Patient, implant, and surgical factors that impact stem fixation in total shoulder arthroplasty

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INTRODUCTION: Identifying the clinical impact of implant design on patient outcomes is challenged by the spectrum of unknown and/or uncontrolled variability in clinical studies. In silico clinical trials (ISCTs) provide a powerful, parametric way to decouple design, surgical, and patient variables and increase identification and understanding of differential outcomes [1]. Within total shoulder arthroplasty (TSA), humeral stem design has been associated with loosening and stress shielding, both of which contribute to implant fixation. This study aimed to utilize a validated ISCT modeling approach to explore contributors to these outcomes for two contemporary TSA humeral stems.

METHODS: Forty-five patient-specific humeral bone models (21M, 24F) were reconstructed from CT scans. Each model was implanted with the appropriately sized shoulder stem per surgical technique from two TSA systems (Figure 1a): A clinically established system with demonstrated long-term history of good fixation based on ten-year prospective, observational data [2], registry outcomes [3], and a 10A ODEP rating [4] (Comprehensive®, Zimmer Biomet, Warsaw, IN), and a next generation equivalent device recently introduced to clinical use (Identity®, Zimmer Biomet, Warsaw, IN) with identical indications for use. Both systems offer multiple stem lengths and proximal porous coating, with key differences being a broader metaphyseal profile and contact between the prosthetic head and bone resection for the Identity stem. A stem from each system was implanted within each patient model, with additional parametric variations of stem length, stem diameter, varus / valgus tilt, and head condition conducted in order to simulate surgical variability. This resulted in approximately 500 unique virtual cases. Proximal peri-implant bone density (BMD) and relative stem size (RSS) were evaluated as intra-operative indicators of fixation (Figure 1b). Three physiological loading conditions were then applied to finite element models of each of these surgical configurations to quantify bone-implant primary stability (interface micromotion, Figure 1c) and stress shielding index (SSI, based on cortical strain energy density, Figure 1d), endpoints previously shown to correlate with clinical performance [5,6]. Results from the 3000 simulations were stratified by clinical factors using group-wise statistical tests. A random forest algorithm trained on 80% of the dataset with a 5-fold cross validation was used to rank feature importance in predicting micromotion and stress shielding on the unseen 20%. Correlation (R^2) and mean absolute error (MAE) between actual and predicted values were also computed.

RESULTS: In silico endpoints for fixation varied significantly according to stem design (Figure 2). For the Identity stem, there was a clinically small but statistically significant increase in micromotion ($p < 0.001$) with stem downsizing, varus tilt, and lack of head contact. Micromotion results for both systems across the cohort were below 150µm. Random forest models accurately predicted micromotion of the unseen set ($R^2 = 0.72$ and MAE = 15.74 µm). Prediction accuracy for stress shielding was reduced ($R^2 = 0.542$ and MAE = 0.24). Micromotion was most influenced by stem design, patient weight, and BMD; stress shielding was primarily influenced by RSS, BMD, and stem tilting.

DISCUSSION: In silico clinical trials provide a strong basis for identifying specific patient, surgical, and design factors that impact implant performance. Their clinical relevance exceeds what is typically obtained through traditional benchtop or simulation-based pre-clinical methods, and resulting insights into performance add to what is achievable through conventional clinical studies, provided the clinical relevance of the trial has been established [7]. Here, through a virtual cohort of 45 patients, amplified to over 500 virtual surgical configurations to reflect variations in sizing and/or implantation, and then propagated to over 3000 mechanistic predictions of implant performance, the impact of proximal stem geometry on four unique anatomic (BMD), geometric (RSS), and functional (micromotion, SSI) metrics was explored. Importantly, these results suggest that a broader metaphyseal fit increases contact with high density bone resulting in improved (decreased) micromotion, despite allowing for the use of a stem with smaller diaphyseal diameter (smaller RSS). Clinical evidence for long canal filling stems shows decreased RSS to be associated with reduced stress shielding [8]; the impact on SSI in this study with two shorter, metaphyseal engaging stems was not statistically significant.

SIGNIFICANCE/CLINICAL RELEVANCE: This in silico clinical trial demonstrated that broader metaphyseal stem design can contribute to increased stem fixation in total shoulder arthroplasty; other factors such as bone density, patient weight, and stem size can also influence fixation results. Further studies are needed to assess actual clinical performance.

REFERENCES: [1] Favre et al., ABME 49, 2021. [2] Codd et al., JSES 34, 2025. [3] NJR 21st Annual Report. [4] https://www.odep.org.uk/ [5] Maquer et al., ABME 52, 2024. [6] Mueri et al., IEEE Trans BME, 2025. [7] Bischoff et al., CMPB 242, 2023. [8] Nagels et al., JSES 12, 2003.

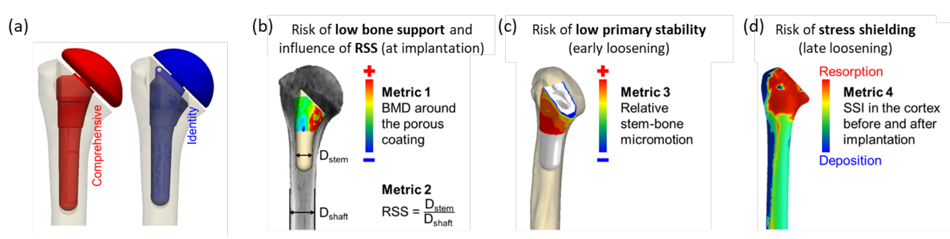

Figure 1: (a) Two humeral stems virtually implanted in patient specific model. (b) Bone mineral density (BMD) and relative stem size (RSS) metrics as intra-operative indicators of stem fixation. (c) Interfacial micromotion and (d) stress shielding index (SSI) as post-operative indicators of stem fixation.

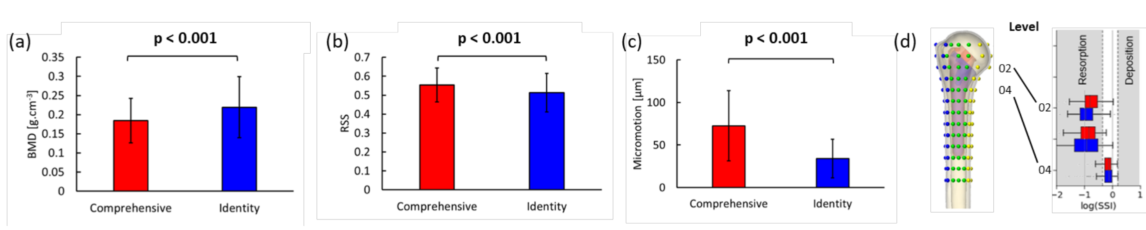

Figure 2: (a) BMD, (b) RSS, (c) micromotion, and (d) SSI (evaluated at several locations along the humerus; level 3 = medial calcar) between stem designs.