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Original Article

Risk factors for cut-out failure of Gamma3 nails in treating unstable intertrochanteric fractures: An analysis of 176 patients

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Abstract

Background: Cut-out failure is one of the most common complications in the Gamma3 nail fixation system. The purpose of this retrospective study was to determine pre-operative or intra-operative risk factors for cut-out failure of lag screws in unstable, intertrochanteric fractures fixed with short Gamma3 nails.

Methods: One hundred and seventy-six patients over 60 years of age, with unstable intertrochanteric fractures (AO/OTA 31-A2, 31-A3) treated with short Gamma3 nails were included in this study. All patients completed a minimum of 1-year follow-up. Analysis of post-operative radiographs included assessment for cut-out failure of lag screw, appropriateness of the entry point, posterior lag screw axis, fracture gaps, posterior displacement of the proximal fragment, and tip-apex distance.

Results: Of the 176 patients in this study, 22 patients were identified with cut-out failure. Multivariate logistic regression analysis revealed that improper entry point in an antero-posterior projection (odds ratio 10.39, 95% confidence interval 1.74−78.4), posterior displacement distance of the proximal fragment in a lateral projection (odds ratio 1.35, 95% confidence interval 1.17−1.59), and female sex (odds ratio 17.14, 95% confidence interval 1.88−876.11) were correlated with cut-out failure.

Conclusion: This study emphasizes the importance of an optimal position of reduction in the lateral projection in reducing the risk of cut-out failure. In addition, sex difference in bone mineral density, proximal femur geometry, and the bone strength in elderly females may explain why female sex is a risk factor.

Keywords: Cut-out; Failure; Gamma nail; Intertrochanteric fracture; Risk factor

1. Introduction

Use of intramedullary nails and a dynamic hip screw system have been the mainstays of fixation implants for intertrochanteric fractures.[1] For the treatment of unstable intertrochanteric fractures, intramedullary nails or dynamic hip screws augmented with trochanteric stabilizing plate are the preferred options.[2] Trochanteric fractures in the elderly are commonly associated with early and late complications,

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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including thromboembolism, decubitus complications, infection, and mechanical problems with osteosynthesis and implants.[3] Notably, a high mortality rate is documented in patients with advanced age, mostly related to medical comorbidities.[3] Fixation failure in hip fractures can lead to increased length of hospital stay, a downgrade of residential status in the short-term, decreased quality of life and functional status, additional costs, and decreased survival of the prosthetic revision.[4] Cut-out failure is one of the most common complications in the Gamma3 nail fixation system, with a reported incidence ranging from 1.6 to 4.3%.[5−8] In these patients, additional surgical intervention including removal of the implant, re-osteosynthesis, or conversion to hip prosthesis may become necessary.[9,10] However, revision surgeries for failed internal fixation remain a challenge for orthopedic surgeons, mainly due to poor soft tissue and bone quality, leg length discrepancy, disuse osteopenia, and profound muscle wasting. Therefore, it could be of immense importance for these elderly patients to identify risk factors for cut-out failure and, if possible, to prevent this complication. Risk factors for cut-out failure in a different generation of intramedullary nails have been reported, including fracture pattern, quality of reduction, tip-apex distance and lag screw position.[7,11,12] The only study addressing risk factors for mechanical failure in Gamma3 nails has been reported by Abram et al. These authors raised the concept of “three-point” proximal fixation in peri-trochanteric femoral fractures; however, quality of fracture reduction was not found to be a risk factor for cut-out failure.[13]

In our study, we hypothesized that cut-out failure is associated with suboptimal implant position as well as suboptimal fracture reduction. Therefore, this study aimed to identify possible risk factors for cut-out failure of Gamma3 nails in the treatment of unstable intertrochanteric fractures, including suboptimal implant position and fracture reduction.

