Unstable Proximal Femur Fractures Treated With Proximal Femoral Locking Plates: A Retrospective, Multicenter Study of 111 Cases

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Objectives: A few small case series have found that proximal femur fractures treated with a proximal femur locking plate (PFLP) have experienced more failures than expected. The purpose of this study was to review the clinical results of patients with acute, unstable proximal femur fractures treated with proximal femoral locking plates in a large, multicenter patient cohort.

Design: This is a retrospective clinical study.

Setting: The study included patients from 12 regional trauma centers and tertiary referral hospitals.

Patients: One hundred eleven consecutive patients with unstable proximal femur fractures stabilized with a PFLP and having required clinical and radiographic follow-up at a minimum of 12 months after injury.

Intervention: Surgical repair of an unstable proximal femur fracture with a PFLP.

Main outcome measurements: Treatment failures (failure of fixation, nonunion, and malunion) and need for revision surgery.

Results: Forty-six patients (41.4%) experienced a major treatment failure, including failed fixation with or without nonunion (39), surgical malalignment or malunion (18), deep infection (8), or a combination of these. Thirty-eight (34%) patients underwent secondary surgeries, including 30 for failed fixation, nonunion, or both. Treatment failure was found to occur at a significantly higher rate in patients with major comorbidities, in femurs repaired in varus malalignment, and using specific plate designs.

Conclusions: Proximal femoral locking plates are associated with a high complication rate, frequently requiring revision or secondary surgeries in the treatment of unstable proximal femur fractures. Given the high complication rate with PFLPs, careful attention to reduction, use of a PFLP implant, and consideration should be given to alternative implants or fixation techniques when appropriate.

Key Words: proximal femur, locked plate, locking plate, peritrochanteric fracture, intertrochanteric fracture, unstable, failure, femur, fracture, plate, proximal, PFLP, prox fem, locking, locked, fail

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

Unstable proximal femur fractures pose a challenging surgical problem, as reduction and fixation are difficult to achieve and maintain because of strong deforming forces, complex fracture patterns, comminution, and/or poor bone quality. Clinical outcomes after operative treatment of proximal femur fracture have been shown to be dependent on achieving optimal mechanical alignment and union.[1–9] Plating offers several theoretical advantages over intramedullary implants, including the opportunity to obtain and maintain an anatomical reduction,[10] and avoidance of iatrogenic surgical trauma to the abductor mechanism.[11,12] Varied results have been reported for the treatment of proximal femur fractures treated with plating. The most successful results reported for plating of injuries were obtained with early fixed-angle plate designs.[7,9,13] Proximal femur locking plates (PFLP) have been developed with improvements over previous plate designs, including anatomic precontouring to fit the proximal femur, and locking screw capabilities with multiple fixation points into the femoral head and neck. Although biomechanical studies have shown PFLPs to be stronger or equivalent to other fixation methods for fractures of the proximal femur,[14,15] early clinical results, have shown concerning outcomes with treatment failures as high as 70%.[5,8,16–20] These studies on the treatment of proximal femur fractures with PFLPs however are limited by small sample sizes or the inclusion of heterogeneous injury patterns hereby limiting the conclusions that can be drawn.

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The primary purpose of this study was to assess clinical results of a large, multicenter series of unstable proximal femur fractures treated surgically using a PFLP. Our hypothesis was that failure was occurring at a higher rate than expected and that by evaluating a large sample, risk factors for failure could be identified.

PATIENTS AND METHODS

Institutional review board approval of participating institutions was obtained. One hundred eleven patients treated between January 1, 2005 and December 31, 2010 at 10 regional level I and 2 level II trauma centers were included. All patients had undergone PFLP fixation for an acute unstable proximal femur fracture (Orthopaedic Trauma Association [OTA] 31-A2 and 31-A3),[21] (Fig. 1) and had a minimum follow-up of 12 months or until established treatment failure. Periprosthetic fractures were excluded. Mean follow-up was 18.8 months (range, 2–53 months).

