

SURFACE ROUGHNESS OF CERAMIC FEMORAL HEADS AFTER IN VIVO TRANSFER OF METAL: CORRELATION TO POLYETHYLENE WEAR

BY YOUNG-HOO KIM, MD, ALLAN RITCHIE, PHD, AND CATH HARDAKER

Investigation performed at The Joint Replacement Center of Korea, Ewha Womans University College of Medicine, Seoul, Korea, and DePuy-Johnson and Johnson International, Leeds, United Kingdom

Background: A dark metallic-appearing smear, resembling a lead pencil mark, may be seen on a ceramic femoral head component at revision total hip arthroplasty. The purpose of this study was to investigate the hypothesis that such a mark on a retrieved ceramic femoral head is associated with increased surface roughness of the head and increased polyethylene liner wear in total hip replacement.

Methods: Fifteen ceramic prosthetic femoral heads retrieved from fifteen patients at revision arthroplasty were examined in this study. Thirteen heads had been in vivo for an average of 10.8 years (range, 7.8 to 14.2 years). The remaining two heads had been in vivo for less than one month. The surface roughness characteristics of the explanted ceramic heads, the linear wear of the polyethylene liner, and the patient activity levels after the primary replacement and before the revision were determined.

Results: Four of the thirteen ceramic heads that had been in vivo for ≥ 7.8 years had severe smears ($>6\%$ of the surface area), and the remaining nine heads had slight smears ($<6\%$ of the surface area). The two heads that had been in vivo less than one month had severe smears. The mean Ra and Rpm, the values for surface roughness, were 44.95 nm and 571.15 nm, respectively, in the hips with slightly smeared regions and 180.77 nm and 1245.88 nm, respectively, in the hips with severely smeared regions ($p = 0.002$). The mean linear liner wear rate was 0.10 mm/yr in the hips with slightly smeared heads and 0.19 mm/yr in the hips with severely smeared heads ($p = 0.002$). The activity score for all patients was 5 or 6 points on a 6-point scale.

Conclusions: The results of this study confirm the hypothesis that a visual dark metallic-appearing smear on a ceramic femoral head correlates with increased surface roughness of the head and increased polyethylene wear. These findings imply that contact of a ceramic femoral head with a metallic material, such as may occur with femoral head reduction or dislocation of a total hip replacement, is best avoided to prevent this metallic smear phenomenon.

Wear-related complications have been a major cause of revision following total hip arthroplasty. The surface roughness of the prosthetic femoral head plays an important role in generating polyethylene wear debris after total hip arthroplasty^{1,2}. It has been reported that cobalt-chromium heads have rougher surfaces than ceramic heads³ and produce more wear than ceramic heads in studies with use of a hip simulator⁴⁻⁷; however, studies on the wear of polyethylene liners in vivo have had conflicting results⁸⁻¹⁷.

At revision surgery, a dark metallic-appearing smear resembling a lead pencil mark may be seen on a ceramic femoral head. The purpose of this study was to investigate the hypothesis that ceramic femoral heads exhibiting a metallic-appearing

smear, compared with those that do not, have a rougher surface and are associated with greater in vivo polyethylene wear.

Materials and Methods

The study was approved by our institutional review board, and all patients provided informed consent. We examined fifteen ceramic femoral heads retrieved at the time of revision from fifteen patients who had a mean age at the time of the operation of 49.9 years (range, thirty-one to sixty-one years), a mean weight of 65.8 kg (range, 48 to 78 kg), and a mean height of 164.8 cm (range, 154 to 176 cm). The mean duration of implantation was 10.8 years (range, 7.8 to 14.2 years) for thirteen heads and less than one month for two heads. One of

these two heads was retrieved at a primary total hip arthroplasty because the ceramic head had been scratched very much by the rim of the metallic acetabular component during reduction of the femoral head. The other one was retrieved at open reduction of a dislocated total hip replacement. All heads articulated with a polyethylene liner made of ram-extruded 415 GUR polyethylene. The polyethylene had been irradiated in a vacuum and was packaged in a vacuum state. All hips had a 28-mm femoral head.

Analysis of Retrieved Femoral Heads

The surface characteristics of the fifteen explanted ceramic heads were evaluated with use of three different methods: visual assessment, interferometry (Wyko RST 500 interferometer; Wyko, Tucson, Arizona), and environmental scanning electron microscopy. On the basis of visual assessment, the femoral head was considered to be nonsmeared if no smeared region was visible on the femoral head. The femoral head was considered to be slightly smeared if the smeared region was <6% of the total head surface, and it was considered to be severely smeared if the smeared region was >6% of the total head surface.

