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Analysis of UHMWPE wear particles produced in the simulation of hip and knee wear mechanisms with the RandomPOD system

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Abstract

If the wear rate of ultrahigh molecular weight polyethylene (UHMWPE) components of prosthetic joints is high, the microscopic UHMWPE wear particles that are produced in large numbers are known to cause osteolysis. This may lead to the loosening of fixation of the implant. Conventional UHMWPE GUR 1020 wear particles produced with the novel RandomPOD wear test system were analysed by scanning electron microscopy. Worn UHMWPE surfaces were analysed as well. The wear tests included the simulation of both hip (flat-on-flat) and knee (ball-on-flat) wear mechanisms against polished CoCr in serum. The same non-cyclic motion and load input were used in both cases. The diameter of the hip wear particles was 0.30 µm ± 0.15 µm. The knee wear particles were on the average five-fold larger, 1.5 µm ± 0.9 µm in diameter. The principal wear mechanism was moderate adhesive wear, which was macroscopically manifested as burnishing. The sizes of the particles and the burnishing were in agreement with clinical findings. The RandomPOD was shown to be the first pin-on-disc wear test device to meet these principal validation criteria regarding simulation of wear mechanisms for both the prosthetic hip and the prosthetic knee.

Keywords: randomness; wear mechanism; wear particle; wear simulation

Introduction

Ultrahigh molecular weight polyethylene (UHMWPE) is the most popular bearing material in prosthetic joints due to its chemical inertness, wear resistance, resilience, impact strength, and machinability [1]. Unfortunately, the UHMWPE wear particles produced clinically are mostly in the size range of 0.1 µm to 10 µm [2–7] which makes them biologically most active [8]. In large amounts they may cause a biological reaction leading to loss of bone around the prosthesis by osteolysis and eventually loosening of the fixation. Therefore in the laboratory simulation of wear mechanisms of prosthetic joints the wear particle analysis is one of the most important validation methods [9].

If the particles produced in the laboratory closely resemble clinical particles, it is likely that the underlying wear mechanisms are the same. When this is the case the laboratory evaluation of wear of new materials becomes meaningful and useful. If the test conditions are such that the device produces realistic wear for established materials, primarily regarding the particle size, it is likely that the wear that the device produces for new material candidates predicts their clinical wear behavior at a reasonable level of credibility. Two absolute prerequisites for realistic wear mechanisms are known to be multidirectional motion and a protein-containing lubricant [1]. Visually this results in a burnished appearance of the UHMWPE bearing surface, which is in agreement with clinical observations [2]. In scanning electron microscopy of retrieved components, the burnished zone shows fringes (Fig. 1) which gives an idea how the microscopic wear particles are formed [10].

Recently the non-cyclic characteristics of the relative motion and load in wear testing has been introduced to better represent the highly complex clinical environment compared with strictly cyclic input that has been used so far [11–13]. This unique RandomPOD wear test system has been used with both flat-on-flat and ball-on-flat contact geometries (Fig. 2). The former is designed principally for hip wear simulation, whereas the latter can be used to simulate wear mechanisms of non-conforming joints such as the knee. The shape and orientation of the specimens was the only difference between the two types of test. In both cases, the UHMWPE bearing surface was burnished. It was hypothesized that burnishing is a visual indication that the wear mechanisms, indicated especially by the wear particle size, are clinically relevant. Samples of used serum lubricant from RandomPOD tests were digested, particles were filtered on a nucleopore membrane and analysed with a scanning electron microscope. The particles were compared with those isolated from periprosthetic tissue samples and analysed by other research groups.

Materials and methods

Samples of used serum lubricant from tests simulating hip and knee wear mechanisms [12,13] had been kept in a freezer. The lubricant was HyClone Alpha Calf serum SH30212.03 without additives, diluted 1:1 with Milli-Q grade distilled water. The same lubricant was used for 6 days in the tests. In both tests, the UHMWPE material was conventional GUR 1020, ISO 5834-1/-2; preforms were sawn from a compression molded sheet and packed and gamma-irradiated by 25 kGy in nitrogen. The counterface was ground and polished (R_a = 0.01 µm) CoCr, ISO 5832-12. The relative motion consisting of x and y translations, and the z-axis load were non-cyclic [11]. The slide track always remained within a cirle of 10 mm diameter. The sliding velocitiy varied between zero and 32 mm/s so that the average was 15.7 mm/s. The maximum acceleration was 300 $\mathrm{mm/s^2}$. The direction of sliding changed 500°/s on the average. The load varied between zero and 142 N so that the average was 72 N. A smoothened, 5 Hz random step signal was used as the input. The maximum change rate of the load was 300 N/s.

