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IN VIVO FEMORAL HEAD DAMAGE AND ITS EFFECT ON POLYETHYLENE WEAR

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Abstract

The purposes of this study were to determine the spectrum of femoral head damage in patients undergoing revision total hip arthroplasty and to determine the impact of that damage on polyethylene wear. One hundred and eight consecutive modular metal femoral heads were retrieved at revision surgery. The mean Ra value was 0.18 ± 0.18 μm. The roughest femoral heads (mean Ra = 0.56 μm) were from retrievals correlated with Mode-2 wear (recurrent dislocation and complete wear through of the polyethylene liner). Five million cycles of wear tests were performed using retrieved femoral heads against both new conventional and highly cross-linked polyethylene. The mean wear rate of conventional polyethylene was 15.9 ± 4.3 mg and that of highly cross-linked polyethylene was 0.04 ± 0.14 mg per 1 million cycles ($p < 0.001$). Highly cross-linked polyethylene was more resistant to wear than conventional polyethylene, even when mated against roughened femoral heads.

Key words: total hip arthroplasty, surface roughness, wear, highly cross-linked polyethylene, conventional polyethylene

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Introduction

Previous experimental and retrieval studies indicated that roughening of the femoral head surface increased the wear rate of conventional polyethylene wear [1-10]. Surface roughness of the metal femoral head has been reported to increase with time after implantation [7-14]. Case reports have documented that recurrent dislocation can cause severe damage to the surface of the femoral head [15,16]. Despite these reports, little data exists on the surface damage of femoral heads in vivo and the impact of time and wear mechanism on the degree of damage.

Recent advances in polyethylene preparation have resulted in the development of highly cross-linked polymers. Good experimental results [17] and early to mid-term clinical results [18-20] have been reported. Although experimental studies indicated that the wear rate of highly cross-linked polyethylene was less than that of conventional polyethylene when mated against intentionally roughened femoral heads [3-5], no studies described the wear rate of highly cross-linked polyethylene against retrieved femoral heads with various degrees of surface roughness.

The purpose of this study was (1) to determine the distribution and degree of the surface roughness of metal femoral heads retrieved from a large number of patients undergoing revision hip replacement, (2) to correlate surface roughness of the femoral head with wear mode [21], and (3) to use a hip joint simulator to determine the effect of in vivo damage on wear of conventional and highly cross-linked polyethylene.

Materials and Methods

Patient Data

One hundred and eight consecutive modular metal femoral heads were retrieved at revision surgery. All the retrieved heads were made from cobalt-chromium (CoCr) alloy and mated against conventional or highly cross-linked polyethylene. The demographic characteristics of the patients are listed in Table 1.

Failure Mechanism and Wear Mode

Failure mechanism and wear mode [21] of total hip arthroplasty were assessed. Mode-1 wear results from the motion between the intended two primary bearing surfaces such as the prosthetic femoral head against the polyethylene acetabular bearing surface. Mode-2 wear refers to the condition of a primary bearing surface that moves against a secondary surface that is not intended to move against. Mode-3 wear refers to the condition of the primary surfaces with the interposition of third-body particles. Mode-4 wear refers to two nonprimary surfaces rubbing together, such as impingement of the prosthetic femoral neck on the rim of the acetabular component.

Factors Measured Against Wear

Several factors including diameter of the head, prosthesis fixation, manufacturer of the head, and duration of implantation were assessed in terms of impact on femoral head damage. The diameter was 22-mm in 6 heads, 26-mm in 1 head, 28-mm in 64 heads and 32-mm in 37 heads. The prosthesis fixation was cementless in 61 (57%) hips, cemented in 21 (19%) hips and hybrid (cementless acetabular component and cemented femoral component) 26 (24%)

hips. The manufacture of the metal femoral head was Zimmer (Warsaw, IN) in 37 hips, Striker Howmedica Osteonics (Allendale, NJ) in 25 hips, DePuy, a Johnson and Johnson (Warsaw, IN) in 23 hips, Smith and Nephew Orthopedics (Memphis, TN) in 7 hips, Centerpulse Orthopedics (Austin, TX) in 3 hips, Wright Medical Technology (Arlington, TN) in 3 hips, Biomet (Warsaw, IN) in 2 hips, and unknown in 8 hips. The average duration of implantation before retrieval was 5.8 years (range, 1 day to 10.1 years) (Table 2).