All procedures were performed or supervised by an orthopaedic trauma fellowship–trained orthopaedic surgeon. Surgery consisted of direct or indirect reduction and proximal femur plating using a lateral approach. Plating was performed using one of three 4.5 mm PFLPs (Fig. 2): first or second generation LCP Proximal Femoral Plate (Synthes, Paoli, PA) and Peri-Loc PFLP (Smith & Nephew, Memphis, TN). The

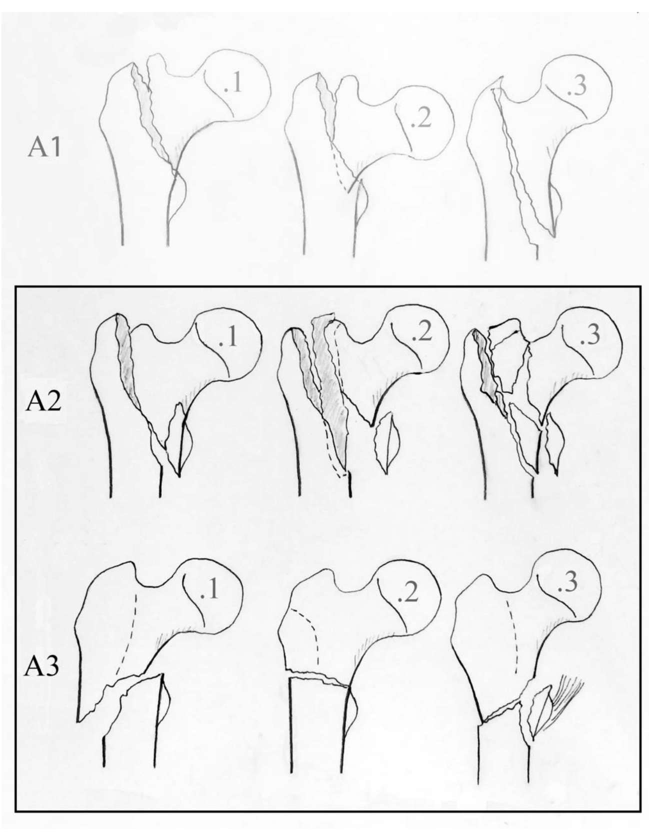

FIGURE 1. Patients treated in this study underwent PFLP fixation for an acute unstable proximal femur fracture (OTA) 31-A2 and 31-A3.[21]

FIGURE 2. Photograph demonstrating geometry of proximal end of PFLP: PFLP on the left was prone to fail compared with plate on the right. **Editor's Note:** A color image accompanies the online version of this article.

plating constructs were applied in compression or bridging mode at the discretion of the treating surgeon based on the injury pattern.

Postoperatively, patients were typically mobilized with the assistance of a physical therapist on the first postoperative day if awake, alert, and they had no other conditions restricting mobility. Patients with multiple injuries were mobilized as soon as was reasonable in the context of their associated trauma. Surgeons' postoperative protocols were similar, that is, patents' weight bearing was protected (non–weight bearing or toe-touch weight bearing) for 8–12 weeks until there was significant progression of healing, and then advanced progressively. Each treating

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surgeon evaluated his/her own patient's radiographs. Alignment of the proximal femur was determined by comparing intraoperative or immediate postoperative radiographs, as well as follow-up and final radiographs to the contralateral hip. Fracture union was defined as by radiographic (bridging of the fracture site by callus at 3 cortices or obliteration of the fracture line, ie, restoration of cortical continuity) and clinical criteria (no or scant fracture site pain with mobility).

Data on patient and injury factors (age, sex, mechanism of injury, associated injuries, facture classification), treatment methods (manufacturer, fixation pattern), and complications was obtained from retrospective review of our trauma databases, medical records. For all patients, available data at the time of injury and subsequent follow-up visits included physical examination findings and standardized imaging including anteroposterior and lateral radiographs of the hip.

Failure of treatment was defined as:

- Loss of fixation including broken or loosened implants[22]: Screws were considered loose if any interval back out or separation between screw heads and plate, or if a distinct radiographic halo was noted around the screw threads, or if there was notable loss of reduction of the proximal femur.
- Malunion: Healing in position >5 degrees different than contralateral hip on anteroposterior or lateral radiograph or clinical rotation more than 20 degrees different from that of the contralateral extremity as assessed by physical examination.
- Nonunion: Lack of healing resulting in secondary surgery or persistent lack of union as assessed on 3 serial radiographs taken at 2-month intervals.
- Deep infection: Infection adjacent to the implant requiring surgical debridement, with confirmed intraoperative cultures or presence of gross purulence.

