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Distal femur fractures stabilized using titanium lateral locked plates with nonlocking diaphyseal fixation: a retrospective review

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Abstract

Objectives: Multiple treatment modalities exist for treating distal femur fractures. Lateral locked plating has become the method of choice because it prevents loss of reduction due to varus collapse, but has been associated with nonunion rates of up to 30%. Titanium implants may provide a more optimal biomechanical environment for fracture healing. The primary aim of this study is to evaluate nonunion rates and risk factors for nonunion in a series of distal femur fractures stabilized with modern locked titanium implants using all nonlocking diaphyseal fixation. A secondary aim is to evaluate whether diaphyseal fixation with nonlocking screws is associated with fixation complications.

Methods: A 6-year retrospective study identified patients undergoing operative fixation of distal femur fractures with lateral locked plating and nonlocking diaphyseal fixation. Patient demographics, fracture and fixation characteristics were recorded. Follow-up data recorded included fracture union, implant failure in the setting of nonunion and secondary procedures. Statistical analyses used include *t* test, Mann-Whitney *U*, and logistic regression.

Results: Eighty-one fractures met inclusion criteria with 16 fractures resulting in nonunion (19.75%). Comparing union and nonunion cohorts, nonunions were found to be associated with higher body mass index ($P = 0.001$). Fixation construct data found nonunions had a higher average number of diaphyseal screws (4.25 vs. 3.74, $P = 0.038$). Subgroup analysis found a nonunion rate of 4.2% (1 out of 24) in fractures with 3 diaphyseal screw fixation versus 26.3% (15 out of 57) with 4 or more diaphyseal screws ($P = 0.038$). No diaphyseal fixation failures were noted with nonlocking diaphyseal screw fixation.

Conclusion: Our study found using a titanium construct produced a nonunion rate of 19.75%, comparable with historic rates. Interestingly, diaphyseal fixation with more than 3 screws led to higher nonunion rates. No catastrophic failures were observed involving the diaphyseal nonlocking screw fixation.

Keywords: distal femur fracture, lateral locked plating, nonunion, diaphyseal, cortical screw

1. Introduction

Distal femur fractures are increasing in incidence. Although relatively rare, recent literature shows an incidence of 8.7/100,000 a year.[1] These injuries occur in a bimodal distribution typically because of high energy mechanisms in younger patients and low energy in older patients. The increased incidence can largely be attributed to an aging population and low-energy mechanism of injury.[1]

Multiple treatment modalities exist for fracture fixation and are dependent on fracture pattern, patient characteristics and surgeon preference. With the advent of locking screw technology, lateral locked plating (LLP) has become the most common treatment modality used for fixation of distal femur fractures. Lateral locked plating has gained in popularity because of the ability to capture specific fracture fragments and maintaining angular stability in the setting of poor bone quality and mitigating varus collapse in comminuted intraarticular fractures.[2]

An extensive body of research has aimed to identify reasons and risk factors contributing to high rates of nonunion, reported between 9% and 32%,[3–5] of distal femur fractures treated with lateral locked plating. Risk factors that have been identified include open fracture, infection, medial comminution, extent of comminution, plate length, LLP rigidity, smoking, and obesity.[5–7] Rodriguez et al[3] found a nonunion rate of 13.3% and determined that implant metallurgy was the primary predictor of nonunion. Stainless steel plates led to a 4 times higher rate of nonunion compared with titanium plates. Harvin et al[8] found all locking screws placed within the proximal portion of the plate led to a

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2.9 times increase in nonunion. Kandemir postulated the use of titanium implants and nonlocking diaphyseal screws to create a more flexible construct to allow for enhanced axial micromotion.[9,10] These studies highlight the benefits of using a titanium plate and nonlocking diaphyseal screw constructs as compared with stainless steel plates and diaphyseal locking screw constructs. Although titanium LLP is still a rigid construct, it is much less so compared with stainless steel and other higher modulus materials, which can aide in stimulating fracture healing with increased axial micromotion.