The interferometry measurements were undertaken at two different magnifications with use of 20× and 40× lenses. The areas of analysis were 125 by 125 μm and 64 by 64 μm, respectively. At each magnification, six measurements were made of the smeared and nonsmeared regions. The results are presented in terms of Ra and Rpm. The parameter Ra is defined as the mathematical average of all deviations (peaks and valleys) from the mean line of the surface profile. The parameter Rpm (the mean leveling depth) is defined as the distance between the mean line and a line parallel to it, which passes through the highest point. The intrinsic errors of the measurement of Ra and Rpm were 0.0219 nm and 0.157 nm, respectively. The measurement resolution of the interferometer is <1 Å in phase shift interferometry mode and <1 nm in vertical shift interferometry mode. Therefore, the phase shift interferometry mode is more accurate for highly polished surfaces. The vertical shift interferometry mode is appropriate for surfaces that are rough, or highly contoured, or for sharp peaked surfaces typically >0.6 μm in height¹⁷.

The roughness values in the nonsmeared region of each head were used to estimate the roughness values of each head before implantation. In addition, two ceramic heads that had not been implanted were analyzed to confirm that the nonsmeared regions of the retrieved specimens reflected the surface roughness of heads before implantation and thus were appropriate to use as controls.

Further analysis was completed with use of a Camscan 4 environmental scanning electron microscope (University of Leeds, Leeds, United Kingdom) by two scientists who had no knowledge of the clinical and experimental results. Secondary and backscattered images were reviewed at various magnifications (particularly at 250×) to attempt to identify the composition and origins of the materials adherent to the

head surfaces as well as to assess the pits and scratches on the head surfaces.

A stereoscopic zoom microscope (Nikon, Melville, New York) was used to examine grossly the polyethylene liners corresponding to each femoral head for evidence of embedded particle debris. The evidence for particle embedding was examined qualitatively by a research associate who had no knowledge of the clinical and experimental results.

Radiographic Analysis

We measured the linear wear of polyethylene radiographically by determining the migration of the center of the femoral head relative to the center of the cup, according to the computer-aided technique of Kim et al.¹³. The 95% confidence interval was considered a measure of reproducibility. Intraobserver error was ±0.047 mm.

We compared the radiographic measurements with the direct measurements of all fifteen cups to validate this wear-measurement technique. The linear wear was measured directly from the retrieved polyethylene liners with use of a three-dimensional coordinate measuring device (BHN 305; Mitutoyo, Tokyo, Japan). Validation testing revealed that the measuring device tended to underestimate the true amount of penetration by a mean of 0.08 mm. Therefore, the radiographic measurements of penetration were thought to be reproducible.

Activity Levels of Patients

The activity level of the patients between the primary and the revision total hip arthroplasty was assessed with the activity score of Tegner and Lysholm¹⁸. The activity grading scale, in which work and sports activities were graded numerically, was constructed as a complement to the functional score. The patients were given a score according to the activities in which they engaged in daily life. The score ranged from 0 points for a hip-related disability to 10 points for participation in competitive sports at a national level.

Statistics

The Student t test was used to determine possible correlations between the rate of penetration and several specific variables: patient age, gender, and activity level; duration of implantation; and type of head, stem, and cup. Linear regression analysis was used to reveal any relationship between the surface roughness values and the patient age, gender, weight, and activity level; duration of implantation; and type of head, stem, and cup. The Wilcoxon rank-sum test was used to determine any statistical difference in surface roughness between heads articulating with liners with or without embedded debris. A p value of <0.05 was considered significant.