Technique Used to Measure the Surface Damage

Surface roughness of the femoral head was measured using a laser profilometer (Perthometer Concept, Mahr Inc, Göttingen, Germany). Five parallel traces were taken on each sample, with a tracing length of 0.56 mm and a cut-off length of 0.08 mm. Scratched areas were evaluated by visual inspection to ensure measurements of the roughest areas were included. Tracings were obtained through predetermined grids and arithmetic mean surface roughness (Ra) and the mean peak to valley height (Rz) [14] were calculated. Femoral heads with < 0.08 μm (3 μ inches) of Ra value were classified as having low Ra, those with 0.08 to 0.25 μm (3 to 10 μ inches) were classified as having intermediate Ra, and those with > 0.25 μm (10 μ inches) were classified as having high Ra. Scratched surface area was characterized by fine surface scratches with or without maintenance of the reflective surface on visual inspection and demonstrated a loss of the original surface finish. The femoral head was fixed on a rotatable jig and scratched area was manually measured using calipers. The percentage of scratched area was calculated as the ratio of scratched area to the whole bearing surface area of the femoral head.

Laboratory Wear Testing

Polyethylene wear was assessed using the AMTI Hip simulator (Advanced Mechanical Technology, Inc., Watertown, MA). Retrieved femoral heads were classified into 3 groups depending on measured Ra values. Three 28-mm diameter femoral heads were randomly selected from each 3 group. Three new 28-mm diameter CoCr femoral heads with < 0.05 μm (2 μ inches) of Ra value were tested for the control study. These 12 femoral heads were tested against unaged conventional polyethylene and unaged highly cross-linked polyethylene (Longevity, Zimmer, Warsaw, IN). Conventional polyethylene was made of unaged GUR 1050 (Zimmer). Highly cross-linked polyethylene cups were machined from 1 rectangular bar (GUR 1050) which had been irradiated with 10 Mrad (100 kGy) of electron-beam and remelted at 150ºC. Both conventional and highly cross-linked polyethylene was sterilized with gas plasma.

Wear tests were performed employing the MGH modified Bergman kinematics [22]. The maximum load was set at 3300 N and the ranges of motion were ± 23° flexion/extension, ± 10° internal/external rotation and ± 8.3° abduction/adduction. Undiluted bovine calf serum (JRH Bioscience, Lenexa, KS) from 1 lot was used as lubricant. The test was run at 1.1 Hz for 5 million cycles. After wear testing, surfaces of the femoral heads and polyethylene liners were imaged using a scanning electron microscope.

Statistical Analyses

Statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL). The Mann-Whitney U test and Kruskal-Wallis test were performed to evaluate the relationship between surface damage of the femoral head and several factors, and the relationship between polyethylene wear and surface roughness. The Pearson linear correlation coefficient (r) was used to assess correlations among various measurements. Probability values less than 0.05 were considered significant.

Results

Wear Mode

Mode-2 wear [21] was observed in 14 hips. Four hips with complete wear through of the polyethylene liner and 10 hips with recurrent dislocation resulted in Mode-2 wear. Dark metal debris around the hip joint and apparent scratches on the femoral head were observed in these 14 hips. The incidence rate of Mode-3 wear was not evaluated because we did not assess the surface of the retrieved polyethylene. Mode-4 wear judged by the rim damage of acetabular components consistent with impingement against the neck of the femoral component was observed in 64 of 108 (59%) hips.

Surface Damage of the Femoral Head

The mean Ra value of the retrieved 108 femoral heads was 0.18 μm (range, 0.01 to 0.81 μm) and the mean Rz value was 1.38 μm (range, 0.07 to 6.37 μm). Testing of retrieved femoral head showed 106 of 108 (98%) had a mean Ra value > 0.02 μm, which is consistent with previous data [23]. Scratched areas were found in 106 of 108 (98%) retrieved femoral heads. The two that did not have scratches had been implanted for 0.2 and 3.6 years. The scratched areas were usually discrete and on the upper surface of the femoral head which had contacted the polyethylene bearing surface. In the retrieved femoral heads 42 were low Ra, 39 intermediate Ra and 27 high Ra. The mean roughened area was 388 ± 501 mm^2 (range, 0 to 2800 mm^2). The mean percentage of roughened area was 18 ± 21 % (range, 0 to 100 %). In 77 of 108 (71%) femoral heads, roughened area was < 20%. The percentage of roughened area and Ra was significant ($r = 0.572$, $p < 0.001$) as was Rz ($r = 0.580$, $p < 0.001$).

Relationship Between Surface Roughness and Several Factors

Tables 3-6 list results of statistical comparison of different femoral head diameters (Table 3); fixation groups (Table 4); reason for revision surgery (Table 5); and mode of failure (Table 6). Only the reason for revision surgery and Mode-2 failure showed statistical difference (Fig. 1). Failure among femoral heads of different manufacturers was not statistically different (Ra: $p = 0.305$, Rz: $p = 0.273$). No significant correlation was found between duration of implantation and Ra ($r = −0.109$, $p = 0.263$) (Fig. 2A) and Rz ($r = −0.102$, $p = 0.295$) values.

