

Which factor is most important for occurrence of cutout complications in patients treated with proximal femoral nail antirotation? Retrospective analysis of 298 patients

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Received: 24 June 2015 / Published online: 6 February 2016
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Abstract

Introduction Mechanical complications, such as cut-out of the head-neck fixation device, are the most common causes of morbidity after trochanteric femur fracture treatment. The causes of cut-out complications are well defined in patients who are treated with sliding hip screws and biaxial cephalomedullary nails but there are few reports about the patients who are treated with proximal femoral nail antirotation.

Aim The purpose of this study was to evaluate the most important factor about occurrence of cutout complication and also to evaluate the risks of the combination of each possible factors.

Patients and methods Overallly 298 patients were enrolled in the study. Medical records were reviewed for patients' age, fracture type, gender, anesthesia type and occurrence of cut-out complication. Postoperatively taken radiographs were reviewed for tip-apex distance, obtained collo-diaphyseal angle, the quadrant of the helical blade and Ikuta reduction subgroup. The most important factor (s) and also predicted probability of cut-out complication was calculated for each combination of factors.

Results Cut-out complication was observed in 14 patients (4.7 %). The most important factor about occurrence of the cut-out complication was found as varus reduction (p: 0.01), the second important factor was found as implantation of the helical blade in the improper quadrant (p: 0.02). Tip—apex distance was found as third important factor (p:

0.10). The predicted probability of cut-out complication was calculated as 45.6 % when whole of the four surgeon dependent factors were improperly obtained.

Conclusion Although obtaining proper tip-apex distance is important to prevent cutout complication in these fractures, if the fracture is not reduced in varus position and helical blade is inserted in the proper quadrant, possibility of cut-out complication is very low even in the patients with high tip-apex distance.

Keywords Trochanteric fracture · Cut-out · Proximal femoral nail anti-rotation · Complication

Introduction

Treatment for extracapsular proximal femoral fractures (EPFF) continues to be a matter of concern, especially in elderly patients. The mortality rate in the first year for unstable EPFF is reported to be between 11 and 27 % [1–4]. Mechanical complications, such as cutout of the head-neck fixation device, are the most common causes of morbidity after these fractures. Cutout has been reported to occur in up to 8 % of cases, and to account for 84 % of failures of fixation [5].

Although bone quality and the degree of fracture instability (type) are non-modifiable causes of possible mechanical failure, the treating surgeon can control the quality of reduction and correct placement of the selected implant [6]. Baumgaertner et al. [7] first defined the tip-apex distance (TAD) for EPFF which they had treated with sliding hip screws, and suggested that this should be <25 mm to avoid cutout complications. This theory was found by different authors to be either acceptable [8, 9] or not so important [10–13]. The femoral neck and head were

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divided into nine quadrants, and inserting the head–neck fixation device into center–center or inferior-center quadrants was recommended in order to obtain better mechanical stability [14–16]. The quality of the reduction was also seen as important for mechanical stability in these types of fracture [17, 18].

The Proximal Femoral Nail Antirotation (PFNA) (Synthes GmbH, Oberdorf, Switzerland) is a relatively newly developed implant which uses an impacted helical blade for head–neck fixation. Although there are many reports on the clinical results of sliding hip screws, there are few data in the literature on the factors that are important for mechanical stability with PFNA. Our study questions were whether the TAD was important for PFNA, and were there any other important factors that could be modified by the treating surgeon to avoid cutout complications? We aimed to discover the most important surgeon-dependent factor to prevent cutout complications in patients treated with PFNA, and to calculate the predicted probability of cutout complications for each single factor and each combination of surgeon-dependent factors. The study was approved by the local ethical committee.

Patients and methods

This was a retrospective analysis of 394 patients with a diagnosis of EPFF admitted to a single center between May 2009 and May 2014. The inclusion criteria were patients of any age who were treated with PFNA and who had a minimum follow-up of 6 months. Eight patients had died preoperatively or in the early postoperative phase, four had pathological fractures (metastatic tumors) and 80 had a follow-up time of <6 months. Four patients who had cut-through complications were excluded because all of them had lower than 10 mm of TAD and including these patients into the study was thought to effect the reliability of statistical analysis about TAD adversely. Finally, 298 patients [122 men (40.9 %) and 176 women (59.1 %)] were included in the study. A PFNA design with 130° collodiaphyseal angle (CDA) was used for all patients.

