Analysis of 101 Mechanical Failures in Distal Femur Fractures Treated with 3 Generations of Precontoured Locking Plates

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Objectives: To evaluate mechanical treatment failure in a large patient cohort sustaining a distal femur fracture treated with a distal femoral locking plate (DFLP).

Design: This retrospective case–control series evaluated mechanical treatment failures of DFLPs.

Setting: The study was conducted at 8 Level I trauma centers from 2010 to 2017.

Patients and Participants: One hundred one patients sustaining OTA/AO 33-A and C distal femur fractures were treated with DFLPs that experienced mechanical failure.

Intervention: The intervention included the treatment of a distal femur fracture with a DFLP, affected by mechanical failure (implant failure by loosening or breakage).

Main Outcome Measure: The main outcome measures included injury and DFLP details; modes and timing of failure were studied.

Results: One hundred forty-six nonunions were found overall (13.4%) including 101 mechanical failures (9.3%). Failures occurred in different manners, locations, and times depending on the DFLPs. For example, 33 of 101 stainless steel (SS) plates (33%) failed by bending or breaking in the working length, whereas no Ti plates failed here ($P < 0.05$). Eleven of 12 failures with titanium-Less Invasive Stabilization System (92%) occurred by lost shaft fixation, mostly by the loosening of unicortical screws (91%). Sixteen of 44 variable –angled–LCP failures (36%) occurred at the distal plate–screw junction, whereas only 5 of 61 other DFLPs (8%) failed this way ($P < 0.05$). Distal failures occurred on average at 23.7 weeks compared with others that occurred at 38.4 weeks ($P < 0.05$). Variable –angled–LCP distal screw–plate junction failures occurred earlier (mean 21.4 weeks).

Conclusion: Nonunion and mechanical failure occurred in 14% and 9% of patients, respectively, in this large series of distal femur fracture treated with a DFLP. The mode, location, presence of a prosthesis, and timing of failure varied depending on the characteristics of DFLP. This information should be used to optimize implant usage and design to prolong the period of stable fixation before potential implant failures occur in patients with a prolonged time to union.

Key Words: Plate failure, plate breakage, locking plate, locked plate, failure, breakage, loss of fixation

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

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INTRODUCTION

Distal femur fractures are challenging injuries to treat, and the results of treatment are varied.[1–8] Before the development of fixed-angle plating, comminuted distal femur fractures stabilized with traditional plate and screw constructs yielded high rates of nonunion, fixation failure, and varus malunion.[9,10] In the 1990s, the Less Invasive Stabilization System (LISS, Synthes, Paoli, PA), an anatomically designed titanium (Ti) distal femoral locking plate (DFLP), was designed to provide multiple fixed-angle points of fixation with self-drilling, self-tapping unicortical screws and a system for minimally invasive plate application.[11] The predominant strategy was to optimize fixation, especially in the osteoporotic condylar segment, without disruption of the fracture biology using a minimally invasive system. Early studies reporting the results of LISS plates showed promising results with union rates of 90%–100%.[5–7] Over the next decade, a second generation of DFLPs was developed to provide the surgeon greater flexibility, that is, allowing for the placement of both traditional and locking screws. More recently, a third generation of DFLPs was created, which allows for the placement of polyaxial or variable angled (VA) locking

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screws.[9,10,12,13] VA locking screws allow the surgeon the option to apply screw fixation to preferred areas of bone or to avoid existing implants such as lag screws, nails, or arthroplasty components. While this evolution of DFLPs over the past few decades has presumably improved our ability to manage these complex injuries, comparative reports of mechanical failure remain few and preliminary.[2,13–16]

Distal femur fractures may take many months to achieve union after treatment, and healing is not guaranteed. Multicenter studies have shown nonunion rates of 18%–25% in patients with femur fractures treated with DFLPs, typically associated with fixation failure.[1–3] Many of these cases showed considerable soft tissue injury, comminution or bone loss, an overly stiff construct, a morbid host that might require prolonged observation for healing, or staged procedures such as bone grafting or revision fixation.[17] Mechanical testing studies have compared some DFLPs with varying results,[18–21] and DFLP failures have been reported through a handful of specific mechanisms, including screw cutout from the condyles,[22] screw failure from bone,[23] locking screw–plate junction failure,[15] plate breakage,[15,22] and others.[24] In addition, several studies have suggested that DFLPs may sometime allow an overly stiff construct to impair healing and may impart unbalanced callus formation across the fracture site.[9,10] No study to date has adequately compared the relationship of mechanical failure with DFLP systems, their materials, and locking screw technologies.