Previous studies evaluating distal femur fractures include heterogenous cohorts that underwent fixation with stainless steel or titanium implants with a mix of all locking, hybrid or all nonlocking diaphyseal fixation.[8,10,11] Most of the constructs fell into the hybrid or all locking diaphyseal fixation cohort making comparison difficult. Additionally, Freeman et al[12] investigated the use of hybrid diaphyseal fixation (with a combination of nonlocking and locking diaphyseal screws) versus all locking diaphyseal screw constructs which supported that hybrid fixation may prevent early diaphyseal fixation failure in osteoporotic bone.

The aim of this study is to evaluate distal femur fractures that underwent open reduction internal fixation with modern locked titanium implants using all nonlocking diaphyseal fixation. To our knowledge, there are no previous studies evaluating this specific construct alone. Our hypothesis is that titanium implants and all nonlocking diaphyseal screws will lead to lower nonunion rates compared with historically reported nonunion rates of ~10–30%.[4] In addition, we aimed to identify variables associated with nonunion. Secondary outcome measures will include mode of failure in the setting of nonunion and any evidence of catastrophic failure (Fig. 1).

2. Methods

After Institutional Review Board approval, a retrospective chart review was undertaken at an American College of Surgeons Level 1 trauma center. All research was conducted in accordance with the Declaration of the World Medical Association and informed consent was obtained when required. Patients were identified using Current Procedural Terminolgy codes (27511 and 27513) for open reduction internal fixation of extraarticular and intraarticular distal femur fractures from January 2014 to January 2020. All fractures were treated by orthopedic trauma fellowship trained surgeons.

Inclusion criteria were patients between ages 18 and 89 years with distal femur fractures that underwent open reduction and internal fixation using titanium lateral locked plating with all nonlocking diaphyseal screw fixation. Patients needed at least 6 months of follow up to meet inclusion criteria. Periprosthetic and interprosthetic distal femur fractures were also included.

Exclusion criteria were patients older than 90 years per institutional policy, pathologic fractures, constructs augmented with additional implants, plate metallurgy other than titanium and hybrid or all locking diaphyseal screw fixation. Most of the patients were excluded because of inadequate follow-up or incomplete electronic health record documentation.

For patients meeting inclusion criteria, data was collected including age, sex, body mass index (BMI), cardiac history, diabetes, renal failure, smoking history, and drug use. Fracture related data was recorded including closed versus open fracture, open fracture type according to Gustilo-Andersen classification,[13] OTA/AO fracture classification,[14] prior total knee and/or total hip arthroplasty, mechanism of injury and laterality. Data also included whether staged fixation was undertaken with initial external fixation. Definitive fixation data included plate length, number of diaphyseal screws and working length. Working length was defined as the distance from the most distal diaphyseal screw and most proximal within the articular block. If a lag screw was placed through the plate in the metaphyseal region of the femur it was considered the most proximal screw in regard to working length. In addition, proximal screw density was calculated by dividing the number of diaphyseal screws by the number diaphyseal screw holes within the plate similar to prior studies.[3,10] All fractures were treated with a Zimmer Biomet A.L.P.S. distal femur titanium lateral locking plate (Zimmer Biomet, Warsaw, IN), as such, the plate length definition and the distal locking screw area of the plate were uniform.

Duration of follow up was recorded along with time to fracture union. Fracture union was defined as 3 out of 4 cortices with bridging callus and pain-free weight bearing. Infection data were recorded and defined as oral antibiotic treatment for superficial wound issues, local wound care or additional procedures for infection debridement for deep infection. Nonunion was defined as bridging callus of less than 3 out of 4 cortices, failure of callus progression for 6 months and continued pain with weight bearing. Post-operatively, our institution's protocol is standardized to include 6–8 weeks of non-weight bearing, though active range of motion is encouraged. Immediate or early weight bearing was not used for this cohort. In addition, any unplanned procedures to promote fracture union were also considered nonunions in addition to implant failure. In the setting of nonunion, radiographs were inspected for implant failure along with location and mode of failure if present. Locations of failure included the distal articular block, along the working length, or proximal diaphyseal failure. Modes of failure include screw pullout with plate loosening, screw breakage or plate breakage requiring an unplanned revision surgery.

In our study population, on review of the imaging, all diaphyseal screws were placed bicortically unless spanning a prior intramedullary implant (ex: cephalomedullary nail, femoral stem) where unicortical screws were placed in this segment of the plate. Distal screw fixation consisted of all-locking screws and filled all distal holes of the plate.