Complete information about the patients was obtained from the hospital's digital database, the Hospital Information System of PROBEL. The patients' age, gender, side of fracture, anesthetic method used, preoperative and postoperative radiographs and follow-up information from the outpatient clinic were evaluated. Radiographic evaluation was performed using the Picture Archiving and Communication System (PACS). Radiographic evaluation included: [1] Preoperatively: fracture type (Orthopedic Trauma Association (OTA) classification) [19]; [2] Postoperatively: obtained CDA, TAD, Cleveland-Bosworth

quadrants [14] and Ikuta reduction subtype [17]. Measurement methods of TAD and CDA, and determination of the quadrants are illustrated in Fig. 1a–e, respectively. Ikuta reduction subgroups were determined on lateral views as follows: if the proximal and distal main fragments were in line, then it was termed subtype N; if the proximal fragment was aligned anteriorly with the distal fragment it was termed subtype A; and conversely, if the proximal fragment was aligned posteriorly with the distal fragment it was termed subtype P. Because of difficulties about taking appropriate lateral radiographs, lateral fluoroscopy views of last intraoperative control were used for measurements for the patients who had not appropriate postoperative lateral radiographs. The patients who had cutout complications were identified from follow-up information and radiographs.

The variables were grouped for statistical analysis as follows:

Age: patients were divided into two groups: < or ≥ 60 years, < or ≥ 70 years and < or ≥ 80 years.

Gender: male/female.

Anesthetic type: spinal or general.

Fracture type: types 31 A1 and 31 A2.1 fractures were accepted as stable, and types 31 A2.2–3 and 31 A3 as unstable [20].

Obtained CDA after the reduction: <130° or $\geq 130^\circ$ [18].

TAD: ≤ 25 or > 25 mm.

Quadrant: center–center and inferior-center quadrants were accepted as proper and the remaining quadrants were accepted as improper [15, 16].

Ikuta reduction subgroup [17]: Ikuta subtype N was accepted as proper and subtypes A and P were accepted as improper.

All of the procedures were performed in the lateral decubitus position without a traction table by 12 different orthopedic surgeons. Patients received antibiotic prophylaxis [cefazolin sodium (Sefazol), Mustafa Nevzat İlaç Sanayi/Istanbul] for 24 h and anticoagulant prophylaxis (enoxaparin sodium (Clexane), Sanofi/Istanbul) for 30 days postoperatively. In the first 6 weeks patients were allowed either partial weight-bearing using crutches or no weight-bearing, based on intra-operative achieved stability and postoperative radiographic findings. Patients who were not allowed weight-bearing (inappropriate TAD quadrant or varus reduction) were mobilized with a walker.

Statistical analysis

SPSS version 17 for Windows was used for statistical analysis. The Mann–Whitney *U* test was used to compare continuous data. Univariate analysis was performed with