The aim of this study was to evaluate the details of mechanical failure in patients with distal femur fractures treated with several generations of LPs. Our null hypothesis was that different DFLP systems would fail similarly, that is, in a similar mechanical manner, location, and period after DFLP application.

METHODS

This retrospective case–control series specifically evaluated mechanical failure after treatment of patients with Orthopaedic Trauma Association/AO (OTA/AO) 33-A and C distal femur fractures using locked plating at 8 ACS Level 1 trauma centers between 2011 and 2018. One thousand 87 distal femur fractures were treated with locked plating and evaluated for mechanical failure.

Inclusion criteria included the following:

1. Skeletal maturity to 100 years old
2. 33-A or C-type distal femur fracture according to the OTA/AO classification[25]
3. Treated with anatomically designed distal femur locking plate
4. Adequate radiography
5. Experienced mechanical or fixation failure (described further).

One hundred one (9.3%) patients with a distal femur fracture experienced mechanical failure and met inclusion criteria. The average patient age was 57.3 ± 16 years, and 60% were women. The mean follow-up was 113 weeks (range, 1–531 weeks). Additional demographic and injury data are summarized in Table 1. Most of these DFLP surgeries were performed using modern plating techniques, that is, long plates, spaced screws, and a long working length, although surgical technique was not the focus of the study.

Failed cases were grouped by DFLP for subanalysis:

1. Eleven failures were treated with titanium (Ti) alloy DFLP system that uses 5.0 mm unicortical screws designed for minimally invasive application LISS; DePuy Synthes, West Chester, PA)
2. Thirty-five failures were treated with 1 of the 2 SS-FA DFLP systems: [24 Periloc; Smith & Nephew, Memphis, TN, and 11 fixed-angle Locking Condylar Plate, DePuy Synthes, West Chester, PA]
3. Forty failures were treated with a SS-VA DFLP system (Variable-Angle Locking Condylar Plate, DePuy Synthes, West Chester, PA)
4. Thirteen failures were treated with 1 of the 2 Ti-VA DFLP systems, either the Non-Contact Bridging plate (NCB, Warsaw, IN) or AxSOS LP system from Stryker Orthopedics (Mahwah, NJ).
5. Three fractures were treated with a Ti-VA DFLP system (AxSOS, Stryker Orthopedics, Mahwah, NJ)
6. Two failures were treated with a Ti DFLP system that included a large, central condylar FA screw surrounded by VA screws, a combination condylar screw cluster (PolyAx, Zimmer-Biomet, Warsaw, IN)

Soft tissue, bone loss, and mobility were handled similarly at each participating center. High-energy injuries in polytraumatized patients and high-energy open distal femur

TABLE 1. Patient, Demographics, and Injury Factors

Factors	
No. of patients	101
Mean age, y (SD)	58.1 ± 16.0
Female sex (%)	66.5.0%
Osteoporosis	39 (39.4%)
OTA/AO classification	
● Type 33A1	3 (3.0%)
● Type 33A2	26 (25.7%)
● Type 33A3	17 (16.8%)
● Type 33C1	15 (14.7%)
● Type 33C2	23 (22.8%)
● Type 33C3	16 (15.8%)
Soft tissues	
● Closed fractures	59 (58.4%)
● Open fractures	42 (41.6%)
Type 1	2
Type 2	10
Type 3a	27
Type 3b	3
Periprosthetic fractures	22 (21.7%)
● Below hip replacement only	2
● Above knee replacement only	16
● Interprosthetic fractures	4
Staged treatment (total)	34 (33.2%)
● External fixator	28
● Antibiotic beads or spacer	8
● Bone grafts at less than 3 months	6

fractures were typically treated with a staged protocol of temporary external fixation, followed by staged open reduction and internal fixation, with timing of definitive surgery based on the discretion of the attending surgeon. All open fractures were treated with early intravenous antibiotics and surgical debridement. Bone loss was typically addressed expectantly if deemed minor and with staged bone grafting if more significant. Weight-bearing was determined by the attending orthopaedic surgeon, with intra-articular fractures typically made protected weight-bearing for 10–12 weeks, whereas extra-articular fractures typically allowed progressive weight-bearing once callus was seen on radiographs.