The method of particle isolation has been published elsewhere [9]. Briefly, five normal NaOH was added to 2 ml of lubricant which was then digested in a closed polytetrafluoroethylene vessel at 65 °C for 6 hours. The digested lubricant was neutralized with 1 normal HCl. The fluid was then filtered through a 0.05 µm pore size nucleopore polycarbonate membrane filter (diameter 47 mm) utilizing vacuum and methanol rinsing to dissolve lipids that otherwise tended to block the filter.

The filters and the worn UHMWPE surfaces were analyzed with a field emission scanning electron microscope (JEOL 6335F FE-SEM). For electrical conductivity the surfaces of the samples were sputtered with Cr (coating thickness c. 15 nm). The average of the longest and the shortest dimension was considered the diameter of the particle. This definition was adopted because automatic edge detection proved unreliable. First, it could not detect single particles from agglomerates. Second, the edge was charged thus appearing brighter than the particle and the background (“edge effect”), which made interpretations based on grayscales difficult. Representative, typical views from the filters and the worn surfaces were analyzed. Separate wear particles were randomly selected and measured. Agglomerates were omitted. The average size and the standard deviation were computed. The n value that was considered sufficient was based on the variability of the size.

Results

In scanning electron microscopy, there was a marked difference in the number and size of UHMWPE wear particles between hip and knee wear simulation. The diameter of the hip wear particles was 0.30 μm ± 0.15 μm ($n = 170$). They could be observed in abundance (Fig. 3). Knee wear particles were few in number (Fig. 4), and their diameter was on the average five-fold larger, 1.53 μm ± 0.89 μm ($n = 113$). In both categories, the mean aspect ratio was close to unity which justified the method of determining the diameter. The worn UHMWPE surface of the hip wear test showed fringes (Fig. 5), the ends of which apparently detached by the effect of the frictional force with continually changing direction, and thus formed the wear particles. The worn UHMWPE surface of the knee wear test showed ripples without orientation (Fig. 6), caused by the non-cyclic biaxial translation of the spherical counterface.

Discussion

The clinical UHMWPE wear particles that have been analysed [2–7] originate from tissue samples obtained at revision surgery. Therefore they represent failed cases which often are related to excessive wear. Small granular particles between 0.1 µm and 1 µm in diameter represent the largest number of particles, both in the hip and in the knee. In addition, elongated particles with a length of a few micrometers are typical in hip tissue samples, and flake-like particles of a few micrometers in diameter are typical in knee tissue samples. The elongated particles are likely to be attributable to abrasion, that is, roughening of the CoCr counterface, which increases the UHMWPE wear rate, and consequently the risk of osteolysis and loosening. In laboratory wear tests, the elongated particles specifically were related to the roughening of the CoCr counterface [14,15]. The flake-like particles are probably caused by delamination due to oxidative damage, which was common in tibial components manufactured in the 1990s and earlier [16]. In the RandomPOD tests, the CoCr counterfaces were polished, and free from any abrasion damage, which may explain why elongated particles with a length of several micrometers were absent. The larger size of the knee wear simulation particles was likely to be related to the type of contact in which the contact stresses were higher and the contact stress field continually moved relative to the UHMWPE disc. The serious types of damage that have been observed in retrieved tibial components, such as delamination, cracking and pitting [16], were absent, because the UHMWPE discs were not aged. In the hip wear simulation, the fringes that were produced (Fig. 5) were similar to those observed in retrieved acetabular cups (Fig. 1).

