

Predictive factors of distal femoral fracture nonunion after lateral locked plating: A retrospective multicenter case-control study of 283 fractures



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ABSTRACT

Introduction: Reported initial success rates after lateral locked plating (LLP) of distal femur fractures have led to more concerning outcomes with reported nonunion rates now ranging from 0 to 21%. Reported factors associated with nonunion include comorbidities such as obesity, age and diabetes. In this study, our goal was to identify patient comorbidities, injury and construct characteristics that are independent predictors of nonunion risk in LLP of distal femur fractures; and to develop a predictive algorithm of nonunion risk, irrespective of institutional criteria for clinical intervention variability.

Patients and methods: A retrospective review of 283 distal femoral fractures in 278 consecutive patients treated with LLP at three Level1 academic trauma centers. Nonunion was liberally defined as need for secondary procedure to manage poor healing based on unrestricted surgeon criteria. Patient demographics (age, gender), comorbidities (obesity, smoking, diabetes, chronic steroid use, dialysis), injury characteristics (AO type, periprosthetic fracture, open fracture, infection), and management factors (institution, reason for intervention, time to intervention, plate length, screw density, and plate material) were obtained for all participants. Multivariable analysis was performed using logistic regression to control for confounding in order to identify independent risk factors for nonunion.

Results: 28 of the 283 fractures were treated for nonunion, 13 were referred to us from other institutions. Obesity (BMI > 30), open fracture, occurrence of infection, and use of stainless steel plate were significant independent risk factors ($P < 0.01$). A predictive algorithm demonstrates that when none of these variables are present (titanium instead of stainless steel) the risk of nonunion requiring intervention is 4%, but increases to 96% with all factors present. When a stainless plate is used, obesity alone carries a risk of 44% while infection alone a risk of 66%. While Chi-square testing suggested no institutional differences in nonunion rates, the time to intervention for nonunion varied inversely with nonunion rates between institutions, indicating varying trends in management approach.

Discussion: Obesity, open fracture, occurrence of infection, and the use of stainless steel are prognostic risk factors of nonunion in distal femoral fractures treated with LLP independent of differing trends in how surgeons intervene in the management of nonunion.

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Introduction

Distal femur fractures are a common orthopedic problem over a range of ages with an overall incidence in the order of 37 per 100,000 person-years [1]. Younger patients suffer injuries predominantly as the result of high-energy trauma while in older patients it is an injury associated with osteoporosis and lower energy mechanism such as falls from standing height. For both groups, surgical treatment options vary with fracture pattern, bone

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stock, and presence of an adjacent implant. Retrograde intramedullary nailing and open reduction internal fixation using plates and screws are the most commonly employed techniques. Lateral locked plating (LLP) has become increasingly popular since the technique was introduced in the late 1990s. Initial studies using LLP reported promising outcomes with nonunion rates in the range of 0–14% but mostly fewer than 6% [2–15]. However, in recent years, initial success rates have given way to more concerning outcomes with reported nonunion rates reaching as high as 17–21%, with reports of decreased callus formation, problems with healing of up to 32%, and other complications [16–20]. The increase in reported nonunion rates is of recent interest. This increase may be multifactorial and attributable, in part, to an increased use of the technique, application to a broader range of patient types, and an overall increased frequency of LLP use in the treatment of higher energy fracture patterns. Recently reported factors associated with higher nonunion rates have included comorbidities such as obesity, diabetes, open fracture, age, fracture comminution, alcoholism, post-operative smoking, as well as technical factors such as plate length and screw density of the fixation constructs, use of titanium vs. stainless steel, and cortical reduction [17,21–25].

The primary objective of the present study was to identify patient comorbidities, injury, and construct characteristics that are independent predictors of increased risk of nonunion when LLP is used in the fixation of distal femoral fractures. Our main goal was to use these independent predictors to develop a predictive algorithm of nonunion risk to be used in a clinical setting to counsel patients at risk. A secondary objective was to examine the variation among institutional nonunion rates at our three affiliated Level 1 trauma centers to determine whether reported nonunion rates may also be associated to overall management approach. Our hypothesis was that despite potential variability between institutional criteria for the diagnosis of nonunion and for intervention, there would still be identifiable patient comorbidities, injury, and construct characteristics predictive of nonunion risk that are independent of management approach. Identifying these factors will allow a treating surgeon to identify high-risk cases preoperatively so that measures to promote healing such as more comprehensive metabolic workups, medical intervention, early bone grafting, use of osteoinductive agents, and bone stimulators may be implemented. Further, these findings will be useful to help surgeons counsel patients with these injuries about anticipated outcomes.

