

Locked Lateral Plating Versus Retrograde Nailing for Distal Femur Fractures: A Multicenter Randomized Trial

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Objectives: The 2 main forms of treatment for distal femur fractures are locked lateral plating and retrograde nailing. The goal of this trial was to determine whether there are significant differences in outcomes between these forms of treatment.

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Design: Multicenter randomized controlled trial.

Setting: Twenty academic trauma centers.

Patients/Participants: One hundred sixty patients with distal femur fractures were enrolled. One hundred twenty-six patients were followed 12 months. Patients were randomized to plating in 62 cases and intramedullary nailing in 64 cases.

Intervention: Lateral locked plating or retrograde intramedullary nailing.

Main Outcome Measurements: Functional scoring including Short Musculoskeletal Functional Assessment, bother index, EQ Health, and EQ Index. Secondary measures included alignment, operative time, range of motion, union rate, walking ability, ability to manage stairs, and number and type of adverse events.

Results: Functional testing showed no difference between the groups. Both groups were still significantly affected by their fracture 12 months after injury. There was more coronal plane valgus in the plating group, which approached statistical significance. Range of motion, walking ability, and ability to manage stairs were similar between the groups. Rate and type of adverse events were not statistically different between the groups.

Conclusions: Both lateral locked plating and retrograde intramedullary nailing are reasonable surgical options for these fractures. Patients continue to improve over the course of the year after injury but remain impaired 1 year postoperatively.

Key Words: distal femur, locked lateral plating, retrograde intramedullary nail

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

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INTRODUCTION

Distal femur fractures tend to be unstable injuries most commonly treated with surgical fixation to promote mobilization of the patient and the affected limb. Even when fixed well, these fractures remain challenging injuries that may

cause patients significant morbidity.¹⁻⁴ Operative fixation offers the ability to restore and maintain alignment of the extremity during the healing process.⁵ The 2 common methods of fixation are intramedullary nailing and plate fixation. The biomechanics of both techniques have been validated, and the effects of construct stiffness continue to be investigated.^{3,6-10} Both have reasonable success and are considered standard of care.¹¹⁻²² Each method has risks, and some surgeons prefer one method over the other.

The advent of precontoured, locked plating systems allowed for multiple points of fixed angle (locked) screw fixation to be placed in the short, metaphyseal, and diaphyseal segment. This mitigated the tendency of the fracture to fall into varus commonly seen with earlier nonlocking plating constructs.²³ Early reports of success with these lateral locked plates, particularly when combined with the use of newer minimally invasive techniques, effectively superseded the use of older implants (condylar buttress plate, 95-degree-angled blade plate, dynamic compression screw, and older generation retrograde femoral nails).^{11-17,24-27} Precontoured locking plates became the preferred mode of fixation in the early 2000s.

As more distal femur fractures were plated, limitations and complications became noted.^{2,3,27-33} Initial enthusiasm for locked plating was dampened by reports of nonunion, delayed union, plate failure, and need for secondary intervention. Retrograde femoral nailing remained a popular treatment choice because these offered a strong, centrally placed implant that minimized the moment arm from the medial cortex (compared with lateral plating). These could be introduced providing “relative stability” in a soft tissue friendly manner. Because newer nailing systems featuring multiple, multiplanar interlocks became available, nailing became increasingly popular. Some surgeons find obtaining acceptable reductions with nailing difficult and favor open reduction with plating constructs.

