

Particle size and morphology of UHMWPE wear debris in failed total knee arthroplasties—a comparison between mobile bearing and fixed bearing knees

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Abstract

Osteolysis induced by ultrahigh molecular weight polyethylene wear debris has been recognized as the major cause of long-term failure in total joint arthroplasties. In a previous study, the prevalence of intraoperatively identified osteolysis during primary revision surgery was much higher in mobile bearing knee replacements (47%) than in fixed bearing knee replacements (13%). We postulated that mobile bearing knee implants tend to produce smaller sized particles. In our current study, we compared the particle size and morphology of polyethylene wear debris between failed mobile bearing and fixed bearing knees. Tissue specimens from interfacial and lytic regions were extracted during revision surgery of 10 mobile bearing knees (all of the low contact stress (LCS) design) and 17 fixed bearing knees (10 of the porous-coated anatomic (PCA) and 7 of the Miller/Galante design). Polyethylene particles were isolated from the tissue specimens and examined using both scanning electron microscopy and light-scattering analyses. The LCS mobile bearing knees produced smaller particulate debris (mean equivalent spherical diameter: 0.58 μm in LCS, 1.17 μm in PCA and 5.23 μm in M/G) and more granular debris (mean value: 93% in LCS, 77% in PCA and 15% in M/G).

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Introduction

Osteolysis induced by particulate wear debris has been recognized as the major cause of long-term failure in total joint arthroplasties. The granulomatous response to particulate ultrahigh molecular weight polyethylene (UHMWPE), polymethylmethacrylate, or metallic debris has been implicated as the cause of osteolytic lesions [7,17,20]. Although a large volume of literature exists concerning osteolysis and polyethylene wear in retrieval studies of total knee replacements, all these series report on fixed bearing designs [2,4,13,16, 24]. In a previous investigation comparing fixed bearing

and mobile bearing designs, we found that the prevalence of intraoperatively identified osteolysis during primary revision surgery was much higher ($p < 0.02$) in mobile bearing knees (47%) than in fixed bearing knees (13%) after long implantation times (96–103 months) [11]. We postulated that mobile bearing knees produced smaller sized particles. The purpose of this study was to compare the particle size and morphology of UHMWPE particulate wear debris between failed mobile bearing and fixed bearing knee replacements.

Materials and methods

From July 1997 to December 2000, 27 failed knee prostheses with osteolysis were available for extraction of polyethylene wear particles. All knees were originally affected by osteoarthritis and all of the primary total knee arthroplasties were performed at our hospital. The failed prostheses were divided into two groups. The first group consisted of 10 low contact stress (LCS) mobile bearing knees (DePuy,

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Warsaw, IN), which included seven meniscal bearing and three rotating platform knees. The fixation mode for all of these prostheses was cement. The patients were eight females and two males, with an average age of 65 years (range from 51 to 73 years) at the time of revision. The average time interval from the primary surgery to revision was 116 months (range from 62 to 146 months). The second group consisted of 17 fixed bearing prostheses, including 10 porous-coated anatomic (PCA) knees (Howmedica, Rutherford, NJ) and 7 Miller/Galante (M/G) knees (Zimmer, Warsaw, IN). The fixation methods included 15 cemented and 2 cementless. The patients were 13 females and 4 males, with an average age at the time of revision of 65 years (range from 58 to 73 years). The average time interval from the primary surgery to revision was 99 months (range from 48 to 168 months).

At the time of revision surgery, all interfaces between bone and prosthesis or cement were routinely checked for evidence of osteolytic resorption. Excision of the tan hypertrophic synovial membrane was performed. Tissue specimens were obtained from interfacial and lytic zones. A refinement of the basic method suggested by Campbell et al. [3] was used to digest the tissue and isolate polyethylene particles. The tissues were diced, and added to 10 cc of 5 N NaOH, and digested at 65 °C for 1–5 h in a shaking water bath. All digest solutions and deionized water were triple filtered through 0.2 µm nylon filters. To prevent contamination of the low density particle fraction by lipids, the tissues were immersed in a 2:1 chloroform/methanol mixture for 24 h before digestion. To isolate the polyethylene particles, the digested material was centrifuged over a variable density gradient comprising 2.0 ml each of 5%, 10%, 20%, and 50% sucrose. Three milliliters of digest were placed on the top of the gradient, and the tubes were spun at 40,000 rpm at 5 °C for 3 h. The top layer of the gradient was collected by pipetting into cleaned 15 ml glass capped vials. Particles were then washed free of sucrose by adding 30 cc of hot filtered water to the tubes with agitation for 1 h at 60 °C. The vial contents were then transferred to clean ultracentrifuge tubes and topped with 2 cc each of 0.96 and 0.90 g/cm³ isopropanol. The tubes were ultracentrifuged for 1 h at 40,000 rpm at 25 °C. The particles at the interface between the two isopropanol solutions were collected and stored in cleaned vials for characterization.