Statistical Analysis

Patient demographic and clinical variables were compared between patients with and without treatment failure. Differences in continuous variables were assessed for normality (Kolmogorov–Smirnov) before using Student *t* test. Differences in proportions for categorical variables were assessed with either Pearson χ^2 or Fisher exact tests. Proportions were reported as a percentage, parametric continuous variables were reported as a mean ± SD, and nonparametric continuous variables were reported as a median and range. For all analyses, $P < 0.05$ was considered statistically significant. Analyses were performed using SAS V9.1 (SAS Institute, Cary, NC).

RESULTS

Successful primary union in a well-aligned position was achieved in 65 of 111 (58.6%) patients with at mean time to radiographic and clinical union of 18.5 weeks (range, 8–53 weeks). Failed treatment was seen in 46 (41.4%) patients, including loss of fixation—with or without nonunion (39),

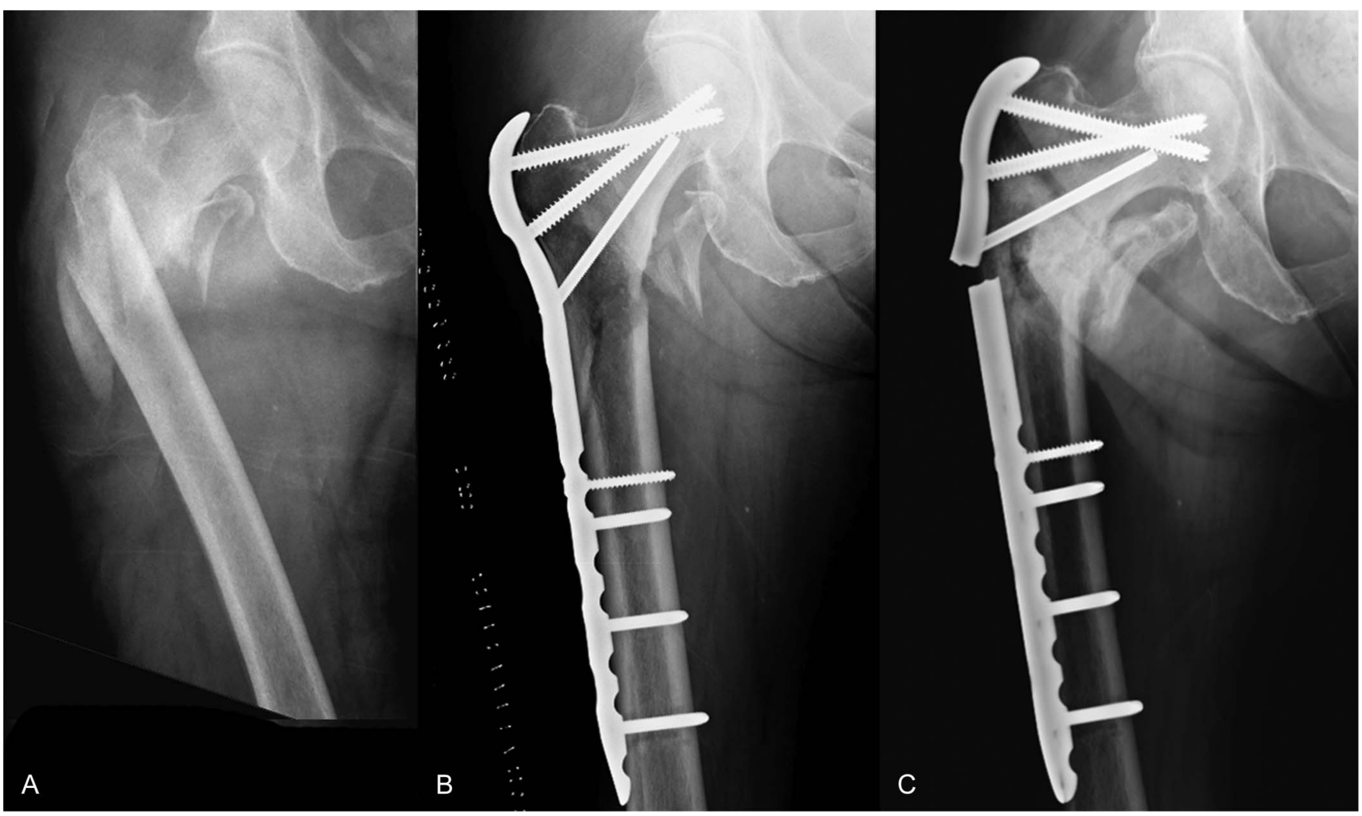

FIGURE 3. A, Anteroposterior (AP) radiographs of hip of a 66-year-old man with a 31-A3.3 proximal femur fracture. B, Postoperative radiographs show restoration of alignment and plating with a PFLP. C, Similar x-rays of the same patient, 4 months after repair showing catastrophic failure requiring revision with unhealed fracture, plate failure, and collapse into varus.