2. Methods

This was a retrospective study in a single medical institution conducted from July 2010 to May 2014, with approval of local institutional board review (IRB number 2015-12-011AC). All intertrochanteric fractures were classified before surgery by attending physicians, according to AO/OTA classification[14] for the choice of the fixation method. The technique chosen for fixation method was consistent throughout the study period. All patients with stable intertrochanteric fracture (AO/OTA 31-A1) were treated with a dynamic hip screw system, while all unstable intertrochanteric fractures (AO/OTA 31-A2, 31-A3) were treated with the Gamma3 nail system (Stryker, Mahwah, NJ, USA). There were 302 consecutive patients who met the established inclusion criteria: 1) >60 years of age, and 2) with unstable intertrochanteric fractures treated with Gamma3 nails. No stable intertrochanteric fractures were treated with Gamma3 nails. A total of 126 patients were excluded for the following reasons: follow-up <12 months, pathological fracture, failure in nonunion after Gamma3 nails, or re-osteosynthesis due to previously failed treatment elsewhere. Ultimately, a total of 176 patients with a mean age of 80.5 years (range 60−100 years) were enrolled in our study, including 22 patients with cut-out failure. Fall from the standing position (considered a low-energy injury mechanism) was recorded in most of the patients (168 of 176, 95.5%).

All surgical procedures were performed on a fracture-traction table with the patient in a supine position. Anatomical fracture reduction was defined as smooth Shenton's line and equal fracture gaps along the fracture site in the antero-posterior projection and smooth anterior cortex without translation on the lateral projection; this could be achieved by close reduction in most of the patients. Open reduction with the aid of a bone hook, Hoffmann retractor, or reduction forceps was reserved for failed closed reduction. Wiring was rarely utilized in AO/OTA 31-A2, 31-A3 fractures because of fracture comminution, short oblique or transverse fracture pattern, or poor bone quality. Wiring was performed to aid reduction before nailing in only two patients (1.1%) with long-oblique fracture pattern (AO/OTA 31-A2 in one patient and 31-A3 in the other). Following surgery, all patients were taught to ambulate bearing only partial weight with the aid of crutches or walkers, until there was radiographic evidence of callus formation. All patients were followed after surgery at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year, and then annually. Standard antero-posterior and lateral radiographic projections of the affected hip were obtained to evaluate fracture healing, progressive fracture displacement, and fixation failures. The primary end-point of this study was cut-out failure, defined as upward penetration in the antero-posterior projection, or anterior/posterior penetration of the femoral head in the lateral projection.

With regard to radiographic evaluation, AO/OTA classification at the time of injury, improper entry point, posterior lag screw axis, angle between the lag screw and femoral neck axis, fracture gaps, posterior displacement of the proximal fragment, posterior displacement distance of the proximal fragment, and tip-apex distance[15,16] were recorded on immediate post-operative radiographs. The Lauenstein−Hickey method[17] was consistently utilized throughout the study to obtain immediate post-operative lateral radiographs in the recovery room. The patient was instructed to flex the knee and hip on the affected side, with the sole of the foot against the medial side of the opposite leg, near the knee if possible. Then, the patient was asked to rotate onto the affected side until the whole femur was in contact with the cassette.[17] Optimal image quality in the antero-posterior projection was defined as symmetric visualization of acetabulum, femoral head, neck and greater trochanter with partially visible lesser trochanter. In the optimal lateral projection, the femoral neck would be overlapped with greater trochanter. Radiographs could be repeatedly obtained in the recovery room if there was suboptimal image quality.

The proper entry point of the Gamma3 nail system is located at the tip of the greater trochanter or within 5 mm medial to this point, in an antero-posterior radiograph. Any entry point lateral to this point was defined as an improper

