

Long-Term Evaluation of a Compliant Cushion Form Acetabular Bearing for Hip Joint Replacement: A 20 Million Cycles Wear Simulation

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ABSTRACT: Soft bearing materials that aim to reproduce the tribological function of the natural joint are gaining popularity as an alternative concept to conventional hard bearing materials in the hip and knee. However, it has not been proven so far that an elastic cushion bearing can be sufficiently durable as a long term (~20 years) articulating joint prosthesis. The use of new bearing materials should be supported by accurate descriptions of the implant following usage and of the number, volume, and type of wear particles generated. We report on a long-term 20 million cycle (Mc) wear study of a commercial hip replacement system composed of a compliant polycarbonate-urethane (PCU) acetabular liner coupled to a cobalt-chromium alloy femoral head. The PCU liner showed excellent wear characteristics in terms of its low and steady volumetric wear rate ($5.8\text{--}7.7 \text{ mm}^3/\text{Mc}$) and low particle generation rate ($2\text{--}3 \times 10^6 \text{ particles/Mc}$). The latter is 5–6 orders of magnitude lower than that of highly cross-linked polyethylene and 6–8 orders of magnitude lower than that of metal-on-metal bearings. Microscopic analysis of the implants after the simulation demonstrated a low damage level to the implants' articulating surfaces. Thus, the compliant PCU bearing may provide a substantial advantage over traditional bearing materials. © 2011 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res* 29:1859–1866, 2011.

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A main concern in the developing implants for total hip replacement (THR) is the interaction between the implant's bearing surfaces as they contact during motion. Abrasive and adhesive wear mechanisms can lead to formation of wear debris. The accumulation of debris can activate macrophages to stimulate the production of antibodies, which attack the debris, the implant, and the surrounding bone. This process can cause osteolysis, aseptic loosening, and failure of the implant.^{1,2}

A new alternative, which has gained interest in recent years, is that of soft bearing materials aimed at reducing wear by maintaining a fluid film between the articulating surfaces, reproducing the tribological function of the natural joint. The theoretical and actual wear properties of soft orthopedic bearings have been explored since the 1980s.^{3–5} These studies demonstrated clear advantages towards this type of bearing compared to hard bearings in terms of reduced friction and wear. Only recently, however, have cushion bearing implants been produced and their performance characterized in laboratory and animal studies.^{6–9}

The use of joint simulators provides a means of testing materials in prosthesis form under conditions similar to their intended use. A recent advancement in hip joint simulation is the realization that multidirectional motion reproduces clinically relevant wear mechanisms, wear debris, and wear magnitudes in polymer implants.¹⁰ Thus, anatomical positioning, movement,

and physiological loads that occur during normal gait must be correctly simulated, even while ignoring wider ranges of load and motion that are applied during many activities.

The results of short-term wear and fatigue simulator tests of polycarbonate-urethane (PCU) compliant bearing systems (Fig. 1a) under physiological conditions are promising with respect to their low wear volume^{9,11,12} and in vivo response to wear particles.¹³ A commercial hip system based on a PCU acetabular liner and cobalt alloy (CoCr) femoral head (Tribofit® Hip System, AIC, Memphis, TN) has been available in Europe for 5 years. Few short-term (2–4 years) follow-up reports are available, but demonstrate excellent results by the Harris and Oxford hip scores.^{14,15}

Previously,¹⁶ we measured the wear rate of the PCU bearing over 8 million simulated gait cycles by means of gravimetry, filtration, and Bio-Ferrography (BF). The latter technique, which is new to the orthopedic community, has several advantages. The PCU demonstrated a low particle generation rate, with the majority of particle mass lying above the biologically active range of polymeric particles ($0.2\text{--}10 \mu\text{m}$) thought to induce osteolysis.¹⁷

However, it should be shown that this material can endure many more cycles (e.g., 20 million, commonly taken as equivalent to 20 years of clinical use,^{18,19} although some reports suggests 10 years in vivo as a better estimate²⁰). Such long-term hip experiments are rare in the literature.²¹ In addition, the wear rate at the back side of the PCU liner should also be studied, and the surface of the liner should be characterized microscopically to evaluate the state of the implant following service and its potential in vivo performance.