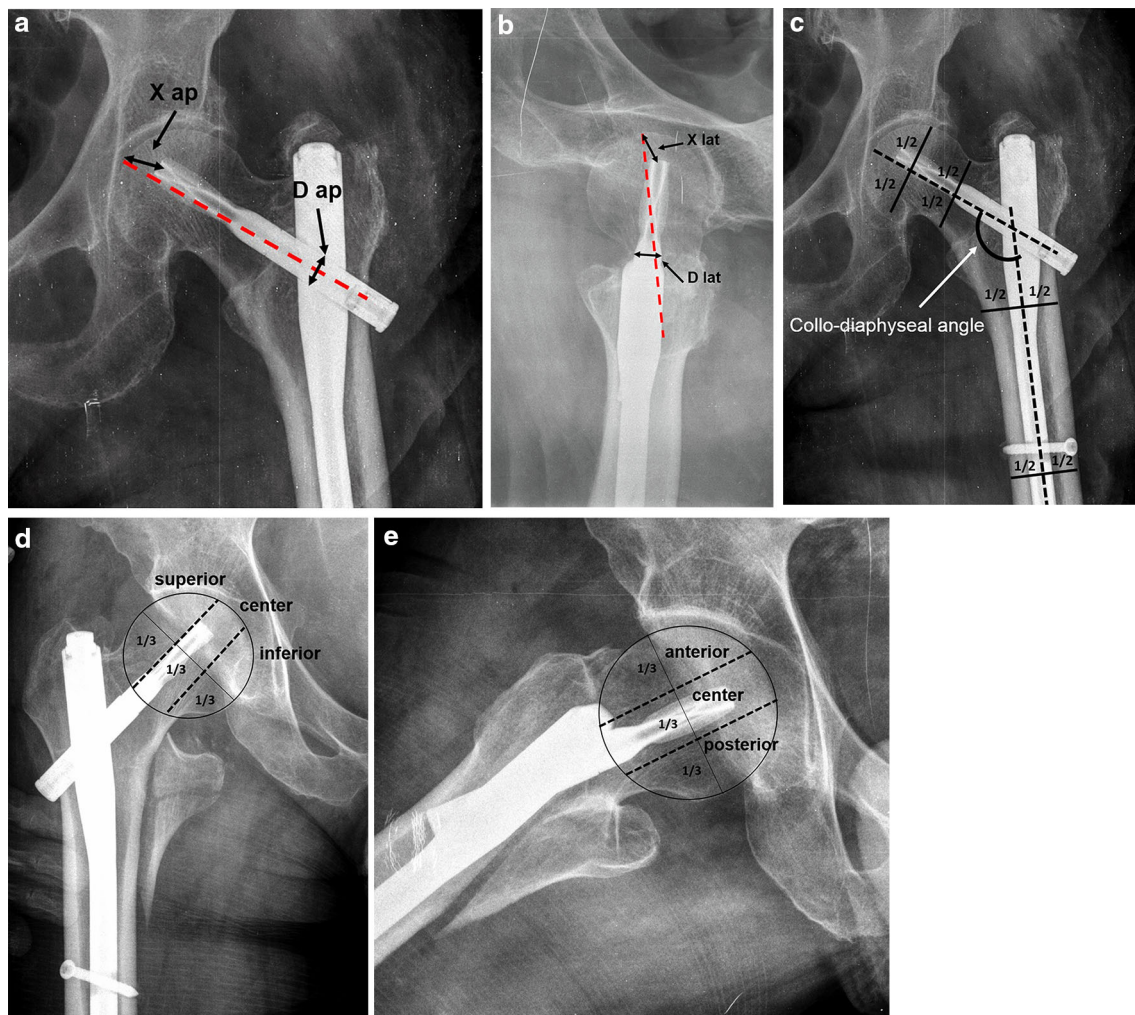


Fig. 1 Measurement methods of TAD (a, b), CDA (c) and determination of the quadrants (d, e). $TAD [X_{ap} \times (D_{true}/D_{ap})] + (X_{lat} \times (D_{true}/D_{lat}))$ (D_{true} known true diameter of the helical blade)

Pearson's Chi squared test. Comparison was made between the groups in which cutout complications had occurred and those in which they had not. After that, multiple logistic regression analysis was performed to identify independent clinical predictors for cutout. After performing a likelihood ratio Chi squared test, four variables with the smallest p value (all of which were surgeon-dependent factors) were chosen for the multivariate model. The regression model fit was estimated with the Hosmer–Lemeshow goodness-of-fit test. Adjusted odds ratios (OR) and 95 % confidence intervals (CI) were derived using the method of maximum likelihood, and the probability of cutout complications was evaluated for each combination of predictors as performed by Kocher et al. [21]. Also, the relationship between increasing numbers of the predictors and the occurrence of cutout complications was determined using the multiple logistic regression test. $P < 0.05$ was accepted as being statistically significant.

Results

The mean age of the patients was 74.9 years (20–101; SD 14.5) and 150 (50.3 %) of the fractures were on the right side. Cutout complications were observed in 14 patients (4.7 %). The mean time to recognition of cutout complications was 5.2 weeks (0–10; SD 3.9), and the mean follow-up time of the remaining 284 patients was 20.3 months (6–46; SD 10.9). The mean TAD and percentages of cutout complications for each quadrant are shown in Fig. 2.