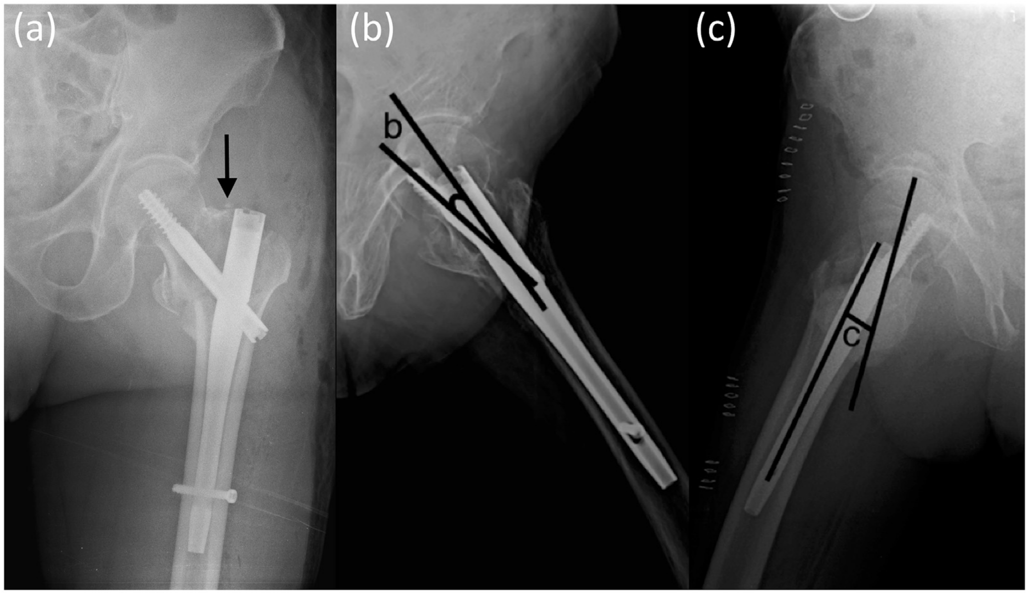

Fig. 1. (a) Demonstration of the proper entry point: the arrow indicates the ideal entry point in the antero-posterior projection; (b) Angle between the lag screw and femoral neck axis is the angle “b” in lateral projection; (c) Posterior displacement distance is the distance “c” between the femoral shaft axis and femoral neck axis at the level of the intertrochanteric fracture line in a lateral projection.

entry point (Figs. 1a and 2). In a lateral projection, the angle between the lag screw and the femoral neck axis was measured. The angle between the lag screw and the femoral neck axis was recorded as a negative value for a lag screw axis located posterior to the femoral neck axis. To avoid measurement errors when converting to a qualitative parameter, a posterior lag screw axis was defined as an angle $<-15°$ (Figs. 1b and 3). Fracture gaps, described in millimeters, were

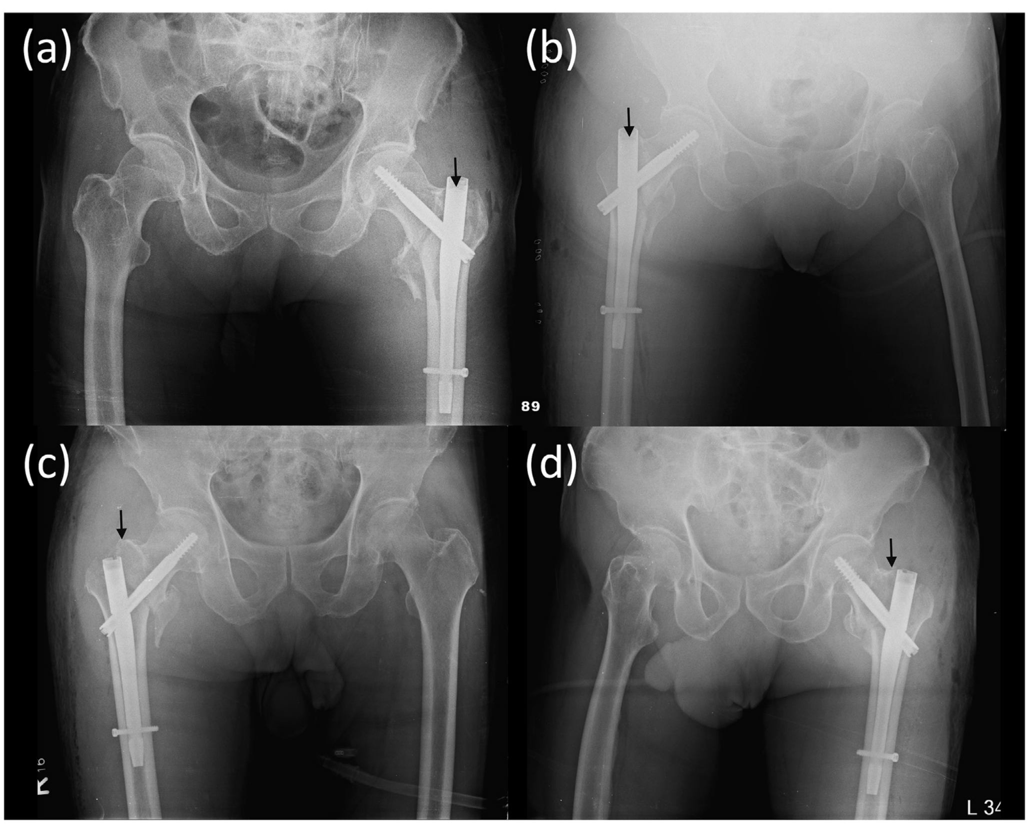

Fig. 2. Demonstration of proper (a, b) and improper (c, d) entry points in the antero-posterior projection; the arrow indicates the ideal entry point in the antero-posterior projection.