Radiographic union was defined as bridging callus across the fracture line(s) on 3 of 4 cortices seen on orthogonal radiographs and patient comfort with ambulation.[1–3] These criteria were determined by the treating orthopaedic trauma surgeon. Radiographic findings were confirmed by a second, independent orthopaedic trauma surgeon who was blinded from outcomes. Discrepancies were mediated by an independent, blinded third orthopaedic trauma surgeon. Mode of failure and timing to failure were noted. *Mechanical failure* was defined as loose, broken, or bent implants or changes in bony or implant alignment likely to affect function or outcomes (ie, 10 degrees). It was estimated that most fractures should be healed at 4 months and a plate construct might be expected to remain stable that long. Therefore, early implant failure was defined as occurring at <4 months.[1] The occurrence of any additional fracture complications or secondary surgeries was noted.

Mechanical failures were defined as loss of fixation, including screw loosening, breaking (or a combination) along the femoral shaft, plate breakage or bending with a loss of alignment >10 degrees adjacent to the fracture, screw cutout from the condyles, or dissociation of the condylar plate locking screw junction. *Biologic failures* were defined as established fracture nonunion (typically treated with revision surgery to gain union).

RESULTS

Patient demographics, injury pattern, and treatment details of patients with mechanical failure are summarized in Table 1. Fracture pattern (OTA/AO A vs. C), soft tissue injury (open vs. closed), timing of repair (primary open reduction and internal fixation vs. staged surgery), or whether the fracture was periprosthetic did not affect the mode of mechanical failure. DFLP failures according to the plate type, material, locking screw mechanism, failure mode, and timing of failure are summarized in Table 2. There were also 45 fractures with a strictly biologic failure (the DFLP remained well-fixed but nonunion resulted in revision surgery) resulting in a total of 146 failures overall that underwent revision surgery (13.4%). Mechanical failures occurred at the shaft in 41 cases, working length in 30, and in the condylar region in 30. Failures did not occur differently when comparing 46 extra-articular with 55 intra-articular fractures ($P = 0.65$) or 59 closed with 42 open fractures. However, 22 mechanical failures (21.7%) were periprosthetic or interprosthetic fractures: 10 of these 22 fractures (45.5%) failed by bending or breaking in the working length compared with 20 of 79 failures by this means in native femurs ($P = 0.041$). No other differences were seen between these groups.

TABLE 2. DFLP Failure by Location and Mechanism

	Material		Stainless Steel			Titanium			
	Locking Screws		Variable Angle	Fixed Angle			Variable Angle		Combination
	Mechanism of Failure	All Plating Systems [Time to Failure, Weeks]	Synthes VA-LCP (FA-SS)	Synthes FA-LCP (FA-SS)	Smith & Nephew Periloc (FA-SS)	Least Invasive Stabilization (FA-Ti)	Zimmer NCB (VA-Ti)	Stryker AxSOS (VA-Ti)	Biomet PolyAx
	All mechanical failures	101	40	11	24	11	10	3	2
		34.4 ± 29.1	34.4 ± 33.5	31.3 ± 19.6	29.5 ± 18	40.7 ± 27.3	38 ± 18.4	31 ± 7.5	57.5 ± 19.3
Shaft region	Loosened screws	16	4	0	3	8	1	0	0
		42.3 ± 29.1	59.1 ± 37.5		30.7 ± 9.5	40.7 ± 30	22.0		
	Broken screws	14	6	1	3	1	1	1	1
		39.2 ± 35.4	41.6 ± 45.9	33.0	12.5 ± 4.5	31.0	72.0	38.0	88.0
	Combination loose and broken screws	11	2	3	2	1	2	0	1
		30.2 ± 20.5	33 ± 38.2	20.4 ± 14.5	17.9 ± 7.2	67.7	31 ± 12.7		27.0
Working length	Bent plate	7	2	2	3	0	0	0	0
		29.2 ± 24.5	41.1 ± 52.1	22 ± 16.6	26.1 ± 9.9				
	Broken plate	23	9	3	7	0	3	1	0
		41.7 ± 23.2	42 ± 34.2	48.7 ± 18.3	39.3 ± 16		42.7 ± 1.2	32.0	
Condylar region	Plate–screw failure	20	15	2	1	0	2	0	0
		23.7 ± 24.9	20 ± 23.5	30.3 ± 32.1	72.0		20.3 ± 19.4		
	Screw cutout	10	2	0	5	1	1	1	0
		28.2 ± 20.3	31.4 ± 34.7		23.6 ± 20.1	23.0	55.0	23.0	