Shanbhag et al. [5] studied the size of clinical UHMWPE wear particles and found that the mean size of knee wear particles, 1.7 µm ± 0.7 µm, was more than 3 times that of hip wear particles, 0.5 µm ± 0.3 µm. The present results are in line with this. Similarly in the study by Mabrey et al. [6], the mean particle size from the knee and the shoulder was 1.2 µm, and that from the hip was 0.7 µm. Schmalzried et al. [4] found that the average area of knee particles was twice that of hip particles, 1.2 μm^2 vs. 0.61 μm^2. On the other hand, Hirakawa et al. [3] did not find a difference in particles less than 10 μm in size between the hip and the knee. The mean diameter was 0.7 μm in both. The same mean value, 0.7 μm, was observed by Elfick et al. [7] for hip particles.

The wear particles produced in the RandomPOD hip wear simulation were similar to those produced earlier in circular translation with the SuperCTPOD device [17], and with the BRM [15] and HUT-4 hip joint simulators [18]. The particle diameters in these three studies (conventional, gamma-sterilized UHMWPE against polished CoCr in diluted HyClone serum) were 0.25 μm ± 0.10 μm, 0.28 μm ± 0.16 μm, and 0.49 μm ± 0.23 μm, respectively. This indicates that the principal wear mechanism was the same despite the fact that the RandomPOD performed, as the first wear test device, non-cyclic motion and load. The wear factor however, in the RandomPOD, 3.92×10^{-6} mm^3/Nm, was considerably higher than those in the above-mentioned cyclic devices, the values in which were 1.63×10^{-6} mm^3/Nm, 0.36×10^{-6} mm^3/Nm, and 0.57×10^{-6} mm^3/Nm, respectively. In the knee wear simulation also, the particles showed similarity to those produced in an earlier cyclic ball-on-flat study [19] with respect to the larger size. Similarly, the RandomPOD knee wear factor, 2.04×10^{-6} mm^3/Nm, was six times higher than that in the cyclic ball-on-flat test, 0.33×10^{-6} mm^3/Nm.

The principal wear mechanism in the RandomPOD tests appeared to be the so-called moderate adhesive wear [1], which is visually manifested as burnishing of the UHMWPE wear surface [2]. Although the moderate adhesive wear is the principal wear mechanism of a well-functioning prosthetic joint, the number of wear particles may still be large, due to their small size [2]. It has been estimated that the clinical wear rate of the UHMWPE component should be below 0.1 mm/year so that the number of particles produced does not reach the level where they can start the osteolytic reaction [20].

This study was limited to the wear of conventional UHMWPE against polished CoCr. Possible future studies of interest could include crosslinked and vitamin E stabilized new types of UHMWPE, roughened CoCr surfaces in order to deliberately cause abrasive wear of UHMWPE, and artificial aging of gamma-irradiated UHMWPE specimens, which could lead to the most serious wear mechanism, delamination. Crosslinking of UHMWPE reduces the wear and risk of osteolysis efficiently [21–24]. The addition of vitamin E to UHMWPE not only improves oxidative stability but also reduces the biologic activity of the wear particles [25,26]. The latter advantage is however controversial [27]. It was recently shown that the standardized method of artificial aging of gamma-irradiated conventional UHMWPE [28] does not lead to delamination in knee wear simulation, and so extended times, possibly several months, in the oxygen bomb should be considered [29].

The study supported the hypothesis that burnishing in tests incorporating multidirectional motion and serum lubrication indicates clinically realistic wear mechanisms, particularly the moderate adhesive wear. The sizes of UHMWPE wear particles produced by the RandomPOD wear test system with the flat-on-flat and ball-on-flat contact geometries were in agreement with analyses of particles isolated from periprosthetic tissues of patients with total hip and total knee prostheses. The RandomPOD was shown to be the first wear test device to meet this principal validation criterion of wear simulation for both the prosthetic hip and for the prosthetic knee. The randomness of motion and load made it possible to produce, by merely changing the contact geometry, both hip and knee wear simulation by the same tribosimulator and the same type of non-cyclic motion and load input. This creates interesting prospects for tribological studies on implants of other joints, such as the ankle [30] and the shoulder [31], and of the spine [32] by the RandomPOD wear test system.

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Figure captions

Fig. 1. Scanning electron micrograph from burnished load bearing zone of conventional UHMWPE acetabular cup removed from patient after 97 months in vivo. Cup articulated against 32 mm CoCr head.

