Abstract

Purpose: To investigate the effect of implant positioning on ulnohumeral contact using patient-specific distal humeral implants.

Methods: Seven reverse-engineered distal humeral (DH) implants were manufactured based on computed tomography scans of their osseous geometry. Native ulnae were paired with corresponding native humeri and custom distal humeral implants in a loading apparatus. The ulna was set at 90˚ of flexion and the humerus was positioned from 5˚ varus to 5˚ valgus in 2.5˚ increments under a 100N compressive load. Contact with the ulna was measured with both the native distal humerus and the reverse-engineered DH implant at all varus-valgus (VV) angles, using a joint casting method. Contact patches were digitized and analyzed in four ulnar quadrants. Output variables were contact area and contact pattern.

Results: Mean contact area of the native articulation was significantly greater than with the distal humeral hemiarthroplasty (DHH) implants across all VV positions. Within the native or DHH condition, there was no change in contact area due to VV positioning. While there was no change in contact pattern in the native joint, whereas in the DHH joint, medial ulnar contact was significantly affected by VV angulation. Lateral ulnar contact was variably affected, but generally decreased as well.

Conclusions: Ulnar contact patterns were changed as a result of VV implant positioning using reverse-engineered distal humeral implants, most notably on the medial aspect of the joint. Implant positioning plays a crucial role in producing more native contact patterns.

Clinical relevance: Recent clinical evidence reports nonsymmetrical ulnar wear after DHH. This work suggests that implant positioning is likely a contributing factor and that exact implant positioning may lead to better clinical outcomes.

Introduction

Distal humeral fractures represent 30% of elbow fractures, with an incidence of 5.7 per 100,000 per year [1,2]. For younger, active patients with comminuted unreconstructable fractures, or for salvage of nonunion or malunion after nonoperative or operative treatment of distal humerus fractures, distal humeral hemiarthroplasty (DHH) can be an attractive option [3,4]. The procedure involves replacing the distal humerus (DH) with an implant (usually metal), which is in direct contact with native articular cartilage of the radial head and greater sigmoid notch of the ulna.

Evidence supports that contemporary commercially available DHH implants result in decreased contact area as compared to the native joint [5–7]. Because the implant designs are generalized for widespread use, their potential to replicate natural contact mechanics may be limited. One proposed strategy to improve articular contact mechanics of DHH is to develop implants which closely match the anatomy being replaced. Three-dimensional medical imaging, computer modeling and additive manufacturing techniques have enabled the development of patient-specific implants. These “reverse-engineered” implants are reproduced from the osseous or cartilaginous anatomy of the uninjured contralateral distal humerus. Evidence supports that paired humeri have very similar anthropometric features and that the contralateral humeral characteristics can be used as an approximation of the native geometry of the fractured humerus, both proximally[8,9] and distally[10]. Patient-specific hip [11–13], spine[14] and cranial [15,16] prosthetic components, as well as patient-specific cutting guides for total knee replacement, have also been previously reported [17–19].

Contact patterns are indicative of load transmission across a joint and are an important metric for determining if implants are performing similarly to the native joint, or if the risk for cartilage wear is elevated. It has been reported *in vitro* that DHH causes cartilage damage with commercially available implants [20]; however the paucity of clinical studies limits our understanding of the extent of cartilage damage *in vivo.* There is increasing clinical evidence to suggest that ulnohumeral contact area is disproportionately affected by DHH [3,4,19,20]. Contact with rigid non-anatomic implants changes contact area and creates an asymmetric loading point, elevating contact pressure beyond normal physiological limits, which could possibly predispose patients to early arthritis [5,22]. We postulate that DH implant positioning could be playing an important role. While changes in elbow contact patterns after DHH throughout simple flexion-extension motions have been investigated [23], changes in contact patterns through positioning at varying varus-valgus (VV) angulations have not. We believe that positioning changes load transmission across the elbow, and could have long-term implications on cartilage wear. Hence, the objective of this study was to evaluate changes in ulnohumeral joint contact as a result of clinically relevant VV positioning errors[24]. Specifically, we employed an experimental model using patient-specific implants and joint casting to quantify ulnohumeral contact area and contact pattern before and after DHH with patient-specific DHH implants for different implant VV positions. We hypothesized that contact area will decrease as a result of DHH with patient-specific implants, and that contact patterns will change at different implant VV positions.

