

Long-Term Wear Evaluation of a Polycarbonate-Urethane Cushion Form Bearing in Artificial Hip Joints

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Statement of Purpose: There is growing interest in the use of compliant materials as an alternative to hard bearing materials such as polyethylene, metal and ceramics in artificial joints. Polycarbonate-urethane (PCU), for example, is a promising candidate material for hip arthroplasty in terms of its mechanical properties, frictional behavior and lubrication, which are similar to natural cartilage. It has, however, to be elucidated if a low-modulus cushion bearing can be adequately durable to withstand long-term use. Additionally, the use of new bearing materials should be supported by accurate descriptions of the implant following usage and of the number, size distribution and volume of wear particles generated, for instance, via *in-vitro* simulation. The current study aimed to evaluate the wear performance of a novel PCU acetabular buffer over 20 million gait cycles (Fig. 1a, TriboFit[®], AIC, Memphis, TN).

Methods: Five 46 mm buffers were tested, coupled with 40mm CoCr spherical femoral heads. Four independently-controlled motions were induced in anatomical positioning, according to ISO 14242-2 gait pattern for a total 20 million cycles (Mc). The PCU implants were examined every 1Mc and weighed to evaluate gravimetric changes due to wear. Wear particles released into the lubricant were isolated using a novel Bio-Ferrography (BF) method and conventional filtration, and were analyzed by scanning electron microscopy (SEM). Additional implant characterization was conducted by environmental-SEM, laser profilometry, and atomic force microscopy (AFM) of the articulating surface. A detailed description of the methodology can be found elsewhere [1].

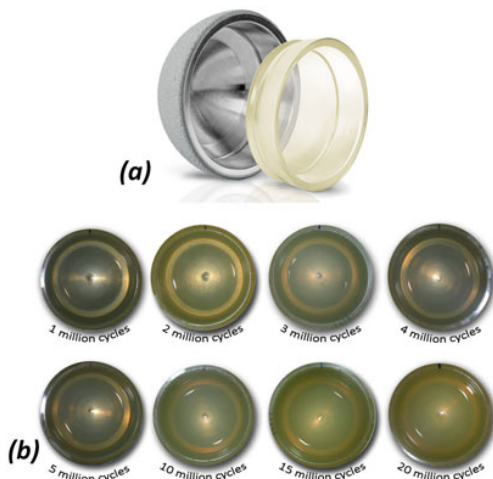


Figure 1. Photographs of the pliable PCU acetabular buffer (a) at different time points of simulator testing (b).

Results: The implants' articulating surfaces remained smooth, and showed no signs of scratches, discoloration or fatigue, following 20 Mc (Fig 1b). An initial 'run-in' particle generation rate of 1×10^8 particles/Mc was reduced gradually to $1-3 \times 10^6$ particles/Mc after 2Mc and remained steady thereafter. Gravimetric and BF methods produced a steady-state volumetric wear rate of 8.2-9.2 mg/Mc ($8-9 \text{ mm}^3/\text{Mc}$), whereas filtration yielded a lower wear rate: 6.9 mg/Mc ($5 \text{ mm}^3/\text{Mc}$). The wear particles isolated by filtration and BF were similar and mean sizes were found to be 10-14 μm .

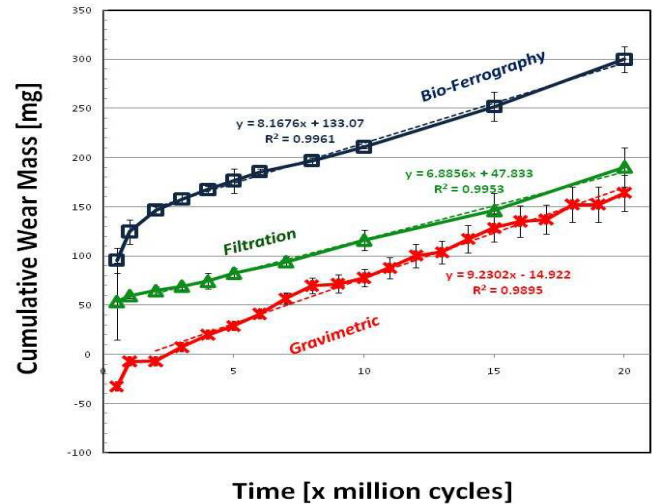


Figure 2. Characteristic wear curves of a PCU acetabular buffer determined based on gravimetric measurement of the implant, and wear particles isolated by filtration and bio-ferrography.

Conclusions: Current findings demonstrate that the PCU bearing has excellent fatigue and wear resistance. PCU demonstrates a significantly lower wear rate compared to traditional UHMWPE bearings ($30-100 \text{ mm}^3/\text{Mc}$). In fact, the wear rate was found to be in the low range reported for polymer bearings, and similar to the new generation of highly cross-linked UHMWPE (HXLPE). PCU wear particles were found to be generated in quantities 5 orders of magnitude lower than that of UHMWPE, 6 orders lower than HXLPE, and 6-8 orders lower than that reported for metal on metal bearings. Additionally, with PCU wear particle sizes being considerably larger than those of hard bearing materials, and mostly not in the biologically active range ($0.1-10 \mu\text{m}$), it seems that the osteolytic potential of PCU is lower than that of PE.

References:

[1] Elsner et al., Acta Biomater. 2010 6(12):4698-4707