Fig. 2. CoCr and UHMWPE specimens from RandomPOD tests. Left, CoCr disc (dia. 28 mm) and UHMWPE pin (dia. 9 mm) for hip wear simulation. Right, CoCr specimen with spherical surface (radius 28 mm) and UHMWPE disc (dia. 14.2 mm) for knee wear simulation.

Fig. 3. Scanning electron micrograph of UHMWPE particles produced in RandomPOD hip wear simulation. Background is nucleopore polycarbonate membrane filter with 0.05 μm pore size.

Fig. 4. Scanning electron micrograph of typical UHMWPE particle produced in RandomPOD knee wear simulation. Particles were few in number and they were on the average five-fold larger than hip wear particles.

Fig. 5A. SEM image from bearing surface of UHMWPE pin after RandomPOD hip wear simulation.

Fig. 5B. As Fig. 5A but with higher magnification.

Fig. 6A. SEM image from bearing surface of UHMWPE disc after RandomPOD knee wear simulation.

Fig. 6B. As Fig. 6A but with higher magnification.

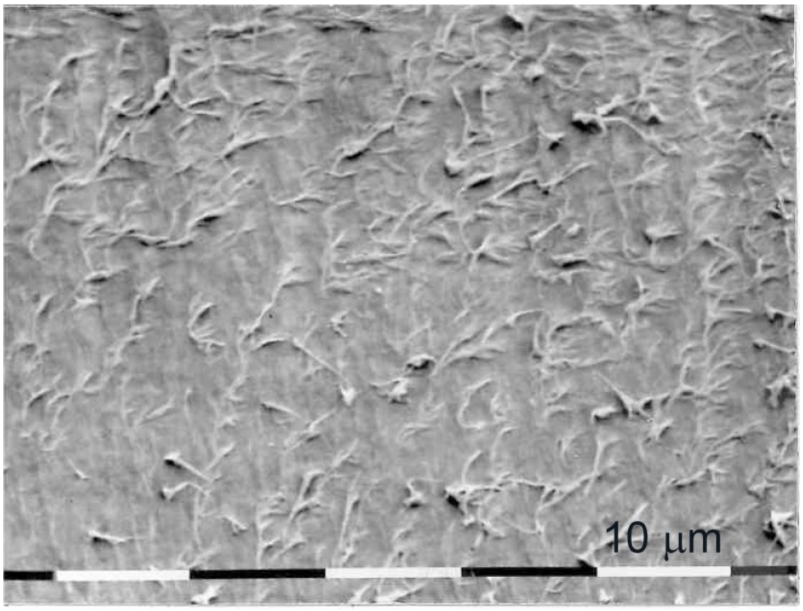


Figure 1.

Figure 2.