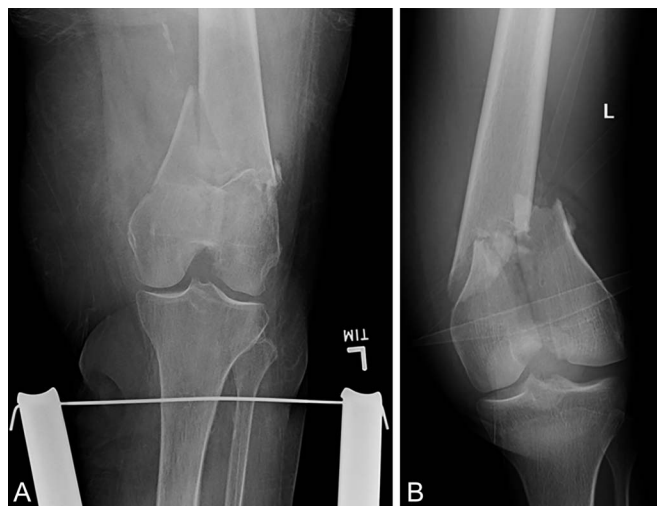


FIGURE 1. A, Anteroposterior image of an extra-articular supracondylar distal femur. Fracture with an intact medial metaphyseal wedge fracture. B, Anteroposterior image of a distal femur fracture with simple split through articular surface and minor metaphyseal comminution.

The purpose of this study was to determine whether locked lateral plating (LP) or retrograde femoral nailing [intramedullary nail (IMN)] offers a better option for the treatment of these fractures. The null hypothesis was that there would be no difference between groups about patient-reported outcome measures or clinical and radiographic outcomes. Distal femur fractures treated with locked plates were compared with similar fractures treated with retrograde intramedullary nails in an IRB-approved, multicenter, randomized controlled trial.

MATERIALS AND METHODS

Patient Recruitment

Over a 75-month period, adult patients presenting to one of 20 trauma centers with an extra-articular or simple articular split distal femur fracture, with or without metaphyseal comminution, which the surgeon believed could reasonably be treated with either a locked lateral plating construct or a retrograde femoral nail were offered enrollment if they met inclusion criteria (Figs. 1A, B).³⁴

Specifying an alpha level = 0.05, a beta = 0.20, power analysis determined that a sample of 126 patients (63 per group) to ensure detection of a 1/2 SD improvement in functional testing was needed. Goal enrollment was set for 160 patients to account for loss to follow-up and errors in randomization. General outcome was determined by the SF-12 and EuroQol 5D. Disease-specific outcomes was assessed by the Short Musculoskeletal Functional Assessment measure (SMFA) and the Knee Society Score.³⁵ For our primary outcome, we considered an important difference in SF-12 and EQ5D to correspond to a moderate effect.^{36,37} In both cases, the value is at least 1/2 the SD, equivalent to a 6-point difference in score.

Participating surgeons used a web-based randomization program to obtain the treatment procedure: “NAIL” or “PLATE.”

Inclusion criteria included skeletal maturity, fracture of the metaphyseal distal femur with or without simple intra-articular extension, and fracture requiring operative treatment amenable to either IM nail or plate, (see **Text, Supplemental Digital Content 1**, <http://links.lww.com/JOT/B828>, Inclusion/Exclusion Criteria).

Irrigation and debridement of open wounds and application of a knee spanning external fixator, were not exclusionary, as long as the initial debridement took place within 24 hours and definitive fixation took place within 3 weeks after injury.³⁸

Exclusion criteria are listed in **Supplemental Digital Content 1** (see **Text**, <http://links.lww.com/JOT/B828>, Inclusion/Exclusion Criteria).

A randomization scheme was established with permuted blocks for open and closed fractures using a Health Insurance Portability and Accountability Act (HIPAA) compliant computer-based system. Demographic data including the patient’s medical history, medications, smoking, injury severity score, age, sex, and surgical history were collected. Standard fracture characteristics and surgical variables were collected.

Outcomes

The primary outcomes were the patient-reported scoring systems SMFA, SF-12, and EuroQol 5D. Secondary outcomes were malalignment, range of motion, mobility scores, and complications. The SMFA, SF-12, EuroQol 5D, and clinical examination including range of motion were collected at 3, 6, and 12 months. Patient-reported abilities in stair climbing (1 best, 5 worst) and walking (1 best, 6 worst) were evaluated at the same time points.³⁵ Patients were queried regarding ongoing need for ambulatory aids and pain medication. Anteroposterior (AP) and lateral radiographs of the uninjured contralateral side were obtained preoperatively after enrollment. Radiographs were obtained of the operative side postoperatively and at each follow-up visit and evaluated for any change in alignment, progression toward union, and loosening or failure of implants. Angular deformity of 5 degrees or more in any direction from that noted on contralateral films was characterized as abnormal. All radiographs were evaluated by attending-level orthopaedic traumatologists. Complications were documented prospectively and included infection, loss of reduction, implant failure or removal, and need for revision surgery. Statistical analysis was performed by a PhD statistician and used *t* tests for continuous variables and the Fisher exact test for ordinal variables.