After performing the Mann–Whitney U test a statistically significant difference between the two groups was seen (cutout complications either did or did not occur) for both TAD and obtained CDA ($p < 0.01$, $p < 0.01$, respectively) (Table 1).

There was statistically significant difference between the groups for CDA, TAD and inserted quadrant as a result of Pearson's Chi squared test ($p = 0.001$, $p = 0.002$ and

$p = 0.005$, respectively) (Table 2). Statistical analysis of Ikuta reduction subgroup showed almost statistical significance ($p = 0.056$) (Table 2). The logistic regression test showed that obtained CDA $<130^\circ$ was the strongest factor

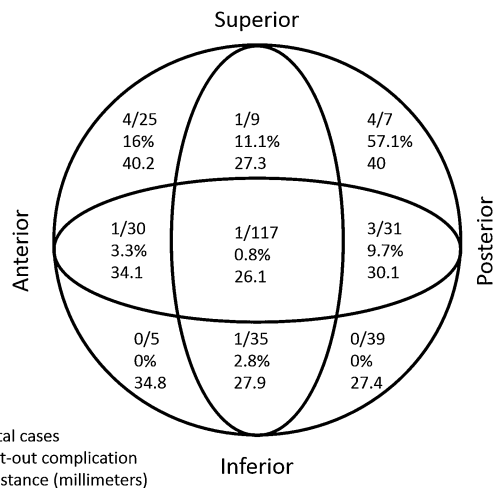


Fig. 2 Percentage of cut-out complication and mean tip apex distance (millimeters) for each quadrant

for cutout complications ($p = 0.01$, OR 4.76); the second most important factor was implantation in the improper quadrant ($p = 0.02$, OR 6.18) (Table 3). The four variables with the smallest p -value were; obtained CDA, implanted quadrant, Ikuta reduction subgroup and TAD. The predicted probability of cutout complications occurring for these four variables in our patient group is given in Table 4. If all four predictors (variables) were present the predicted probability was calculated to be 45.5 % (Table 5).

Discussion

Mechanical failure is one of the main concerns of physicians treating proximal femoral fractures. It is important to avoid this kind of complication in order to minimize the morbidity of these injuries. The most common type of mechanical failure has been reported to be cutout of the neck–head fixation device (screw, blade, etc.) from the femoral head [5, 22]. In the recent literature various studies [23–30] have evaluated the factors thought to be important

Table 1 Comparison of the two groups which cut-out complication was observed and not-observed

Variable	Cut-out group ($n:14$) mean \pm standard deviation (minimum–maximum)	Healed group ($n:284$) mean \pm standard deviation (minimum–maximum)	p value ^a
Age (years)	77.1 \pm 7.6 (64–88)	74.8 \pm 14.8 (20–101)	0.87
Tip-apex distance (millimeters)	43.1 \pm 11.2 (25–58)	28.7 \pm 10.6 (4–64)	<0.01
Collodiaphyseal angle ($^\circ$)	125.6 \pm 9.3 (110–140)	133.5 \pm 6.9 (114–151)	<0.01

Bold values indicate statistical significance

^a Mann–Whitney U test

Table 2 Comparison of the variables for the patients with and without cut-out complication

Variable	Cut-out complication group (n/n)	Healed group (n/n)	p value ^a
Number of patients	14	284	
Age (≥ 60 / <60)	14/0	244/40	0.13
Age (≥ 70 / <70)	11/3	210/74	0.69
Age (≥ 80 / <80)	5/9	142/142	0.29
Sex (male/female)	5/9	117/167	0.68
Anesthesia (spinal/general)	12/2	248/36	0.86
Fracture type (stable/unstable)	6/8	114/170	0.84
Obtained CDA ($\geq 130^\circ$ / $<130^\circ$)	7/7	242/42	0.001
TAD (>25 mm/ ≤ 25 mm)	13/1	145/139	0.002
Quadrant (central–central or inferior–central/the others)	2/12	150/134	0.005
Ikuta reduction subgroup (normal/anterior–posterior)	8/6	224/60	0.056

Bold values indicate statistical significance

CDA collodiaphyseal angle, TAD tip-apex distance

^a Pearson’s Chi squared test

Table 3 Odds ratios and *p* values of most important factors about cut-out complication as a result of logistic regression test