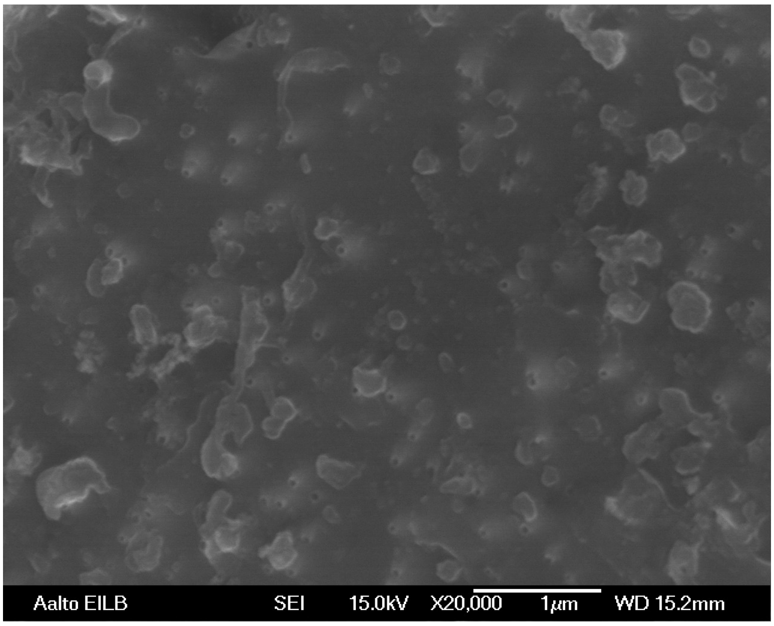
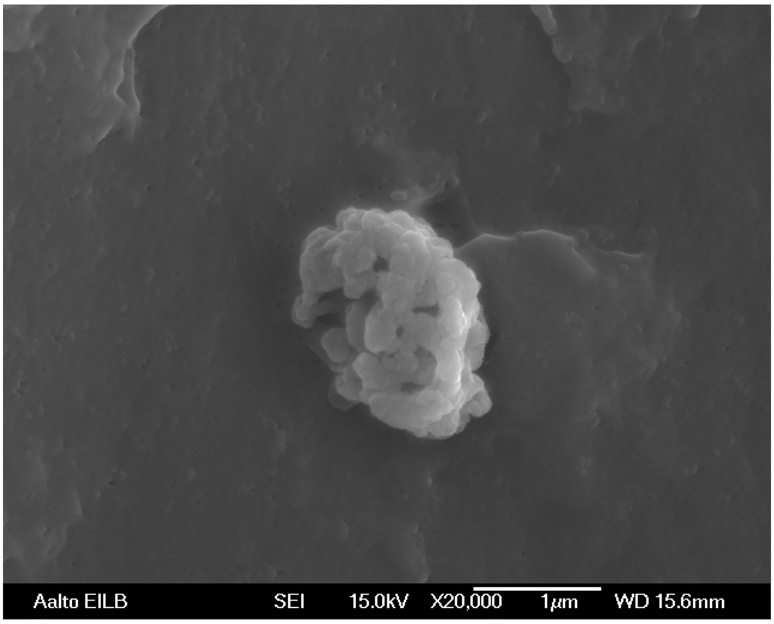


Figure 3.



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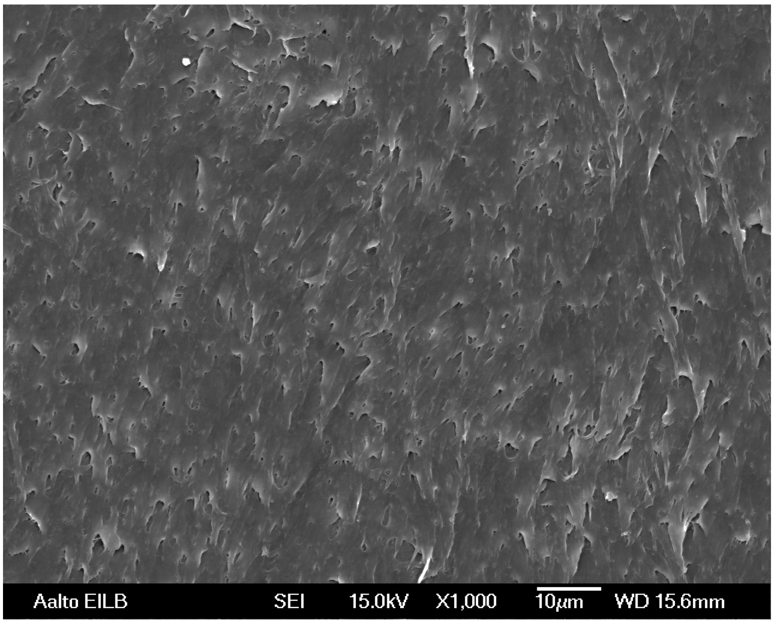

Figure 5A.