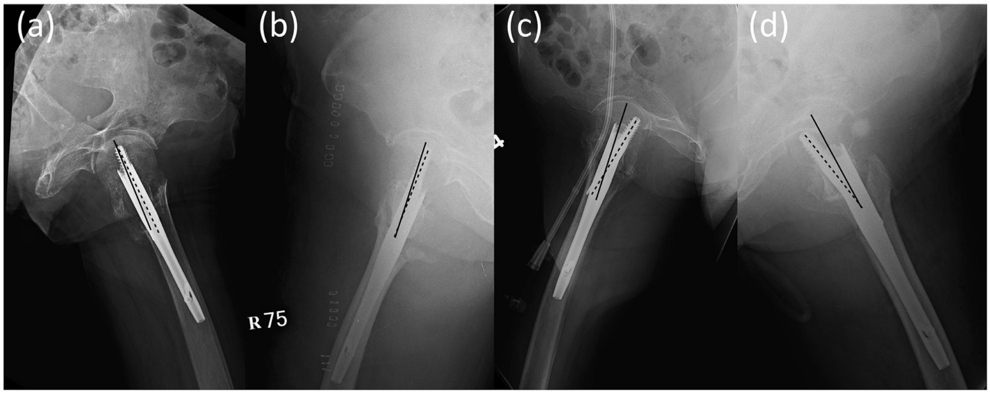

Fig. 3. Demonstration of central screw axis (a, b) and posterior lag screw axis (c, d) in the lateral projection; the solid line and dashed line indicate the femoral neck axis and lag screw axis, respectively.

measured as the greatest distance between fracture fragments perpendicular to the fracture line in both antero-posterior and lateral projections. In the lateral projection, both the femoral shaft axis and femoral neck axis were identified. The distance between these two axes at the fracture site was measured as the posterior displacement distance of the proximal fragment. Posterior displacement of the proximal fragment was recorded when the distance was >10 mm (Figs. 1c and 4). Each radiographic variable was measured twice, by an independent research fellow and a radiologist, on an immediate post-operative radiograph. For continuous variables, these measurements were calibrated for magnification on the basis of the diameter of lag screw (10.5 mm) compared with the projected size on the radiograph. The results were obtained from the mean of all four values measured. Different opinions on the categorical variables were resolved by discussion. The research fellow and the radiologist had not participated in the surgery, and they were both blinded to the results of cut-out failure throughout the study.

Data were entered and analyzed with PC SAS Version 9.4 (SAS Institute, Cary, NC, USA). Data were represented as mean, range, and standard deviation for continuous variables, or number and percentages for categorical variables. The Fisher's exact test was used to compare differences between the two groups for each discrete variable because one or more of the cells in the contingency table has an expected frequency of less than five. The Student's t-test was used to compare the differences between the groups for each continuous variable. Possible risk factors associated with cut-out failures at a significance level of 0.20 or less were considered in a multivariable logistic regression analysis. Backward variable selection method was employed to choose the 'best' model, with the significance test for a risk factor entering and remaining at the significance level of 0.05 in the 'best' model. The results were expressed in an adjusted odds ratio with 95% confidence interval.

3. Results

All 176 patients in this study completed a minimum of 12 months of follow-up after surgery. A total of 22 cut-out failures were recorded at a mean time of 16.0 weeks after surgery (range, 2−68) (Figs. 5 and 6). Patient demographics of the two groups are shown in Table 1. The cut-out group had a greater percentage of women (90.9%), than did the non-cut-out group (54.5%). There were no statistically significant differences between the two groups in age, AO/OTA fracture classification, or medical comorbidities.