Laboratory Wear Results

After 5 million cycles of wear tests, the average wear rate was 15.9 ± 4.3 mg in the conventional polyethylene and 0.04 ± 0.14 mg in the cross-linked polyethylene per 1 million cycles ($p < 0.001$). The average conventional polyethylene wear rate was 17.1 ± 4.3 mg in the 9 retrieved femoral heads and 12.1 ± 1.3 mg in the 3 new femoral heads per 1 million cycles ($p = 0.036$). An average conventional polyethylene wear rate was 22.3 ± 3.1 mg in 3 retrieved femoral heads with high Ra, 15.4 ± 0.72 mg in those with intermediate Ra and 13.6 ± 1.2 mg in those with low Ra per 1 million cycles ($p = 0.022$) (Fig. 2B). High correlation was found between conventional polyethylene wear rate and Ra values ($r = 0.927$, $p < 0.001$)

(Fig. 2C). The mean highly cross-linked polyethylene wear rate was 0.16 ± 0.27 mg per 1 million cycles in the 3 retrieved femoral heads with high Ra, however, no measurable wear was found in those with intermediate Ra, low Ra and in new femoral heads (Fig. 2D). Investigation of the surface of the femoral head and conventional polyethylene after experiments showed various degrees of scratches (Fig. 3). Multiple scratches were observed on the surface of the conventional polyethylene mated against the femoral head with high Ra.

Discussion

This study represents the largest group of retrieved femoral heads analyzed after revision hip arthroplasty. The surface damage of the femoral head in vivo tended to be restricted to a small surface area and global damage was uncommon. Severe damage was only seen in retrieved femoral heads with Mode-2 wear.

The previous studies report an average Ra value of retrieved metal femoral heads ranging from 0.02 to 0.38 μm [7-14]. These differences in measured Ra values are likely multi-factorial and may be attributed to differences in sampling areas of the femoral head, type of prosthesis, failure mechanism of prosthesis, patients' activity, measurement method and deviation of instruments. Few studies have measured or evaluated the surface area damaged [24-26]. Our study demonstrated significant correlations between percentage of scratched area and surface roughness of the retrieved femoral heads, suggesting that severe damage to the femoral head increased both the surface roughness and the extent of scratched areas. It was reported that even 1 scratch on the metal surface could produce a substantial increase in the amount of conventional polyethylene wear [27]. Multiple severe scratches, which were found in the retrieved femoral head with Mode-2 failure (Fig. 1), likely have had a greater effect on conventional polyethylene wear.

Previous studies have shown a significant relationship between wear of conventional polyethylene and the counterface roughness using pin-on-disc and hip joint simulator experiments [1-6,27-30]. Laboratory study using a hip simulator demonstrated that higher degrees of cross-linking improve wear resistance and decrease particulate volume [17]. McKellop et al [3] tested conventional and highly cross-linked polyethylene articulating with femoral heads of differing surface roughness, and reported significantly less wear of the cross-linked polyethylene liners ($P = 0.004$). Shen and McKellop [5] reported higher wear rates of cross-linked polyethylene when mated against severely roughened femoral heads (Ra = 1.1 μm) compared to those mated against smooth femoral heads (Ra = 0.06 μm). Saikko et al [4] reported that the mean wear rate for highly cross-linked polyethylene was 2.4 ± 0.3 mg per 1 million cycles against moderately roughened femoral heads (Ra = 0.158 μm) compared to 11.6 ± 0.07 mg for conventional polyethylene against polished femoral heads (Ra = 0.010 μm). Prior studies have been performed with artificially roughed femoral heads which in general produce global damage and may not be as clinically relevant. This is the first study that assessed impact of varying surface damage of retrieved femoral heads on laboratory wear of conventional and highly cross-linked polyethylene. Our results showed that highly cross-linked polyethylene performs better when mated against retrieved severely roughened femoral heads, suggesting high resistance to wear of commercially available cross-linked polyethylene in vivo.

One limitation of this study was that we did not evaluate in vivo polyethylene wear of 108 patients. Surface damage and wear of the retrieved polyethylene were not assessed. The question remained whether retrieved femoral heads with high Ra have actually had high wear rate in vivo. Another limitation is that we could not demonstrate whether the various positions of the scratched area are relevant to wear. Although scratched areas were usually observed on the upper surface of the femoral head, it is not clear how degree middle to lower surface damages which might occur at the time of dislocation affect the wear. Future laboratory wear tests using femoral heads with different scratched positions may be needed to determine this.

In conclusion, this study demonstrated that the in vivo damage of femoral heads tends to be limited providing a base line for future studies on wear. The roughest femoral heads were the result of Mode-2 wear. Revisions performed for Mode-2 wear need to incorporate this information when selecting bearing surface. In 5 million cycles of wear tests using retrieved femoral heads, there were significant correlations between surface roughness of femoral heads and conventional polyethylene wear. Highly cross-linked polyethylene appears more resistant to wear than conventional polyethylene when mated against roughened femoral heads.

