In-vivo Stiffness Measurements for Distal Femur Fractures Fixed with Locked Plating

Christopher Parks, MD[1]*; Michael J. Gardner, MD*[2]*; William M. Ricci, MD*[1]*;*
Christopher McAndrew, MD, MSc[1]
[1]*Washington University in Saint Louis, St. Louis, Missouri, USA;*
[2]*Stanford University Department of Orthopaedic Surgery, Redwood City, California, USA*

Purpose: Correlations between fixation stiffness and fracture healing outcomes have been the subject of much recent investigation in both clinical series and animal models. Clinical studies have been limited by a lack of a quantitative evaluation of construct stiffness. A novel device measuring intraoperative construct stiffness after the application of a distal femur locking plate was designed and validated for use in this study. The purpose of this study was to measure and correlate in vivo construct stiffness to clinical outcomes using this device. We hypothesized that a correlation would exist between stiffness and callus formation.

Methods: Patients who sustained a distal femur fracture (OTA 33) who underwent locked plating were prospectively enrolled. Average age was 63 years (range, 29-98) and average body mass index was 32.7 kg/m2 (range, 18-45.9). Four patients sustained injuries from a high-energy mechanism and the rest were ground level falls. Two fractures were open. 12 of the fractures were classified as OTA 33A, 1 as OTA 33B, and 5 as OTA 33C. Four fractures were above total knee arthroplasty. Construct design, plate length, number of screws, screw type, and points of fixation were at the discretion of the operating surgeon (1 of 3 orthopaedic traumatologists participating in the study). Constructs were designed purposely to produce either relative stability via bridging (to induce secondary bone healing) or absolute stability (to induce primary healing). Absolute stability was defined as an anatomic reduction with lag screw(s) or compression across the major metadiaphyseal fracture fragment, while relative stability was defined as any plate construct that was placed in a bridging fashion. Intraoperative stiffness was measured using the custom device following final fixation (Fig. 1). Data regarding the construct, including working length (WL), plate length (PL), WL/PL ratio, and number of proximal and distal screws were collected. Patients were followed clinically and data were collected including standard demographics, LEM (lower extremity measure) scores, radiographic union, clinical union, and complications (delayed union, nonunion, fixation failure, deep and superficial infection). Using 3-month follow-up radiographs, a callus score (0, no; 1, minimal; 2, moderate; 3, robust) and a modified RUST (Radiographic Union Score for Tibial fractures) score were determined by 3 orthopaedic trauma surgeons blinded to intraoperative stiffness measurements.

Results: 18 of the 28 enrolled patients completed the study. There was no difference in stiffness between 3 constructs designed to have absolute stability (mean stiffness of 4.79 N/

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mm [range: 1.07-7.67]) and 15 designed for relative stability (mean stiffness of 4.79 N/mm [1.76-8.20]), P = 0.99. The mean WL for the absolute and relative stability constructs were 78.7 mm and 90.3 mm respectively and they were not statistically significantly different (P = 0.57). One patient had a delayed union, one had a deep infection with loss of fixation, and one patient had a nonunion. There was no difference in the stiffness measurements when comparing patients with a complication to patients without a complication, P = 0.52. Mean LEM score for patients who had a complication (38.7) compared to no complication (64.1) was significantly different, P = 0.019. A scatterplot with callus score as a function of stiffness and modified RUST score as a function of stiffness did not reveal any correlation (R2 = 0.016 and 0.009, respectively). There was no correlation between stiffness and WL or stiffness and WL/PL ratio (R2 = 0.16 and 0.15 respectively). When stratified for the number of distal screws (4, 5, or 6), stiffness was not significantly different (P = 0.926).

Conclusion: This is the first time the stiffness of a construct has been measured in vivo and correlated to clinical outcomes. In this study, we did not find correlations between callus formation or healing, and construct stiffness. We also did not find correlations between callus formation and WL or WL/PL. This may have been due to the mechanical properties of the plate itself and its large contribution to the overall stiffness of the construct. A power analysis was unable to be performed due to the lack of knowledge of clinically relevant stiffness, although this study may provide future studies with stiffness estimates. This methodology and these preliminary findings may lay the groundwork for further investigations into this prevalent clinical problem.