Descriptive and quantitative data was calculated including averages, standard deviations and incidence. Statistical analysis was performed using IBM SPSS Version 28.0 (IBM Corporation, Armonk, NY). Continuous data were analyzed using *t* test assuming unequal variance, and categorical data were compared using Mann-Whitney *U* test. Multivariate analysis was performed using logistic regression. A *P*-value of <0.05 was considered significant.

3. Results

From 2014 to 2020, 219 distal femur fractures that underwent operative intervention were identified. Of those, 81 patients met inclusion criteria with the most common reason for exclusion being hybrid or all locking diaphyseal fixation. Thirty additional patients were excluded because of lack of adequate documentation or follow up.

Data were divided into union and nonunion cohorts with patient demographic data for each listed in Table 1. The overall average age was 58.7 years with no significant difference in age between the 2 groups (union group: 21–89 years; nonunion group: 21–74 years). In regard to medical comorbidities, no significant difference was noted between the 2 cohorts for each variable. Average body mass index was 30.9 in the union group

Figure 1. A–C, Example of a distal femur fracture treated successfully by lateral locked plating with fracture healing; (D–F) demonstrates a distal femur fracture nonunion with associated hardware failure.

Table 1

Patient demographics.

	Union	Nonunion	*P*
N	65	16	
Sex	28 M/37 F	5 M/11 F	
Age	60.1	53.1	0.095
Laterality	37 L/28 R	7 L/9 R	
BMI	30.9	39.7	0.001
Diabetes	17	5	0.68
Renal failure	4	1	0.99
Drugs	18	5	0.78
EtOH	17	7	0.17
Cardiac history	12	2	0.57
COPD	7	4	0.14
Smoking	22	6	0.78

and 39.7 in the nonunion group which reached statistical significance ($P = 0.001$).

Table 2 illustrates mechanism of injury and fracture classification. The most common mechanism of injury was ground level fall with no significant difference for injury etiology between the 2 groups. Fracture characteristics, including OTA/AO classification, periprosthetic fracture and incidence of open fracture, among the groups did not reach significance.

Fracture fixation characteristics are listed in Table 3. Use of staged fixation or initial external fixation, working length and the use of lag screws did not show significant difference between the 2 groups. Of the 81 fractures meeting inclusion criteria, 16 fractures were classified as nonunions (19.75%). In the union group, average plate length was 9.58 holes compared with an average of 10.81 holes in the nonunion group which did not reach

Table 2

Fracture characteristics.

	Union	Nonunion	P
Mechanism			
Ground level fall	35	8	
MVC/MCC	15	8	
GSW	7	0	
Fall from height	6	0	
Ped struck	2	0	
OTA/AO classification			
A	33	7	0.69
C	32	9	0.61
Fracture type			
Periprosthetic	22	3	0.24
Open	12	2	0.57

significance ($P = 0.921$). On average, 3.74 nonlocking diaphyseal screws were used in the union group while an average of 4.25 were used in the nonunion group which reached statistical significance ($P = 0.038$). Proximal screw density was calculated for each group but did not reach significance ($P = 0.67$).

Average follow-up was 1 year and the average time to union roughly 5 months. Infection was noted in 3 patients (3.1%) in the union group and 1 patient (6.3%) in the nonunion group which was not statistically significant ($P = 0.55$). Of note, it was observed that the nonunion group had 3 plate failures with plate breakage within the working length of the construct. The remaining nonunions developed symptomatic nonunions with no hardware failure. No catastrophic diaphyseal screw failures were noted in either group.

Further subanalysis evaluated the use of 3 cortical diaphyseal screws compared with 4 or more nonlocking diaphyseal screws. There was no significant difference when comparing patient demographics, medical comorbidities, fracture characteristics, and fracture fixation data. Proximal screw density and plate length for both groups were not significantly different. Twenty-four fractures underwent fixation with 3 diaphyseal screws with only 1 nonunion (4.2%) while 15 of the 57 (26.3%) fractures with 4 or more nonlocking diaphyseal screws failed to unite which reached statistical significance ($P = 0.022$). Power analysis showed a 66.9% predictive power for a nonunion when comparing 3 cortical shaft screws with 4 or more diaphyseal cortical shaft screws.