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LEGENDS TO FIGURES

Fig. 1. Retrieved high Ra femoral head coupled with completely worn conventional polyethylene liner.

Fig. 2. (A) Relationship between duration of implantation and Ra (μm).

(B) Wear of conventional polyethylene.

(C) Relationship between conventional polyethylene wear rate and Ra (μm).

(D) Wear of highly cross-linked polyethylene.

Fig. 3. Photographs of femoral heads and conventional polyethylene cups couples after 5 million cycles of wear experiments.

(A) High Ra femoral head.

(B) Low Ra femoral head.

(C) Conventional polyethylene coupled with (A).

(D) Conventional polyethylene coupled with (B).

Figure 1
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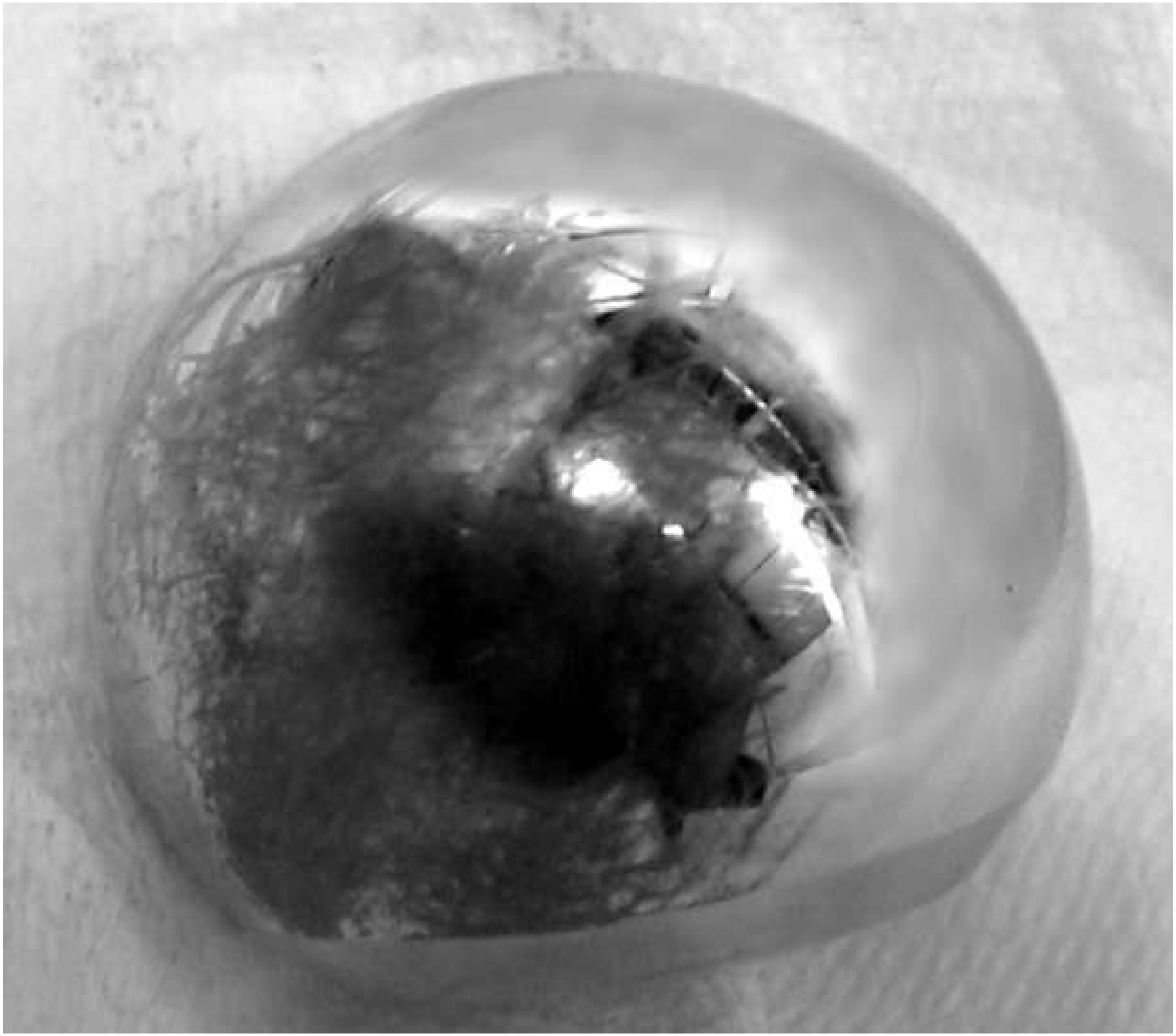

