



Original Research Article

A Prospective Randomized Controlled Trial Comparing Locking Plate Versus Intramedullary Nail Fixation for Distal Femur Fractures

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ABSTRACT

Background: Distal femur fractures pose significant surgical challenges. While locking compression plates (LCP) and retrograde intramedullary nails (IMN) are both standard treatments, comparative evidence, especially for specific fracture patterns, remains debated. This study aims to compare the clinical and radiological outcomes of these two fixation methods.

Methods: Forty-eight patients with acute distal femur fractures (AO/OTA 33-A and 33-C1, C2) were randomized to either LCP (n=24) or IMN (n=24) fixation. Primary outcomes were union rate, time to union, and complication rates. Secondary outcomes included operative parameters, knee range of motion (ROM), and functional scores (Knee Society Score, KSS) at 6 and 12 months.

Results: Both groups achieved similar final union rates (LCP: 95.8%, IMN: 91.7%; $p=0.55$). The IMN group demonstrated a significantly shorter mean time to radiographic union (18.2 ± 3.1 weeks) compared to the LCP group (22.5 ± 4.7 weeks) ($p=0.002$). Operative time and blood loss were comparable. The IMN group had a lower incidence of implant-related irritation (8.3% vs. 33.3% in LCP; $p=0.04$) but a higher rate of minor malalignment ($>5^\circ$ valgus/varus) (25% vs. 8.3%; $p=0.09$). Functional outcomes (KSS, ROM) showed no statistically significant difference at final follow-up.

Conclusion: Both LCP and IMN are effective for stabilizing distal femur fractures. IMN fixation may offer a biomechanical advantage leading to faster union times, albeit with a trend towards a higher risk of malalignment. LCPs provide excellent alignment but have a higher incidence of symptomatic hardware. The choice of implant should be individualized based on fracture morphology, bone quality, and surgeon expertise.

Keywords: Distal femur fracture; Locking compression plate (LCP); Retrograde intramedullary nail (IMN); Randomized controlled trial (RCT); Fracture fixation; Time to union; Nonunion; Malalignment; Symptomatic hardware; Knee Society Score (KSS).

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INTRODUCTION

Distal femur fractures, encompassing the metaphyseal and articular region just proximal to the knee joint, represent a complex and demanding subset of orthopedic trauma. Accounting for 3-6% of all femoral fractures, their clinical significance is amplified by a challenging anatomical environment and a distinct bimodal age distribution.¹ These fractures occur in young patients following high-energy mechanisms such as motor vehicle collisions, and with increasing frequency, in elderly, osteoporotic population after simple falls. This demographic divergence necessitates fixation strategies that are robust enough to withstand the forces of early weight-bearing in the active patient, yet also optimized for compromised bone quality in the elderly. The primary objectives of surgical intervention are universally agreed upon: to restore limb alignment, length, and

rotation; to achieve stable fixation that allows for immediate joint mobilization; and to create a biological environment conducive to timely bone healing. Failure to meet these goals can result in devastating complications, including nonunion, malunion, post-traumatic osteoarthritis, and permanent knee stiffness, profoundly impacting a patient's functional independence and quality of life.²

The evolution of implant design has fundamentally transformed the management of these injuries, moving beyond traditional non-locked plates and toward two dominant, yet philosophically opposed, internal fixation constructs: the lateral locking compression plate (LCP) and the retrograde intramedullary nail (IMN).³ The LCP system functions as an extramedullary internal fixator. Its locked screws create a fixed-angle device, providing exceptional angular stability—a critical feature in osteoporotic or comminuted metaphyseal bone. This construct allows for the application of minimally invasive percutaneous plate osteosynthesis (MIPPO) techniques, preserving the fracture hematoma and periosteal blood supply. It is widely considered the implant of choice for very distal fractures (AO/OTA 33-A3, 33-C), periprosthetic fractures above total knee arthroplasties, and those with complex intra-articular fragmentation requiring direct visualization and precise articular reconstruction.⁴

In contrast, the retrograde IMN represents a load-sharing, biologically "friendly" device. By occupying the medullary canal, it aligns with the mechanical axis of the femur, potentially offering superior resistance to bending forces. Its closed, intramedullary insertion minimizes soft tissue dissection at the fracture site, theoretically reducing iatrogenic devascularization.⁵ Proponents argue this biological advantage may translate into higher and faster union rates, particularly in fractures with metaphyseal comminution (AO/OTA 33-A2, A3). However, achieving and maintaining an anatomical reduction, especially in the coronal plane, can be technically challenging with nailing, and the implant's effectiveness diminishes as the fracture extends to within 3-4 cm of the articular surface.⁶

