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Implant cut-out following cephalomedullary nailing of intertrochanteric femur fractures: Are helical blades to blame?

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ABSTRACT

Introduction: Implant cut-out remains a common cause of cephalomedullary nail (CMN) failure and patient morbidity following surgical treatment of intertrochanteric femur fractures. Recent studies have suggested an increased rate of CMN cut-out with helical blades as opposed to lag screws. We compared rates of overall cut-out between helical blades and lag screws and used bivariate and multivariate analysis to determine the role of proximal fixation method among other variables on risk for cut-out. Subgroup analysis was performed on the basis of failure mechanism; superior migration (Fig. 2) versus medial perforation (Fig. 3).

Methods: Three-hundred and thirteen patient charts were retrospectively reviewed over an 8-year period; 245 patients were treated with helical blades and 68 with lag screws. Radiographs were reviewed for fracture pattern, Tip-Apex Distance (TAD), Parker's Ratio (PR) and reduction quality. Rate of implant cut-out was compared between groups and multiple logistic regression was used to analyze the ability of several independent variables to predict implant cut-out.

Results: Twenty cut-outs occurred; 15 with helical blades and 5 with lag screws. No difference in the rate of cut-out was observed between the two groups ($p = 0.45$). Poor fracture reduction was found to be a significant predictor of implant failure via bivariate and multiple logistic regression analysis ($p = <0.01$, OR 23.573). Helical blade fixation, fracture instability, $TAD \geq 25$, and $PR \geq 0.45$ were not predictive of implant cut-out during multivariate analysis. Similarly, patient smoking status and surgeon trauma fellowship training did not significantly increase the odds of implant cut-out. Failure by medial perforation occurred in 12 instances, all involving helical blades. Failure by superior migration occurred at a significantly higher rate with lag screws than helical blades ($p = 0.02$).

Conclusion: CMN cutout is likely multifactorial. A direct association between helical blade fixation and implant cut-out was not observed in our study. Amongst modifiable risk factors for implant failure, poorer fracture reduction was predictive of failure by cut-out. Subgroup analysis highlights differing modes of failure between lag screws and helical blades which warrants further investigation. Ideal TAD during helical blade fixation remains unknown.

Introduction

Intertrochanteric femur fractures are among the most frequent injuries treated by orthopedic surgeons. As the population ages, the number of hip fractures treated each year is expected to increase significantly [1]. Surgical stabilization is standard of care, facilitating patient mobilization and return to weight-bearing. In recent years, the fixation device of choice has shifted away from sliding compression screws toward cephalomedullary nails (CMNs), due, in-part, to improved stability in unstable fracture patterns and increased surgical training in this technique during residency [2]. Despite this, implant cut-out continues to be a source of morbidity following treatment of intertrochanteric femur fractures [3].

The helical blade is a feature design of contemporary CMNs, thought to achieve superior stability over traditional lag screws through compaction of cancellous bone [4]. Both options for

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proximal fixation are available in the Trochanteric Fixation Nail (TFN) System (Depuy Synthes, Raynham, MA), with choice of implant relegating to surgeon preference or institutional norms. A recent study by Stern et al. suggested a higher rate of cut-out in fractures fixed with helical blades as opposed to lag screws [5]. The purpose of this study was to review our institution's experience with cephalomedullary fixation of low energy intertrochanteric hip fractures to compare rates of implant cut-out between CMNs fixed proximally with helical blades versus lag screws. We hypothesized that helical blades would be associated with higher rates of cut-out in our study population. Tip-Apex Distance (TAD), Parker's Ratio (PR), fracture reduction quality, as well as patient and surgeon-related factors were also evaluated for their ability to predict cut-out. Subgroup analysis was performed on the basis of mechanism of cut-out, being classic superior migration versus medial perforation [3,6].

Methods

Following institutional review board approval, we performed a retrospective review of all patients undergoing cephalomedullary nail fixation at our academic medical center between January 1, 2009 and December 30, 2017. Patients were identified via database query for CPT code 27,245 (open treatment of an intertrochanteric, peritrochanteric, or subtrochanteric femur fracture with intramedullary implant). Patients 55 years or older sustaining a low-energy intertrochanteric fracture were included. Patients suffering periprosthetic fractures, pathologic fractures, and subtrochanteric fractures were excluded. A minimum follow-up period of 3 months was utilized similar to previous studies [5,7].