Figure 2A
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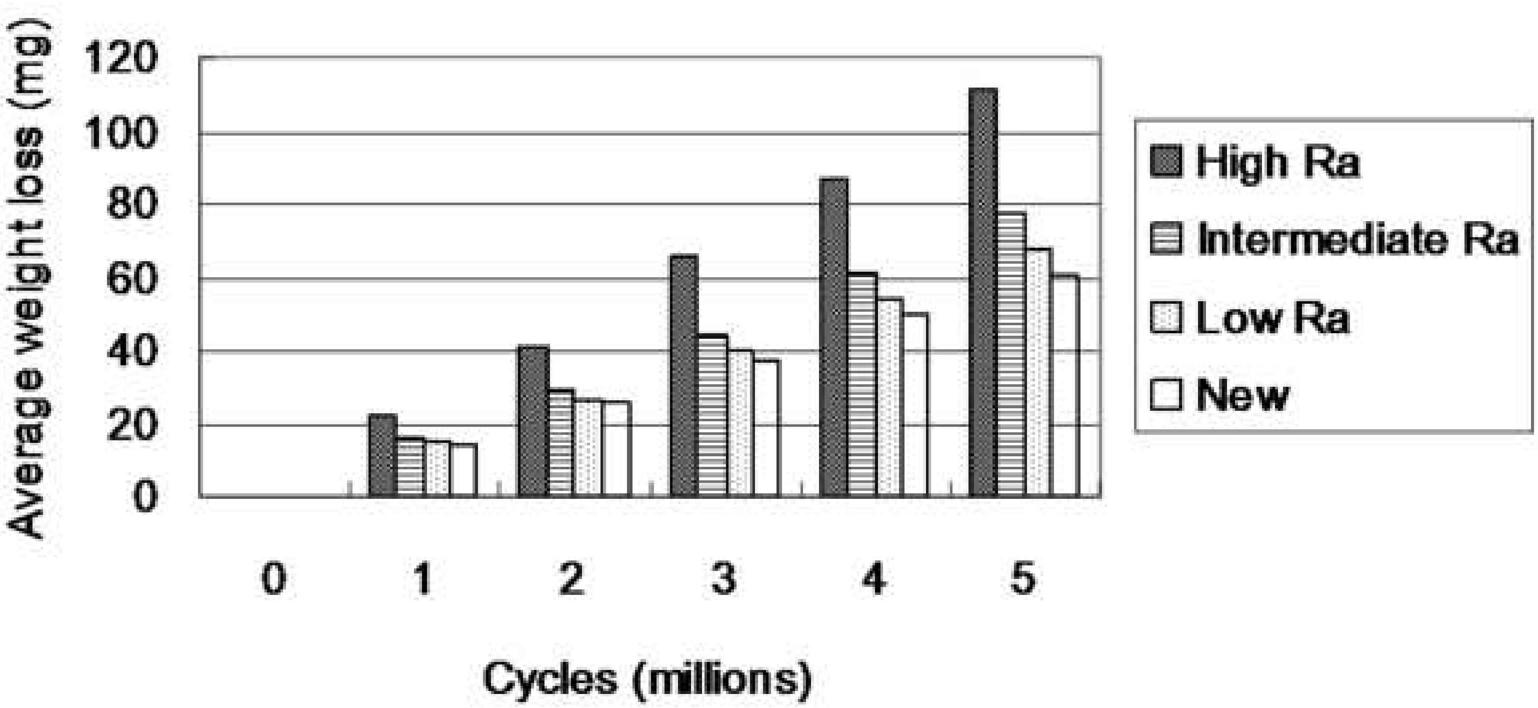