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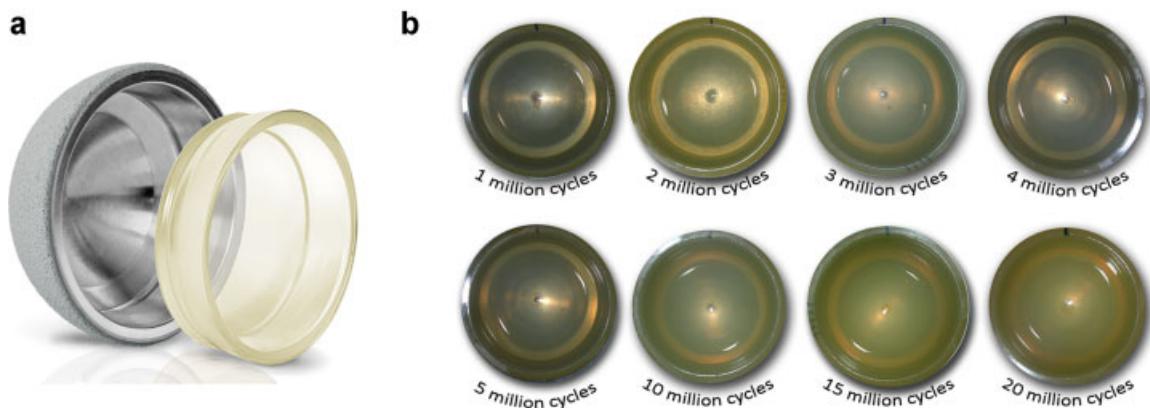


Figure 1. (a) Side view of the TriboFit® PCU liner. The liner is fixed to the metal shell backing by snap-fit mechanism based on a ring shaped flange. (b) Photographs of the liner after 1, 2, 3, 4, 5, 10, 15, and 20 Mc.

METHODS

Six commercial Tribofit® Hip Systems composed of a PCU acetabular liner with a 46/40 outer/inner diameter (mm) and a 40-mm CoCr head were used. The average surface roughness of the heads was ~ 6 nm, and the radial clearance between the head and the liner was ~ 200 μm . Three additional liners were used as dry controls, being maintained at room conditions (25°C , $\sim 30\%$ humidity). Three other liners served as soak controls, being maintained in the test medium (37°C). All components were supplied in their original sterile packaging.

Wear simulation was conducted on a specially designed simulator with anatomical positioning and six stations (FSM, AIC, R&D Center, Netanya, Israel).¹⁶ Adult bovine serum (0.2 μm filtered), diluted with distilled water (1:4 by volume) to approximate protein concentration of 1.6 g/100 ml, was used as the lubricant. The 6 tested samples were pre-soaked for 48 h in the lubricant. Next, they were cleaned and dried, and their initial weight was recorded. Five of the samples were then randomly assigned to undergo full gait simulation according to ISO-14242. Three independently controlled motions (abduction-adduction, flexion-extension, and internal-external rotation and vertical loading were applied on each station. The 6th sample served as a load-soak control, and was only loaded with the vertical load component. The simulation was conducted for 20 million cycles (Mc), with stops at 0.5 and 1 Mc, and successive 1 Mc intervals. At each stop, lubricant samples were collected. The implants were washed with distilled water, dried, and then removed from their metal backings and rinsed again with 20 ml of distilled water that was taken for the evaluation of back-side wear. The implants were then wiped with lint-free wipes and dried in open air for 30 min, weighed, and visually inspected. The soak and dry controls were processed similarly to verify that the measurement process did not affect the measured weight. The lubricant was replaced for the continuing simulation.

The wear rate was determined by three methods¹⁶: gravimetry, filtration, and BF. BF utilizes a magnetic field across an interpolar gap to isolate magnetically susceptible particles on a glass slide.^{16,22–25} Magnetization of the non-magnetic polymer particles was first attained by nonspecific adsorption of the paramagnetic lanthanide cation Er^{3+} . Linear regression of the cumulative implant mass-loss or

cumulative production of wear particle mass was used to determine the wear rate. More details are provided elsewhere.¹⁶

Since the PCU liners were fixed to their metal backing by a snap-fit mechanism based on a ring-shaped flange (Fig. 1a), particles originating from the articulating surface were released directly into the lubricant, whereas particles produced by unintentional rotary motion of the liner against the metal backing remained trapped at the interface and were assumed to be exposed only when the implant was removed from its backing. Back-side wear was thus determined based on analysis of the back-side washing, without performing enzymatic digestion or dilution.

