

Mechanical Failure in Distal Femur Fractures with 3 Generations of Precontoured Locking Plates: Analysis of 105 Patients Treated at 8 Trauma Centers

Cory Alan Collinge, MD; Alexander Francis Reeb, MS; Andres Felipe Rodriguez-Buitrago, MD; Michael T. Archdeacon, MD; Michael John Beltran, MD; Michael J. Gardner, MD; Kyle James Jeray, MD; Anna Noel Miller, MD; Brett D. Crist MD; Stephen A. Sems, MD; Nihar Samir Shah, MD

Harris Methodist Hospital Fort Worth, Fort Worth, TX, United States

Purpose: Distal femur fractures remain challenging injuries to treat, with complication rates of 20% to 35%, including failed fixation, nonunion, and malunion. Fixation with distal femur locking plates (DFLPs) has become the most common technique used. Over the past 3 decades, implant manufacturers have developed (and subsequently modified) a number of DFLPs in an effort to improve clinical results and address surgeon user needs, including the use of different materials (stainless steel [SS] versus titanium [Ti]) and the incorporation of fixed angle (FA) or variable angle (VA) locking screws. The aim of this study was to evaluate treatment failure in a large patient cohort with distal femur fractures treated with a DFLP.

Methods: This retrospective case-control series evaluated mechanical treatment failures in 1187 patients with OTA 33-A and C distal femur fractures treated with DFLPs at 8 Level I trauma centers from 2010 to 2017. 152 patients (12.8%) experienced treatment failure with 43 being strictly biologic (nonunion without mechanical fixation failure) and 105 involving mechanical failure. Of the mechanical failures, 11 distal femurs were treated with a Ti-FA, unicortical screw DFLP system designed for minimally invasive application (“Less-Invasive Stabilization System” or “Ti-LISS”, DePuy Synthes); 24 with an SS-FA DFLP (“Periloc”, Smith & Nephew), 12 with an SS-FA DFLP (“Locking Condylar Plate®” or “FA-LCP”, DePuy Synthes, West Chester, PA); 44 with a SS-VA DFLP (“VA-LCP”, Synthes), and 14 “other” DFLPs. DFLP details, modes of failure, and time to failure were studied.

Results: Of 105 mechanical failures, only 11 DFLPs failed by screw cut-out from the condyles and most failures (80%) occurred at the level of the femoral shaft and /or fracture site. Failures occurred in a number of different manners, depending on the DFLP and its properties. 33 of 104 SS plates (33%) failed by bending or breaking at the level of the fracture while no Ti plates failed at this location ($P<0.05$). 11 of 12 failures with Ti-LISS (92%) occurred via shaft fixation, mostly by screw loosening (91%). 16 of 44 VA-LCP failures (36%) occurred at the distal plate-screw junction, while only 5 of 61 other DFLPs (8%) failed in that way ($P<0.05$). Distal failures occurred on average at 23.7 weeks compared to femoral shaft and fracture site failures that occurred at 38.0 and 38.9 weeks, respectively ($P<0.05$). VA-LCP distal screw-plate junction failures occurred on average at 21.4 weeks.

Conclusion: Mechanical failure occurred in 9% of patients with a distal femur fracture treated with a DFLP. The mode, location, and timing of failure varied depending on the characteristics of DFLP and relatively few (<10%) failed by cut-out from the distal condylar segment. 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.

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.