Patients and methods

A retrospective case-control study was conducted of all acute supracondylar femoral fractures treated with LLP by the orthopedic trauma services at our three affiliated Level 1 trauma centers between August 2004 and December 2010. Minimum age for inclusion in the study was 18 years with a minimum follow up of three months. Patients who were not fully healed at three months but had no follow-up at or after six months were excluded, as their healing was not able to be determined.

Supracondylar fractures were defined as AO/OTA types 33 A and 33 C occurring within 15 cm of the joint line. Open fractures and periprosthetic fractures occurring in the presence of a total knee arthroplasty (TKA), total hip arthroplasty (THA) or prior intramedullary implant (femoral nail) were included in the analysis. Fractures with extension into the articular surface of the distal femur were included irrespective of the surgeon's chosen method of articular reduction and fixation as long as LLP was utilized for stabilization of the extra-articular component.

All fractures were treated with a LLP system. Due, however, to hospital contracting, our devices included primarily LISS plates (Synthes, USA) and condylar locking plates (Synthes, USA) of either

stainless or titanium manufacture. Surgeons used constructs with variable numbers of locking screws as they deemed necessary, applied and spread in any pattern they felt to be appropriate. All LISS constructs involved only locking screws with either unicortical or bicortical purchase on both sides of the fracture. Condylar locking plates (non LISS) involved in the proximal aspect of the fracture a combination of cortical screws (bicortical purchase) supplemented with one or more locking screws of bicortical purchase. At least one cortical screw was first used to bring the plate closer to the bone and for buttressing effect as needed. Distal to the fracture, locking screws alone were predominantly used. Post-op follow up and weight bearing restrictions were also at the discretion of the treating surgeon.

Given the retrospective nature of the study and the intent to assess whether management criteria affected an institution's nonunion rates, nonunion was liberally and unconventionally defined as the need for a secondary surgical procedure to improve healing (i.e., bone grafting, hardware exchange, other) or to otherwise resolve a problem associated with poor healing (i.e., hardware failure, revision fixation, conversion to arthroplasty, amputation, etc.). The criteria for intervention were not pre-defined, which meant that each surgeon treated a distal femoral fracture that exhibited poor healing progression based on his or her own experience and preference. Reason for intervention could be conservative (i.e., revising a nonunion only at the time of mechanical failure) or proactive (i.e., proceeding with bone grafting based on patient symptoms or radiographic findings at any time in the post-operative course).

Each patient record was reviewed for:

Patient factors and comorbidities

- a) sex
- b) BMI/obesity
- c) history of diabetes
- d) smoking history
- e) chronic steroid use
- f) receives dialysis,

Injury related factors

- a) open vs. closed fracture
- b) AO classification
- c) periprosthetic fracture
- d) development of infection,

Management factors

- a) institution where treatment was rendered (A, B, or C)
- b) the time to intervention from initial repair
- c) the reason for intervention (hardware failure vs. other)
- d) construct characteristics including material of the implant, plate length, and screw density (number of screws placed/total screw holes in plate).

A subgroup of 13 patients who had their primary surgery done at a different institution but had their nonunion treated at one of ours were included in our analysis of patient and fracture factors but excluded from our calculations of institutional nonunion rates. IRB approval was obtained from all institutions prior to data collection.

Statistical analysis

Patient and fracture characteristics were compared between two groups (patients who underwent surgical revision for

nonunion and those who did not require intervention) using the following statistical tests: Student *t*-test for age, BMI, screw density, and plate length, Fisher's exact test to compare gender, obesity (BMI > 30 kg/m²), diabetes, smoking, steroids, dialysis, fracture type, presence of infection, and plate material, Pearson Chi-square for institution and AO classification. Wilson's method was utilized to determine 95% confidence interval around the observed proportion of distal femur fractures that developed nonunion and needed revision [26]. Multivariable logistic regression with the likelihood ratio test for assessing significance was applied to determine the independent risk factors for surgical intervention for nonunion with the odds ratio and 95% confidence interval (CI) calculated for significant predictors [27]. A multivariable clinical algorithm was constructed based on significant risk factors to estimate the probability of intervention for nonunion [28]. Statistical analysis was performed using IBM SPSS Statistics software version 21.0 (IBM, Armonk, NY). Two-tailed values of *P* < 0.05 were considered statistically significant. Power analysis revealed that a minimum of 40 fractures with nonunion and a minimum of 200 healed fractures (i.e., controls) would provide 80% power using logistic regression modeling to detect moderate effect sizes of 0.80 for all tested variables and would allow up to 11 covariates analyzed simultaneously using a backward selection procedure while yielding reliable coefficients and odds ratios [29].