Imaging of the articulating surface was performed by environmental SEM (ESEM, Quanta 200 FEG, FEI, Eindhoven, The Netherlands) under low vacuum, without sputtering of conductive material. Profiling of the articulating surfaces was conducted by a “LEXT” OLS3100 confocal scanning laser microscope. The scanned area ranged from 48×64 to $480 \times 640 \mu\text{m}^2$, with a scanning resolution of 0.05 μm . Surface roughness was evaluated by atomic force microscopy (AFM, PicoSPM™, Molecular Imaging, Phoenix, AZ). Imaging was done under contact mode, using tips made of Si_3N_4 (Veeco, Santa Barbara, CA). Topography, deflection, and 3D images were acquired. Roughness parameters were determined using the raw data and SPIP™ software version 5.

RESULTS

All five test samples successfully survived 20 Mc without any adverse events. Visual inspection did not reveal changes in their appearance (Fig. 1b). However, microscopic evaluation showed that the texture of the articulating surface became smoother than that prior to testing. A low level of damage to the PCU implants' articulating surface was identified at high magnification (Fig. 2c and d). Some wear grooves were evident along the articulating path. Also, small pits (0.5–4 μm diam.) were scattered over the surface (Fig. 2c). The surface finish that had been dominated by protrusions prior to simulation (Fig. 2a and b) became dominated