RESULTS

A total of 372 patients were screened, and 212 did not meet inclusionary criteria. One hundred sixty patients were recruited, and 156 patients were randomized to locked LP or IMN (80 LP, 76 IMN) and underwent those procedures (Fig. 2). Four patients who were randomized were noted to have met exclusionary criteria and were excluded. Thirty patients did not complete the full 12-month follow-up. Sixteen patients were lost to follow-up, 10 patients withdrew consent, and 4 patients died during the 12-month follow-up period. One hundred twenty-six patients (62 LP, 64 IMN) were followed for 1 year. The average age of the patients was 51 (range 16–90) years and was not different between the groups

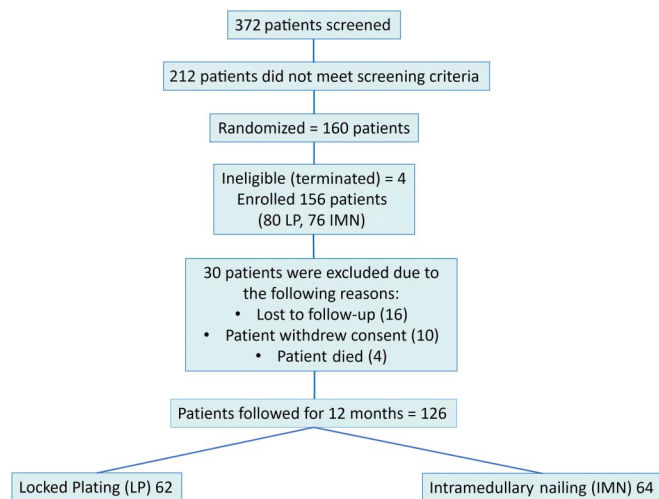


FIGURE 2. Exclusion chart. full color online

(*P*-value = 0.29). There were 71 men and 55 women, evenly distributed between the groups (*P*-value = 0.17). Thirty-four of 126 (27%) of the fractures were open injuries, evenly distributed between the groups (*P*-value = 0.63) and were all Gustilo type II and IIIA injuries. Eighty-three of 126 patients (66%) had 33-A supracondylar fractures, and 43 of 126 (34%) had 33-C-1 or 33-C-2 fractures with a simple intra-articular extension. The average patient ISS was 12.6 (range 9–43) and was not significantly different between the groups. There were 4 patients with supracondylar fractures above total knee arthroplasties, 2 in each group. There were no differences in the demographic distribution or the fracture patterns between the groups.

Nailing

Retrograde intramedullary nailing was performed using a midline incision with the patient in the supine position. Simple split articular injuries were treated with either percutaneous clamping or an open lateral subvastus or lateral parapatellar approach, with strategically placed lag screws placed before nail insertion. After nail insertion, multiple, multiplanar interlocking screws were routinely placed in the distal segment (Fig. 3A). An average of 2.83 interlocking screws was used distally. Fifteen blocking screws were used in 13 of the 64 patients with IMN, most commonly placed from laterally to medially, anterior to the nail to address an extension deformity (6 cases). The average surgical time was 125 ± 61 minutes. Immediate range of motion was permitted, and weightbearing was begun at 6 weeks postoperatively for extra-articular fractures and at 10–12 weeks if intra-articular extension was present. (see **Text, Supplemental Digital Content 2**, <http://links.lww.com/JOT/B829>, Implants Used, Intramedullary Nails).