Radiographic assessment of the two groups is shown in Table 2. Improper entry point, posterior lag screw axis, and posterior displacement of proximal fragment were more frequently observed in the cut-out group, and this difference was statistically significant. Greater posterior angle between the lag screw and femoral neck axis, fracture gaps in antero-

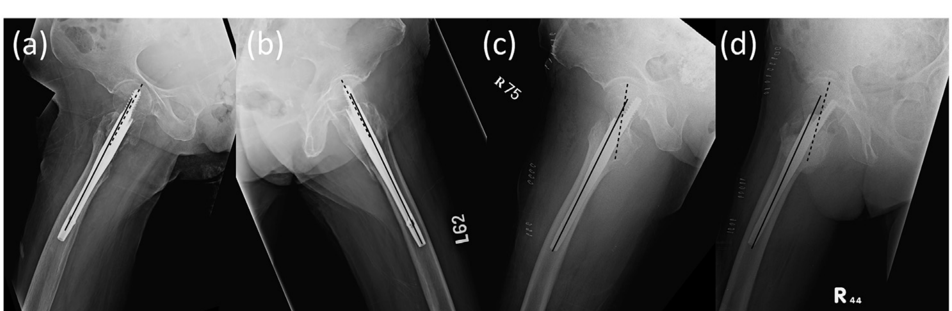

Fig. 4. Demonstration of optimal reduction of proximal fragments (a, b) and fragments with posterior displacement (c, d); the solid line and dashed line indicate the femoral shaft axis and femoral neck axis, respectively.

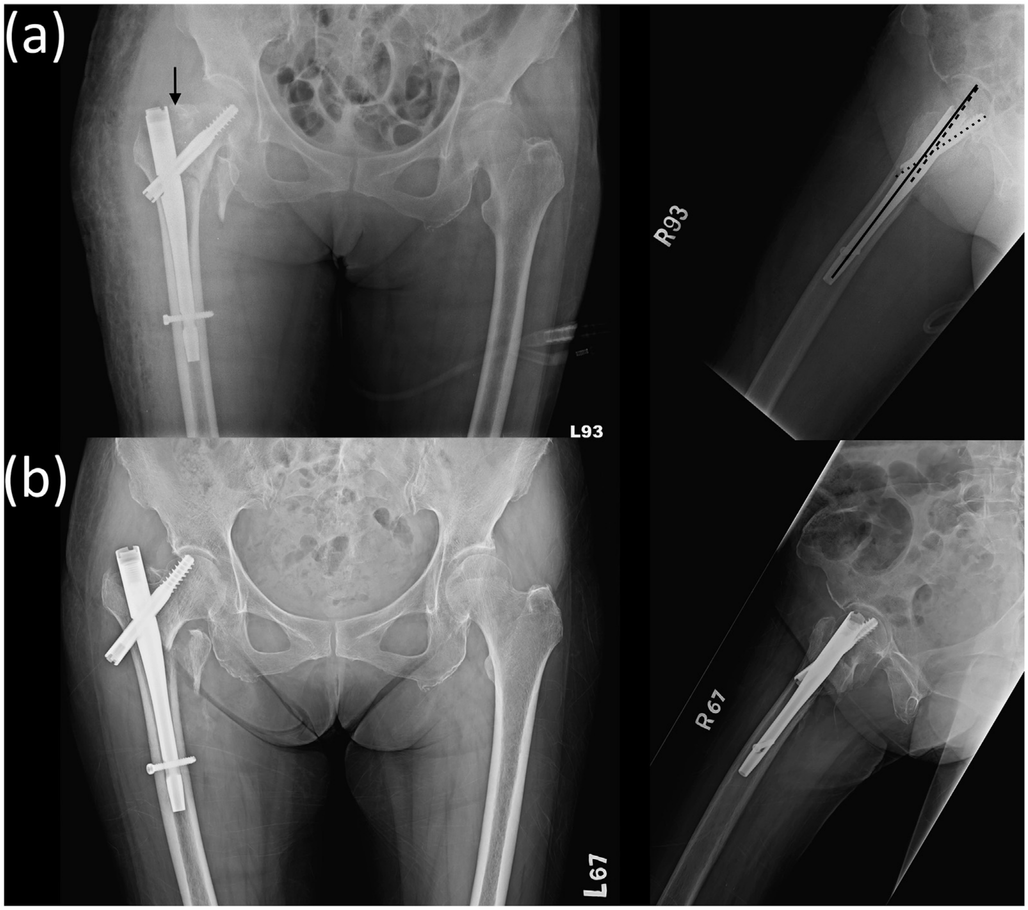

Fig. 5. Case demonstration of a 72 year-old female. (a) Immediate post-operative radiographs, with improper entry point and improper posterior lag screw axis; (b) Cut-out failure after 6 weeks; the arrow indicates the ideal entry point in the antero-posterior projection; the solid line, dashed line, and dotted line indicate the femoral shaft axis, femoral neck axis and lag screw axis, respectively.

