Clinical Validated Model of Humeral Tray in Reverse Total Shoulder Arthroplasty
Mehul A. Dharia, Jeffrey E. Bischoff, James D. Wernle
Zimmer Biomet, Warsaw, Indiana

Introduction: Computational models used in pre-clinical evaluation of humeral trays used in reverse total shoulder arthroplasty (RTSA) are typically validated by comparison of model predictions with the benchtop test measurements; both attempting to closely represent the clinical use of the device. Evidence from the devices in clinical use can strengthen the validity of the setup used by model and the benchtop test. This study presents how a RTSA humeral tray model can be validated not only against the test but also using clinical evidence.

Materials and Methods: The Comprehensive Reverse Shoulder (CRS) system has been in clinical use for RTSA since 2008. Some clinical fractures (Figure 1A) were reported for the very early generation titanium (Ti) tray. A laboratory test (Figure 1B) was developed to replicate this failure mode where the tray is only supported by the post in the stem, and the load is applied to the tray from the glenosphere. A corresponding FEA model was constructed (Figure 1C). Four tray designs were considered using design feature variations in tray thickness and post radius (Figure 2), as well as in material: (1) design 1-Ti tray; (2) design 2-updated Ti tray (tighter tolerance control in post radius and tray thickness); (3) design 3-Ti tray (increased post radius); (4) design 4-CoCr tray (same tray design as 3 but manufactured from CoCr material). The load capacity predicted using model stresses was compared to the 5Mc fatigue load limit measured in the benchtop test, as well as to the available clinical fracture rate, to ensure agreement among all three. The areas of peak stress (FEA) and fracture initiation (benchtop) were compared with each other, as well as to fractured retrievals (clinical) to establish clinical validity of the failure mode.

Results and Discussion: For all models, peak maximum principal stresses were predicted in the post radius at the superior side of the distal surface; high stresses were also predicted on the inferior side of the proximal surface of the trays (Figure 3A). These locations matched with the crack locations observed in the fatigue test samples (Figure 3B), as well as in clinical retrievals (Figure 1A). The predicted fatigue load capacity trends among tray designs correlated well with that measured in the benchtop testing, as well as with the available clinical fracture rate data. Compared to design 1, the predicted fatigue load capacity of tray designs 2, 3, and 4 were increased by 41%, 99% and 229%, respectively. This correlates well with available clinical fracture rate of 2.6% and 0.12% for designs 1 and 2, respectively; and 0% for designs 3 and 4. Figure 4 presents the comparison of predicted fatigue load capacity among different tray designs (normalized to design 1) along with the clinical fracture rates. The modeling method used in this study is considered validated based on the correlation of peak stress locations with the fracture locations, and the correlation of predicted trends of fatigue load capacity among tray designs with the load capacity from the benchtop test as well as available clinical fracture rates. This clinically validated modeling approach can be utilized to rank order the predicted performance among different RSA tray designs.

Translational Impact: A novel clinically validated FEA model was developed to predict relative load capacity of RTSA trays, which correlated with both the benchtop test and the available clinical data. Clinically validated FEA models can provide insight into the potential mechanisms for clinical failures, and further guide the implant design innovation process to improve the device strength in future designs.

Figure 1. (A) Clinical fracture (B) Representative laboratory test (C) FEA model cross-section

Figure 2. Tray design features

Figure 3. (A) Predicted peak stress locations (B) Crack locations in laboratory test sample

Figure 4. Predicted fatigue load capacity and clinical fracture rates for all 4 designs