Plating

Sixty-two of the patients had been randomized to plating. Stainless steel plates and screws were used in 42 of 62 patients (68%) and titanium implants in 20 of 62 patients (32%). Lateral subvastus and lateral parapatellar approaches were used, with minimally invasive techniques of submuscular plate placement and percutaneous insertion of proximal screws used in most of the cases (Fig. 3B). The average number of plate holes above the fracture was 10.6 (range 3–20). The average surgical time was 124 ± 51 minutes, which did not differ from nailing (*P* = 0.96). As with nailing, immediate range of motion was permitted, and weightbearing was permitted at 6 weeks postoperatively for extra-articular fractures and at 10–12 weeks if intra-articular involvement was present. (see **Text, Supplemental Digital Content 3**, <http://links.lww.com/JOT/B830>, Implants Used, Lateral Femoral Locking Plates).

Outcomes

Although there was significant improvement in all patient-reported outcome testing at each follow-up interval (Tables 1–4) [see **Figures, Supplemental Digital Content 4**, <http://links.lww.com/JOT/B831>, SMFA (all Patients); see **Figure, Supplemental Digital Content 5**, <http://links.lww.com/JOT/B832> (LP vs. IMN); see **Figure, Supplemental Digital Content 6**, <http://links.lww.com/JOT/B833>, Bother Index (LP vs. IMN); see **Figure, Supplemental Digital**

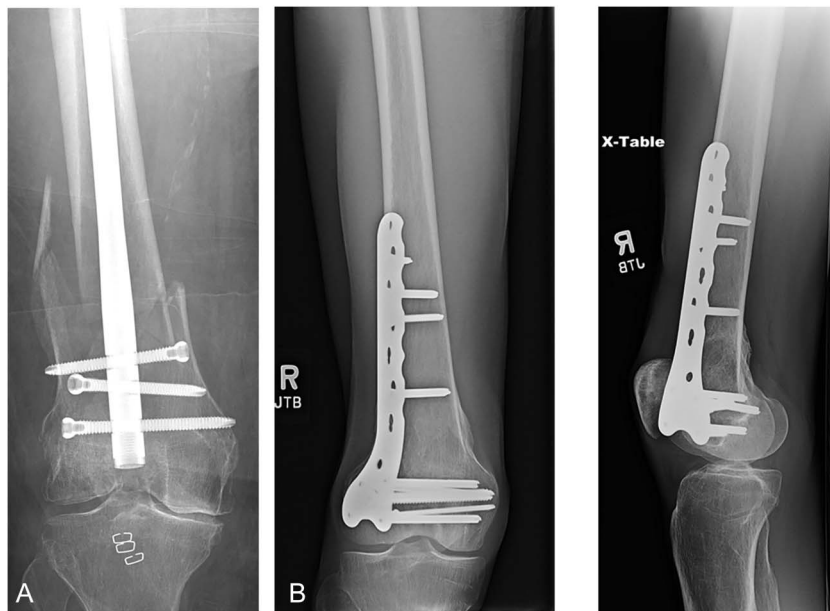


FIGURE 3. A, Anteroposterior radiograph of fracture fixed with intramedullary nail. B, Anteroposterior radiograph of fracture fixed with lateral locked plate and screw construct with union.

Content 7, <http://links.lww.com/JOT/B834>, EQ Health (LP vs. IMN); see **Figure, Supplemental Digital Content 8**, <http://links.lww.com/JOT/B835>, EQ Index (LP vs. IMN)], many patients remained affected by their injury at 12 months postoperatively. Although there was a trend toward improved functional scoring in the IMN group, there were no statistical differences in any of the functional outcome measures between the groups (Table 5), and there was no measure that met the level for a clinical difference.

Malalignment of 5 degrees or more in any plane was present in 20 of 62 LPs (32.2%) and 14 of 64 IMNs (22%), which was notable but not significantly different ($P = 0.4$). In all cases, this malalignment was established at the time of surgery, rather than because of failure of fixation and loss of alignment postoperatively. The most common deformity seen was coronal plane valgus. This was seen in 17 of 62 (27.4%) of plates and 8 of 64 (12.5%) of nails, ($P = 0.05$). Varus angulation of 5 degrees or more was seen in 3 of 62 plating cases (4.8%) and 6 of 64 nailings (9.4%), which was not statistically significant. There were very minor sagittal plane abnormalities, none greater than 5 degrees and no difference between the groups.