Materials and Methods

Reverse-engineered implant design

Seven distal humeral hemiarthroplasty implants were reverse-engineered from the native distal humeri shapes from seven different left cadavers (5 male, 2 female, average age 66 yrs, SD: 22.5 yrs). Computed tomography (CT) scans of each fresh frozen cadaveric elbow specimen were performed using a GE Discovery CT750 HD scanner (GE Health Care, Pewaukee, WI, USA) at 120 kV and 292 mAs with a slice thickness of 0.625 mm (in-plane pixel sizes ranging from 0.492 - 0.586 mm). The CT data was imported into Mimics v14.12 (Materialise, Leuven, Belgium), and the distal humeral bone geometry was extracted using threshold based segmentation, which included any voxel with an attenuation value of 250 HU or greater [5,23,25]. These three-dimensional models were wrapped, exported in the stereolithography (STL) format, and remeshed using a radial basis function in Matlab (The Mathworks, Natick, MA, USA). The resulting models comprised uniformly sized triangles with approximately 0.4 mm edge lengths. A Boolean geometry subtract operation was performed using custom Blender script (The Blender Foundation, Amsterdam, NL), which cropped the model to the articular region and created interface geometry for attaching an existing custom humeral stem component. Stainless steel prosthesis prototypes based on these computer models were manufactured using a sPro™ 125 direct metal selective laser melting (SLM) machine (3D Systems Corp., Rock Hill, SC, USA), and polished until a smooth mirror-like finish was obtained on the articular surfaces of the prosthesis [23].

Specimen Preparation

Each paired ulna and humerus, having been previously denuded and frozen at -20°C, were thawed prior to use. The cartilaginous surfaces were rehydrated with a 0.9% normal saline solution, and hydration was maintained throughout testing by frequent irrigation. Segments of the native distal humerus and native proximal ulna, each 10 cm in length, were potted in 1.5" PVC pipes using dental cement (Modern Materials, Heraeus Kulzer, South Bend, IN, USA). The bones were positioned such that the ulna and humerus were reduced into their natural position at full extension until the cement had set, as shown in Figure 1a. In addition, a custom stem component with an attachment site for the DHH implant was potted for testing the DHH implant with the native proximal ulna.

Custom testing apparatus

A custom apparatus with humeral and ulnar jigs was developed, as shown in Figure 1a. For testing, the ulnar jig was set at 90 degrees of flexion (perpendicular to the humeral jig), as shown in Figure 1b. The ulnar jig was mounted onto a base with ball bearings to permit unrestricted translation and rotation of the ulna in the plane perpendicular to the long axis of the humerus. This allowed the ulna to settle naturally into contact with the distal humerus under compressive loading, guided by the relative shapes of the two articular surfaces. The humeral jig was capable of orienting the distal humerus from 5 degrees varus to 5 degrees valgus in 2.5 degree increments, which includes the 0 degree neutral position. Hence, a total of 5 different VV positions were assessed. The humeral jig was attached to a pneumatic actuator (Bimba Original Line Cylinder, Monee IL, USA) that was controlled by a proportional pressure controller (Mac Valves, Wixom, MI, USA) to generate 100N of compressive load.

Experimental testing

A repeated-measures study design was employed. For each elbow, contact with the native proximal ulna was tested with both the native distal humerus and the patient specific prosthesis. Approximately 3 mL of medium-viscosity impression polymer

(Reprosil Vinyl Polysiloxane Impression Material, Dentistry International Inc., Milford DE, USA) was applied to the ulnar articulating surface. In order to maintain constant viscosity, mixing and application of the casting material was accomplished within 60 seconds at room temperature [7]. After the casting material was applied to the ulna, contact between the distal humerus and ulna was established by reducing the joint with 100 N of compressive load applied by the pneumatic actuator. The ulnar jig was secured in place with three clamps after the joint was reduced in a stable configuration, and the casting material set for 10 minutes, after which the load was removed and the joint was separated.

Contact area calculation

A technique described by et al.[26] was used to quantify ulnohumeral contact area. Prior to casting, the three-dimensional topography of the articulating surface of the native ulna was digitized using a MicroScribe G2X digitizer (Immersion Corp., San Jose, CA, USA) and the surface geometry was recorded as a 3D point cloud. After the joint was separated, the contact patches were identified as areas where the casting material had been displaced and the articular surface of the ulna were visible. These contact patches were digitized. The olecranon and coronoid processes of the ulna were also digitized as reference landmarks, which allowed contact area to be registered to the ulnar articular surface. Surfaces were reconstructed from the contact patch digitization data using Meshlab, as shown in Figure 1c. The surface area of the patches, which corresponded to contact area, was calculated. This contact area was reported in terms of percentage of the entire articulating surface of the ulna in order to normalize for different specimen sizes.

Contact pattern analysis

The contact patterns were analyzed by separating the articular surface of the ulna into quadrants (superior lateral, superior medial, inferior lateral, inferior medial), as shown in Figure 2. In this way, the amount of contact in each quadrant could be measured and quadrants where contact was more sensitive to DHH and/or changes in VV orientation could be identified. All contact patches from the same specimen were co-registered to the same model to visualize changes in contact distribution across the surface of the ulna at the five VV angles studied. Contact patches from DHH conditions were overlaid on contact patches from the native joint to calculate overlap in contact area.