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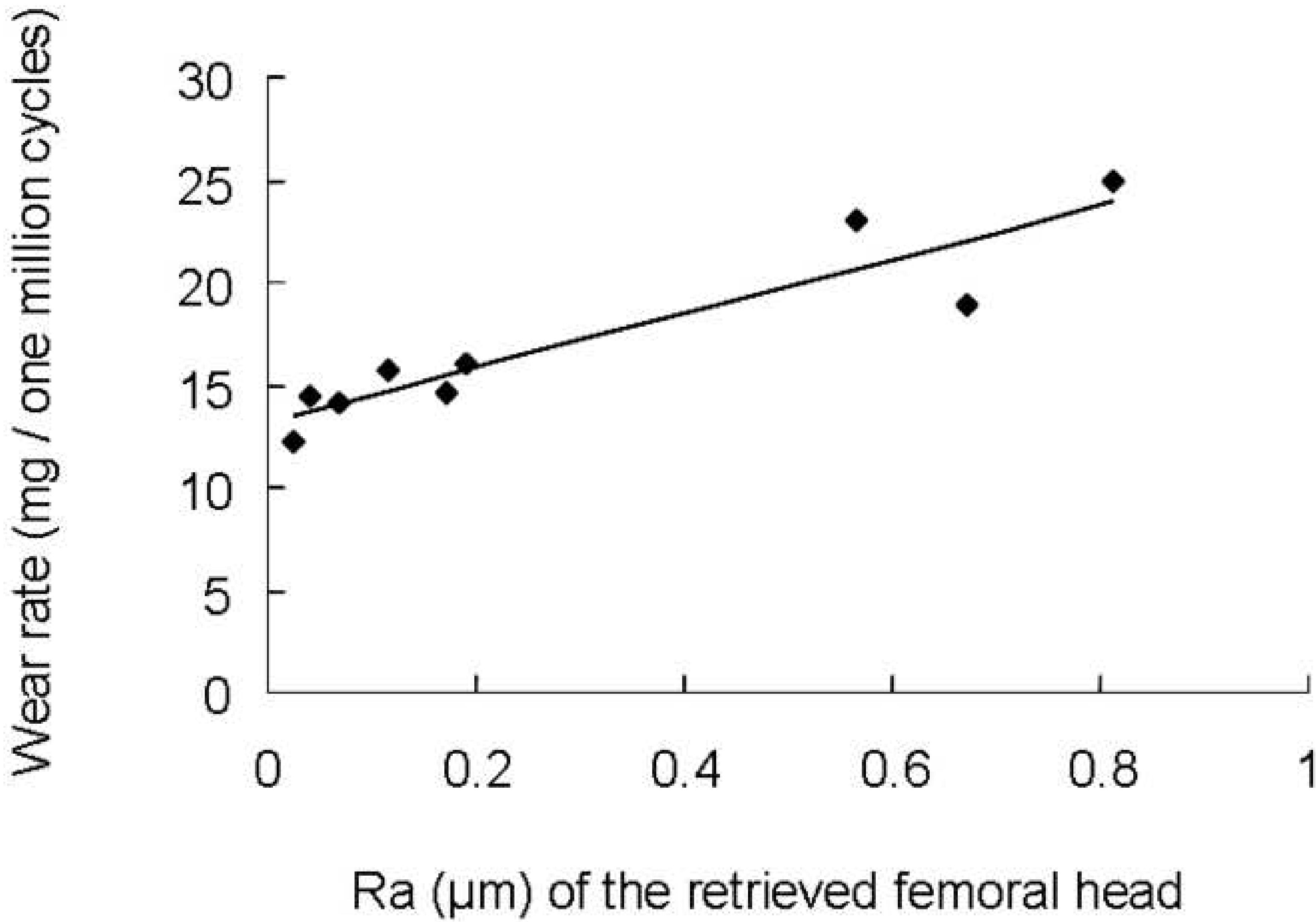

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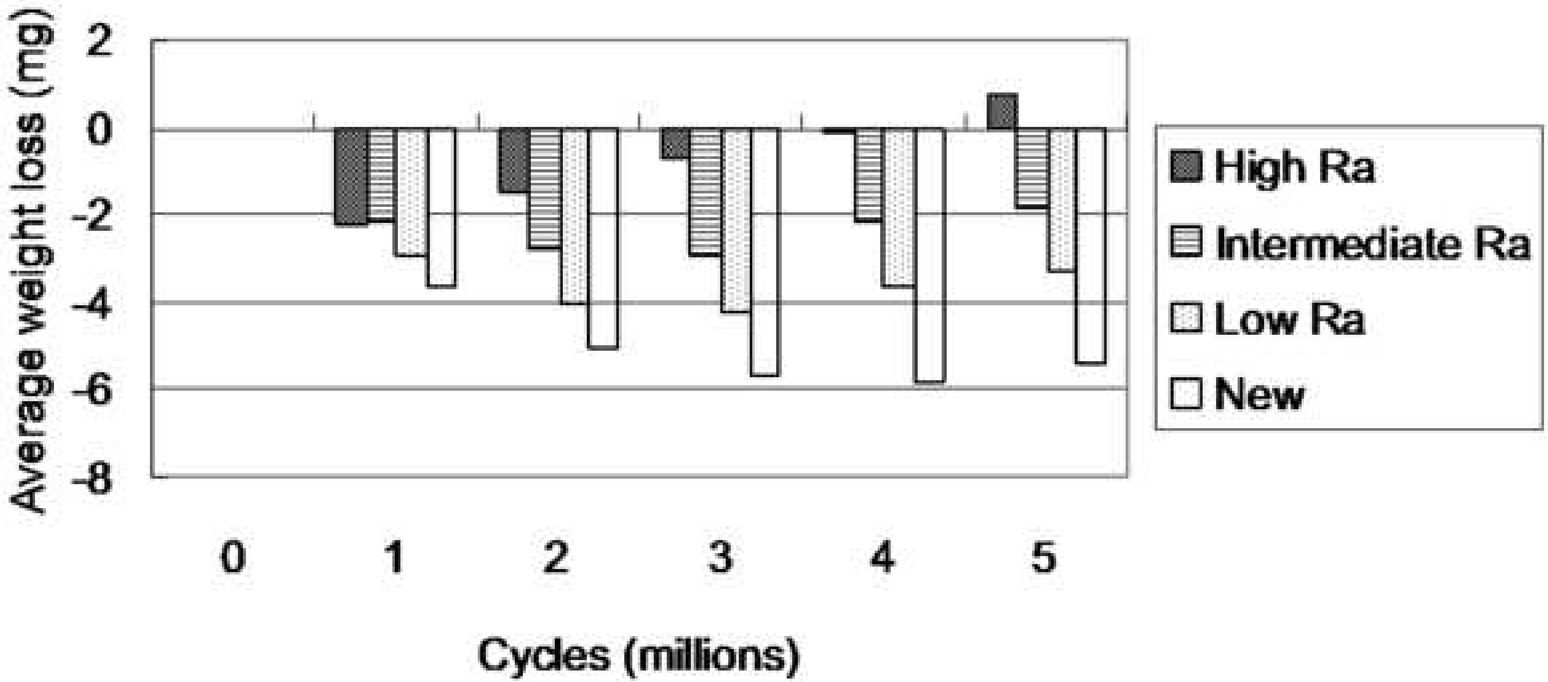