Multivariate logistic regression analysis (Fig. 2) demonstrated that BMI ($P < 0.001$, OR 5.5, CI 1.55–19.50) and the number of diaphyseal screws, 4 or more, ($P = 0.038$, OR 2.4, CI 1.04–5.55) were both significantly associated with nonunion. Plate length failed to reach significance ($P = 0.921$).

4. Discussion

Our study found 81 fractures that met inclusion criteria with 16 fractures nonunions (19.75%) comparable with historic data.

Table 3

Fracture fixation data.

	Union	Nonunion	P
External fixation	7	1	0.59
Lag screws	13	3	0.91
Number proximal screws	3.74	4.25	0.038
Plate length (holes)	9.58	10.81	0.921
Working length (mm)	81.75	93.17	0.554
Proximal screw density	0.41	0.40	0.67

Nonunion was found to be associated with higher BMI ($P = 0.001$) and a higher number of diaphyseal screws (4.25 vs. 3.74, $P = 0.038$). Subgroup analysis found a nonunion rate of 4.2% (1 out of 24) in fractures with 3 diaphyseal screw fixation versus 26.3% (15 out of 57) with 4 or more diaphyseal screws ($P = 0.038$). Fixation construct data found no significant difference in regard to plate length, working distance, and screw density. Of note, no catastrophic fixation failures were noted with nonlocking diaphyseal screw fixation.

The increasing incidence of distal femur fractures is a concerning trend, especially given the reported rates of nonunion up to 32%.[3,4,15] It has been postulated that an appropriate amount of strain at the fracture site is necessary to promote callus formation and fracture healing. The goal is to promote axial micromotion while limiting shear and excessive strain. Multiple modifications have been described to impart fixation construct dynamization including using titanium implants, unicortical versus bicortical screw fixation, longer working lengths, nonlocking diaphyseal fixation and removing screws across the fracture site.[10]

In a study by Harvin et al,[8] nonunion rate was found to be 32% in 96 patients. All locked proximal diaphyseal fixation was identified as a risk factor for nonunion compared with hybrid diaphyseal fixation with a 2.9 times greater risk of nonunion. Although titanium plates had a 1.6 times greater risk of nonunion compared with stainless steel implants this did not reach significance. In contrast, Rodriguez et al[3] found a nonunion rate of 13.3% in 271 patients and found the use of stainless steel plates had a 41% rate of nonunion compared with 10% with titanium implants. Assessment of individual factors including number of proximal screws, plate length, total screw density and proximal screw density did not have statistically significant effects on fracture union.

Cadaveric studies have also attempted to identify optimal fixation constructs to promote fracture union of distal femur fractures. Cui et al[15] evaluated various diaphyseal fixation constructs with lateral locked plates. They found the screw nearest the fracture site influenced construct stiffness and failure strength more so than the characteristics of the more proximal screws. Henschel et al[16] completed a biomechanical evaluation of various diaphyseal fixation methods including all locked, all nonlocking, far cortical locking and active locking screws. They found all nonlocking diaphyseal screws did not affect construct stiffness. Longer working length with all locked screws enhanced shear motion while far cortical locking screws limited shear with an increase in axial micromotion. In contrast, Habet et al[17] completed a similar biomechanical analysis assessing diaphyseal fixation and found far cortical locking was associated with greater shear motion compared with all locked and nonlocking fixation. Finally, Kandemir et al[9] completed a biomechanical study investigating stainless and titanium plate with hybrid and locking diaphyseal fixation. They found titanium plates with all locked diaphyseal fixation enhanced axial micromotion which the authors felt may be advantageous to induce interfragmentary micromotion for fracture healing. Diaphyseal nonlocking fixation with titanium plates was not investigated.

Previous literature has provided contradictory evidence relating to the ideal fixation strategies to combat distal femur nonunions. Clinical data has been mostly retrospective in nature comparing heterogenous groups in regard to plate metallurgy and diaphyseal fixation. Our study is the first to investigate only titanium plates and diaphyseal nonlocking screw fixation in regard to nonunion rates in distal femur fractures. Despite the