Several drops of the final deionized water solution were placed in the center of a 0.1 µm polycarbonate filter. The filter was dried and coated with gold for scanning electron microscopic (SEM) analysis (Hitachi S-3500 N, Tokyo, Japan). At least 50 particles were counted in the SEM photographs for each sample. The particle size was defined as the equivalent sphere diameter by image analysis software (NIH image, PC version). Types of particle morphology were categorized as granular (diameter < 1 µm, aspect ratio < 4), bead (diameter > 1 µm, aspect ratio < 4), fibril (diameter < 1 µm, aspect ratio > 4) and larger shred (diameter > 1 µm, aspect ratio > 4) [14,19].

The most common method for examining wear debris is by SEM analysis. However, amorphous particles and agglomerates are often seen on the SEM image, introducing a degree of subjectivity to the measurements. Thus, an additional light-scattering analysis (Mastersizer 2000, Malvern, PA) was conducted. Hahn et al. [9] reported the utility of a light-scattering technique for in situ analysis of submicron size wear debris in synovial fluid samples. They indicated that the light-scattering technique yielded particle sizes in excellent agreement with SEM-determined particle sizes, despite deviations from true sphericity. A 2-mW He-Ne unpolarized laser beam was spatially filtered, expanded to 9 mm, and collimated. The polyethylene particles suspended in the final deionized water solution were allowed to move across the beam. Diffracted and transmitted lights were focused by a lens onto the detector, which was in the focal plane of the lens. Mie scattering theory and the refractive index of polyethylene ($n = 1.54$) were used, and the speed of pump and stirrer were held constant.

Results

The morphology of polyethylene wear debris isolated from tissue specimens are shown in Fig. 1. A higher percentage of granular debris appeared in the mobile bearing knees (93% for LCS) than in the fixed bearing knees (77% for PCA and 15% for M/G) (Table 1).

