuals. Indeed, it is highly likely that variations in the quality of bone housing the lag-screw will affect its stability and therefore the risk of cut-out.

Another finding in our series was that the risk of cut-out is $6.4 \times$ greater in women between 70 and 85 years of age if the TAD was greater than 30.7 mm - to our knowledge, the first such data reported in the literature. We hypothesise that in female patients below 85 years of age, the position of the lag-screw with respect to the femoral head is the factor most influential to the risk of cut-out, while in women above the age of 85 years other factors, more directly correlated with the bone quality and patient characteristics, come into play.

In the interests of comprehensiveness, we also analysed more general variables of patients with pertrochanteric hip fractures to see whether they would be of any interest. However, we observed no statistically significant differences in the incidence of cut-out related to AO/OTA fracture classification, laterality, type of device, pre-trauma anti-resorption medication, or surgical waiting times. As part of this analysis, however, we did find that there was no statistically significant correlation between the occurrence of cut-out and weight-bearing immediately after surgery. As far as we know, this is the first time such a finding has been reported in the literature, and therefore further studies are warranted to confirm our results.

In conclusion, we find that TAD should still be considered the most accurate predictive factor for cut-out among those suggested in the literature, as the increase in distance between lag-screw tip and femoral head apex is the main risk factor of this complication. In our case series, the cut-off for increased cut-out risk was 30.7 mm, unlike the 25 mm commonly cited in the literature,\textsuperscript{7,11,25,26} but our findings do confirm reports that peripheral positioning of the lag-screw, specifically in the postero-superior portion of the femoral head, is associated with a greater risk of cut-out. In contrast, whether or not the patient was allowed to bear weight in the immediate post-operative period seemed to have no influence on the occurrence of this complication, although this latter finding may be the result of beta error and therefore requires confirmation.

**Supplementary material**

A table showing multivariate regression analysis on the female population stratified by age range is available alongside this article online at www.bjr.boneandjoint.org.uk

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Author Contribution
G. Caruso: Conception and experimental design, Data interpretation, Manuscript preparation.
M. Bonomo: Conception and experimental design, Data interpretation, Manuscript preparation.
G. Valpiani: Data Analysis, Data Interpretation, Manuscript proofing.
G. Salvatori: Experimental design, Manuscript proofing.
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Conflicts of Interest Statement
None declared

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