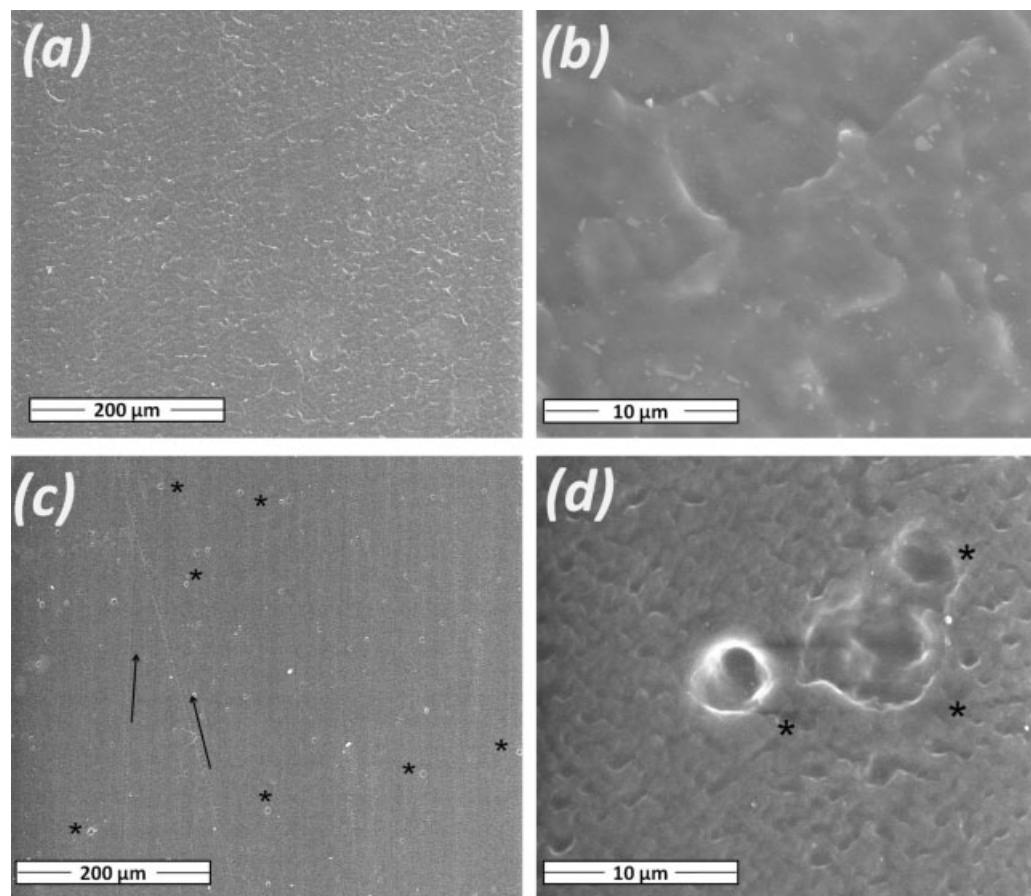


Figure 2. SEM observations of the articulating surface of the liner. (a) Appearance prior to simulation, (b) higher magnification prior to simulation, (c) appearance after 20 Mc, (d) higher magnification of pits after simulation. Wear grooves and pits are marked by arrows and asterisks, respectively.

by small depressions after simulation (Fig. 2c and d). This finding was also observed in the 3D images acquired by profilometry (Fig. 3). The roughness measurements varied slightly among specimens, apart from specimen 3, which had a rougher surface (Table 1). After 20 Mc, both the average roughness (R_a) and the core roughness depth (S_k) were reduced compared to a reference sample (Table 1). The latter property is a measure of the nominal peak-to-valley roughness, with the predominant peaks and valleys removed. Figure 4 shows the 3D AFM images (a1, a2) and the Abbott–Firestone curves (b1, b2) of the reference specimen and tested specimen 4, respectively. Note the larger scale of the z -axis in Figure 4a1 compared to a2. A smoother, more uniform surface is evident after the simulator test (a2), with some pits (dark holes). The more uniform surface is also evident when comparing b1 to b2, the latter showing a flattened cumulative probability distribution (each point on the curve shows what linear fraction of a profile lies above a certain height).

Gravimetric measurements showed that a constant wear rate was reached after 2 Mc and maintained for the test duration (Fig. 5b). During the initial run-in

phase, the mass gain due to water absorption masked the mass loss due to wear, making it unfeasible to determine the run-in wear rate, even after correction against the load-soak control. Linear regression of the cumulative weight loss data showed that the implants lost 9.2 mg/Mc, which is equivalent to a volumetric wear rate of $7.7 \text{ mm}^3/\text{Mc}$. The cumulative wear masses of particles isolated by filtration and BF are presented in Figure 5a. Additional data on temporal changes in the particle generation rates are presented in Figure 5b. BF was found to be more sensitive towards particle isolation compared to filtration, as depicted by a larger mass of particles captured during the initial run-in period and a slightly higher wear rate during the steady phase. The slope of the cumulative wear mass curves represents the wear rate in mg/Mc, and linear regressions in the steady-state phase (2–20 Mc) demonstrated excellent fit ($R^2 \geq 0.99$), with a wear rate of 6.9 mg/Mc ($5.8 \text{ mm}^3/\text{Mc}$) for filtration, and 8.2 mg/Mc ($6.9 \text{ mm}^3/\text{Mc}$) for BF. Back-side wear had a negligible contribution to the total wear mass (<0.03 mg/Mc).

The particle generation rates from filtration and BF were generally consistent. The initially high rate of