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malunion (18), deep infection (6), or a combination of these. The 39 cases of failed fixation were noted at an average of 15.8 weeks after index ORIF (range, 6–28 weeks). Proximal screws were the source of failure in 28 cases (72%) of fixation failure (Fig. 3), occurring by breakage alone (12), loosening or subsidence alone (7), bending alone (1), or a combination (8) of these. Plate breakage occurred in 8 patients and one bent 40 degrees, with all failures occurring through a screw hole(s) corresponding to the high subtrochanteric level. In 2 patients, fixation failed by "plate lift-off" after screw breakages along the shaft.

Immediate postoperative malalignment was seen in 9 cases, with 8 exhibiting greater than 5 degrees of varus and 1 greater than 5 degrees valgus alignment. Two proximal femurs repaired in varus malalignment also had external rotation deformity of 20 degrees or greater (both 25 degrees). Two of the 9 cases of varus malalignment underwent early revision ORIF. Five of the remaining 8 cases of varus malalignment ultimately experienced loss of fixation. Seven of 9 patients primarily repaired in greater than 5 degrees of varus required revision ORIF.

Forty-four secondary surgeries were performed on 38 patients (34%). Two additional patients were awaiting total hip replacement for posttraumatic reconstruction.

The association of patient, injury, and treatment variables with treatment failure is presented in Table 1. To summarize, treatment failure in our series was attributable to a number of risk factors, including patients with major comorbidities, fixation in varus malalignment greater than 5 degrees, or using a early or later generation Synthes PFLP.

TABLE 1. Association of Patient, Injury, and treatment Factors With Treatment Failure

	Treatment Failures	Nontreatment Failures	*P*
Patient variables			
Age, y	51.1	41.2	0.43
Sex (male), %	67.0	69.0	0.77
BMI	24.6	25.7	0.69
Tobacco user, %	59	42	0.07
Major comorbidities, %*	50	19	<0.01
Injury variables			
High-energy mechanism, %†	80.9	72.1	0.67
Fracture pattern (OTA)			
31-A2 versus A3 and 32 <5 cm below lesser trochanter, %	52.5	43.9	0.18
Treatment variables			
Plate used, %			<0.01
Synthes (early generation)	19 (37)	34 (63)	
Synthes (later generation)	20 (45)	24 (55)	
Smith & Nephew	4 (17)	20 (83)	
Repaired in >5 degree varus, %	15	1	<0.01

*Comorbidities, including those expected to affect bone density: Diabetes mellitus; chronic respiratory, renal, or hepatic failure; alcoholism; other metabolic bone disease, seizures.

†High-energy mechanism: automobile or motorcycle crash, fall from a height, pedestrian struck by motor vehicle, gunshot wound, and industrial accident.

DISCUSSION

Well aligned, primary union was achieved in only 58.6% of the 111 patients treated in this multicenter series of patients with unstable intertrochanteric femur fractures stabilized with a PLFP. Thus, 41.4% of patients failed treatment, which was largely attributable to problems with failed fixation with or without nonunion (35%) and malunion/malalignment (18%). A common scenario was fixation failure with collapse into varus malposition followed by revision surgery (25) or healing without further intervention (12). Secondary surgeries were performed in 34% of patients, including 30 patients undergoing revision of fixation, 6 for deep infection (3 converted to hip arthroplasty), 5 with implant removal (3 early for intra-articular screw), and 3 for excision of heterotopic bone. Furthermore, varus malalignment of greater than 5 degrees was accepted in 14 patients, in most cases after fixation was lost to some extent, but the fracture progressed to union in a maligned position.