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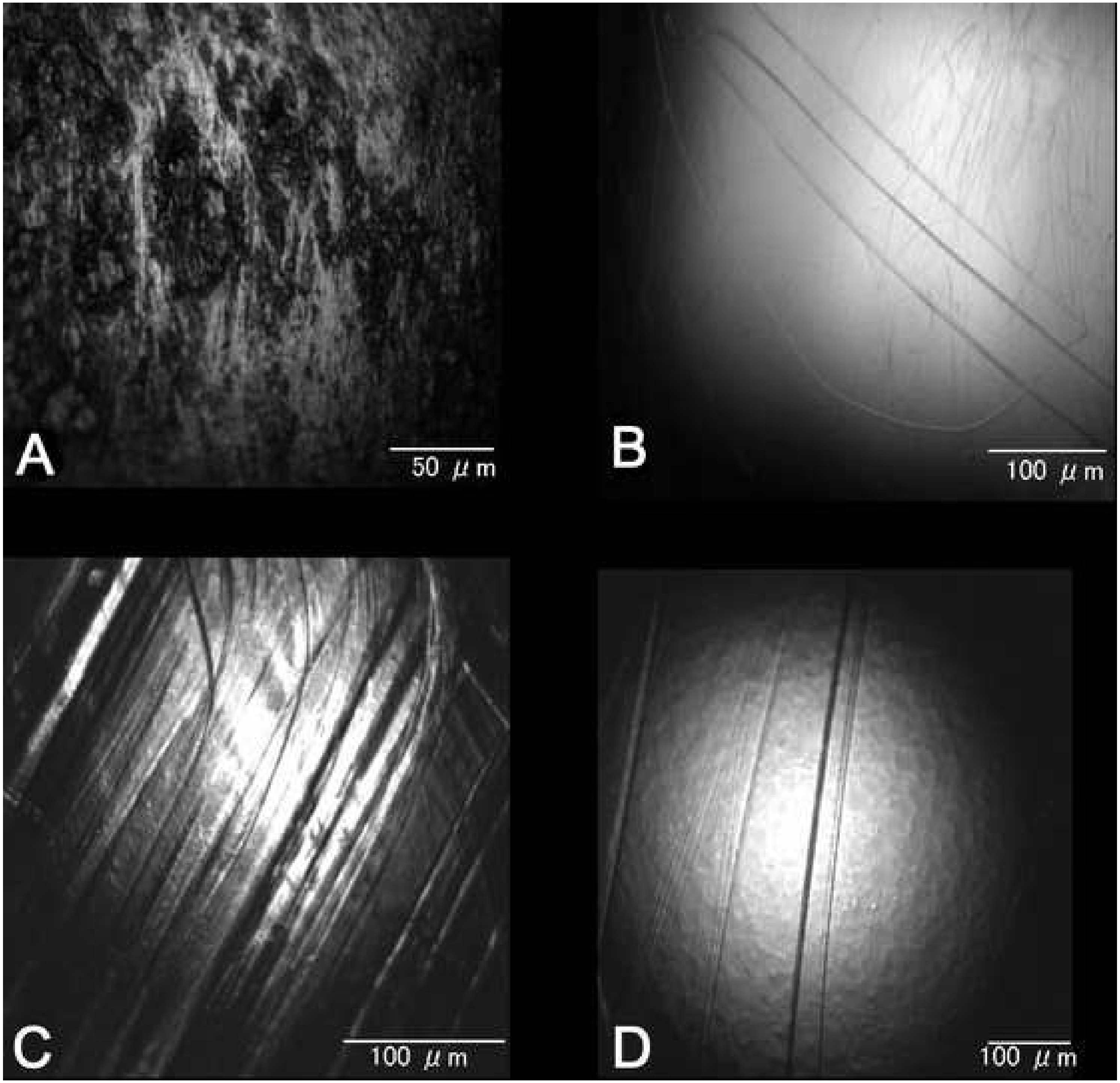