While group analysis showed was a strong trend toward DFLP systems failing by different mechanical modes (P = 0.055), head-to-head DFLP comparison clearly demonstrated that DFLP systems failed differently. For example, 9 of 11 LISS plates (82%) experienced failure by [unicortical] screws loosening from the femoral shaft, whereas no LISS plates bent, broke, or had condylar screws detach from the plates. Other systems had fewer problems along the shaft. Of 40 VA-locking condylar plates (LCPs), for example, only 10% of cases had failed screw fixation at the shaft, while 27.5% of these plates bent or broke, and 37.5% had dissociation of the condylar screws from the distal plate. For the 24 Periloc DFLPs, 41.7% of DFLPs bent or broke, and only 4.1% had condylar screws dissociated from the plate, while 16.4% loosened along the femoral shaft (P = 0.010). FA screws failed by condylar screw cutout (6 of 46, 7%) at a similar rate as VA screws (4 of 53, 8%) [P = 0.284]. The FA Periloc DFLP experienced failure by screw cutout from the condyles in 20.8% of 24 failures, compared with only 6.1% of failures of all other plates combined (P = 0.022). VA screws failed more by condylar screw–plate dissociation (17 of 75, 23%) versus FA screws (3 of 46, 7%) [$P < 0.02$].

DFLPs failed in different regions according to their material makeup: SS DFLPs failed similarly in the 3 regions (24 shaft, 26 working length, and 25 condylar region) compared with Ti DFLPs, which failed at the shaft in 65% of cases (17 of 26, $P < 0.001$). Mechanical failures varied according to the plate's material (SS or Ti) and by its condylar plate–screw locking mechanism (VA vs. FA). For example, 82.6% of 23 plates that broke and 86.7% of 30 plates that broke or bent in the working length of the construct were manufactured from SS, whereas only 13.3% of Ti plates failing by breaking and none by bending ($P < 0.001$). VA DFLPs failed by plate–screw dissociation in the condylar region in 18.9% of cases compared with 2.7% of 46 FA DFLPs (P = 0.002), and 72.7% of 11 plates that loosened from the shaft were LISS plates, whereas 75% of 20 plates that failed by dissociation of the condylar locking screws were VA-LCPs. There was also a strong trend in the timing of those failures according to different failure modes. The earliest failure mode manifested was dissociation at the condylar plate–screw junction averaging 23.7 ± 24.9 weeks, compared with broken or loosened screws at the shaft at 39.2 ± 35.4 and 42.3 ± 29.1 weeks, respectively. Plate breakage was not seen until an average of 41.7 ± 23.2 weeks (P = 0.052).