Results

A total of 283 acute supracondylar femur fractures in 278 patients met inclusion criteria between August 2004 and December 2010. Of these, 41 fractures were surgically treated for nonunion; 13 of these fractures had been referred from an outside institution. A total of 28 nonunions occurred after treatment was rendered by our staff for a combined institutional nonunion rate of 10%.

Median follow-up for all 283 fractures was 12 months (interquartile range: 9–24 months). Among the patients who underwent a secondary surgical procedure, the median time for intervention for nonunion from their original fixation with LLP was 12 months (interquartile range: 6–15 months)

Table 1 summarizes demographic data and the univariate analysis of patient, fracture, and construct characteristics associated with surgical intervention for nonunion. Table 2 summarizes the multivariable analysis. Only obesity (BMI > 30), an open fracture, the occurrence of infection, and the use of a stainless steel plate were statistically significant (*P* < 0.01) independent risk factors predictive of nonunion requiring intervention. Age, gender, diabetes, steroid use, dialysis, smoking, AO classification, plate length, screw density, and institution were of no predictive value. As a sensitivity analysis, we repeated our analysis (Table 2) excluding the 13 cases referred to us from outside institutions. With only 28 nonunion cases in our model our strongest predictors (open fracture and infection) remain significant risk factors but obesity and the use of stainless steel do not.

Table 1

Univariate analysis of patient and fracture characteristics associated with surgical intervention for nonunion in distal femur fractures treated with lateral locking plates.

	Surgical intervention (N = 41)	No intervention (N = 242)	<i>P</i> value
Patient characteristics			
Age, years	62.4 ± 16.1	66.5 ± 17.1	0.21
Gender			0.26
Female	27 (66%)	180 (74%)	
Male	14 (34%)	62 (26%)	
BMI, kg/m ²	32.9 ± 9.0	28.5 ± 7.1	<0.01*
Obesity (BMI > 30)	22 (54%)	88 (36%)	0.03*
Diabetes	12 (29%)	56 (23%)	0.43
Smoking	7 (17%)	27 (11%)	0.30
Steroids	1 (2%)	15 (6%)	0.48
Dialysis	1 (2%)	5 (2%)	1.00
Institution			0.96
A	13 (32%)	73 (30%)	
B	15 (37%)	94 (39%)	
C	13 (32%)	75 (31%)	
Fracture characteristics			
AO classification			0.52
A	19 (46%)	132 (55%)	
C	16 (39%)	86 (35%)	
Periprosthetic	6 (15%)	24 (10%)	
Fracture type			<0.01*
Open	15 (37%)	36 (15%)	
Closed	26 (63%)	206 (85%)	
Infection	7 (17%)	6 (3%)	<0.01*
Plate length	15.0 ± 3.3	15.7 ± 2.5	0.13
Screw density (filled/total holes)	0.72 ± 0.12	0.73 ± 0.14	0.69
Plate material			<0.01*
Stainless steel	15 (37%)	20 (8%)	
Titanium	26 (63%)	222 (92%)	

*Statistically significant. Plus-minus data are mean ± SD.

Using open fracture, infection, obesity, and stainless steel, as our four statistically significant independent variables, a predictive algorithm for nonunion was developed using maximum likelihood estimation in logistic regression (Table 3). When none of these variables are present (titanium used instead of stainless steel), the overall risk of nonunion requiring intervention is calculated at 4%, but increases up to 96% when all risk factors are present including the use of a stainless steel plate. Obesity alone, when stainless steel is used, carries a risk of 44%, but drops to 11% if a titanium plate is used instead. Infection alone, when stainless steel is used, carries a risk of 66%, but drops to 24% with a titanium plate. Fig. 1 illustrates the probability of intervention for nonunion when titanium or stainless steel plates are used for specific combinations of the other three independent multivariable risk factors among the 41 fractures treated for nonunion and the 242 that healed. The distribution of the risk factors is significantly different with more risk factors present among the nonunions (Chi-square = 33.39, *P* < 0.0001). Nonunions had more associated risk factors as well as specific combinations including open fractures and the presence of infection.

Excluding the 13 patients with nonunions whose initial surgeries were done at referring institutions, nonunion rates

Table 2

Multivariable predictors of surgical intervention for nonunion with sensitivity analysis.