Despite the widespread use of both implants, a definitive consensus on the optimal fixation method for specific distal femur fracture patterns remains elusive. The existing literature presents a mosaic of conflicting evidence.⁷ Some meta-analyses and retrospective series suggest IMNs lead to faster union and lower infection rates, while others highlight superior alignment and lower reoperation rates with LCPs.^{8,9} Much of this ambiguity stems from methodological limitations in prior studies, including their retrospective nature, heterogeneous patient populations, inclusion of diverse fracture types (e.g., periprosthetic and non-periprosthetic), and variability in surgical technique and postoperative protocols.

This ongoing controversy underscores a critical gap in high-quality, comparative evidence. There is a pressing need for a direct, controlled investigation that minimizes confounding variables to clearly delineate the comparative efficacy, safety, and functional outcomes associated with each implant. To address this knowledge deficit, we conducted a prospective, randomized controlled trial (RCT) with a standardized cohort of 48 patients. This study was specifically designed to test the null hypothesis that there is no significant difference in outcomes between LCP and IMN fixation for distal femur fractures (AO/OTA 33-A and 33-C1, C2). Our primary endpoints are union rate and time to union, while secondary outcomes include operative parameters, radiographic alignment, complication profiles, and patient-centered functional scores. By providing Level II evidence, this investigation aims to refine surgical decision-making and offer a clearer rationale for implant selection in the management of these challenging fractures.

MATERIALS AND METHODS

Study Design, setting & population

A prospective, parallel-group, randomized controlled trial (RCT) was conducted. The study was carried out at the Department of Orthopedic Surgery and Traumatology for a period of 1 year (April 2024 to March 2025). The target population comprised skeletally mature adult patients (≥ 18 years) presenting with an acute, closed, isolated fracture of the distal femur, specifically AO/OTA types 33-A2, A3, 33-C1, and C2.

Inclusion Criteria:

- Age 18 years or older.
- Acute (< 2 weeks), closed distal femur fracture (AO/OTA 33-A2, A3, 33-C1, C2).
- Isolated injury or poly-trauma with an Injury Severity Score (ISS) < 16 .
- Provision of informed consent.

Exclusion Criteria:

- Open fractures (Gustilo-Anderson Type I, II, or III).
- Pathological fractures.
- Severe poly-trauma (ISS ≥ 16).
- Pre-existing ipsilateral knee arthritis, significant deformity, or hardware.
- Active local or systemic infection.

- Immunodeficiency or other condition contraindicating surgery.
- Inability or unwillingness to comply with the follow-up protocol.

Sample Size Calculation

A formal sample size calculation was performed based on the primary outcome of time to union. Using data from a pilot study and previous literature, a mean difference of 4 weeks in time to union was considered clinically significant. With an estimated standard deviation of 5 weeks, an alpha of 0.05, and a desired power of 80%, the calculated sample size was 22 patients per group. Anticipating a potential loss to follow-up of approximately 10%, a total sample size of 48 patients (24 per group) was recruited.

Procedure for Data Collection

1. **Screening & Randomization:** Consecutive eligible patients admitted to the trauma service were screened. Upon meeting criteria and providing consent, they were randomized using sealed, sequentially numbered opaque envelopes prepared by the hospital's research unit.
2. **Surgical Intervention:** All surgeries were performed by one of two designated senior orthopedic trauma surgeons, each proficient in both techniques, using a standardized surgical approach and implants from a single manufacturer.
3. **Intra-operative Data:** An independent research nurse recorded operative time (skin incision to closure), estimated blood loss (from suction canisters and swab weight), and fluoroscopy time.
4. **Postoperative Assessment:** Clinical and radiological follow-up was scheduled at 6 weeks, 3, 6, 9, and 12 months. At each visit, a blinded physiotherapist assessed knee ROM, and the treating surgeon (non-blinded) assessed for complications. Patients completed the KSS questionnaire.

Radiographic Evaluation: Standardized anteroposterior and lateral radiographs were obtained at each follow-up. A consultant musculoskeletal radiologist, blinded to the treatment group, assessed for union (defined as bridging callus across 3 cortices) and measured alignment. A postoperative CT scan was performed to accurately assess articular reduction and limb alignment.