posterior and lateral views, and posterior displacement distance of the proximal fragment were found in the cut-out group with a statistically significant difference.

Analysis of risk factors is shown in Table 3 and a multivariate logistic regression model was used. The following factors were significantly related to cut-out failure: improper entry point (adjusted odds ratio: 10.39; range, 1.74−78.40), posterior displacement distance of proximal fragment (adjusted odds ratio: 1.35; range, 1.17−1.59) and female sex (adjusted odds ratio: 17.14; range, 1.88−876.1).

4. Discussion

The main goal of this study was to identify pre-operative and intra-operative risk factors for cut-out failure following insertion of the Gamma3 nail. Multivariate analysis revealed that improper entry point in the antero-posterior projection, posterior displacement distance of the proximal fragment in the lateral projection, and female sex were independent predictors for cut-out failure.

The ideal entry point of the Gamma3 nail is at the tip of or slightly medial to the greater trochanter, which is located posteriorly and laterally to the piriformis fossa. Because fracture lines commonly extend laterally to this point, an improper entry point can arise when the awl is inserted into the fracture gap instead of at the tip of greater trochanter. This can lead to further medialization of the proximal fragment, disruption of Shenton's line during nail insertion, and valgus alignment of the proximal fragment, with a residual medial gap in the antero-posterior projection after compression. Established reduction can be altered during nail insertion into an improper entry point. If a fracture line exists at the entry point, we recommend routine use of a rongeur and a flexible reamer with a ball tipped reaming rod to remove the cortex located anteromedially to the entry point. This step should be repeated until fracture reduction remains unchanged during nail insertion. Ostrum et al. found that an entry point lateral to the tip could lead to angulation and larger gaps.[18] We agree with the author's suggestion that the proper entry point is at the tip or slightly medially.

Anteriorly or posteriorly deviated lag screw position has been reported to be another factor for cut-out failure in several fixation devices.[7,11,19,20] In our study, lag screws were placed more posteriorly in the cut-out group than in the non-cut-out group, in a lateral projection. Mean angle between the lag screw and femoral neck axis in the cut-out group was −16.8° (range, −36 to −4), significantly greater than −5.7° (range, −28 to 14) of the non-cut-out group. However, posterior lag screw