DISCUSSION

Treatment of distal femur fractures has been associated with high rates of failure, which has led to an evolution of technology available to the treating surgeon.[9,10] Clinical analysis of the constructs from this technological evolution has so far been lacking. This study seeks to critically evaluate the modes and timing of failure of these different systems. Early distal femur plate fixation was characterized by screw cutout and loss of plate–screw fixation in the condylar region of the distal femur where bone is often osteoporotic, screw density is limited, and traditional plate–screw fixation based on compression is easily lost through toggling.[11] Fixed-angled DLFP technology was specifically designed to address these issues. Two large clinical series have demonstrated revision surgery rates of 19% and 13% to achieve union in 64 and 36 patients, respectively.[1,3] Risk factors for failure were established, although neither study addressed specific mechanisms of mechanical failure. Ricci et al[1] reported implant failure in 25 of their 64 nonunions (7% of all treated patients) and that 72% of these failures occurred in the shaft segment, 16% in the working length, and 16% involved the condylar fixation. Schmidt et al[26] performed a mechanical study on 6 different DFLP systems, all of which were clinically evaluated in our study. While their study was preliminary, they concluded that mechanical properties, for example, stiffness and fatigue resistance, varied according to features of the DFLP system evaluated. Our study has specifically evaluated 1087 DFLP cases used to treat distal femur fractures at 8 trauma centers and found mechanical failure in 101 cases (9.3%). There were also 45 fractures with a strictly biologic failure, where the DFLP remained well-fixed, but nonunion resulted in revision surgery, resulting in a total of 146 failures overall receiving late revision (13.4%). Ours is the first study that shows that DFLP design affects fixation failure and its timing in a large clinical series. We acknowledge that the relationship of nonunion and mechanical failure is deeply intertwined, that is, the maxim about osteosynthesis—"all fixation fails if fracture healing is not achieved." DFLP fixation that resists mechanical failure for a prolonged period may allow more patients to successfully achieve union. Finally, as plating systems continue to evolve, manufacturers may use some of this information to optimize implant design in the future.

We found that mechanical failures among DFLP systems occurred by different modes, in different regions, at different times, and were affected by the presence of a prosthesis(es). It is of interest that most mechanical failures occurred away from the condylar segment despite the concerns of surgeons using early-generation plates: 41.6% of DFLPs lost fixation along the shaft, 29.7% in the working length, and 29.7% in the condylar segment. When failure did occur in the condylar region, it typically occurred by failure of the plate–screw locking mechanism (66.7%). This failure mode represented 37.5% of 40 VA LCP mechanical failures compared with only 8.1% of 61 failures of this type in other DFLPs (P = 0.022). Most of these early VA screw–plate failures at the condyles fell into unacceptable varus malalignment, and all underwent revision surgery. Although fracture classified as extra-articular versus intra-articular or closed versus open failed similarly, periprosthetic/interprosthetic fractures failed more commonly by bending or breaking in the working length (46% of 22) compared with native femurs (25% of 79, P = 0.041). The timing of failures at the VA plate–locking screw junction occurred earlier than failures by other modes (mean 23.7 weeks vs. 36.2 weeks, respectively; P = 0.010). Tank et al[15] reported on fixation failures in 22.2% of 36 VA-LCP (SS) cases, including 5 failures of locking screw fixation at the condylar plate (in addition to 3 broken or bent plates). Tidwell et al[27] mechanically tested Synthes' SS distal femur LPs (SS VA-LCP vs. SS FA-LCP) and found that the FA-LCP provided greater resistance to rotational failure at the condylar plate–screw interface. It is of importance that as the off-axis angle of VA screws increased, the mechanism's resistance to failure decreased linearly. McDonald et al subsequently reported 9.3% fixation failures in 118 fractures with only 2 cases resulting from dissociation of condylar screws from the plate. The authors attributed the low rate of plate–screw failures due to the application of most of the condylar VA screws without angular divergence and returning to retighten those screws after the construct was created.

Other DFLP systems showed unique, specific failure patterns. The LISS system seemed particularly vulnerable to fixation failure along the femoral shaft segment. Ten of 11 LISS system fixation failures (90.1%) occurred along the femoral shaft by unicortical screw loosening,[8] screw breakage,[1] and a combination of both.[1] LISS had only 1 other failure case, a screw cutout of the condylar segment. Button et al[23] described 4 fixation failures in 22 LISS cases where fixation failed along the femoral shaft, including 2 where the plate was not positioned flush on the lateral femur, and the short unicortical screws seemed to have missed bone. Kregor et al[6] reported 7 construct failures in 103 distal femur fractures treated with LISS that occurred by loosening in the shaft region of the femur. LISS′ self-drilling, unicortical locking screw design was created for ease of insertion but may have made them susceptible them to osteonecrosis or torsional failure. Likely for these reasons, these first-generation DFLP LISS′ screw design strategies have not been widely used in subsequent DFLPs.