Statistical Analysis

The sample size requirements were determined based on a power calculation. Prior studies using reverse-engineered DHH implants to measure contact area in our laboratory have shown that 75% (standard deviation [SD] 9%) of the ulnar surface is in contact with native articulations, while 49% (SD 16%) of the ulnar surface is in contact using the reverse-engineered DHH implants[1]. We believe that a difference of approximately 25% between the native articulation and using the DHH implants is the minimum clinically important difference in contact area measurements. In the lateral olecranon quadrant, they measured 85% (SD 7%) of total ulnar area was covered using the native articulation, while 28% (SD 33%) was covered using DHH implants. To detect such differences with an alpha of 0.05 and a power of 0-8, for a 2-sided comparison we needed 7 specimen per group. Statistical significance was determined by an analysis of variance (three-way ANOVA) for the dependent variables of contact type (native versus DHH), quadrant location, and alignment angle (0, 2.5 and 5.0

degrees varus and valgus). A Tukey correction at the significance level of less than 0.05 ($p<0.05$) was applied to correct for repeated statistical testing.

Results

Changes in contact area due to implant positioning

Contact area of the native joint was similar at all VV angles and was greatest at the neutral 0° position. Positioning the joint at 2.5° or 5.0° varus or valgus (VV) tended to decrease joint contact by less than 5% (see Table 1), and these changes were not statistically significant ($p = 0.78$). Likewise, with the DHH implants, contact area was greatest at the 0° neutral position, with subtle decreases of less than 10% in contact area when positioned at any of the prescribed VV angulations. These decreases were also not statistically significant ($p = 0.46$).

Mean contact area of the native articulation was significantly greater than the contact area with the DHH implants across all VV conditions ($p<0.05$), as shown in Table 1. The mean absolute decrease in ulnohumeral contact area, following placement of the subject specific implants, was 31% ($p<0.05$). At the neutral position, the native joint contact patch covered 44%±6% of the total articulating surface. In comparison, the DHH joint contact patch only covered 19%±6% of the total articulating surface. At the 5.0° varus or valgus angles, contact with the native distal humerus covered 44%±6% and 44%±8 of the ulnar articulating surface, respectively. For the DHH implants, contact covered 13%±7% and 9%±5%, respectively. In the patient specific implant conditions, there was a decrease in contact area at greater VV angulations, but this was not statistically significant.

Changes in contact pattern due to implant positioning

The percentage of the ulnar surface in contact with the distal humerus (native or DHH) at different VV angulations and in different ulnar quadrants, is shown in Figure 3. On the superior lateral side of the ulna, there was no significant change in contact area when using the DHH implant for any VV angle, when compared to the native condition. On the inferior lateral side, there was a significant decrease in contact area at both the 2.5° and 5.0° varus conditions ($p<0.05$). On both the superior and inferior medial sides, there were significant decreases seen in both 2.5° and 5.0° valgus angulations ($p<0.05$). On the superior medial side, a significant decrease in contact area occurred at the neutral position and at the 5.0° varus position as well. Shifting of the contact patch at prescribed VV angulations, for a representative sample specimen, can be noted from Figure 4. For the reverse engineered condition, there is minimal medial contact especially at valgus orientations, compared to the native articulation. There is a noticeable shift in contact from lateral to medial as the orientation is changed from valgus to varus.

Discussion

Recent clinical evidence has identified increased ulnar cartilage wear and nonsymmetrical contact patterns after DHH, however the reason for this remains unknown. We hypothesized that VV implant positioning likely contributes to decreases in contact area and changes in contact pattern at the ulnohumeral joint. The results of this study support both hypotheses. Specifically, we observed that medial ulnar contact area was significantly affected by changes in the VV angulation. Lateral ulnar contact area was variably affected, but generally decreased as well.

Patient-specific DHH implants consistently caused a significant reduction in overall contact area compared to the native joint articulation in the neutral position. This change was expected and is in agreement with the findings by et al.[23]. By performing passive flexion trials with both the native joint and the patient-specific implants using both the radius and the ulna, they observed an ulnohumeral contact area decrease of 42% (SD 19%, p=0.008) due to DHH with reverse-engineered prostheses [23]. A likely explanation for this change in articular contact between native and DHH is the high stiffness of the metallic implants compared to the relatively soft articular cartilage (the Young's modulus of the metallic implants is approximately 200 GPa, whereas the Young's modulus of articular cartilage is approximately 1 MPa [27]). Interestingly, VV positioning did not significantly change the contact pattern in the native DH joint. Previous studies have shown that the native elbow contact size and pattern depends to a slight extent on the joint position, but that at all loads and flexion angles, a bicentric contact and an important central joint space width emerge because of the concave incongruity of the joint [28]. This implies that the shape of the native elbow helps distribute loads evenly across the joint during VV movements, which are common in everyday life. In comparison, with the patient-specific implants, VV positioning significantly changed the ulnar contact distribution patterns (Figure 3 and 4). The most significant contact pattern changes were observed on the medial side of the ulna, especially at the valgus positions. These results indicate that loads passing through the lateral aspect of the joint did not change as much as a result of DHH, especially on the superior part of the ulna.