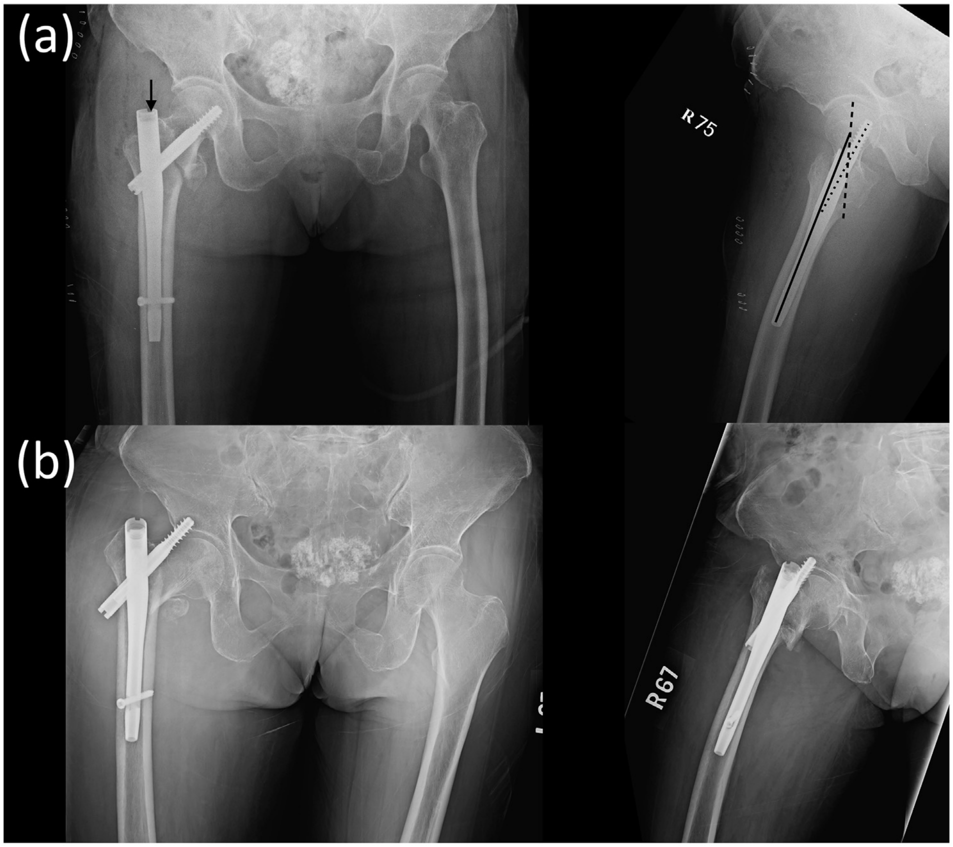

Fig. 6. Case demonstration of a 79 year-old female. (a) Immediate post-operative radiographs, with posterior lag screw axis and posterior displacement of proximal fragment; (b) Cut-out failure after 6 weeks; the arrow indicates the ideal entry point in the antero-posterior projection; the solid line, dashed line and dotted line indicate the femoral shaft axis, femoral neck axis, and lag screw axis, respectively.

axis was not a risk factor for cut-out failure in the multivariate logistic regression model.

In our study, posterior displacement of the proximal fragment represented one of the risk factors for cut-out failure. In a multivariate logistic regression model, every increase of 1 mm in posterior displacement would lead to a 1.35 times increase in risk for cut-out failure. In unstable intertrochanteric fractures, there may be a posterior sagging of proximal fragments. By raising the foot on a fracture-traction table, posterior lifting using closed or open methods might correct this displacement.[21] Another cause of posterior displacement of the proximal fragment is loss of reduction in rotation during insertion of the intramedullary nail or lag screw. A derotation device is not included in the Gamma3 nail system. To prevent loss of reduction in unstable intertrochanteric fractures with significant posteromedial comminution, derotational K-pins can be placed away from the axis of the targeting device and insertion trajectory.

Tip-apex distance (TAD) has been well-studied as a measurement to predict cut-out failure of peri-trochanteric fractures, with a recommendation for a distance of 25 mm or less.[7,13,15,16,20,22] In our practice, we have routinely attempted to optimize TAD in all surgical procedures. The mean TAD was 19.7 mm, much less than 25 mm. This may be the reason why TAD was not found to be a risk factor for cut-out failure in this study.

Sex differences have been reported in proximal femur geometry. With increasing age, factors including femoral shaft bowing, cortical thickness, and canal diameter change to different extents.[23–27] Karakaş et al. found that anterior

Table 1
Patients demographics.

	Non-cut-out group (n = 154)	Cut-out group (n = 22)	*p*
Age (years) (range; SD)	80.4 (60–98; 12.1)	80.8 (70–100; 8.3)	0.894[a]
Sex			
Female	84 (54.5%)	20 (90.9%)	0.001[b]
Male	70 (45.5%)	2 (9.1%)	
AO/OTA fracture classification			
AO 31-A2	124 (80.5%)	19 (86.4%)	0.511[b]
AO 31-A3	30 (19.5%)	3 (13.6%)	
Medical comorbidities			
DM	9 (40.9%)	41 (26.6%)	0.129[b]
HTN	89 (57.8%)	13 (59.1%)	0.549[b]
CVD	16 (10.4%)	4 (18.2%)	0.226[b]
CAD	30 (19.5%)	5 (22.7%)	0.454[b]
COPD	6 (3.9%)	2 (9.1%)	0.262[b]
CKD/ESRD	15 (9.7%)	0 (0%)	0.123[b]

SD, standard deviation; DM, diabetes mellitus; HTN, hypertension; CVD, cerebrovascular disease; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; ESRD, end-stage renal disease.
[a] Student's t test.
[b] Fisher's exact test.