The orthopaedic literature contains contradictory evidence for the use of PFLPs in patients with unstable intertrochanteric femur fractures.[5,6,8,16,17,20] For example, Glassner and Tejwani[17] described their initial experience with 7 of 10 failed PFLPs for a variety of proximal femur fractures and nonunions. Wieser and Babst[6] reported a 29% failure rate with the PFLP in proximal femur fractures, concluding that the device should only be used when weight bearing could be avoided and in the presence of posteromedial support. Streubel et al[5] described failure in 11 of 29 (37%) patients treated for unstable peritrochanteric fractures (OTA 31-A3) with a PFLP. Interestingly, that same institution had previously presented excellent early clinical results with treatment failure in only 1 of 31 (3%) patients with a proximal femur fracture treated by a single surgeon with the same manufacturer's plates.[24] Finally, Zha et al[8] reported only 1 nonunion and 1 plate breakage (2% failure rate) in 94 patients with intertrochanteric and subtrochanteric femur fractures treated with submuscular plating using a locking PFLP manufactured in China (Trauson or Kanghui, China). It does not seem, at least perhaps until now, that a multicenter study has conclusively identified the risks for treatment failure in patients treated for unstable intertrochanteric and subtrochanteric femur fracture treated with a PFLP. Furthermore, subgroup analysis has not previously been feasible because of the small patient populations studied.

Our 46% rate of treatment failure does not compare particularly well to proximal femur fractures treated with other devices,[1,9,24–27] although these reports have typically included limited patient numbers or have not described or stratified their injury patterns very well. A few reports have shown excellent clinical results for proximal femur fractures treated with 95 degrees blade plates[9] or nails,[1] but most other reports using these implants describe more modest results with failure rates ranging between 3% and 15%, with some as high as 41%.[7,25–27,29] In a meta-analysis of previous studies on 31-A3 proximal femur injuries fractures (and before PFLP's were widely available), Kregor et al[3] determined that grade B evidence supported the use of nails over traditional

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95 degrees devices. Recently, Forward et al compared the mechanical properties and failures of a cephalomedullary nail, PFLP, and angled blade plate in a subtrochanteric fracture model. The CMN construct withstood significantly more cycles, failed at a significantly higher force, and withstood a significantly greater load than either of the plate constructs.[30]

These analyses are relevant to our discussion as we acknowledge that a selection bias exists as an unknown number of unstable proximal femur fractures were likely treated with intramedullary nails. We propose that in many of the cases studied here, the plate was selected for more difficult fractures, for example with factors such as medial column comminution or displacement at typical nail insertion sites, segmental, or other patterns necessitating an open reduction, or others. Because this cohort represented a distinct and challenging subset of proximal femur fractures, a higher rate of complications and failures might be expected. However, this is speculative, as we do not have that data. In an informal survey of the contributing surgeons in this study, most of the authors (10 of 12 surgeons) use intramedullary nails for many or most intertrochanteric and subtrochanteric fractures, and some only use the PFLP for fractures in select cases (eg fracture comminution/displacement at the nail insertion point, young patients to avoid abductor muscle injury). This may help explain the excellent results of Zha et al[8] whose continuous series of intertrochanteric and subtrochanteric fractures treated with PFLP (in a decidedly older population and predominantly using minimally invasive techniques) conflict with the few other clinical reports from institutions where nails were also used for these fractures. Interestingly, even in reporting their excellent results, Zha et al were reluctant to recommend PFLP for most unstable proximal femur fractures.

Failure in our series was attributable to a number of risk factors including the existence of comorbidities expected to affect bone health, patients with femurs fixed in varus malposition, and those whose femurs were plated with a plate manufactured by Synthes (early or later generation). Metabolic bone diseases are a known predictor of treatment failure for patients undergoing repair of a hip and other fractures. Varus malalignment occurred in 8 patients and 5 of those resulted in fixation failure. Varus alignment has been identified as a predictor of treatment failure after plating and intramedullary nailing of proximal femur fractures.[29] This complication is often touted as a reason for plating proximal femur fractures as the plate, if applied correctly, can be used as a reduction tool to aid in reduction.[10,31,32] Our study did not evaluate the exact methods by which fracture reduction was achieved except for direct or indirect means. Malalignment has been recognized as a potential pitfall when using indirect reduction techniques and authors have stressed vigilance toward intraoperative realignment and assessment as the key for preventing alignment problems.[33] Proximal femur fractures are associated with complex deformities and strong muscle forces that must be overcome to gain reduction. Clearly, even experienced orthopaedic trauma surgeons are not immune to this complication, and we strongly assert that careful attention to detail is necessary to minimize the tendency for varus malalignment, as well as other complications.