The average knee flexion was 111 degrees ($SD \pm 29$ degrees) in the LP group and 114 degrees ($SD \pm 28$ degrees) in the IMN group, which was not statistically

different ($P 0.51$). At 1 year, 16% of patients treated with LP and 12% of patients treated with IMN lacked at least 5 degrees of extension, which was not significantly different. Two-thirds of all patients were weightbearing by 3 months, and all were weightbearing by 6 months. At 1 year, the average patient could walk 10 blocks, could go up and down stairs using a rail for assistance, and occasionally used a cane. At 1 year, 40% of patients were taking no pain medication, 60% were taking some form of pain medication, and 18% were taking some form of narcotic (Table 5).

There was an adverse event rate of 20%, which was not statistically different between the groups. There were 5 DVTs and 1 PE death. Three other patients died during the 12-month follow-up period due to causes not directly related to their fracture or fixation. Revision surgery for nonunion was required in 7.8% of LPs and 4.8% of IMNs, which was not statistically significant. There was only one failure of fixation noted, which involved a plate case. This event occurred early enough that it was believed that this did not represent a nonunion. The most common reason for secondary procedures was implant removal, which was seen in 15% of IMNs (all but one for interlocking screws removal) and in 10% platings, in which the entire plate and all screws were removed.

TABLE 1. SMFA Change Over Time

SMFA	Nail	Plate	Both
3 mo	38.76	41.58	40.18
6 mo	29.82	31.92	30.84
12 mo	22.18	26.83	24.42

TABLE 2. Bother Index Change Over Time

Bother Index	Nail	Plate	Both
3 mo	40.46	36.75	38.59
6 mo	28.23	29.94	29.06
12 mo	22.97	28.53	25.64

TABLE 3. EQ Health Score Change Over Time

EQ Health	Nail	Plate	Both
3 mo	69.23	72.81	71.04
6 mo	74.24	73.04	73.66
12 mo	79.07	71.9	75.62

DISCUSSION

In an early small, prospective study comparing locked plating (LISS) and retrograde intramedullary nailing, Markmiller et al found similar rates of infection, range of motion, alignment, and functional scoring at 1 year. The authors concluded that both treatments were better than nonlocked condylar plating.³⁹ In a large retrospective study, Hoskins et al found a statistically significant and clinically relevant difference in the quality of life (EQ 5D) at 6 months for patients undergoing intramedullary nailing versus locked plating, although the difference did diminish by 12 months. They also found a small but significant decrease in malalignment with nailing.⁴⁰

Far more investigation has been performed comparing locked plating versus intramedullary nailing in the setting of periprosthetic distal femur fractures above total knee arthroplasty than in native distal femur fractures. In a retrospective study, Aldrian et al⁴¹ found no statistical difference in function or union but did find a small trend toward fewer complications with IMNs. Gausden et al⁴² found more extension deformity with nailing but that this did not lead to an increased rate of complications or reoperations. Meneghini et al⁴³ found the overall failure rate for plating to be twice that of IMNs. Li et al,⁴⁴ in a meta-analysis comparing plating and nailing, found no difference in healing time, rate of union, operative time, or rate of complications; although when they removed one article they believed to be an outlier, they found a lower reoperation rate with nailing. Shah et al,⁴⁵ in a systematic review, found that plating had significantly lower rates of overall complications and reoperation rates, although nail patients returned to full weightbearing faster and were more likely to return to the preinjury activity level. Quinzi et al, in a systematic review and meta-analysis comparing locked plating, intramedullary nailing, and distal femoral replacement, found no difference in the 3 groups in complications or reoperations. They did find that infection was more frequent in distal femoral replacement than plating, malalignment was more common with nails than with plating, and periprosthetic fractures were more common after distal femoral replacement or locked plating than after nailing.⁴⁶

Thus, there remains some question as to whether one treatment truly does offer significant benefit over the other. In

a systematic review from the Cochrane Library from 2015, Griffin et al found that there were “serious limitations of the available evidence concerning current treatment of fractures of the distal femur in adults.” They concluded that “the currently available evidence is incomplete and insufficient to inform current clinical practice,” and they recommended that a multicenter, randomized trial that focused on validated functional outcome measures be undertaken.⁴⁷

This multicenter, randomized controlled trial of patients with distal femur fractures, determined that both plating and nailing are reasonable options for treatment and that neither treatment is statistically or clinically better than the other with the outcome measures used. Many patients in both groups continue to have significant disability at 1 year. At 12 months after injury, the average patient had an SMFA of 24, and a bother index of 25. Normal values in an uninjured population with an average age of 51 years have been reported to be between 13 and 14 for both the SMFA and the bother index.⁴⁸ Patients were able to walk approximately 10 blocks and could climb stairs using a railing for assistance.