Patient charts were reviewed for demographic details, mechanism of injury, and smoking status. Time to surgery and time to fracture healing or implant failure was determined for each patient. Procedure details including method of proximal fixation (helical blade vs lag screw), implant manufacturer, and implant dimensions were collected from each patient's surgical record. Fracture patterns were classified according to the revised AO/OTA classification system for proximal femur fractures and further subgrouped as "stable" (31A1) or "unstable" (31A2, 31A3) [8].

Radiographic measurements were completed on digital radiographs utilizing a universal pixel-based measurement software [9]. Tip-Apex Distance (TAD) and Parker's Ratio (PR) were measured on final intraoperative fluoroscopy images as described by Baumgaetner et al. and Parker et al. respectively [7,10]. A fracture reduction grade was scored for each case based on a modification of the criteria proposed by Baumgaetner et al. [7]. Fractures were graded as "good," "acceptable" or "poor" based on three radiographic criteria, each earning one point, as judged on the final fluoroscopic films. These were (1) alignment on the AP film in which a point was awarded for anatomic or valgus alignment, (2) neutral alignment on the lateral film, and (3) absence of displacement > 4 mm on either view with the exception of a displaced lesser trochanter fragment. All measurements were made by a single investigator.

All statistical analyses were performed with SPSS version 23 (IBM Corporation, Armonk, NY). The treatment groups (helical

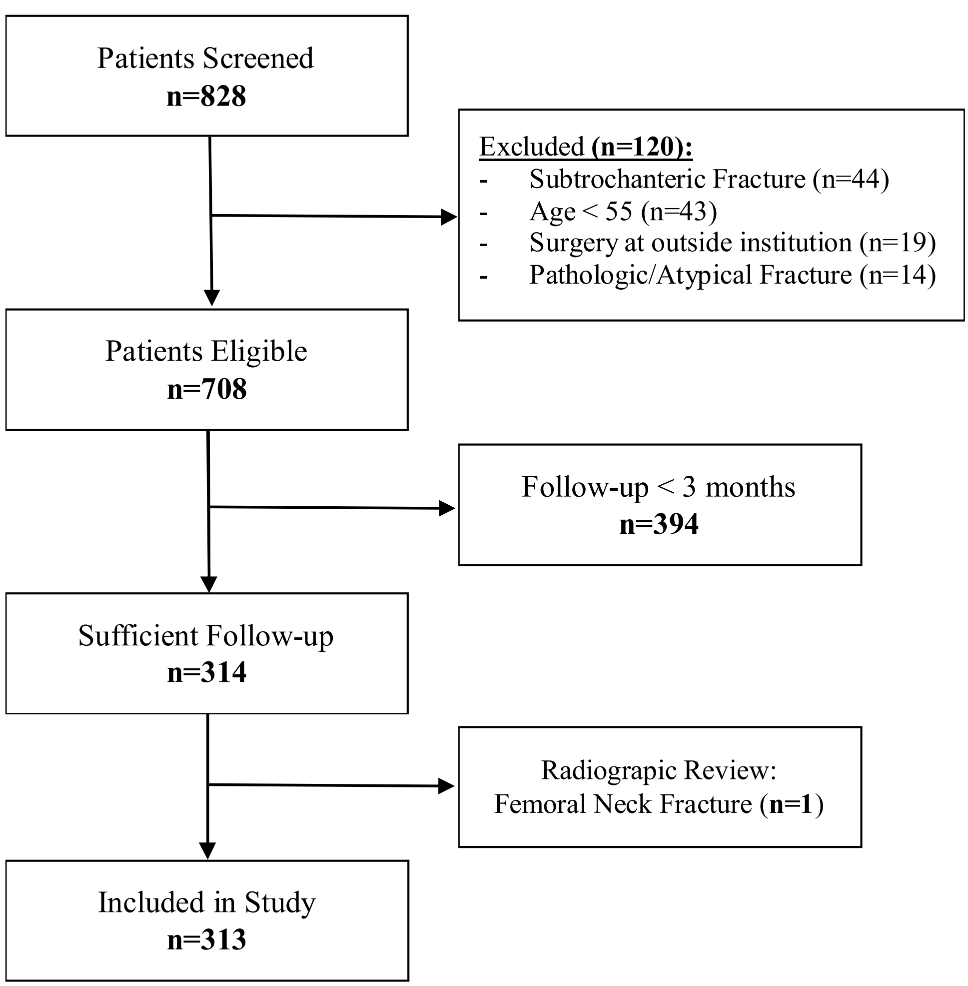

Fig. 1. Flowchart depicting patient selection process.

blade versus lag screw) were analyzed for statistical similarity utilizing Student's t-test and Chi-square analysis. Difference in cut-out rate between the two groups was determined by Fisher's exact test. Bivariate analysis of independent variables and failure by cut-out was performed via chi-square analysis. Previously defined cutoff values of 25 for TAD and 0.45 for PR were utilized [7,10]. Finally, multiple logistic regression was used to analyze the ability of the independent variables to predict implant cut-out.