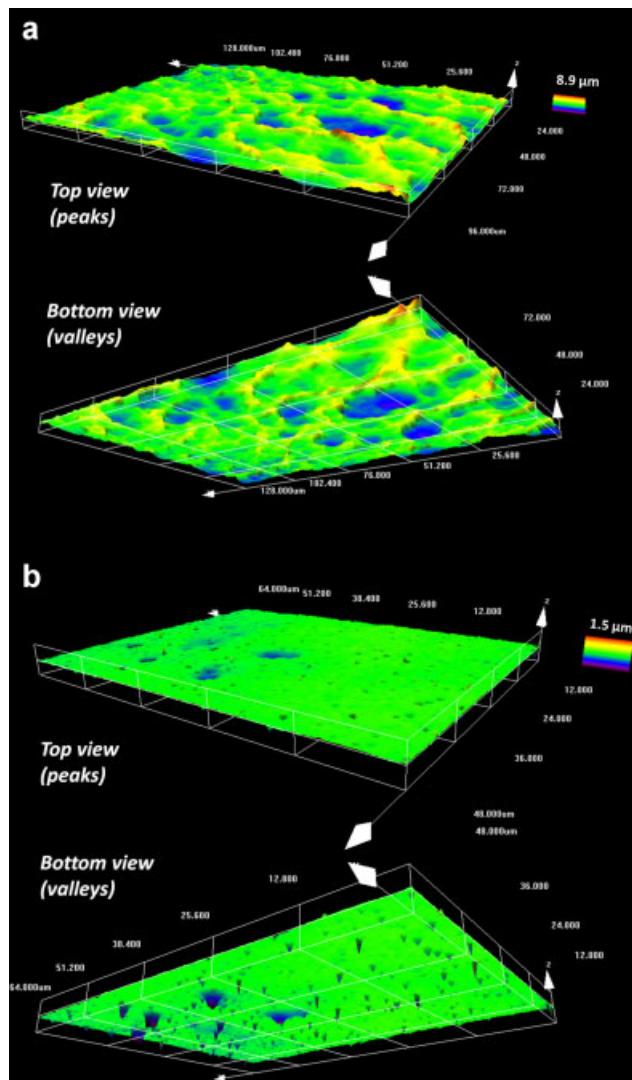


Figure 3. Typical 3D profilometry images ($\times 100$ mag.) of the articulating surface: (a) control implant, (b) an implant after 20 Mc.

$0.7\text{--}2 \times 10^8$ particles/Mc measured during the run-in period was reduced to $2\text{--}3 \times 10^6$ particles/Mc throughout most of the experiment, with the exception of a small increase measured by filtration at the last time

Table 1. Roughness Measurements Made by AFM and Non-Contact Laser Profilometry of the Articulating Surfaces of Five Samples after 20 Mc Load Cycles, in Comparison to an Untested, Reference Sample

	Profilometry		AFM	
	R_a (nm)	R_a (nm)	S_k (nm)	
Control	783.0	66.7	252.0	
Sample #1	43.5	54.2	152.0	
Sample #2	45.0	26.6	92.3	
Sample #3	291.0	32.4	114.6	
Sample #4	30.0	37.3	112.5	
Sample #5	34.5	57.7	206.5	

R_a , average roughness; S_k , core roughness depth.

point (6×10^6 particles/Mc). The concentrations of particles generated by the implants' back side were 1–2 orders of magnitude lower than those measured for the articulating side. Their generation rate increased from 1×10^4 to 2×10^5 particles/Mc between 10 and 20 Mc, respectively. The mean particle diameters were found to be 8–13 μm (median: 8–12 μm , range: 1–73 μm) for particles captured by filtration, and 13–18 μm (median: 10–13 μm , range: 3–122 μm) for BF.

DISCUSSION

We demonstrated good long-term wear characteristics of the PCU liner, which supports its use as an orthopedic bearing material in THR. A steady wear rate was reached after a run-in period of 2 Mc, and was maintained throughout 20 Mc. Gravimetry and BF yielded a wear rate of $6.7\text{--}7.6 \text{ mm}^3/\text{Mc}$; filtration yielded a lower wear rate of $5.9 \text{ mm}^3/\text{Mc}$. The higher wear rate by BF has been explained.¹⁶ The steady-state wear rate was substantially lower than that for conventional UHMWPE bearings ($30\text{--}100 \text{ mm}^3/\text{Mc}$), and of the same order of magnitude as highly cross-linked UHMWPE (HXLPE)^{26–29} and metal-on-metal³⁰ (MoM) bearings (Fig. 6a). One potential limitation of direct comparison between different wear studies is the variability in testing conditions (load cycles, motions, and lubricants), as well as lack of consistency in head sizes. Nevertheless, by using the smallest available head size/liner configuration (40/46 mm), which experiences the highest load per contact area, and by complying strictly with ISO-14242 test conditions, we believe that our simulation conditions provide a conservative wear approximation. Another reason for testing the smallest size is that in theory larger sizes of compliant PCU fluid film lubrication systems demonstrate reduced wear.³¹ This is contrary to traditional UHMWPE, for which more wear is measured for larger head/cup combinations, presumably due to the longer sliding distance per step.³²