Results

Analysis of Retrieved Femoral Heads

Thirteen heads were alumina ceramic, and two heads were zirconia ceramic. Patient demographic information and component data are summarized in the Appendix. On visual

TABLE I Results of the Interferometry Measurements on the Smearred and Nonsmearred Regions on All Heads at Forty-Times Magnification

	Ra* (nm)	Standard Deviation	95% Confidence Limit	Rpm* (nm)	Standard Deviation	95% Confidence Limit
Nonsmearred region	7.81 (2.53-28.94)	10.05	2.54	76.49 (20.27-265.75)	107.43	27.18
Slightly smearred region	44.95 (11.44-200.80)	102.39	27.83	571.15 (86.94-1331.15)	695.01	188.90
Severely smearred region	180.77 (15.3-331.27)	147.81	64.78	1245.88 (920.31-1913.5)	986.69	432.43

*The values are given as the mean, with the range in parentheses.

evaluation, severe smears were observed on six components and slight smears were seen on nine components (Fig. 1). Four of the thirteen heads that had been in vivo for more than 7.8 years had severe smears, and the remaining nine heads had slight smears. Both of the heads that had been in vivo less than one month had severe smears. The area of smearing on the heads ranged from <1% to 10% of the total surface of the head. The results of the measurements by interferometer on the smearred and nonsmearred regions on all heads are summarized in Table I, and the results of the measurements by interferometer on all heads are graphically illustrated in the Appendix.

The roughness values for the nonsmearred regions of the ceramic heads compared well with the roughness values for two heads that had never been implanted. The mean Ra and Rpm values for the ceramic heads that had not been implanted were the same as those for the nonsmearred regions of the fifteen implanted ceramic heads (Ra, 7.81 nm; Rpm, 76.49 nm). The mean Ra and Rpm values for the slightly smearred regions (nine heads) were 44.95 nm and 571.15 nm, respectively. The mean Ra and Rpm values for the severely smearred regions (six heads) were 180.77 nm and 1245.88 nm, respectively. The differences in Ra and Rpm values between the slightly smearred and severely smearred regions were significant ($p = 0.002$), irrespective of magnification.

The mean surface roughness values for the slightly smearred regions in the nine ceramic heads without third-body debris embedded in the corresponding polyethylene liner (Ra = 44.95

nm; Rpm = 571.15 nm) were lower than those for the severely smearred regions in six ceramic heads associated with embedded debris (Ra = 180.77 nm; Rpm = 1245.88 nm). The differences in roughness values between the two groups were significant ($p = 0.02$ for both). However, no correlation was found, on the basis of the numbers, between roughness parameters of the ceramic heads (slightly or severely smearred) and the following parameters: age, gender, weight, and activity level of the patient; duration of implantation; and type of head, stem, and cup ($p > 0.05$ according to linear regression analysis).

Environmental scanning electron microscopic evaluation of the ceramic heads revealed small pits and scratches on the surfaces of ceramic heads in six of nine slightly smearred heads and in all of six severely smearred heads. The difference was not found to be significant on the basis of the numbers ($p = 0.078$) (Fig. 2).

Environmental scanning electron microscopic evaluation of the smearred regions demonstrated a higher atomic number than the ceramic substrate in the backscattered image (Fig. 3). This is indicative of metal deposits on the surface of the ceramic head. However, confirmation of this was difficult because the film of deposited material was very thin (on the order of 3 μm). Therefore, complete chemical identification of the material with energy-dispersive x-ray spectrometry was not possible. Some regions also had particles with a lower atomic number than that of the ceramic substrate, which perhaps was attributable to organic contamination of the head surface.

Radiographic Analysis

Validation testing of the measuring technique revealed a good correlation between the radiographic and direct measurements of polyethylene wear ($R^2 = 0.95$), and it demonstrated that the radiographic measurement underestimated the direct measurement by a mean of 0.08 mm (see Appendix). The mean linear wear rate was 0.10 mm/yr (range, 0.09 to 0.12 mm/yr) in the hips with slightly smearred heads and 0.19 mm/yr (range, 0.16 to 0.24 mm/yr) in the hips with severely smearred heads. This difference was significant ($p = 0.002$).

The mean linear wear rate of the polyethylene was 0.10 mm/yr (range, 0.09 to 0.12 mm/yr) in the hips with a low mean Ra and mean Rpm (44.95 nm and 571.15 nm, respectively) and 0.19 mm/yr (range, 0.16 to 0.24 mm/yr) in the hips

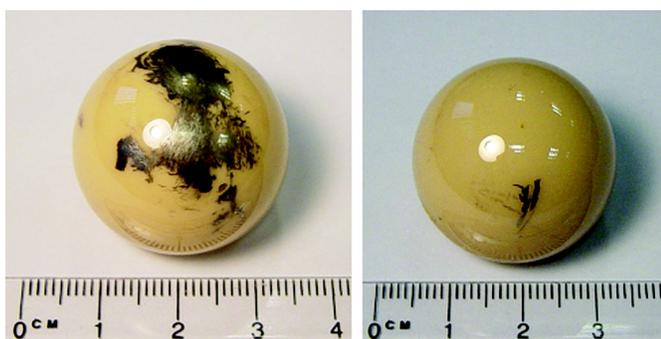


Fig. 1

Photographs showing two ceramic femoral heads. The smearred area on both heads is >6% of the total head surface.