Results

In total, 828 consecutive patients underwent CMN fixation of peritrochanteric femur fractures during the study period. Seven hundred and eight patients met inclusion criteria of which 314 (45.0%) ultimately had adequate clinical and radiographic follow-up (Fig. 1). One patient, in which implant failure occurred, was subsequently excluded after radiographic review revealed a basicervical fracture pattern. The final study population included 233 females and 80 males with average patient age of 80.3 years. Average follow-up was 9.3 (range, 3.0–65.7 months). Ground-level falls were the most frequent mechanism of injury. Seventy-three patients (23.3%) had a documented history of osteoporosis. Two hundred and six fractures were stable while 107 fractures were unstable. Two hundred and forty-five patients underwent repair with helical blades versus 68 with lag screws. The vast majority were repaired with Trochanteric Fixation Nails (TFN, DePuy Synthes, Raynham, MA). Only 11 patients were treated with Gamma Nails (Stryker, Kalamazoo, MI). There was no significant difference in demographic details, smoking history, implant dimensions, or proportion of stable and unstable fractures between the two groups (Table 1). A higher proportion of patients treated with lag screws had a prior diagnosis of osteoporosis ($p = 0.045$).

Fig. 2. Helical blade failure by superior migration.

Fig. 3. Helical blade failure by medial perforation.

Table 1
Comparison of treatment groups.

	Helical Blade (245)	Lag Screw (68)	*p*
Age, mean	81.0	77.7	0.13
Gender			0.67
Male, n (%)	181 (73.8)	52 (76.5)	
Female, n (%)	64 (26.2)	16 (23.5)	
Active Smoker			0.15
No, n (%)	227 (92.7)	66 (97.1)	
Yes, n (%)	18 (7.3)	2 (2.9)	
Fracture Pattern			0.83
Stable, n (%)	162 (66.1)	44 (64.7)	
Unstable, n (%)	83 (33.9)	24 (35.3)	
Implant Length			0.45
Short, n (%)	169 (69.0)	52 (76.5)	
Intermediate, n (%)	3 (1.2)	1 (1.5)	
Long, n (%)	73 (29.8)	15 (22.0)	
Outcome			0.45
Cut-out, n (%)	15 (6.1)	5 (7.4)	
Healed, n (%)	230 (93.9)	63 (92.6)	

A total of 20 cut-outs occurred (6.4%) of which 15 were with blades (6.1%) and 5 were with screws (7.4%). Average time to cut-out was 53.6 days. No significant difference in the rate of cut-out was observed between the two groups ($p = 0.45$). Similarly, no difference in cut-out was observed when analysis was limited to

Table 2
Cut-out, TFN only.

	Helical Blade (245)	Lag Screw (57)	*p*
Cut-out, n (%)	15 (6.1)	4 (7.0)	0.50
Healed, n (%)	230 (93.9)	53 (93.0)	

Table 3
Bivariate analysis of failure by cut-out.