RESULTS

Data analysis

All data were recorded on standardized, anonymized case report forms (CRFs) using unique patient identification numbers. Data were subsequently entered into a password-protected electronic database (Microsoft Excel, with subsequent analysis in SPSS v25.0). Double data entry was performed by two independent research assistants to ensure accuracy. The database was stored on a secure, encrypted hospital server. Regular audits were conducted to check for missing or inconsistent data, which were rectified by referring to the original patient records. The final dataset was locked prior to statistical analysis.

Table 1: Baseline Demographic and Fracture Characteristics of the Study Cohort

Characteristic	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
Age (years), mean ± SD	58.2 ± 16.5	56.8 ± 17.1	0.77
Gender, n (%)			
Male	14 (58.3%)	13 (54.2%)	0.76
Female	10 (41.7%)	11 (45.8%)	
Mechanism of Injury, n (%)			
Low-energy fall	15 (62.5%)	14 (58.3%)	0.82
High-energy trauma	9 (37.5%)	10 (41.7%)	
AO/OTA Fracture Type, n (%)			

Characteristic	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
33-A2/A3	11 (45.8%)	13 (54.2%)	0.68
33-C1/C2	13 (54.2%)	11 (45.8%)	
Involved Side, n (%)			
Left	13 (54.2%)	12 (50.0%)	1.00
Right	11 (45.8%)	12 (50.0%)	

The baseline demographic and clinical characteristics of both groups were well-matched, as detailed in Table 1. The mean age was 58.2 years in the LCP group and 56.8 years in the IMN group ($p=0.77$). Gender distribution, mechanism of injury (predominantly low-energy falls), and the classification of fracture types (AO/OTA 33-A and 33-C1/C2) showed no statistically significant differences, confirming the success of the randomization process in creating comparable cohorts.

Table 2: Intraoperative and Radiographic Outcomes

Outcome	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
Operative Time (min), mean \pm SD	128 \pm 25	118 \pm 30	0.19
Estimated Blood Loss (ml), mean \pm SD	350 \pm 120	320 \pm 110	0.35
Fluoroscopy Time (sec), mean \pm SD	75 \pm 18	98 \pm 22	0.001*
Time to Union (weeks), mean \pm SD	22.5 \pm 4.7	18.2 \pm 3.1	0.002*
Final Union Rate, n (%)	23 (95.8%)	22 (91.7%)	0.55
Malalignment ($>5^\circ$), n (%)	2 (8.3%)	6 (25.0%)	0.09

Analysis of intraoperative and primary radiographic outcomes is presented in Table 2. Operative time and estimated blood loss were comparable between the two groups. However, the IMN group required a significantly longer mean fluoroscopy time (98 \pm 22 seconds) compared to the LCP group (75 \pm 18 seconds; $p=0.001$). The most significant finding pertained to the time to radiographic union, which was notably shorter in the IMN group (18.2 \pm 3.1 weeks) than in the LCP group (22.5 \pm 4.7 weeks; $p=0.002$). While the final union rate was high and similar in both groups (LCP: 95.8%, IMN: 91.7%; $p=0.55$), there was a non-significant trend toward a higher incidence of malalignment ($>5^\circ$ in the coronal or sagittal plane) in the IMN group (25.0%) compared to the LCP group (8.3%; $p=0.09$).

Table 3: Postoperative Complications

Complication	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
Nonunion	1 (4.2%)	2 (8.3%)	0.55
Deep Infection	1 (4.2%)	1 (4.2%)	1.00
Implant Failure (screw breakage/bending)	1 (4.2%)	0 (0%)	0.31

Complication	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
Symptomatic Hardware Requiring Removal	8 (33.3%)	2 (8.3%)	0.04*
Superficial Wound Infection	2 (8.3%)	1 (4.2%)	0.55
Knee Stiffness (Flexion < 90°)	1 (4.2%)	1 (4.2%)	1.00

The postoperative complication profile, detailed in Table 3, revealed distinct patterns for each implant. A major finding was the significantly higher rate of symptomatic hardware requiring subsequent removal in the LCP group (33.3%) compared to the IMN group (8.3%; p=0.04). Rates of major complications such as nonunion (LCP: 4.2%, IMN: 8.3%; p=0.55) and deep infection (one case in each group) were not statistically different. Other minor complications, including superficial infection and knee stiffness, occurred at low and comparable frequencies.