Mechanical failure occurred by different modes and locations depending on the material makeup of the DFLP as well. Mechanical failure occurred in 75 SS DFLPs evenly between the 3 relevant regions of DFLP fixation (ie, 25 condylar, 26 fracture, and 24 femoral shaft), whereas Ti DFLPs failed most commonly by 15 screw-related failures at the shaft (mostly with LISS), compared with only 4 failures at the fracture and 5 at the condyles (P = 0.028). In addition, 26.1% of 99 SS DFLPs failed by plate breakage or bending within the working length, compared with only 12% of 35 Ti DFLPs that broke (none bent, P = 0.059). The biomechanical advantages of Ti versus SS for orthopaedic plates and screws, that is, elasticity and fatigue properties, are yet to be fully established. Three studies have evaluated this topic, but specific modes of implant failure were not reported in any of them. Rodriguez et al[2] found association between plate material and nonunion in 271 patients with distal femur fractures: 41% of stainless constructs resulted in nonunion compared with only 10% of titanium constructs ($P < 0.001$). Gaines et al[13] retrospectively compared 109 patients with distal femur fractures treated with several of the DFLPs evaluated in our study, that is, Ti DFLPs (LISS and DePuy's Polyax) with SS DFLPs (FA LCP and Periloc). Reported nonunion rates were 7% and 23%, respectively (P = 0.05). The Southeast fracture consortium[3] studied 339 distal femoral fractures, 55% were repaired with Ti LISS and 45% repaired with a SS FA LCP. No difference was seen between either implant in failed fixation at <3 months (3.2% vs. 5.2%, P = 0.98). Two mechanical testing studies performed have compared Ti and SS DFLPs. As expected, both studies found Ti constructs were found to be less stiff and closer to the modulus of elasticity of human bone; however, conclusions diverged on fatigue failure. Schmidt et al[26] showed a range of fatigue failures between DFLPs, but their preliminary results favored Ti over SS DFLPs. Kandemir et al[21] compared Ti versions with SS versions of the same DFLP (AxSOS, Stryker, Mahwah, NJ), finding the fatigue life of the Ti version was approximately 50% less than that of the identical SS implants. Failure modes were similar in plates of both materials, that is, angulation between the fracture fragments >10 degrees through the condylar plate–locking screw junction. The authors hypothesized that their testing led to failures of the locking screw mechanism with Ti being less effective than SS in that function.

This study has several limitations. As a retrospective study, there are some data inherently undocumented, for example, the number of standard versus locked screws. We can note that our condylar screw clusters for VA-LPs typically contained 0 or 1 standard screw with the remainder being locking screws. Those screws were typically placed in relative axis with the plate hole except for instances where there were other implants that surgeons needed to work around, that is, C-type fractures or periprosthetic fractures. Second, due to the nature of the study, we did not evaluate techniques of fracture reduction or plate application or extrapolate their possible effects on outcomes, although these variables are clearly important to consider. We also acknowledge that mechanics affect biology and vice versa and that the 2 cannot be flawlessly separated and studied. Finally, our study did not directly evaluate the relative failure rates between plating systems. This focus of analysis was intentional because our goal was not to advocate for one manufacturer's merchandise but to evaluate these LPs for differences in failure so that discussion might be entertained how to potentially improve results. Strengths of this study are important to note as well. First, this study seems to be the first comprehensive evaluation designed to analyze the mode, location, and timing of mechanical failure for distal femur LPs. Second, the mechanically failed LPs evaluated in our study and most of the patients treated here included long LPs applied with modern principles, and thus the results should be reliable and relevant.

The failure of distal femur fractures treated with DFLPs over a 5-year period at 8 Level 1 trauma centers occurred by different modes, locations, and at different times after repair. There are differences in failure patterns based on material and configuration of the DFLP used as described in this report. Based on this information, limiting treatment failure in these complex injuries seems possible by addressing DFLP vulnerabilities in the short-term through appropriate preoperative planning and utilization and in the long-term through improved implant design. We suspect that these difficult injuries will still frequently experience mechanical failure, but by pushing that terminal event farther into the future, more of our patients will have time to heal before failure occurs.

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