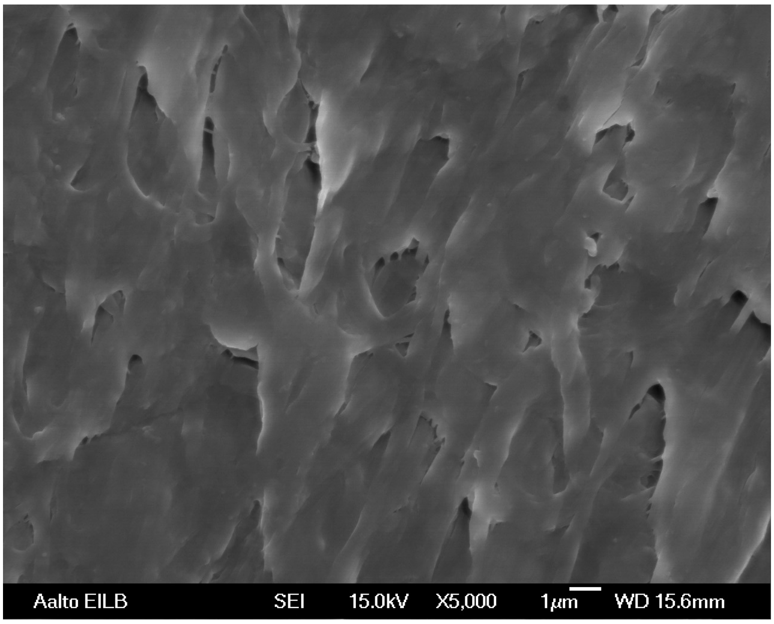

Figure 5B.

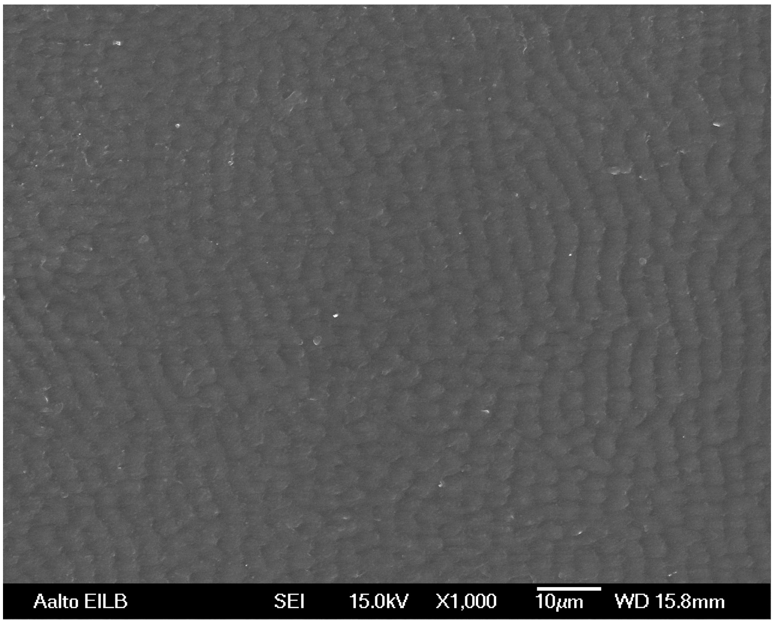

Figure 6A.

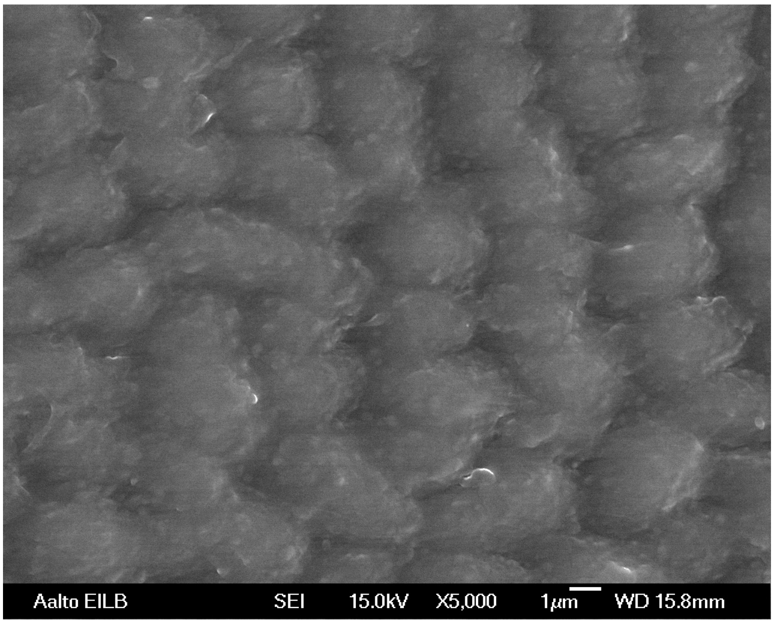

Figure 6B.