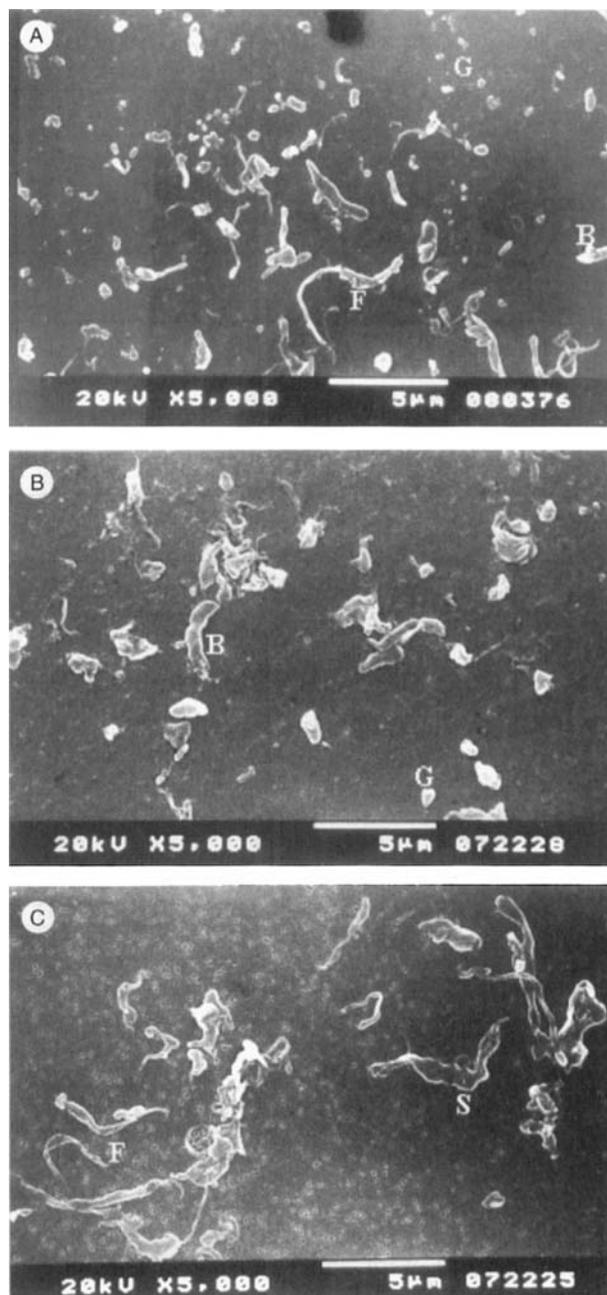


Fig. 1. SEM microphotographs of UHMWPE wear debris of LCS knee (A), PCA knee (B), and M/G knee (C). Note: G: granule, B: bead, F: fibril and S: larger shred.

The size distribution of polyethylene debris analyzed by light scattering is illustrated in Fig. 2. The debris from the LCS and PCA knees showed a two-peaked particle size distribution (Fig. 2), while the M/G knees had only a single peak. Particle sizes ranged from 0.02 to 15 microns. There was higher percentage of smaller particles (Peak I) in LCS knees compared to that in PCA knees.

The average particle sizes of polyethylene debris analyzed by SEM and light-scattering instruments are

Table 1
The morphology distribution of UHMWPE wear debris of failed knee prostheses

	Granular (%)	Bead (%)	Fibril (%)	Larger shred (%)
LCS (<i>N</i> = 10)	93	6	<1	N/A
PCA (<i>N</i> = 10)	77	17	4	2
M/G (<i>N</i> = 7)	15	37	46	2

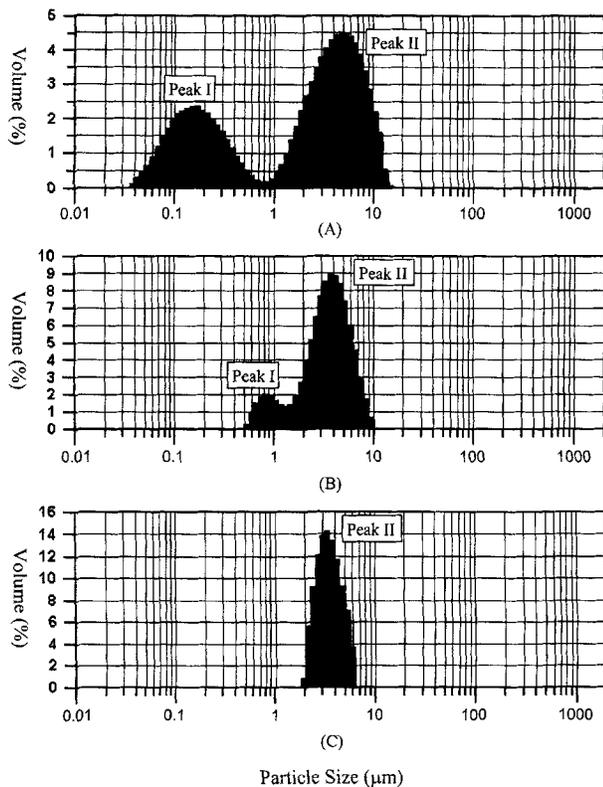


Fig. 2. The particle size distribution of UHMWPE of LCS knee (A), PCA knee (B), and M/G knee (C) by light-scattering analysis.

listed in Table 2. Debris from mobile bearing knees (LCS: 0.58 μm) were smaller than that from fixed bearing knees (PCA: 1.17 μm and M/G: 5.23 μm).

Table 2
The average particle size of polyethylene wear debris of failed knee prostheses

	Duration (years)	Average particle size (μm)	
		SEM ^a	Light scattering ^b
LCS (<i>N</i> = 10)	5–12	0.58 \pm 0.12	0.2 \pm 0.1
PCA (<i>N</i> = 10)	4–14	1.17 \pm 0.09	0.9 \pm 0.2
M/G (<i>N</i> = 7)	8–10	5.23 \pm 1.27	N/A

^a Average debris size of failed knee prosthesis by SEM viewing.