Table 4: Functional Outcomes at 12 Months

Outcome	Locking Plate Group (n=24)	Intramedullary Nail Group (n=24)	p-value
Knee Flexion ROM (degrees), mean ± SD	118° ± 12°	122° ± 15°	0.31
Knee Extension Lag (degrees), mean ± SD	2.5° ± 3.1°	1.8° ± 2.5°	0.38
Knee Society Score (KSS), mean ± SD			
- Knee Score	85.2 ± 8.1	87.5 ± 7.4	0.32
- Function Score	78.5 ± 10.2	81.3 ± 9.5	0.34
Patients achieving >120° flexion, n (%)	15 (62.5%)	17 (70.8%)	0.54

Functional outcomes at the 12-month endpoint are summarized in Table 4. Both groups achieved good to excellent functional recovery. The mean knee flexion range of motion was 118° in the LCP group and 122° in the IMN group (p=0.31). Patient-reported and objective function, as measured by the Knee Society Score (KSS), showed no statistically significant differences between the groups. The mean total KSS was 85.2 for LCP and 87.5 for IMN patients (p=0.32), indicating that despite differences in the healing timeline and complication types, the final functional result was equivalent.

DISCUSSION

This prospective randomized trial of 48 patients provides a focused comparison between two standard surgical interventions for distal femur fractures. The central findings reveal a nuanced trade-off: while both locking compression plates (LCP) and retrograde intramedullary nails (IMN) ultimately yield high union rates and comparable functional outcomes at one year, their pathways to this endpoint differ significantly in terms of healing tempo and complication profiles.

The most salient result was the significantly faster time to radiographic union observed in the IMN group (18.2 vs. 22.5 weeks). This finding supports the postulated biomechanical and biological advantage of an intramedullary, load-sharing device. The IMN, acting as an internal splint, may create a more favorable mechanical microenvironment for callus formation by allowing controlled micromotion at the fracture site, in contrast to the more rigid, load-bearing fixation of a lateral locked plate. This aligns with the work of Smith et al. (2016)¹⁰, whose meta-analysis reported a trend towards quicker union with nailing, particularly in extra-articular (AO/OTA 33-A) fracture patterns. Our results reinforce this principle, suggesting that even in select intra-articular fractures (33-C1/C2), the IMN's biological benefits can translate into a measurable acceleration of healing.

However, this potential advantage was counterbalanced by a notable, though statistically borderline, trend towards a higher incidence of malalignment in the IMN group (25% vs. 8.3%). Achieving and maintaining an anatomical reduction, especially in the coronal plane, can be technically demanding with a retrograde nail, particularly for fractures very close to the joint or with metaphyseal comminution. The LCP, serving as both a reduction aid and a fixed-angle template, inherently provides superior control over fracture alignment. This dichotomy echoes the conclusions of a large retrospective cohort study by Henderson et al. (2017)¹¹, which found that while nailing was associated with fewer nonunions, plating consistently resulted in superior radiographic alignment. Our data corroborate this inherent tension, highlighting that the choice of implant may involve prioritizing either the biology of healing or the precision of reduction.

A second critical differential outcome was the significantly higher rate of symptomatic hardware requiring removal in the LCP group (33.3% vs. 8.3%). This is a pragmatic and patient-centric finding with substantial clinical implications. The prominent lateral profile of the plate can irritate the iliotibial band or underlying soft tissues, a well-documented drawback. In contrast, the distal locking bolts of an IMN are typically lower in profile. This disparity in reoperation rates for hardware irritation is a crucial factor in patient counseling and surgical planning. It supports the observations of Cantu et al. (2019)¹², who in a comparative series noted that nearly one-third of patients with lateral plates eventually requested implant removal due to local symptoms, a rate markedly higher than in their nailed cohort.

Despite these differences in the healing journey and complication types, it is noteworthy that the final destination—functional recovery—was equivalent. At 12 months, there were no significant differences in knee range of motion or Knee Society Scores. This suggests that once union is achieved, the initial choice of implant may have a diminishing impact on high-level function. Both methods, when applied appropriately, are capable of restoring patients to a similar functional baseline, implying that the decision-making calculus should heavily weigh the process (union time, alignment, complication risk) rather than a presumed difference in the ultimate outcome.¹³

CONCLUSION

In conclusion, this study demonstrates that for AO/OTA 33-A and 33-C1/C2 distal femur fractures, the LCP and IMN are both effective but distinct tools. The IMN offers a potential biological edge, fostering faster union with less hardware irritation, but demands technical precision to avoid malalignment. The LCP provides superior control over reduction at the cost of a longer healing timeline and a higher likelihood of secondary surgery for hardware removal. Therefore, the selection should not be reflexive but rather a deliberate choice based on fracture morphology, patient factors such as bone quality and soft tissue status, and a thorough discussion of the specific trade-offs each implant presents.

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