In addition to low wear volume, long-term clinical THR performance is affected by the size, shape, and surface morphology of wear particles, and by the related biological response. Particles generated by MoM prostheses are predominantly in the nm size range.³⁰ The number of these particles exceeds the number of μm -size UHMWPE or PCU particles. Specifically, the number of PCU particles generated per million cycle in our study was 5, 6, and 6–8 orders of magnitude lower than that of UHMWPE, HXLPE, and metal bearings, respectively (Fig. 6b).

Nanometer-sized metal particles, typical of MoM hard bearings, are disseminated throughout the body—in the lymph nodes, spleen, and bone marrow.^{33,34} The high activity of metallic nano-debris results in their enhanced corrosion and release of metal ions. Certain ions induce hypersensitivity and implant intolerance reactions.^{35,36} Particles produced by UHMWPE bearings are larger and are therefore

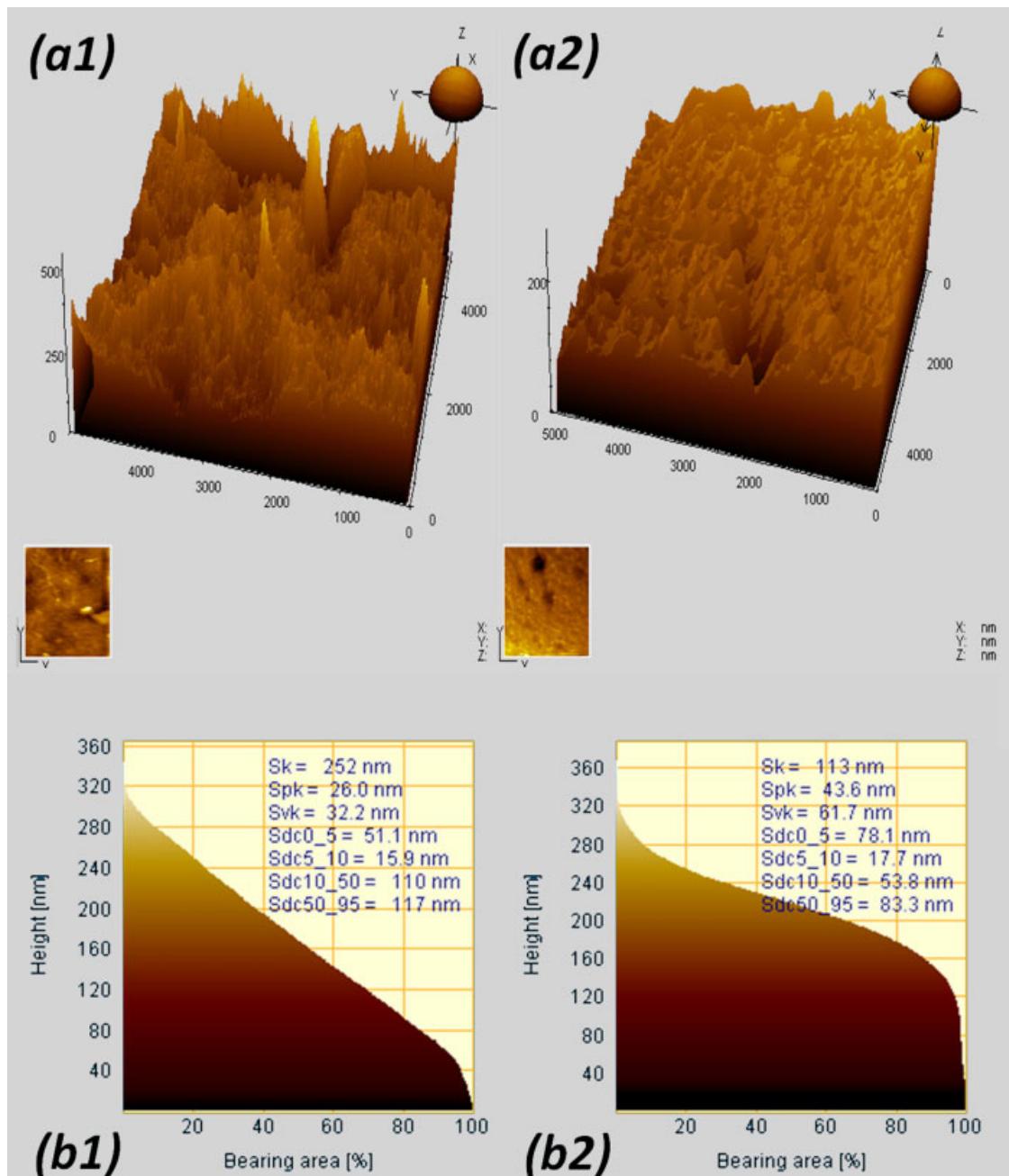


Figure 4. AFM data demonstrating the effects of 20 Mc on the front-side surface of the liner. 3D image of a control liner before (a1) and after (a2) loading of sample #4. Note the different scale of the z-axis in a1 and a2. (b1 and b2) The Abbott–Firestone curves corresponding to a1 and a2, respectively. Note the more uniform, smoother surface in a2 and b2 compared to a1 and b1.

less likely to spread throughout the body. However, the major part of UHMWPE particles mass lies in the 0.2–10 μm size, where they are most active, stimulating macrophages to produce high levels of the cytokine TNF- α .¹⁷ In contrast, only 3.4% of the PCU wear particle mass lay within this range; the majority of particle mass was associated with larger sizes. Another potential advantage of PCU is that, while HXLPE and UHMWPE materials share similar values of biological activity,³⁷ a recent study showed that PCU is less inflammatory to periprosthetic tissue and bone

compared to HXLPE.³⁸ A study of functional biological activity (FBA) of HXLPE, which takes into account the wear volume and specific biological activity, found significantly lower FBA values compared to non-cross-linked UHMWPE, due to the reduced wear volume found with HXLPE material.³⁷ Thus, based on the combination of larger wear particles, less reactivity, and lower particle generation rate, we hypothesize that the osteolytic risk of PCU is lower than that of hard bearings. Further long-term clinical follow-up is needed.