Predictor	Entire cohort (N = 283 fractures)			Excluding 13 cases (all nonunions) where initial surgery performed at referring institution (N = 270)		
	Odds ratio	95% CI	<i>P</i> value	Odds ratio	95% CI	<i>P</i> value
Obesity (>30 kg/m ²)	2.9	1.4–6.3	0.005	NS	NS	0.143
Open Fracture	4.0	1.8–9.0	<0.001	5.3	2.2–12.7	<0.001
Infection	7.3	2.0–27.8	0.004	8.2	2.0–34.5	0.008
Stainless steel	6.3	2.7–15.1	<0.001	4.0	1.5–11.4	0.032

CI = confidence interval; NS = not significant.

Table 3

Predictive algorithm of surgical intervention for nonunion based on combinations of significant multivariable risk factors.

Obesity (>30 kg/m ²)	Open fracture	Infection	Plate material	Probability of intervention ^a
No	No	No	Stainless Steel	21%
Yes	No	No	Stainless Steel	44%
No	Yes	No	Stainless Steel	52%
No	No	Yes	Stainless Steel	66%
Yes	Yes	No	Stainless Steel	76%
Yes	No	Yes	Stainless Steel	85%
No	Yes	Yes	Stainless Steel	89%
Yes	Yes	Yes	Stainless Steel	96%
No	No	No	Titanium	4%
Yes	No	No	Titanium	11%
No	Yes	No	Titanium	14%
No	No	Yes	Titanium	24%
Yes	Yes	No	Titanium	33%
Yes	No	Yes	Titanium	48%
No	Yes	Yes	Titanium	55%
Yes	Yes	Yes	Titanium	78%

^a Determined from multivariable logistic regression modeling.**Table 4**Inter-institutional nonunion rates, time to intervention, and interventions done for hardware failure.^a

Institution	Nonunion rate (%)	Median time (days) to intervention (range)	Interventions for hardware failure (%)
A	11/84 (13.1%)	285 (184–335)	2/11 (18%)
B	10/104 (9.6%)	266 (123–440)	5/10 (50%)
C	7/82 (8.5%)	425 (225–1278)	5/7 (71%)

^a Excludes 13 patients who initially had surgery elsewhere.

and times to intervention were calculated for our three affiliated institutions (Table 4). While Chi-square testing could not establish a significant difference in the nonunion rates between the three hospitals ($P = 0.96$), the time to intervention was longest (425 days) in the institution with the lowest nonunion rate (Institution C at 8.5%). This institution also had the most cases operated for hardware failure perhaps suggesting that this hospital's management approach tends towards longer waiting times and late intervention. Conversely, the institution with the highest nonunion rate (Institution A at 13.1%) had a shorter mean time to

intervention (285 days) with most of these interventions for reasons other than hardware failure. Intervention for hardware failure at Institution A was only 18%, suggesting that at this institution surgeons may tend to intervene earlier, rather than waiting for late failure of hardware to occur. The nonunion rate and times to intervention for Institution B are subject to the confounder that some of the surgeons at Institution C also operate at Institution B. The differences between Institutions A and C were of most interest in this sub-group because there was no surgeon cross-coverage.

Discussion

Optimistic early reports on the success of LLP and the LISS system in the management of distal femur fractures with low reported rates of delayed healing have contributed to a proliferation in the use of this technique for trauma and geriatric care [2–5]. Reports describing the use of LLP for the treatment of established nonunion may have also contributed to a perception that risk of nonunion with the use of locked plating was decreased when compared to retrograde nailing or alternative techniques [29–32]. More recently, though, concern has developed as the reported rates of nonunion after LLP fixation of distal femur fractures now vary over the larger range of 0–21% and problems with healing have been reported to be as high as 32% in a recently published review of the literature [2–19]. Another recent study reports worse outcomes with LLP than with the standard 95-degree-angled blade plate in the treatment of distal femur fractures [20].

Many of the published studies of LLP treatment of distal femur fractures have reported small numbers of patients. Only a few of these studies have had the power or intent to seek predictors of nonunion such as patient comorbidities, injury factors, and technical or instrumentation related factors [1,17,21–24]. Those that did have reported factors predictive of nonunion including obesity, diabetes, open fracture, age, fracture comminution, alcoholism, post-operative smoking, and fixation construct characteristics including plate length and screw placement, posterior

