In Vitro Performance of a Reverse Engineered Distal-Humeral Hemiarthroplasty Implant

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Introduction: Hemiarthroplasty is a treatment option for distal humerus fractures whereby the native distal humerus is replaced with a metal prosthesis, while the proximal ulna and radius remain intact. The intact cartilage surfaces may be subjected to decreased contact area and increased stress due to the design of existing prostheses and material incompatibility (metal-on-cartilage), which could lead to cartilage degradation [1,2]. The aims of this in vitro study were to assess the performance of a patient-specific reverse engineered distal-humeral hemiarthroplasty implant and compare it to an existing hemiarthroplasty design. We hypothesized that the reverse engineered implant which more closely resembles the native distal humerus shape will offer improved contact mechanics over an off-the-shelf design.

Methods: Five unpaired cadaveric elbows underwent CT scans to determine optimal distal humerus implant size and for 3D computer model generation. For each specimen, a reverse engineered implant was designed (Figure 1) based on the osseous anatomy of the distal humerus. The implant was manufactured from stainless steel using a direct metal selective laser melting (SLM) machine. The arm was then mounted on a joint motion simulator apparatus [3] by clamping the proximal humerus. Cables were sutured to the biceps, brachialis, and triceps, and routed along physiological lines of action to pneumatic force actuators. An elbow joint capsulectomy was performed, and the medial and lateral collateral ligaments were cut and loaded with 20 N. Infrared motion trackers (Optotrak Certus, Northern Digital Inc.) were rigidly attached to the humerus, ulna, and radius. The biceps, brachialis, and triceps muscles were loaded with 20, 20, and 40 N, respectively, and the joint was manually guided from 0 to 120° flexion while the elbow kinematics were recorded. The distal humerus was excised and a universal distal humeral stem component was guided into place using computer navigation. An optimally sized commercially available axisymmetric distal humerus implant component (Latitude Anatomic, Tornier Inc.) was installed on the stem, and passive flexion was repeated with the same muscle load configuration. The commercially available implant was removed and replaced with a reverse engineered implant, and passive flexion repeated. The bones were denuded and 4 nylon fiducial markers were attached. The fiducial markers and cartilage articular surfaces were digitized using an optically tracked stylus tool. The bones underwent CT scans in air, which permitted reconstruction of bone and cartilage 3D computer models [4]. The computer models were registered to the corresponding positions recorded during the experiment in 15° increments via the fiducial and articular surface digitizations. The contact patterns across the contact surfaces of the proximal ulna and radius were calculated based on cartilage-cartilage or implant-cartilage overlap of the registered 3D computer models. The contact configuration (native articulation, commercially available implant, reverse engineered implant) and flexion angle were analyzed using a repeated measures ANOVA, with statistically significant differences reported for \( p < 0.05 \). The net contact patch across the entire flexion range of motion was calculated for each contact configuration in order to map the characteristic contact distribution. To measure changes in contact location, the contact surfaces were subdivided into quadrants (Figure 2) and the magnitude of each quadrant covered by the net contact patch was calculated for each implant design and compared to the native articulation using paired sample t-tests.

Results: The total ulnar and radial contact areas as a function of flexion angle for each contact condition are shown in Figure 3. Compared to the native articulation, ulnar contact areas were significantly smaller for both implant designs. Radial contact areas were significantly smaller for the commercially available design. Comparing the two implant designs, the ulnar contact area was significantly greater using the reverse engineered implant, but no significant differences were observed for radial contact area. The average percentages of each quadrant covered by the net contact patches are depicted in Figure 4 for the ulna and radius. Significant decreases in contact area occurred in more regions using the commercially available design (3 ulna quadrants and 3 radius quadrants) versus the reverse engineered design (1 ulna quadrant and 2 radius quadrants).

Discussion: There was a decrease in ulna and radius contact using either the reverse engineered or commercially available implant design. Ulnar contact area was significantly greater when the reverse engineered design was used versus the commercially available design; however, the difference was small and not clinically significant. Based on the contact coverage reported for each quadrant, the reverse engineered design was better able to reproduce the contact patterns of the native articulation; however, there was significantly less contact area in the lateral olecranon quadrant of the ulna and the medial quadrants of the radius. Future refinements to the reverse engineered design, such as accounting for variable cartilage thickness across the distal humerus, may improve the performance of this design. Unfavorable contact mechanics will likely persist unless a more compatible implant material can be identified.
Significance: These findings suggest that optimizing the geometry of hemiarthroplasty implants can, to some extent, promote more natural contact mechanics. Based on these findings, future efforts should focus on refining the shape of distal humeral hemiarthroplasty implants and investigating more flexible implant materials to reduce the likelihood of cartilage degradation resulting from altered contact.

Acknowledgments:

**Figure 1:** Depiction of commercially available (Latitude, left) and reverse engineered (right) distal humeral hemiarthroplasty implant designs.
**Figure 2:** Depiction of the ulna and radius contact surfaces with quadrants labeled and identified by different colors.
Figure 3: Average ulna (top) and radius (bottom) contact areas as a function of flexion angle. Shaded areas represent +/- 1 standard deviation.
**Figure 4:** Percent coverage of each ulna (top) and radius (bottom) quadrant by the net contact patch. Error bars are 1 standard deviation. Statistically significant differences from the native contact patch measured using t-tests are depicted (* denotes $p < 0.05$, ** denotes $p < 0.01$).