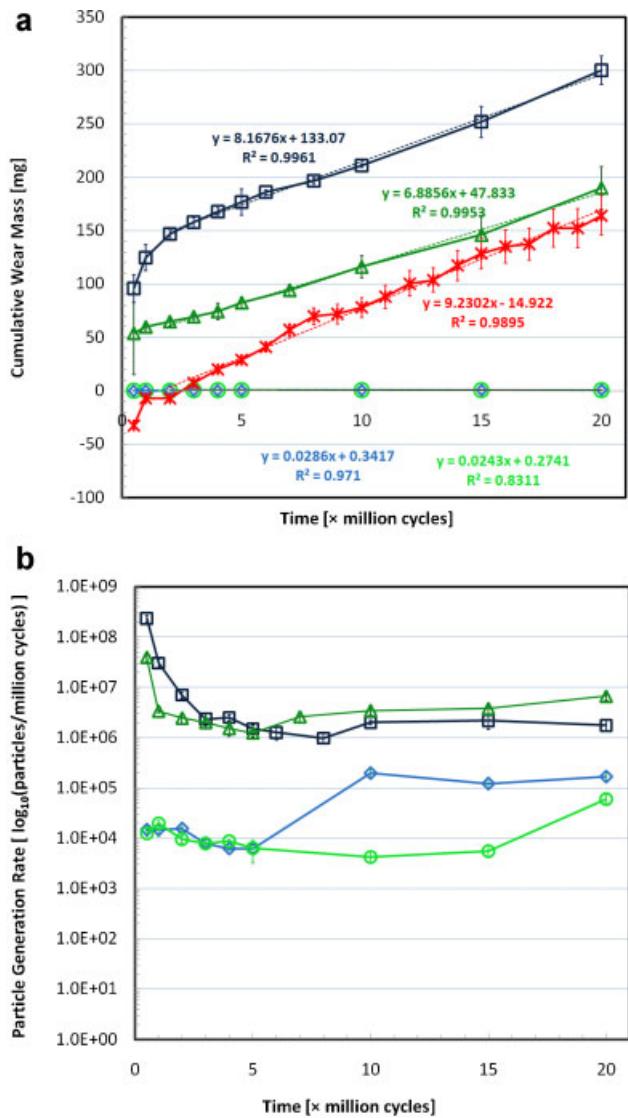


Figure 5. (a) Cumulative mass of worn liner during 20 Mc, as determined by gravimetric measurements (\star), analysis of wear particles isolated by filtration (Δ , articulating surface; \square , back-side surface), and by Bio-Ferrography (\square , articulating surface; \diamond , back-side surface). (b) Particle generation rate during 20 Mc. Data are presented as mean \pm standard error of the mean.

Another long-term aspect of implants performance is their fatigue resistance. Cross-linking of UHMWPE increases wear resistance, but decreases fracture resistance. Increased concern exists for HXLPE not only due to its initially lower fatigue strength compared to un-aged UHMWPE, but also because larger head sizes with thinner PE can now be used.³⁹ While still uncommon, there is growing evidence on failures of HXLPE liners, specifically due to femoral neck impingement on the rim of an acetabular liner.^{39–41} The behavior of the PCU liner is interesting with this respect. Although we did not evaluate neck-socket impingement, the microscopic examination of the PCU material after 20 Mc did not indicate the onset of fatigue damage, which typically occurs following long-term loading of hard bearing materials. On the

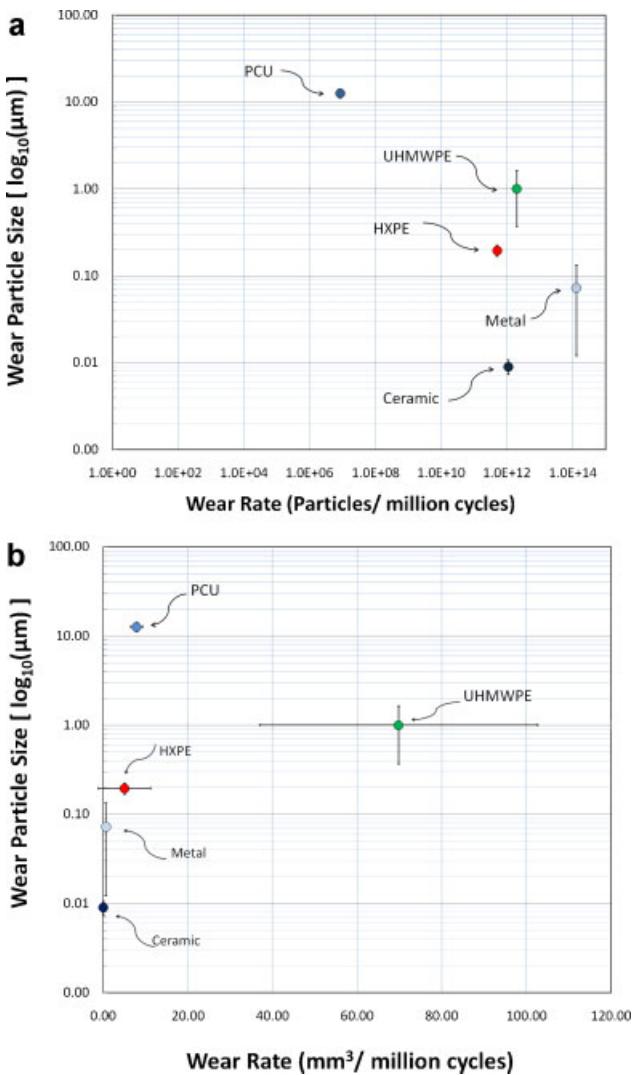


Figure 6. Overview of typical wear particle sizes versus wear rates reported for various acetabular liners used in THR^{28–30,37,42} with respect to the PCU results. Data are presented based on the volumetric wear rate (a) and wear particle generation rate (b).

contrary, the quality of the articulating surface improved over time with reduced surface roughness (Table 1, Figs. 3 and 4). This finding could be explained by microscopic viscoelastic rearrangement of soft segments of the polymer, which lead to polishing of the articulating surface.

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