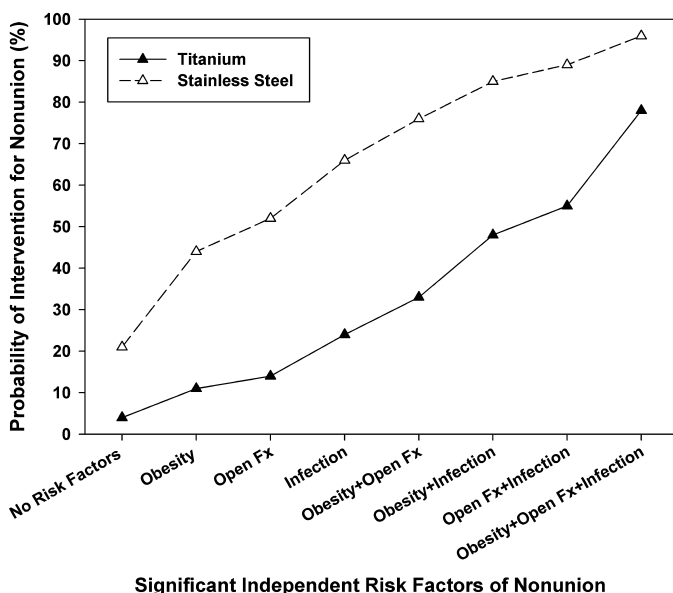


Fig. 1. Probability of intervention for nonunion when titanium or stainless steel plates are used for specific combinations of the other three independent multivariable risk factors (obesity, open fracture, infection) among the 41 fractures treated for nonunion and the 242 that healed.

cortical contact, as well as the material of manufacture of the implant [17,21–25].

The majority of the studies assessing predictors of nonunion have had two common limitations: they were mostly retrospective, and they all had different ways of defining nonunion. While the present study suffers from similar limitations, we propose that by adopting a liberal definition of nonunion and not delineating any strict management protocols, any statistically significant nonunion predictors that are then identified may be of higher clinical relevance. We recognize that a retrospective multicenter and multi-surgeon study can never have a truly consistent definition of nonunion to determine when intervention is required. In any retrospective study there will surely be many participating surgeons each defining and treating nonunion in a somewhat different way. However, this variability also happens to be the reality and nature of clinical practice. It would be difficult to argue with the statement that the treatment of nonunion is likely one of the least standardized practices in orthopedic traumatology. It can also be argued that even if a large prospective study were to be designed, there are presently no quantitative methods to measure the extent of a nonunion that could then be used to clearly define consistent criteria for intervention. Most radiographic measures, including CT, show high inter-observer variability when classifying a fracture and assessing healing with clinical exam findings even more inconsistent [33]. For this reason, allowing nonunion to be defined as liberally as possible, yet developing a statistical model capable of identifying significant predictors of nonunion, constitutes a more realistic strategy consistent with the reality of clinical practice.

When comparing management factors between our participating institutions, a longer time to intervention appeared to correlate with a lower nonunion rate and a preferred indication for intervention consisting of hardware failure. This may simply reflect the fact that by waiting longer some patients that appear at first to have a nonunion may actually proceed to healing. Alternatively, even if a fracture is not fully healed, stress shielding of the hardware secondary to some partial healing may shift the fatigue profile of a plate significantly later in time. Thus, some implants may not fail within the lifetime of a frail geriatric patient or before another intervention is performed such as arthroplasty for subsequent arthrosis. Unfortunately, mortality in geriatric fractures of the distal femur approaches that observed for hip fractures [34]. While our observed inter-institutional differences were not statistically significant, they hint that it may be advisable for a clinician to recommend to a patient to wait as long as possible before intervening for a nonunion if associated symptoms and disability allow it.

Conclusion

We conclude that despite varying trends between our three affiliated institutions in terms of nonunion rates, times to intervention, and indications for intervention, statistically significant and independent predictors of nonunion risk can still be identified. In our study, these are a history of obesity, the occurrence of an open fracture, the occurrence of an infection, and the use of stainless steel plates. We used these variables to develop a predictive algorithm that we hope will serve clinicians in counseling and caring for patients at risk.

We propose that a more liberal definition of nonunion consistent with the realities of clinical practice does not limit the value of a well-planned retrospective study. While we do agree it is difficult to compare nonunion rates between different surgeons, institutions, or published studies when nonunion and criteria for intervention are different, we believe that when a large series of retrospective data are pooled, predictive factors will still

be identifiable given a proper statistical model that accounts for any possible biases or confounding, despite differences in management. For future results to be truly comparable between studies, it would be worthwhile for the trauma community to first develop and agree on a strict quantitative and reproducible measure of nonunion that could be used to define strict intervention criteria. Future work should be directed towards this objective but it may ultimately prove an unrealistic goal. Until then, we should not dismiss what can be learned from studies where nonunion is not so rigidly defined.

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Conflict of interest

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