	Healed (293)	Failed (20)	*p*
Age			0.24
<80 years, n (%)	120 (41.0)	6 (30.0)	
≥80 years, n (%)	173 (59.0)	14 (70.0)	
Gender			0.39
Male, n (%)	76 (26.0)	4 (20.0)	
Female, n (%)	217 (74.0)	16 (80.0)	
Osteoporosis			0.16
Prior Diagnosis, n (%)	66 (22.5)	7 (35.0)	
No Prior Diagnosis, n (%)	227 (77.5)	13 (65.0)	
Fracture Type			0.26
Stable, n (%)	191 (65.2)	15 (75.0)	
Unstable, n (%)	102 (34.8)	5 (25.0)	
Proximal Fixation			0.45
Helical Blade, n (%)	230 (78.5)	15 (75.0)	
Lag Screw, n (%)	63 (21.5)	5 (25.0)	
Implant Length			0.82
Short, n (%)	206 (70.3)	15 (75.0)	
Intermediate, n (%)	4 (1.4)	0 (0.0)	
Long, n (%)	83 (28.3)	5 (25.0)	
Parker's Ratio			0.24
<0.45, n (%)	61(20.8)	6 (30.0)	
≥0.45, n (%)	232 (79.2)	14 (70.0)	
Tip-Apex Distance			0.22
<25, n (%)	207 (70.6)	12 (60.0)	
≥25, n (%)	86 (29.4)	8 (40.0)	
Fracture Reduction			<0.01
Good or Acceptable, n (%)	286 (97.6)	14 (70.0)	
Poor, n (%)	7 (2.4)	6 (30.0)	
Surgeon Trauma Experience			0.051
Fellowship Trained, n (%)	254 (86.7)	14 (70.0)	
Not Fellowship Trained, n (%)	39 (13.3)	6 (30.0)	

Table 4
Multiple logistic regression analysis.

	Odds Ratio	95% CI	*p*
Age			
≥80 vs. < 80	0.660	0.218 – 2.000	0.46
Gender			
Female vs Male	0.776	0.211 – 2.849	0.70
Osteoporosis			
Prior Dx vs No Prior Dx	1.239	0.392 – 3.915	0.72
Fracture Type			
Stable vs Unstable	3.130	0.859 – 11.406	0.08
Proximal Fixation			
Helical Blade vs Lag Screw	1.188	0.338 – 4.169	0.79
Tip-Apex Distance			
≥25 vs <25	0.925	0.301 – 2.841	0.89
Parker's Ratio			
≥0.45 vs <0.45	1.935	0.621 – 6.035	0.26
Fracture Reduction			
Good/Acceptable vs Poor	23.537	5.374 – 102.995	<0.01
Surgeon Trauma Experience			
Fellowship vs No Fellowship	2.713	0.816 – 9.016	0.10

Table 5
Cut-out by superior migration only.

	Helical Blade (233)	Lag Screw (68)	*p*
Cut-out, n (%)	3 (1.3)	5 (7.4)	0.02
Healed, n (%)	230 (98.7)	63 (92.6)	

patients repaired with TFNs only (p = 0.50, Table 2). The proportion of stable versus unstable fractures did not differ significantly between patients that experienced cut-out versus those who healed uneventfully. Similarly, no significant difference in TAD or PR was observed between those who failed and those who healed uneventfully. Poor fracture reduction was found to be a significant predictor of implant failure via bivariate and multiple logistic regression analysis (p = <0.01, OR 23.573; Table 3 and Table 4). Helical blade repair, fracture instability, TAD, and PR were not predictive of implant cut-out during multivariate analysis. Similarly, smoking status and surgeon trauma fellowship training did not significantly increase the odds of implant cut-out, although the influence of trauma fellowship training did approach statistical significance (Table 4).

Failure occurred via medial perforation without loss of reduction in 12 cases, all helical blades, and superior migration in 8 cases. When the 12 cases failing by medial perforation were omitted from analysis, the lag screw group exhibited a significantly higher rate of failure by superior migration than the helical blade group (Table 5, p = 0.02). Mean TAD did not differ significantly between those failing by superior migration (23.6) and those that progressed to heal without complication (21.9, p = 0.14). Mean PR, however, was significantly higher in those patients who failed by superior migration (0.56 vs 0.49; p = 0.01).

Discussion

Implant cut-out remains a common cause of CMN failure and patient morbidity following surgical treatment of intertrochanteric femur fractures. Recent studies have suggested an increased rate of CMN cutout with helical blades as opposed to lag screws [5]. We compared rates of cut-out between helical blades and lag screws and used bivariate and multivariate analysis to determine the influence of proximal fixation method among other variables on risk for cut-out. We observed no difference in the rate of cut-out between fractures repaired with helical blades compared to those repaired with lag screws. We observed a significant relationship between fracture reduction quality and implant failure with poorer fracture reductions associated with increased rates of cut-out.