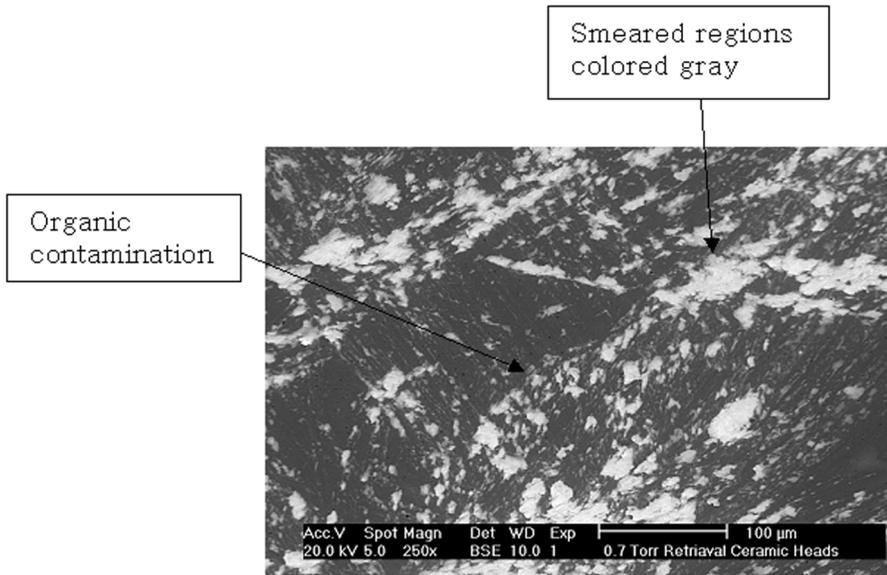


Fig. 2
Environmental scanning electron microscopic evaluations of the ceramic heads revealed small pits and scratches on the surfaces in six of the nine slightly smeared heads and in all six severely smeared heads.

with a high mean Ra and mean Rpm (180.77 nm and 1245.88 nm, respectively). This difference was significant ($p = 0.002$).

The mean polyethylene linear wear rate was 0.20 mm/yr (range, 0.16 to 0.24 mm/yr) for the cups associated with third-body embedded debris and 0.09 mm/yr (range, 0.08 to 0.12 mm/yr) for the cups without third-body embedded debris. This difference was significant ($p = 0.03$). The mean polyethylene linear wear rate was 0.21 mm/yr (range, 0.16 to 0.24 mm/yr) for femoral heads with surface pits and scratches and 0.11 mm/yr (range, 0.09 to 0.12 mm/yr) for the heads without surface pits and scratches. This difference was significant ($p = 0.002$).

No correlation was found, on the basis of the numbers available, between the wear rate of the polyethylene and the

following parameters: patient age, gender, and activity level; duration of implantation; and type of head, stem, and cup ($p > 0.05$) (see Appendix).

Activity Score

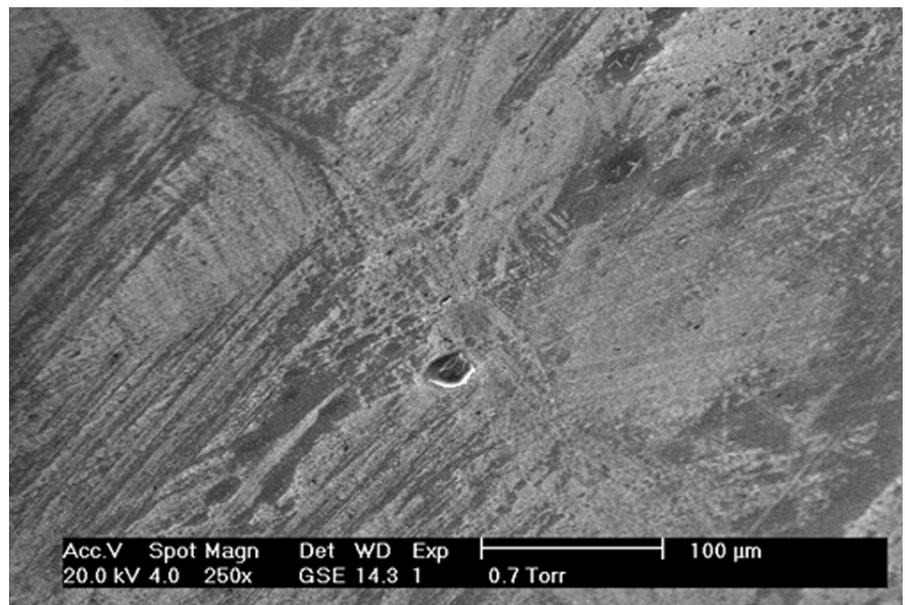
Many patients were quite active despite the usual cautions to avoid activities involving impact after total hip replacement. All patients had an activity score of 5 or 6 points before revision, indicating participation in strenuous farm work (a score of 5 points) or participation in tennis (a score of 6 points).

