

Strength Improvement of Titanium Humeral Trays in Reverse Total Shoulder Arthroplasty

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INTRODUCTION: Modular platform shoulder arthroplasty systems have many advantages including allowing conversion from anatomic TSA to reverse TSA without humeral stem removal but are often associated with overstuffing the joint [1]. To minimize overstuffing, inset trays or onlay trays (with medial tray taper offset) are often used and humeral tray and bearing thicknesses are kept as minimal as possible without compromising their strength. The new Identity® Shoulder System (Zimmer Biomet) with titanium humeral trays for reverse total shoulder arthroplasty (RTSA) was recently launched for clinical use (Figure 1A). A previously validated finite element analysis (FEA) modeling approach [2] was used to evaluate the strength of several Identity humeral tray configurations under expected clinical loads, and compare its strength to other Zimmer Biomet titanium humeral tray designs: Comprehensive Reverse System (CRS) Original launched in 2008, CRS with increased taper post distal fillet and plate thickness (CRS Modified) launched in 2010, and Comprehensive Reverse Mini humeral trays (CRS Mini Standard, CRS Mini Offset) launched in 2019 [2, 3].

METHODS: Identity humeral trays for primary RTSA (called as neutral) are designed as standard (medial tray taper offset) and extended (central tray taper), with multiple thickness (sizes). The neutral trays are designed with both flat bottom (onlay), which sits on the humeral resection, and conical bottom (inset), which is designed to sit in the resection, creating additional joint space. Additionally, two sizes of revision trays are designed with tilt relative to the elliptical taper for adjusting retroversion (Figure 1B). For FEA simulation of an established physical test set up (Figures 2A, 2B), the smallest and largest sizes of neutral onlay designs with standard and extended configurations, smallest size of neutral inset design with extended configuration, and both sizes of revision trays were selected. Compatible liner, stem, and glenosphere components were assembled with the humeral trays using appropriate contact definitions among them. The distal surface of the stem was constrained in all degrees of freedom. A biomechanically motivated load was applied through the glenosphere in several possible combinations of (scapular°, sagittal°) plane angles; only the two most influential on the results are covered here: (0°, 0°) and (0°, 20°). For revision trays, a load was also applied in (0°, -20°) due to non-symmetrical shape of the design. All analyses were performed using Ansys ver. 2019R3 FEA software, and worst-case identified by FEA was physically tested in a benchtop test. The physical test was extended by artificially increasing loads to induce fracture in the worst-case design for assessing the match between fracture location and the peak stress location predicted in FEA. Moreover, the maximum load (load capacity) required to achieve the same peak maximum principal stress as in previous titanium designs (CRS and CRS Mini) was calculated, normalized with respect to CRS original tray design, and compared to evaluate the relative strength of the worst-case Identity design. Predicted load capacity for each of these designs was also compared to its latest internally compiled clinical complaint history.

RESULTS: The neutral onlay extended size +12 design was identified as the worst case when subjected to (0°, 20°) load (Figure 3A). For all the combinations analyzed in this study, peak stresses were predicted in the proximal medial and distal lateral areas of the tray. Among all the load combinations, the (0°, 20°) load predicted the highest stress for all trays, closely followed by (0°, 0°) load. The worst-case Identity humeral tray design passed 5Mc fatigue benchtop test without fracture to confirm that performance requirements were met. Using artificially elevated load, the laboratory fractures were observed below the distal fillet area of lateral web (Figure 1B, 2C), matching the peak stress location in FEA (Figure 2D). The worst-case Identity humeral tray predicted more than 5 times higher load capacity than the CRS original titanium tray and more than twice that of more recent CRS Mini Standard titanium tray (Figure 3B).

DISCUSSION: A validated modeling approach, based on an assessment of model credibility per ASME VV40-2018, was developed a few years ago to estimate the strength of humeral trays [2]. The current study used the same approach to evaluate the strength of Identity humeral titanium trays and compare it to titanium trays that have been on the market longer. The current study results seem to indicate that the lateral web feature in the Identity designs help the bending resistance, decreasing reliance on both plate thickness and material strength for structural support; enabling a strong bone-conserving RTSA titanium tray design. While development of this modeling approach had used available clinical data in addition to the benchtop test data for establishing credibility, such clinical data for Identity trays is not yet available for comparison because of the recent launch of this design.

SIGNIFICANCE/CLINICAL RELEVANCE: The robust model credibility approach extended in this study suggests that the new Identity titanium humeral tray designs are stronger than some previously launched titanium trays. While this was confirmed with the benchtop test, a comparison based on clinical fracture data should be revisited over the coming years, as more data on CRS Mini and Identity trays becomes available. The titanium humeral trays have shown significant strength improvements with each design evolution in an effort to satisfy potentially higher demands of today's patients and more prevalent clinical use of RTSA implants in younger, more active patients.

REFERENCES: (1) Werner et al, Curr. Rev. Musc. Med. 2016 (2) Dharia et al, ORS 2018 (3) Dharia et al, Zimmer Biomet White Paper 2378.1-GLBL-en-REV0519

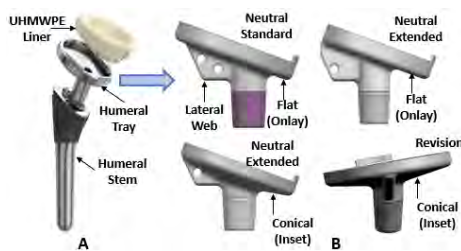


Figure 1. Identity (A) RSA System (B) Humeral Trays

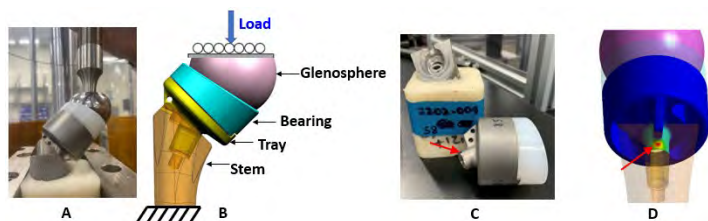


Figure 2. (A) Physical Test (B) FEA Model (C) Test Fracture (D) Model Peak Stress Location

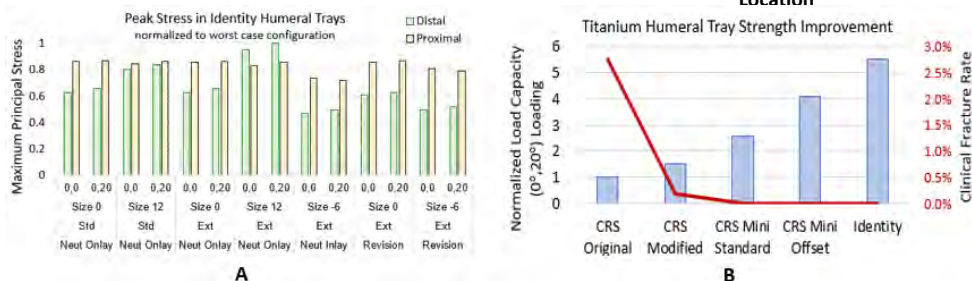


Figure 3. (A) Peak Stress in Identity Humeral Trays (B) Humeral Tray Strength