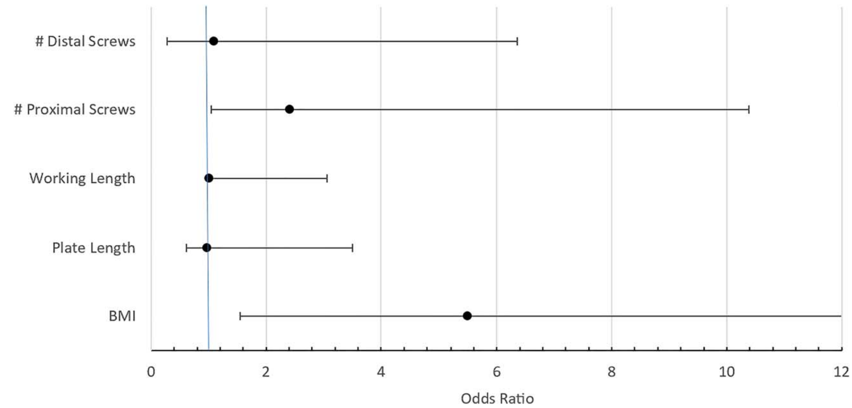

Figure 2. Forest plot representation of multivariate linear regression data demonstrating significance of BMI and # proximal screws in association with fracture nonunion. Vertical blue line represents no effect line.

utilization of more flexible constructs, our non-union rate of 19.75% failed to support our hypothesis. Our results were consistent with previous studies regarding elevated BMI as a risk factor for nonunion in distal femur fractures.[6,7] Interestingly we found diaphyseal fixation with 4 or more diaphyseal nonlocking screws led to higher rates of nonunion. Beltran et al[18] recommended using no more than 4 screws within the diaphysis to allow for fracture micromotion while withstanding physiologic load. This finding may show that 3 cortical screws placed along a sufficient working length might allow for controlled axial micromotion leading to higher union rates but further study is warranted.

This study also aimed to determine whether cortical diaphyseal shaft screws resulted in increased hardware failure, specifically diaphyseal screw pull out. Historically concerns exist regarding hardware failure with diaphyseal cortical screw fixation in the setting of osteoporotic bone typically seen with an aging population.[16,19–21] As a result, it is common practice to use locking screws within the diaphysis.[15,19] Our data showed no incidents of diaphyseal cortical screw pull-out/breakage or catastrophic proximal fixation failure. The average age within our study was 59 years which made it difficult to make inferences regarding nonlocking diaphyseal fixation and osteoporotic bone. This also has financial implications regarding implant costs but a cost analysis was not performed.

Despite this series investigating fixation construct using nonlocking diaphyseal fixation with titanium implants we failed to show enhanced rates of fracture union. Fracture reduction and alignment are variables difficult to assess with routine follow up radiographs and could potentially influence union rates. The difficulty lies in replicating accurate and precise postoperative imaging to allow for consistent measurements. Studies investigating precontoured "anatomic" distal femur implants found coronal alignment/reduction and implant positioning played a major role in fracture union.[22] Peschiera et al[23] found a nonunion rate of 17% with axial malreduction, unbalanced fixation and medial cortical comminution/defect as factors leading to nonunion. Collinge et al[22] also discussed common pitfalls when treating distal femur fractures including plate malposition and malreduction. The authors stress careful scrutiny of radiographs including implant position, fracture length/translation, coronal/sagittal alignment and rotation and recommended obtaining "perfect" anterior/posterior and lateral radiographs intraoperatively before closure.

This study has several limitations including the retrospective study which comes with inherent bias and known limitations. There was no standardization regarding treatment and fracture fixation as this was left to the discretion of the treating surgeon. Additionally lack of consistent postoperative and follow-up radiographs prevented accurate assessment of reduction quality in regard to nonunion rates, which is a potential area of future study. A lack of follow-up may have led to selection bias potentially altering our nonunion rate. A cost analysis was not performed but given a lack of catastrophic failures, even in elderly patients, diaphyseal non-locking cortical screw fixation may be a source of cost savings in the future. Finally, small sample size left our study underpowered making it difficult to make definitive recommendations regarding our results.

5. Conclusion

This study is the first to evaluate titanium lateral plating with nonlocking diaphyseal fixation for distal femur fractures but did not show improved nonunion rates compared with previous reported data. Despite out small sample size, we found use of 4 or more diaphyseal screws lead to higher rates of nonunion which may be an area of further study. Nonlocking diaphyseal screw fixation also was not a source of catastrophic fixation failure even in older patients.

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