

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

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**Purpose:** Distal femur fractures are challenging injuries. Both retrograde nails and locked plates are used for their treatment with good success. Plates are thought to be more stable, but may be more rigid and be more irritating to soft tissues. The purpose of this study was to evaluate the radiographic, functional and physical outcomes of locked plates versus retrograde nails in an IRB-approved randomized controlled trial (RCT).

**Methods:** All adult patients with A1-3 or C1 distal femur fractures were offered entry into an IRB-approved RCT. If consented, randomization scheme was with permuted blocks for open and closed fractures using a HIPAA-compliant computer-based system. Demographic data, fracture characteristics, surgical variables, and outcomes were assessed.

**Results:** 156 patients were randomized to locked plate (80) or intramedullary (IM) nail (76). 126 patients were followed (71 men and 55 women, aged 16 to 90 years [average 51]). The average ISS was 12.6 (range, 9-43) and 34 (27%) were open. 34% had simple intra-articular extension. There were no differences in demographic information or injury pattern. Surgical

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time was  $125 \pm 61$  minutes for nails and  $124 \pm 51$  minutes for plates ( $P = 0.96$ ). Malalignment  $>5^\circ$  in any plane was present in 22% of nails and 32% of plates ( $P = 0.4$ ), but valgus of  $>5^\circ$  accounted for 87% of plate deformities. Valgus  $>5^\circ$  was present in 12% of nails and 20% of plates ( $P = 0.05$ ). Walking ability, stair climbing, pain, and use of supports were graded using categorical values. There were no differences at 3, 6, or 12 months between the groups. The average patient could walk 10 blocks, go up and down stairs using a rail, and occasionally used a cane. At 1 year, 16% of plates and 12% of nails lacked at least  $5^\circ$  of extension. A summary of the 1-year results are seen in the table:

### 1-Year Results

Group	SMFA*	Bother	EQ-Health	EQ-Index	Flexion	Extension	Walking (1 – 6)	Stairs (1 – 5)
Nail	21.5	22.6	79.5	0.78	$114 \pm 29$	$6.2 \pm 21$	2.74	2.3
Plate	27.4	30.8	71	0.68	$111 \pm 28$	$3.7 \pm 11$	2.89	2.66
<b>P value</b>	0.21	0.16	0.08	0.07	0.63	0.57	0.71	0.33

\*SMFA = Short Musculoskeletal Function Assessment.

There was significant improvement in all measures at each interval (see example SMFA below)

Complications included 5 pulmonary embolisms/deep vein thromboses and one death. Revision surgery was needed for nonunion or failure in 5% of nails and 8% of plates and hardware removal in 8 of 54 nails (7 screws and 1 nail) and 6 of 60 plates (plate removal) in which this information was available.

**Conclusion:** Distal femur fractures have significant disability at 1 year. The average patient had an SMFA of 25, bother index of 27, could walk approximately 10 blocks, and climb stairs with the railing. Additionally, 15% had a flexion contracture of  $>5^\circ$ . Malalignment was present in 22% of nails and 32% of plates, with plates having a higher rate of valgus malalignment and full implant removal. Overall functional results trended toward better outcomes in nails than plates for all measures, and although with the current numbers this did not reach statistical significance, the score difference was above the minimum clinical relevance for the SMFA (5.5).