^b Average debris size of failed knee prosthesis in submicron particle (Peak I).

Discussion

In the early era of knee prosthesis design, the tibial component was made entirely of UHMWPE. It was not until in the late 1970's, that metal-backed tibial components were introduced in order to distribute stress more uniformly over the entire base-plate, thus decreasing polyethylene deformation [1,5,6]. Initially the UHMWPE insert and metal base-plate were fixed in one piece. Subsequently, a modular design was introduced, which had advantages compared to the one-piece fixed metal-backed tibial component [15,23], including reduced component inventory for the hospital and ease of soft tissue balancing by selecting different thicknesses of polyethylene insert intraoperatively. The locking mechanism of the modular polyethylene insert can be either fixed or mobile. The characteristics of mobile bearing knees produce both low contact stress and low constraint force, by allowing both congruity (more conforming articular surfaces) and mobility to improve wear resistance and minimize loosening.

Reports of osteolysis after total knee replacement have been rare. Kim et al. [13] reported no osteolysis around femoral components by radiographic assessment of fixed bearing knees. Sanchez-Sotelo et al. [18] identified osteolysis in only two cases out of 100 LCS mobile bearing knees after 5.2 years of follow-up. However, in our clinical finding during primary (or initial) revision surgery, osteolysis occurred in 47% (16/34) of LCS mobile bearing knees and in 13% (6/46) of fixed bearing knees [11]. Stinson [21–23] reported that osteolysis was more common in the presence of granular particles (diameter < 1 μm , aspect ratio < 4). In this study, the SEM viewing (Fig. 1) showed that the LCS mobile bearing knee generated more granular debris (LCS: 93%, PCA: 77%, M/G: 15%) (Table 1) and smaller particular debris (LCS: 0.58 μm , PCA: 1.17 μm and M/G: 5.23 μm). Analysis of light scattering also suggested the same results (LCS: 0.2 μm , PCA: 0.9 μm) (Table 2). Hirakawa et al. [10] reported similar results in that LCS knee implants produced a higher percentage of smaller particles than fixed bearing knees (PCA, AMK, Total Condylar II). Green et al. reported that particles in the phagocytosable size (range from 0.3 to 10 μm) appear to be the most biologically active [8]. The higher percentage of granular and smaller polyethylene particles in LCS mobile bearing knees might be due to a more conformable articular surface and additional undersurface wear compared to fixed bearing knees.

A concentration of phagocytosable polyethylene particles greater than 1×10^{10} particles/g of tissue has been suggested as a prerequisite for cellular reaction to progress to osteolysis [12]. However, the particle concentration in synovial tissue varies depending on the location from which the specimen was obtained. For this reason, we only investigated the relationship between

osteolysis and particle size and morphology, without regarding to particle concentration.

The difference in the morphology (Fig. 1) and the peak size distribution (Fig. 2) of particles suggest that different wear mechanisms were occurring in different designs, probably related to complex factors interacting at the articular surface. Kobayashi et al. [14] discussed the comparison of polyethylene particle size between total knee and total hip arthroplasties. They found that wear particle sizes from total hip arthroplasties (0.3–3.2 μm) were smaller than those from total knee arthroplasties (47–133 μm). Schmalzried et al. [19] reported similar results (hip: 1.4–7.3 μm , knee: 78–216 μm). Both attributed their finding to greater conformity at the articular surfaces in total hip prosthesis. In our study, the mobile bearing knees had a more conforming articulation than either of the fixed bearing designs, and the wear patterns were adhesion and abrasion, which produced smaller and granular particles. While fixed bearing knees had a less conforming articulation, the wear patterns were delamination, pitting and fracture, which produced larger and less granular particles. However, the relationship between morphology or size distribution (Peak I and Peak II) of particles and the wear mechanism could not be determined in the current study. In the report by Schmalzried et al., the particle size distribution had only a single peak by using SEM [19], while our results showed two peaks by using a light-scattering method. We presume that this difference was due to the utilization of different methods.

In conclusion, compared to fixed bearing knees, LCS mobile bearing knee may be at increased risk for osteolysis. These knees tended to produce smaller particulate debris and a higher percentage of granular debris, probably due to more conforming articular surfaces and undersurface wear.

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