	Odds ratio	95 % CI	<i>p</i> value
Obtained collodiaphyseal angle below than 130°	4.76	1.46–15.54	0.01
Tip-apex distance upper than 25 mm	5.86	0.70–48.60	0.10
Improper quadrant	6.18	1.27–30.05	0.02
Non-normal Ikuta subgroup	2.60	0.78–8.63	0.11

Table 4 Predicted probability of cut-out complication

Obtained collodiaphyseal angle <130°	Tip-apex Distance ≥25 mm	Improper quadrant (non central–central or inferior-central)	Ikuta subgroup anterior or posterior	Predicted probability of cut-out complication (%)
No	No	No	No	0.1
No	No	No	Yes	0.4
Yes	No	No	No	1.0
No	Yes	No	No	1.0
No	No	Yes	No	1.1
Yes	No	No	Yes	2.3
No	Yes	No	Yes	2.7
No	No	Yes	Yes	2.9
Yes	Yes	No	No	4.9
Yes	No	Yes	No	5.2
No	Yes	Yes	No	6.3
Yes	Yes	No	Yes	11.9
No	Yes	Yes	Yes	14.9
Yes	Yes	Yes	No	24.3
Yes	Yes	Yes	Yes	45.6

Table 5 Distribution of number of predictors and algorithm for the predicted probability of cut-out complication

Number of predictors ^a	Cut-out (<i>n</i> :14)	Healed without cut-out (<i>n</i> :284)	Predicted probability of cut-out complication (%)
0	0	66	0.1
1	2	94	0.9
2	4	87	5.1
3	4	35	18.6
4	4	2	45.5

^a Predictors are: 1 tip-apex distance >25 mm, 2 quadrant other than central–central or inferior central, 3 collodiaphyseal angle <130°, 4 ikuta subgroup anterior or posterior

in avoiding cutout complications. PFNA is a new-generation implant designed to achieve greater stability in the treatment of these fractures. Our aim was to evaluate the predictive factors for cutout complications in patients treated with PFNA. Our analysis showed that the most important factors to avoid cutout complications were a CDA $\geq 130^\circ$ and insertion of the helical blade into center–center or inferior-center quadrants. A TAD ≤ 25 mm was found to be less important than the above-mentioned factors. If the fracture is reduced in varus position obtained TAD and the quadrant of the fixed angled helical blade are improper in most cases (Fig. 3).

Our study demonstrates that obtaining a CDA $\geq 130^\circ$ is the most important factor in avoiding cutout complications ($p = 0.001$, Chi squared test) ($p = 0.01$, OR 4.76, logistic regression analysis; Tables 2 and 3). As we used a device with a CDA of 130° , we tried to avoid varus reduction because of both the possible scissoring force, which could affect the fracture, and the probability of inserting the helical blade into an improper quadrant (superiorly). Avoiding varus reduction is well known to prevent mechanical complications in these injuries [18, 22, 23, 25]. In addition, a slight valgus reduction is recommended [25]. Reduction of the fracture in the axial plane is also found to

Fig. 3 **a** AO/OTA type A2.1 trochanteric femur fracture. **b**, **c** Fracture is reduced in varus position and the helical blade is in superior-central quadrants. **d** Cut-out complication at 8 weeks postoperatively



be important in preventing mechanical complications [17]. In our study group 6 of the 66 patients in whom Ikuta subtype anterior or posterior reduction had been obtained had cutout complications, whereas 8 of 232 patients with Ikuta subtype normal reductions encountered this complication (Tables 2 and 3).

The optimal position for the head–neck fixation device has been recommended by many authors as center–center or inferior–center [7, 10, 11, 14–16, 31, 32]. Inferoanterior [31] or inferoposterior quadrants were also recommended [22, 33]. In our patient group the fewest cutout occurrences were noted in the inferoposterior, inferoanterior, center–center and inferior–central quadrants, respectively (Fig. 1). These results were compatible with the literature. Kane et al. [10], Goffin et al. [11] and Herman et al. [18] stated that correct positioning of the head–neck fixation device was one of the most important factors in avoiding mechanical failure: our study has demonstrated similar findings. Inserting the helical blade into the proper quadrant was the second most important factor to prevent cutout complications in our study (Table 3). Our study also showed that center–center, inferior–center and inferoposterior quadrants were safe.