The rationale for omitting the radius in this experiment was based on recent studies that have shown that cartilage wear is particularly prevalent at the ulna [3,4,17,18]. Smith et al. [4] described, for the first time, the medium to long-term impact of DHH on ulnar and radial wear with commercially available Sorbie and Latitude implants. Marked ulnar wear was seen in 13 of 16 patients assessed; the wear pattern with the Sorbie prosthesis was more medial and that of the Latitude was mixed in location. Radial wear was not reported in any of the patients assessed. While prostheses design likely influenced this wear pattern, our results demonstrate that even DHH with a more anatomical prostheses design can produce nonsymmetrical ulnar contact patterns. It is likely that both implant positioning, shape and stiffness were the main contributors to contact area and pattern changes observed. Small, clinically relevant VV positioning angles were chosen for the current study, which commonly occur in elbow arthroplasty [24]. et al. [24] reported clinical accuracy in choosing the flexion/extension axis of the elbow compared to a computer-assisted method. They determined the error in surgeons' selections to be a mean frontal plane angle ranging from 6.3˚ varus to 9.6 valgus. While the range of 5˚ varus to 5˚ valgus was chosen for the current study, we believe that larger positioning angles would have magnified the observations noted, but would detract from the clinical relevance.

An important limitation in our study is that the reverse engineered DHH implants used were based on osseous geometry. The osseous geometry of the distal humerus can be readily obtained using clinical CT scan images and we chose to limit ourselves to this accessible imaging modality. Without cartilage thickness distributions, the implants were smaller, which could have had an effect on the contact mechanics of the joint. However, previous work had shown that small changes in sizing did not have a significant effect on contact mechanics [5]. As well, et al. [6] used finite element contact analysis to analyze contact patterns following DHH and found that even implants made from cartilaginous geometry did not match native contact mechanics and suggested that the optimal DH design may lie somewhere in between the osseous and cartilaginous geometry [6]. Considering more compliant biomaterials with an anatomical, but not necessarily custom, implant shape might be both the most clinically viable option. Furthermore, our study had a low sample size of n=7, and this was an *in vitro* simulation testing a compressive load at a single flexion angle of 90˚. This represents a common position for the elbow to be used in activities of daily living and it is often utilized in biomechanical studies. As well, ulnohumeral measurements in extension might have been more erroneous, as the radius was excluded from this study but carries a significant amount of load in extension. The compressive load applied followed the long axis of the humerus due to limitations of the jig. In reality, at 90˚ flexion, the load vector doesn’t exactly follow the humeral shaft or ulnar shaft, but about 45˚ to both [29]. This simplification in the load application could have some effect on the contact location, thus future work should consider more compressive load vectors and other angles of flexion.

Our results suggest that reverse-engineered prostheses reduced the contact area and altered the contact pattern of the joints. Changing prostheses alignment did not change the overall contact area for native or DHH conditions, however changes in contact distribution patterns, especially on the medical aspect of the joint, were observed using DHH implants. This edge loading may cause cartilage wear due to altered contact distribution across the joint. As a result, implant positioning plays an important role in reproducing more native contact patterns and potentially improving long-term clinical outcomes.

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Figure Legends

Figure 1: Experimental setup to test contact mechanics with reverse-engineered distal humeral (DH) implants. a. Elbow jig; actuator applied compressive load of 100N; humeral jig capable of rotating 0, 2.5°, or 5° varus/valgus; ulnar jig capable of 0-90°of flexion. b. Joint compressed at 90° of flexion with casting material applied. c. Surface area of the casting imprint (shown on the left) was registered on the CT model of the ulna (shown on the right).

Figure 2: Ulnar subchondral regions used for analysis of contact patterns. The ulnar surface was divided down the ridge of the greater sigmoid notch (extending from the olecranon to the coronoid process) to create quadrants on the articular surface. The ulna was divided into superior and inferior sections by creating a plane along the transverse ridge.

Figure 3: Percent contact of ulna articular surface in different quadrants, as a function of implant VV angle. Error bars represent standard deviations (n=7). * and ** denote statistically significant differences ($p < 0.05$ and $p < 0.01$, respectively)

Figure 4: Effect of implant VV positioning on contact pattern shift at the ulnar articulating surface for a sample specimen.