

## Δ The Effect of Coronal Plane Angulation on the Outcomes of Operatively Treated Distal Femur Fractures

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**Purpose:** Coronal plane malalignment is common after distal femur fracture fixation, particularly valgus deformity after plating. While varus deformity is known to be problematic in tibial plateau fractures, the influence of coronal plane angulation on outcomes in distal femur fractures is not well documented. The purpose of this study is to compare validated functional outcome and mobility scores of patients with neutral alignment with patients having  $>5^\circ$  of varus or valgus angulation after operative treatment for distal femur fractures.

**Methods:** As part of a prospective multicenter trial of adult patients with A1-3 or C1 distal femur fractures, data on angulation were gathered. Patients were treated by intramedullary nail or locked plate. In addition to demographic and fracture data, mobility scores for (1) stair climbing, (2) walking distance, and (3) ambulatory device use, and validated patient-based outcomes including Short Musculoskeletal Function Assessment (SMFA), Bother Index, and EQ (EuroQol) health index were obtained at 3, 6, and 12 months postoperatively. Angulation was documented in degrees of varus or valgus alignment at each interval as compared with anatomic. For the purpose of this analysis, varus and valgus malalignment were defined as  $= 5^\circ$ . Comparisons were made using Fisher's exact test for categorical variables and t tests for continuous variables.

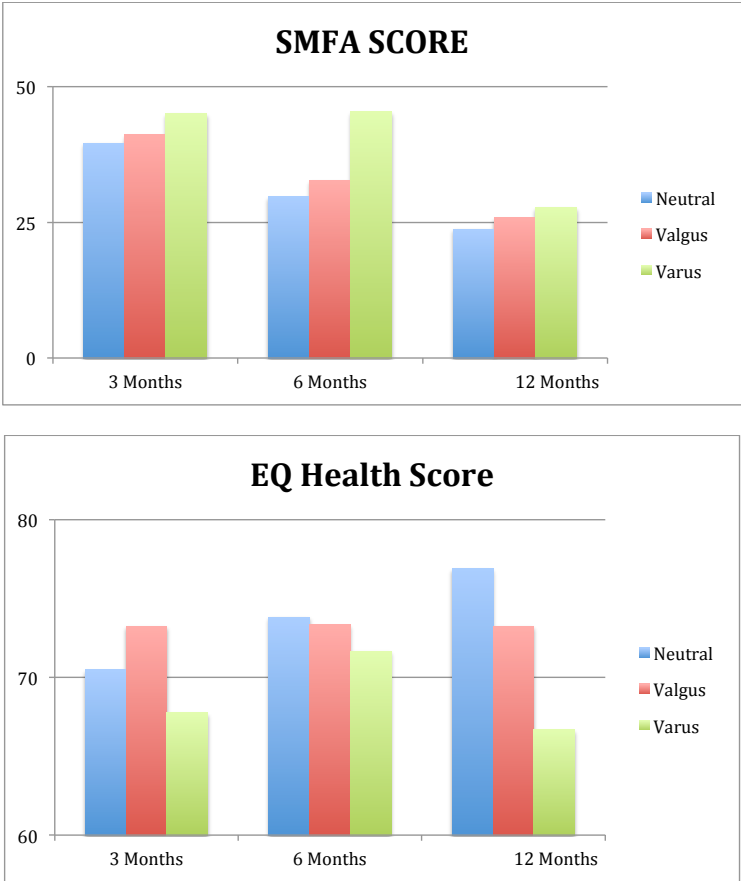
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See pages 49 - 106 for financial disclosure information.

**Results:** Of 123 patients who had initial postoperative coronal plane angulation documented, clinical outcome data were available for 105 at 3 months, 95 at 6 months, and 81 at 1 year. There were 59% men and 41% women, aged 17-91 years (average 50), of whom 47% were treated with an intramedullary nail and 53% were treated with a locked plate. Immediately postoperative radiographs demonstrated valgus alignment = 5° in 24% (avg = 8°; range, 5°-18°) and a varus alignment = 5° in 2% (average = 8°; range, 7°-10°). This distribution remained stable over time with 25% valgus and 4% varus at 1 year. At 3 months, there was no difference between the groups in any of the clinical or functional outcome scores measured. With regard to the mobility scores, patients with varus angulation had a worse stair climbing score at 6 months ( $P = 0.05$ ) and required more ambulatory support at 12 months ( $P = 0.06$ ) than those patients with neutral alignment. At 1 year, the average patient with neutral or valgus alignment needed at most a cane whereas the average patient in varus needed at least a cane and at times a walker. There were no differences at any time point between those with valgus alignment and those with neutral alignment. With respect to the validated patient-based outcome scores, we found no statistical difference in the SMFA, Bother, or EQ-5D between patients with valgus or varus malalignment and those with neutral alignment at any time point (see figure of SMFA and EQ-5D).

**Conclusion:** Valgus malalignment is common after distal femoral fixation; however in this prospective trial, valgus of 5°-8° was well tolerated as it did not affect validated outcome scores or mobility scores. Patients with varus malalignment had worse mobility scores, but SMFA, Bother, and EQ-5D were unaffected. Validated outcome scores may not be sensitive enough to pick up subtle differences in mobility in this population.

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The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.