The TAD theory was originally developed in 1995, and it was stated that values <25 mm were useful in predicting cutout in patients who were treated with sliding hip screws [7, 9, 22, 25]. The importance of TAD for intramedullary devices is unclear in the English literature. Geller et al. [27], Rubio-Avila et al. [8] and Lobo-Escolar et al. [24] have reported a strong relationship between TAD and cutout complications in patients treated with intramedullary devices, but in very recent studies Kane et al. [10], Mingo-Robinet et al. [13] and Herman et al. [18] stated that TAD was not the main factor in preventing cutout. There are two studies that deal with TAD and cutout in patients treated with PFNA [29, 34]. Nikoloski et al. [29] recommended that TAD should be between 20 and 30 mm, and Kraus et al. [34] stated that they had not documented any cutout if TAD was <30 mm. In our study group there were 62 patients with TAD <20 mm and cut-through complications were observed in four of them (6.8 %). These four patients were excluded from the study because the cut-through mechanism was thought to be different from that of cutout. Cutout was observed in four of 131 (3.1 %) patients with TAD of 20–30 mm and also in 10 of 109 (9.1 %) patients with TAD >30 mm. These results were

statistically significant ($p = 0.01$, Chi squared test). When we grouped the patients as having TAD ≤ 25 or >25 mm, there was again a statistically significant difference with regard to the occurrence of cutout complications (Tables 2, 3). Our logistic regression analysis showed TAD to be the third most important factor for the occurrence of cutout complications (Table 3).

Unstable fracture type and advanced patient age have been reported as being important factors in the occurrence of mechanical complications, for both sliding hip screws and biaxial intramedullary nails [23, 30]. Nikoloski et al. [29] reported that all 6 of their patients with cutout complications had unstable fractures treated with PFNA. Our findings are different from these reports: in our study group we observed that advanced age and instability of the fracture were not statistically important for the development of cutout complications.

The first prerequisite for successful osteosynthesis is to obtain a good reduction in these type of fractures. One should make every effort to achieve an ideal reduction prior to implantation of the helical blade. Closed, mini-open or open methods can be used for this effort. After achieving a good reduction, position of the guide wire of the helical blade can be changed by either impacting-distracting or rotating the nail. If the reduction and/or helical blade position is not optimum after implantation of the hardware, it is not feasible to extract the helical blade and correct the blade position or reduction because of the limited bone stock of the femoral head. In this case, delaying the time to weight-bearing or augmenting the helical blade with bone cement can be a good alternative. Bone cement augmentation might enhance the implant anchorage within the head-neck fragment and as a result can reduce the risk of occurrence of cutout complication [35, 36].

With regard to the predicted probability of cutout complications occurring in the presence of improperly obtained surgeon-dependent factor/factors, the importance of both implantation of the helical blade in the recommended quadrants and avoiding varus reduction can be confirmed (Table 4). Even in cases where we could not provide all of the surgeon-dependent factors correctly, cutout complications did not occur (Table 5). We believe that there are other factors as yet unknown regarding these kinds of fracture treatment outcomes.

This study has some limitations. First, it was a retrospective study concerned particularly with surgeon-dependent factors to avoid cutout complications. One of the most important factors here is bone quality, but this was not assessed in this study. This is one of the drawbacks of retrospectively designed studies, and bone mineral density tests should be performed as standard. Fracture reduction was performed without a fracture table in all cases, thus the risk of varus reduction could have been influenced

negatively. The follow-up period was relatively short and patients were not contacted, thus there might have been further complications that were not included in the study.

In conclusion, this study has demonstrated that surgeon-dependent factors such as proper reduction and implantation are important for complication-free healing of EPPFs. In our study group, the most important factor to prevent cutout complications was found to be the avoidance of varus reduction. Our findings showed that avoiding varus reduction and implantation of the helical blade in center-center or inferior-center quadrants are mandatory to reduce cutout complication risk. Further studies with larger populations of patients with more cutout complications may be more reliable for calculating the predicted probability of cutout complications with combination of the variables. The treatment of these fractures will continue to draw attention in the orthopedic literature.

Compliance with ethical standards

Conflict of interest All of the authors declare that they have no conflict of interest.

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