Table 2
Radiographic parameters.

	Non-cut-out group (n = 154)	Cut-out group (n = 22)	p
Improper entry point			
No	137 (89%)	8 (36.4%)	<0.001[b]
Yes	17 (11%)	14 (63.6%)	
Posterior lag screw axis			
No	111 (86.0%)	14 (63.6%)	0.027[b]
Yes	18 (14.0%)	8 (36.4%)	
Angle between the lag screw and femoral neck axis (°) (range; SD)	−5.7 (−28 to 14; 7.8)	−16.8 (−36 to −4; 8.5)	<0.001[a]
Fracture gap, antero-posterior (mm) (range; SD)	4.4 (1.0−11.3; 2.2)	6.1 (2.0−23.5; 4.9)	0.007[a]
Fracture gap, lateral (mm) (range; SD)	5.7 (2.0−31.5; 3.8)	7.7 (2.0−26.1; 6.3)	0.036[a]
Posterior displacement of proximal fragment			
No	114 (87.0%)	8 (36.4%)	<0.001[b]
Yes	17 (13.0%)	14 (63.6%)	
Posterior displacement distance of proximal fragment (mm) (range; SD)	5.0 (1.7−20.0; 3.2)	11.9 (4.4−24.2; 6.1)	<0.001[a]
Tip-apex distance (mm) (range; SD)	19.4 (7.4−43.0; 5.6)	21.4 (12.5−34.1; 6.4)	0.126[a]

SD, standard deviation.
[a] Students' t test.
[b] Fisher's exact test.

bowing increased significantly with age, but only in women.[27] Furthermore, anteversion of the femoral neck was also greater in women.[23] In addition, with increasing age there was a greater difference in loss of net bone mass, bone strength, and trabecular and cortical volumetric bone mineral density in women than in men.[28,29] In our study, female sex was an independent risk factor for cut-out failure. Greater anterior bowing in women might lead to difficulty in insertion of the nail to the proper depth. Thus, during advancement of the nail, the proximal part of the nail might move posteriorly, in line with the trajectory, and push the proximal fragment posteriorly, at the same time. Greater anteversion of the femoral neck may result in a posterior axis of the lag screw. In addition, lower bone mineral density and bone strength in elderly women may affect the mechanical strength of Gamma3 fixation, and lead to cut-out failure.

This study has some limitations. First, a high percentage of patients (37.4%) were excluded because of a follow-up duration less than 12 months. Bias associated with missing data could have occurred to weaken the results. In addition, despite the fact that all 113 of the excluded patients were excluded because of a follow-up duration <12 months, it was observed that all of these patients had an uneventful healing progress, without evidence of cut-out during the last visit. Mean follow-up duration for these patients was 17.3 weeks. The incidence of cut-out failure in our cohort (22 out of 289 patients, 7.6%) was still higher than the incidence reported in the literature.[5−8] Second, we measured fracture gaps in standard antero-posterior and lateral radiographic projections. Computed tomography scan would provide a better method to delineate fracture gaps. Nonetheless, it was not available in this study. Third, to make radiographic assessment reproducibly, we consistently obtained a lateral projection using Lauenstein−Hickey method. However, femoral neck axis and location of the tip of lag screw would be better assessed using the horizontal lateral projection. Moreover, to obtain reproducible, high-quality lateral projection of proximal femur might be difficult even with the use of a single, consistent method. Finally, the sample size of cut-out failure was relatively too small for analysis.

In conclusion, we identified few risk factors for cut-out failure of the Gamma3 nail system, including improper entry point, posterior displacement distance of the proximal fragment, and female sex. This study highlighted the importance of optimal fracture reduction and maintenance during the surgical procedure in the lateral projection. In the lateral projection, posterior displacement of the proximal fragment should be well-recognized and avoided during the whole Gamma3 nail fixation surgical procedure.

Table 3
Risk factors for cut-out failures of gamma 3 nail in multivariate logistic regression analysis.

Factors	Odds ratio	95% Confidence interval	p
Improper entry point	10.39	1.74−78.40	0.007
Posterior displacement distance of proximal fragment	1.35	1.17−1.59	<0.001
Female	17.14	1.88−876.11	0.004

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