A Comparative Cohort Study of Mechanical Failure for Monoaxial and Polyaxial Locking Plates in the Treatment of OTA 33-A and 33-C Distal Femur Fractures Norele Cutrera, MD¹; Cory Collinge, MD²

¹Vanderbilt Medical Center, Nashville, Tennessee, USA; ²Texas Health Harris Methodist Fort Worth Hospital, Fort Worth, Texas, USA

Background/Purpose: Distal femur fractures are challenging injuries to treat. Several generations of plate fixation have evolved over the past two decades, including locked monoaxial unicortical screw and plate systems designed for minimally invasive application (less invasive stabilization system [LISS]), monoaxial locking condylar plates, and polyaxial locking condylar plates (LCPs). Alternate screw trajectories enable surgeons to circumnavigate existing hardware, but design of these polyaxial or "variable angle" systems necessarily changed the plates, the screws, and their interface. A recent preliminary report by Tank et al has suggested that newer variable angle (VA)-LCPs may be associated with early mechanical failure compared to prior systems. The aim of our study is to compare mechanical failure rates in patients with distal femur fractures treated with of early and later generations of locking plates (LISS, LCPs, and VA-LCPs). Our secondary aims are to describe modes, timing, and risks of failure in these cases.

Methods: This retrospective case-control series evaluates mechanical fixation failure patients with OTA 33-A and C distal femur fractures treated with locked plating at a single Level I trauma center from 2010 to 2015. 170 of these patients were treated with a titanium mono-axial unicortical screw and plate system designed for minimally invasive application (LISS, DePuy Synthes); stainless steel monoaxial LCP (Periloc, Smith & Nephew; and Locking Condylar plate, DePuy Synthes; or a stainless steel "variable-angle" LCP (VA-LCP, DePuy Synthes). Exclusion criteria included patients age <18 years, distal femur fracture treated with any device other than a locked distal femur plate, or follow-up <6 months. Patient and injury factors were evaluated. Serial radiographs were analyzed for mechanical failure including implant breakage, bending, loosening, or change in alignment (>5°). Secondary outcome measures were modes of failure, time to failure, and risk factors for failure. Early failure was defined as <6 months and late failure >6 months.

Results: 148 cases were included for study. There were a total number of 23 mechanical failures (15%), including 6 of 37 (16%) LISS, 4 of 47 (8%) LCPs, and 13 of 64 (20%) VA-LCPs (P = 0.26). There were 10 and 13 failures in 33-A and C-type fractures, respectively (P = 0.10). Modes of failure included screw breakage/loosening, plate breakage, and loss of alignment. In the LISS group, all failures consisted of screw breakage or loosening. 3/4 failures (75%) were attributable to screw breakage or loosening in the LCP group. The most common mode of failure in the VA-LCP group was change in alignment, with 8/13 (62%) collapsing into varus (P = 0.03). The average time to failure was 7.2 months, 2.8 months, and 6.8 months for the LISS, LCP, and VA-LCP groups, respectively. Early failures comprised 3/6 (50%) in the LISS group, 4/4 in the LCP group, and 8/13 (62%) in the VA-LCP group.

Conclusion: Our study does not validate the theoretical concern that an altered screw-plate locking mechanism of VA plates could lead to screw disengagement and early mechanical

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.

failure. This is one of the largest clinical studies to date regarding VA plates. This is also the first study to look at VA plates in the context of proper plate application and surgical technique. It is our subjective opinion that, particularly for distal femur plating, technique is essential to outcome. Little things matter, and they are not easily quantified. For example, fracture gap or distraction and plate position all play a role in outcome. Should we really expect a long segmental bone loss construct in a large, strong patient to maintain alignment until healed when we know large forces are at play and it will take a long time to heal?

See pages 49 - 106 for financial disclosure information.