Our study had a few limitations. First, the retrospective nature of the study exposes our conclusions to the familiar risk of selection bias. Additionally, patient charts and imaging were retrospectively reviewed by a single investigator. Furthermore, the rate of loss to follow up was high with only 45.0% of eligible patients satisfying the minimum follow up requirement of 3 months. Follow up patterns in our study, however, were comparable to earlier studies involving the patient population in question [7]. Nonetheless, a substantial number of patients experiencing implant cut-out may have been missed. Specific strengths of this study include the relatively high number of patients and additional measures made to minimize confounding. Multiple previously studied predictors of implant failure including TAD, PR and fracture reduction quality were simultaneously evaluated alongside the main comparison variables through multivariate analysis. Additionally, patient related factors and surgeon trauma fellowship training were also included as independent variables for implant failure.

Contrary to our hypothesis, a significant difference in cut-out rates between helical blades and lag screws was not observed. Similarly, helical blade fixation was not identified as a significant predictor of implant cut-out during multivariate analysis. Our findings differ from recent reports by Stern et al who observed a significantly higher rate of cut-out in intertrochanteric fractures fixed proximally with helical blades. Interestingly, the 15.1% rate of helical blade cut-out observed by Stern and colleagues is considerably higher than the rate of helical blade cut-out in our series (6.5%) as well as rates in previously published studies. In early results of 97 patients treated with helical blades, Gardner et al observed an overall cut-out rate of 5.2%. Similarly, Liu et al reported a cut-out rate of 6.7% in 223 patients fixed with helical blades while Nikoloski et al reported a rate of 6.2% in 178 patients treated with helical blades [6]. Additionally, Turgut et al observed a cut-out rate of just 4.7% in 298 patients treated with Proximal Femoral Antirotation Nails (PFNA) [11]. The reason for this discrepancy is unclear, but may be due to the fact that fracture reduction quality was not examined by Stern and colleagues, which the authors have offered as a potential study limitation [5].

The single variable that was predictive of implant cut-out in our series was the quality of fracture reduction. Fracture reduction grade was based on criteria proposed by Baumgaertner et al. Earlier studies have identified poor fracture reduction as a predictor of implant cut-out [3,7,11]. In 298 patients treated with PFNAs, Turgut et al. found fracture reduction quality, specifically varus mal-reduction, to be the most significant predictor of implant cut-out 11]. Similarly, Liu et al who examined mechanical complications of TFN fixation in 223 patients found the quality of calcar reduction, also derived from the criteria of Baumgaetner et al, to be significantly predictive of implant failure [3]. Approaching, but not reaching statistical significance during bivariate analysis was the influence of surgeon trauma fellowship training on risk for implant cut-out. This may simply be related to the fact the trauma fellowship trained surgeons may be more adept in fracture reduction than their non-fellowship trained colleagues. No threshold value, including the previously defined cutoff values of 25 and 0.45 for TAD and PR respectively, was predictive of cut-out.

It is critically important to consider the differences in failure mechanism between lag screws and helical blades that ultimately result in extrusion of the implant from the femoral head. Traditionally, failure of by cut-out has been described to occur through progressive varus collapse and retroversion of the femoral head resulting in superior migration of the implant into the acetabulum. Improved resistance of the helical blade to cut-out has been previously attributed to radial compaction of cancellous bone as the blade is inserted and has been supported by prior biomechanical studies [4,12]. This same mechanism, however, likely contributes to the risk of helical blade failure by medial perforation, now increasingly recognized as a different mechanism of failure characterized by progressive medial migration of the blade without loss of fracture reduction [3,5]. With respect to the TFN, this failure mechanism has only been shown to occur with helical blade fixation. Indeed, all 12 instances of medial perforation in the current study occurred with helical blades. Whereas a lower TAD has been favored to guard against cut-out, placing the helical in close proximity to the subchondral bone may ultimately increase risk for medial perforation as some degree of implant migration and "telescoping" has been shown to occur in all fractures repaired with helical blades [3,13]. In fact, Liu et al found that a TAD less than 15 mm significantly increased the risk for medial perforation [3]. Likewise, Flores et al observed an increased risk for medial perforation when the TAD was less than 20 mm [14]. The optimal TAD for helical blade fixation, however, remains unknown.

In conclusion, implant cut-out is multifactorial. Overall, a direct association between helical blade fixation and implant cut-out was not observed in our study. Amongst modifiable risk factors for implant failure, poorer fracture reduction was predictive of failure by cut-out. Subgroup analysis highlights differing modes of failure between lag screws and helical blades which warrants further investigation. Optimal TAD during helical blade fixation remains unknown. Patient factors may ultimately be responsible for failures occurring in fractures with otherwise optimal technical repair.

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