Plates had a higher rate of valgus malalignment and full implant removal than did nails. Similarly, valgus has been reported to be the most common deformity in patients treated with locked plates. We used a stringent cut-off of 5 degrees beyond that of the contralateral side, to be as sensitive as possible to deformity, although it is not entirely clear that an angular deviation just beyond this degree affects outcome, particularly that of an elderly or lower functioning patient. This stringent approach did approach statistical significance ($P = 0.05$). The fact that this finding was noted across such a large group of surgeons raises the possibility of implant design being a contributory factor. No substantial deformity was reported in the sagittal plane in either of the groups, although this measurement has been shown to be harder to determine.⁴⁹ Overall functional results trended toward better outcomes in nails than plates for all measures, and although with the current numbers did not reach statistical significance, even if they had, they would not have reached the minimum clinical significance as defined by Cohen and Ware et al, although the bother index difference does almost reach that 6 point difference at 12 months.^{36,37}

The strengths of this study include its multicenter, randomized design and the fairly large size of the treatment groups. Multiple patient-reported scoring indices were used, offering both objective and subjective impressions of outcome at one-year after injury. Weaknesses of this study include not having obtained information on the working length or the screw configuration of the construct in plating constructs, which has been shown to effect fracture healing.^{29,30,50} We recorded angular measurements in the coronal and sagittal plane but did not measure translational deformities, including medial translation of the distal segment, the so-called golf club deformity, associated with increased rates of implant failure and need for secondary procedures.^{32,51} The addition of intra-articular (33-C1, 33-C2) fractures may be beyond the level of comfort for some surgeons with intramedullary nailing. We included 4 periprosthetic supracondylar fractures above a total knee arthroplasty, which may add another minor level of variability. Fracture fixation

TABLE 4. EQ Index Change Over Time

EQ Index	Nail	Plate	Both
3 mo	0.63	0.59	0.61
6 mo	0.73	0.68	0.7
12 mo	0.76	0.7	0.73

TABLE 5. One Year Results

Group	SMFA	Bother Index	EQ-Health	EQ-Index	Flexion	Extension	Walking (1–6)	Stairs (1–5)
Nail	22.2	22.9	79.1	0.76	114 ± 29	6.2 ± 21	2.8	2.4
Plate	26.8	28.5	72	0.7	111 ± 28	3.7 ± 11	2.81	2.7
P value	0.29	0.3	0.11	0.25	0.63	0.57	0.71	0.33

implants continue to evolve and the implants used in this study, at least early on, may be trending toward generationally dated. Even the specific metallurgic make-up of the implants (stainless vs. titanium) may play a role, although to what extent remains unclear.³

Finally, the large, multicenter nature of this study with multiple surgeons could add increased variability or decreased uniformity of treatment, despite our best effects at the outset in the study design.

CONCLUSIONS

Our findings do not reveal any significant advantage in one technique over the other, although there was a trend toward less valgus malalignment with nails than with plates. This study supports both techniques as reasonable treatment options, and surgeons should use the technique with which they are most comfortable. Surgeons should recognize that coronal plane deformity, particularly valgus, is common with plating and is determined at the time of surgery, rather than because of loss of fixation afterward. Obtaining imaging is necessary to avoid fixation in a position that alters the mechanical axis of the limb, up to and including obtaining intraoperative plain films after fracture reduction and provisional fixation are obtained. Flexion contracture is more common than reported previously, and an emphasis on extension early in patient’s rehabilitation is needed. Surgeons should recognize that recovery is slow and that at 1 year, many patients will still have dysfunction. Counseling in this regard will help manage patient expectations.

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