Anatomical Contouring of Large Diameter Heads for Soft-tissue Relief Does Not Alter Load Bearing Contact Area and Wear Performance in Ceramic on Poly Articulation

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Introduction: Large diameter femoral heads in total hip arthroplasty (THA) provide increased range-of-motion and reduced dislocation rates compared to smaller diameter femoral heads. However, several recent studies have reported that contemporary large head prostheses can directly impinge against the local soft tissues leading to anterior hip pain. To address this we developed a novel Anatomically Contoured large diameter femoral Head (ACH) that maintains the profile of a large diameter head over approximately a hemispherical portion and then contours inward the distal profile of the head for soft-tissue relief. We hypothesized that the anatomical contouring of a femoral head for soft tissue relief can be accomplished without affecting load bearing femoroacetabular contact area or wear performance in ceramic-on-polyethylene articulation. The hypothesis was tested by comparing ceramic ACH with ceramic conventional femoral heads in a Finite Element Analysis (FEA) contact simulation and hip simulator wear test.

Methods: To assess the femoroacetabular contact area, a FEA was completed with a 36 mm diameter conventional head and ACH (Fig. 1A). It included a rigid acetabular shell, plastically deformable UHMWPE acetabular liner, rigid femoral head and rigid femoral stem. The femoral stem was placed at 0°, 10° and 20° of anteversion. The acetabular shell and liner were placed in 20°, 40° and 60° of abduction and 0°, 20° and 40° of anteversion. The femoral head to acetabular liner radial clearances modeled were 0.06 mm, 0.13 mm and 0.5 mm. Three loading cases corresponding to peak in vivo loads during walking, chair sit and deep-knee bend were analyzed. This allowed a range of component positions and maximum joint loads to be studied.

ACH and conventional head wear characteristics were assessed with an AMTI 12-station hip simulator test according to ISO 14242-1. Acetabular liners with a 36 mm inner diameter were manufactured from two UHMWPE stocks: (1) Conventional PE liners from compression molded GUR1020 UHMWPE, and (2) VitE-PE liners from 0.1 wt.% Vitamin E blended GUR1020 UHMWPE that was e-beam irradiated to 120 kGy at 100°C. All liners were EtO sterilized prior to testing. Three acetabular liners from both material groups articulated against a conventional head and an ACH creating four head-liner groupings. Two additional liners and heads for each head-liner group served as load-soak components to account for fluid absorption. Testing was carried out to a total of 1.5×10⁶ cycles of simulated gait. Every 0.5×10⁶ interval of simulated gait, liners were cleaned and weighed per ISO 14242-2 to gravimetrically assess wear. Wear rate in milligrams per million cycles (mg/MC) was calculated as the linear regression slope of the data. The hip simulator testing will be continued to a total of 5×10⁶ cycles of gait.

Results: Under all FEA contact simulations there was no difference between the ACH and conventional head implants. The contact area (Fig. 1B) for both prostheses depended on the radial clearance between the head and liner. The conventional head contact area (standard deviation) in mm² for 0.5 mm, 0.13 mm and 0.06 mm of radial clearance was 230.5 (70.2), 419.8 (48.7) and 575.4 (60.1) respectively. Similarly, for the ACH these were 230.5 (70.4), 420.1 (48.7) and 575.9 (59.4). The average data for a head and radial clearance combination included all component placements and load conditions completed. A student t-Test (P=0.05) confirmed that the ACH had the same contact area as the conventional head for all radial clearances.

The linear wear rate of the Conventional PE liners articulating against ceramic conventional head and ACH was 21.4 (4.1) mg/MC and 20.8 (4.2) mg/MC, respectively. The linear wear rate of the VitE-PE liners articulating against conventional head and ACH was -2.5 (1.6) mg/MC and -1.1 (0.7) mg/MC, respectively. The “negative” wear rates for the VitE-PE liners indicate that they gained weight due to absorption. These data are currently based on 1.5 million cycles of wear tests. The hip simulator test will be continued up to 5 million cycles, however we do not expect the wear rates to change based on previous experience.

Discussion: This study showed that, as intended, an anatomically contoured large diameter femoral head designed to provide soft-tissue relief maintained the load bearing articulating contact area and wear rate of a conventional implant when articulating with an UHMWPE liner. The FEA study incorporated various radial clearances and component orientations to account for differences in prostheses design, manufacturing and surgical placement. The wear test results reinforce the findings of the FEA.
as there was no difference in the wear rates of the conventional head and the ACH articulating against either UHMWPE liner material. The “negative” wear rate of the VitE-PE liners indicates that the liners under both motion and load are absorbing more fluid than the load-soak liners under load alone, and this increased fluid absorption makes measuring the extremely low wear rates on these liners difficult. Taken together, these tests demonstrate the anatomical contouring of a femoral head for soft-tissue relief can be accomplished without affecting mechanical performance.

**Significance:** The novel anatomically contoured femoral head prosthesis could mitigate the risk of soft-tissue impingement with contemporary large head implants while retaining their contact and wear characteristics, and their benefits of additional stability and range-of-motion.

**Acknowledgments:**

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**Fig 1.** A) Conventional and anatomically contoured femoral head geometries. B) Contact pressure on liner from gait cycle loading with cup at 40 degrees abduction and 20 degrees anteversion. Femoral stem is at 0 degrees of anteversion. Maximum contact pressure shown is 8 MPa.

**References:**

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