Table 1

Table 1. Demographic Characteristics of the 108 Patients (108 Hips)

Characteristics	
Mean age (range) *(yr)*	61 (22 to 90)
Mean weight (range) *(kg)*	77 (41 to 110)
Gender (no. of patients)	
Male	71
Female	37
Etiology (no. of hips)	
Osteoarthritis	86 (80%)
Developmental dysplasia of the hip	6 (6%)
Osteonecrosis	5 (5%)
Posttraumatic osteoarthritis	5 (5%)
Rheumatoid arthritis	4 (4%)
Femoral neck fracture	1 (1%)
Slipped capital femoral epiphysis	1 (1%)
Reasons of revision (no. of hips)	
Aseptic loosening (femoral and/or acetabular component)	63 (58%)
Osteolysis (femur and/or acetabulum)	15 (14%)
Recurrent dislocation	10 (9%)
Broken polyethylene liner locking mechanism of the acetabular component	6 (6%)
Periprosthetic infection	6 (6%)
Complete wear through polyethylene liner of the acetabular component	4 (4%)
Broken femoral component	2 (2%)
Heterotopic ossification	2 (2%)

Table 2

Table 2. Duration of Implantation of the 108 Patients (108 Hips)

Year	Number of hips
0 – 1	8
1 – 2	8
2 – 3	7
3 – 4	4
4 – 5	8
5 – 6	12
6 – 7	17
7 – 8	12
8 – 9	21
9 – 10	9
10 ≤	2

Table 3

Table 3. Ra and Rz Values of Each Femoral Head Diameter Group

	22 mm (N = 6)	26 mm (N = 1)	28 mm (N = 64)	32 mm (N = 37)	Total (N = 108)	P Value
Ra (μm)	0.29 ± 0.23	0.07	0.18 ± 0.20	0.17 ± 0.15	0.18 ± 0.18	0.298
Rz (μm)	2.19 ± 1.54	0.88	1.32 ± 1.38	1.38 ± 1.03	1.38 ± 1.28	0.144

*The values are given as the mean and the standard deviation.

Table 4

Table 4. Ra and Rz Values Compared by Prosthesis Fixation before Revision Surgery

	Cementless (N = 61)	Cemented (N = 21)	Hybrid (N = 26)	P Value
Age	60.0 ± 14.6	63.8 ± 11.7	61.7 ± 15.6	0.416
Ra (μm)	0.19 ± 0.19	0.17 ± 0.15	0.17 ± 0.20	0.577
Rz (μm)	1.46 ± 1.38	1.31 ± 0.96	1.28 ± 1.30	0.517

*The values are given as the mean and the standard deviation.

Table 5

Table 5. Ra and Rz Values Compared by Reasons for Revision Surgery

	Aseptic loosening (N = 63)	Osteolysis (N = 15)	Recurrent dislocation (N = 10)	Broken polyethylene liner locking mechanism (N = 6)	Periprosthetic infection (N = 6)	Complete wear through polyethylene liner (N = 4)	Others (N = 4)	P Value
Ra (μm)	0.11 ± 0.10	0.19 ± 0.13	0.54 ± 0.10	0.09 ± 0.03	0.16 ± 0.15	0.63 ± 0.14	0.13 ± 0.05	< 0.001
Rz (μm)	0.87 ± 0.72	1.47 ± 0.95	3.72 ± 0.64	0.77 ± 0.26	1.33 ± 1.02	4.65 ± 1.25	1.04 ± 0.25	< 0.001

*The values are given as the mean and the standard deviation.

Table 6

Table 6. Ra and Rz Values Compared by Reasons (Mode-2 Wear or Others) for Revision Surgery

	Mode-2 Wear*		
	Yes (N = 14)	No (N = 94)	P Value
Ra† (μm) *(range)*	0.56 ± 0.12 (0.41 to 0.81)	0.12 ± 0.11 (0.01 to 0.45)	< 0.001
Rz† (μm) *(range)*	3.98 ± 0.91 (3.05 to 6.37)	1.00 ± 0.77 (0.07 to 3.46)	< 0.001

*Mode-2 wear includes four hips with complete wear through of the polyethylene liner and ten hips with recurrent dislocation.

†The values are given as the mean and the standard deviation.