

Surface Modification of Ceramic Biomaterials After *in vivo* Exposure to the Physiological Environment

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Statement of Purpose: High hardness and good wettability aid lubrication of articular bearing surfaces in total hip replacements (THR).[1] These properties provide tribological advantages to ceramic bearings compared to metal bearings.[2] However, the physiological environment in which THR articular bearings function can induce surface modifications on the ceramic biomaterials and alter bearing performance *in vivo*. For example, phase transformation from the tetragonal to the monoclinic phase can occur at body temperature [1] and grain pull-out, noted as stripe wear in micrographs, can occur under high stress *in vivo* loading conditions.[3] The purpose of this study is to characterize surface modifications evident on ceramic THR articular bearings after *in vivo* exposure to the physiological environment and their impact on wettability.

Methods: Modular ceramic femoral heads (n=28) explanted from THR patients after *in vivo* function were acquired. These Explanted Heads were fabricated from isostatically pressed alumina oxide (BioloX Forte, n=21) and zirconia-toughened alumina (BioloX Delta, n=7) and functioned as ball-in-socket ceramic-on-ceramic bearing couples for an average of 4.8 (0.1-10.9) years. Two unused femoral heads of the same materials were used as Control Heads. All heads were previously decontaminated and cleaned, with additional thorough cleaning using ethanol, deionized water and compressed nitrogen gas. Surface damage, surface roughness, and wettability were assessed in 33 analysis zones equally distributed around each head, as defined in ASTM F2033. Damage present in each zone was assessed using an optical microscope at 6-50x magnification and previously defined damage mode descriptions.[4] Damage modes included scratches, pits, metal transfer, stripe wear, and none. Regions with biological debris or tool damage were excluded. Measurement zones for surface roughness and wettability were circled using a fine-tipped pen. Surface roughness in each circled zone was measured using a non-contact interferometer (NP-Flex, Bruker) at ~20X magnification. Wettability in each circled zone was measured as contact angle using a drop shape analyzer (DO4010 Easy Drop, Krüss) and deionized water solvent (1 µl droplets) in a temperature and humidity controlled room. Image analysis software and appropriate mathematical corrections for measuring contact angle on a curved (spherical) geometry were implemented.[3]

Results (Table 1 and Figure 1): Metal transfer and stripe wear were the most frequently observed modes, occurring on 86% and 71% of the heads, respectively. However, the distribution of damage was limited, with average distribution for all modes not exceeding 5%. Compared to Control Heads, zones identified as having no damage or only singular pits/scratches had increased wettability (lower contact angle). In contrast, zones identified as having stripe damage, pits, or scratches had significantly greater roughness (Rvm) and decreased wettability (high contact angle) compared to non-worn regions. A similar trend was noted

Table 1: Frequency and Distribution of Different Damage Modes

Damage Mode	Frequency ^a	Distribution ^b
None	96%	51%±28%
Metal transfer	86%	4%±10%
Stripe	71%	5%±8%
Scratches	25%	2%±4%
Pits	21%	4%±9%

^a Frequency: Percentage of heads having at least one zone exhibiting a given damage mode.

^b Distribution: Percentage of zones with a given damage mode per head and averaged for the entire cohort (n=28).

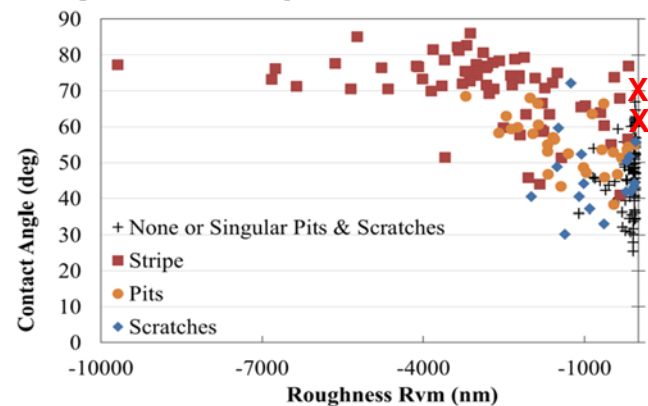


Figure 1: Contact angle and roughness varied for different damage modes on Explanted Heads and Control Heads (X, Forte=62° and Delta=71°). Surface modifications due to stripe damage had the highest contact angles (low wettability).

among Retrieved Heads with metal transfer (not shown in Figure 1 for space considerations), which generally had greater roughness (Rpm) due to material pile-up on the surface and decreased wettability (high contact angle) compared to non-worn regions.

Conclusions: The ceramic biomaterials in the Explanted Heads group exhibited surface modifications after functioning in the physiological environment, resulting in localized wetting behavior that deviated considerably from Control Heads. In regions of low wear, with only minor disruptions to the polished surface finish, wettability was increased compared to Control Heads. This is consistent with the Wenzel model, predicting enhanced wetting for roughened hydrophilic surfaces due to increased interfacial area.[6] However, in regions of high wear, wettability was decreased compared to Control Heads. In those regions, droplet behavior can be modeled using a manipulation of the Cassie-Baxter theory, describing contact angle theory on chemically heterogeneous surfaces.[7]

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