Discussion

The surface characteristics of the femoral head play an important role in generating polyethylene wear debris after

Fig. 3

Environmental scanning electron microscopic evaluation shows that the smeared region demonstrates a higher atomic number than the ceramic substrate in the backscattered image. This would be indicative of metal deposits on the surface of the ceramic head. However, confirmation of this was not possible because the film of deposited material was too thin.



total hip arthroplasty^{1,2}. It has been reported that the adherence of third-body particles to the femoral head increases its surface roughness, and the resultant abrasive wear process increases the wear rate of the polyethylene liner in the total hip arthroplasty¹¹. In the current series, metallic-appearing smears on the ceramic head were found to be transferred metallic debris on the basis of the findings of environmental scanning electron microscopic and energy-dispersive x-ray spectrometric examinations. This debris increased the surface roughness and consequently increased the wear of the polyethylene liner through either an abrasive or a third-body wear mechanism. An increase in surface roughness and wear as a result of transferred metal debris may be one explanation for the sporadic cases of excessive wear of alumina-on-alumina bearings and the poor results with alumina-on-polyethylene bearings^{14-17,19-25}. We confirmed the hypothesis in our study that metallic transfer onto the ceramic femoral head increases surface roughness and consequently increases the wear rate of the polyethylene liner.

The transfer of metal debris to the ceramic head occurs even with relatively minor scratching. Black discoloration of a ceramic head can occur simply by lightly scratching the head on a metal surface. Luchetti et al.²⁶ reported that metal was transferred to a zirconia head when the head was scratched on the metal shell during a closed reduction of a dislocated total hip prosthesis. Therefore, caution is required to avoid contact of the ceramic head with metallic materials during the operation. Because of the hardness of ceramic, one can expect more metal to be transferred to ceramic than to other materials used for a prosthetic head²⁷.

This study also found that the surface roughness of the ceramic head and an increased polyethylene wear rate were associated with the presence of embedded debris in the articulating polyethylene liner. Therefore, third-body contamination should be avoided as much as possible.

Our study has several limitations. The surface characteristics and wear pattern of retrieved femoral heads at revision hip arthroplasty may not represent the surface characteristics and wear pattern of well-functioning total hip replacements. The number of heads examined was small, limiting our conclusions. In addition, the examination was not performed in a population of patients who all had identical components; femoral heads from different manufacturers may have different initial roughness. However, we attempted to normalize the

effect of the manufacturing technique on the initial surface roughness by using a nonsmeared area of each head to estimate the preimplantation roughness of that head.

The results of this study demonstrate that the area of a visual smear resembling a lead pencil mark (metallic transfer) on the ceramic femoral head increases surface roughness and that a severe smear (>6% of surface area) correlates with increased polyethylene wear. These findings imply that contact of a ceramic femoral head with metallic material, such as may occur with femoral head reduction or dislocation of a total hip replacement, is best avoided to prevent this metallic smear phenomenon.

Appendix

 Tables presenting demographic information and component data, a comparison of the direct and radiographic measurements of wear, and the relationship between wear and demographic data and figures showing the roughness of each femoral head are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

Young-Hoo Kim, MD

The Joint Replacement Center of Korea at Ewha Womans University
Dong Dae Mun Hospital, 70, ChongRo 6-Ga, ChongRo-Gu, Seoul, Korea
110-783. E-mail: younghookim@ewha.ac.kr

Allan Ritchie, PhD

Cath Hardaker

DePuy-Johnson and Johnson International, St Anthony's Road, Leeds LS
118 DT, United Kingdom

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