Well more than half of our treatment failures occurred as loss of fixation with subsequent varus malalignment (with or without nonunion) requiring revision surgery. Failure of the proximal screws was the most common source of fixation failure, with failure occurring through broken, loose, or bent screws, or through a combination thereof. Perhaps, there is an opportunity for improved mechanical strength of PFLP constructs by changing the geometry or metallurgy of the proximal plate and screws. Not surprisingly, plate breakage (and a bent pate) also occurred (24%) with all plate failures occurring through a screw hole corresponding to the high subtrochanteric level. In most of the cases, this represents the area of fracture and its inherent instability, and the transition area in the plate for screws fixating the proximal or distal fragments. A similar case for implant redesign might be made regarding this failure mode. Finally, failure of screw fixation along the shaft segment occurred (6%). Previous studies on the subject have also reported that lost fixation primarily affected the proximal screws. Streubel et al[5] reported that 5 of their 11 patients with an unstable 31-A3 fractures failed by varus collapse of the proximal fragment with screw cutout and 4 of 11 by proximal screw breakage. Materials properties, geometry, and manufacturing processes are expected to change the properties of implants. All 3 plates evaluated here were made from 316L stainless steel. Both of the Synthes' PFLPs had identical geometries [two 7.3 mm screw holes at the proximal end and 5.0 mm holes further distally (Fig. 2)], with the only difference being that the early generation plate was bent and the later version forged to shape. The Smith & Nephew implant, which experienced fewer failures, is a wider plate proximally which uses a cluster of offset 6.5 mm screw holes. Mechanical differences between PFLPs have been investigated previously including comparative testing of the plate used in most of the cases in this series, which demonstrated an increased risk for failure. Floyd et al[33] compared Synthes' current "newer" version PFLP devices (N-PFLP) with their first-generation PFLP device (O-PFLP), and a 95-degrees blade plate in mechanical testing using fracture gap model. They found that the N-PFLPs were significantly stiffer, and there was a statistical trend for improved fatigue life compared with the other plates. Catastrophic implant failure occurred for all 5 O-PFLP specimens during cyclic load testing, compared with only 1 of 5 each (20%) in similar testing of the N-PFLP and blade plate. Breakages occurred at the third locking hole, which corresponds to the subtrochanteric fracture site in their unstable gap model.

In our study, the mean time to radiographic and clinical union in successful cases was 18.5 weeks. For the cases of failed fixation, failure occurred on average at 15.8 weeks. These findings are discordant with the generally accepted clinical practice (and the one followed here) of protected weight bearing for 10–12 weeks in patients treated for proximal femur fractures. Given our results, it is possible that the time to initiation of weight bearing should be extended. A contributor to delayed healing may be due to the implant constructs. Since the advent of locked plating, there has been a shift from rigid to flexible fixation.[34–36] Hybrid constructs in which locking and nonlocking screws are spaced along the plate length have demonstrated improved fracture healing compared with filling all implant holes with locking screws.[37,38] Although not the focus of this study, our

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observations in a number of the failures supports the concept that fully locked implants may be too stiff, not allowing the necessary motion at the fracture to promote secondary bone healing. This warrants further investigation.

There are recognized limitations of this study. First, this cohort is not continuous as we have discussed. Second, popular fracture classifications; including the OTA coding system for intertrochanteric (or peritrochanteric) fractures,[21] do not adequately describe all the complexities of fractures patterns that involve these areas. Third, we did not analyze the fixation constructs for implant length, numbers, and types of screws placed proximal and distal to the primary fracture line or utilization of bone grafting or bone graft substitutes. Fourth, assessment of alignment on intraoperative or immediate postoperative radiographs, as well as follow-up and final radiographs was performed by the treating surgeon, who may be unable to acknowledge malalignment on intraoperative or immediate postoperative radiographs, thus we may have underestimated the contribution of immediate postoperative malalignment to the incidence of treatment failure in this series. Finally, there is no alternative treatment or control group included in this study with which to compare these results, and we are left with comparing our results to historical controls.

In summary, the treatment of proximal femur fractures using a PFLP is not universally effective in treating unstable intertrochanteric femur fractures. Treatment failure, including problems with fixation failure, varus malalignment, and secondary surgeries were very common and use of these implants must be carefully considered. Identified risk factors for failure included the presence of major comorbidities, surgical varus malposition, and those repaired with one manufacturer's plates.

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