Retrieval analysis of alumina ceramic-on-ceramic bearing couples

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Background and purpose — Ceramic-on-ceramic (CoC) bearings have been in use in total hip replacement (THR) for more than 40 years, with excellent long-term survivorship. Although there have been several simulator studies describing the performance of these joints, there have only been a few retrieval analyses. The aim of this study was to investigate the wear patterns, the surface properties, and friction and lubrication regimes of explanted first-generation alumina bearings.

Materials and methods — We studied 9 explanted CoC bearings from Autophor THRs that were revised for aseptic loosening after a mean of 16 (range 7–19) years. The 3D surface roughness profiles of the femoral heads and acetabular cups (Srms, Sa, and Ssk) were measured to determine the microscopic wear. The bearings were imaged using an atomic-force microscope in contact mode, to produce a topographical map of the surfaces of the femoral heads. Friction tests were performed on the bearing couples to determine the lubrication regime under which they were operating during the walking cycle. The diametral clearances were also measured.

Results — 3 femoral heads showed stripe wear and the remaining 6 bearings showed minimal wear. The femoral heads with stripe wear had significantly higher surface roughness than the minimally worn bearings (0.645 vs. 0.289, p = 0.04). High diametral clearances, higher than expected friction, and mixed/boundary lubrication regimes prevailed in these retrieved bearings.

Interpretation — Despite the less than ideal tribological factors, these first-generation CoC bearings still showed minimal wear in the long term compared to previous retrieval analyses.

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Ceramic-on-ceramic (CoC) bearings for total hip replacement (THR) were developed in the early 1970s. The earliest designs, typified by the Ceraver-Osteal implant, failed because of inadequate fixation and high fracture rates of the ceramic (Boutin et al. 1988, Mittelmeier and Heisel 1992). Throughout the 1980s, the Mittelmeier Autophor ceramic prosthesis (Smith and Nephew, Memphis, TN) was widely used. The threaded external surface of the acetabular component gave primary stability, but it had no porous surface for bony ingrowth. This design did not improve the rate of aseptic loosening, but the fracture rate was notably reduced (Boutin et al. 1988, Sedel 2000, Tateiwa et al. 2008, Jeffers and Walter 2012). Since the early 1990s, the predominant design has been a rough or porous-coated titanium shell with a ceramic liner.

A recent systematic review of CoC THRs confirmed excellent survivorship of the modern implants of up to 97% at 10 years (Jeffers and Walter 2012). It is likely that the improvements in acetabular fixation as well as in the manufacturing process, design, and quality control of the ceramic bearings have contributed to the excellent clinical results. Ceramic bearings are relatively inert, and they have excellent wear properties (Savarino et al. 2009). There have only been isolated case reports describing osteolysis around CoC bearings possibly making revision surgery easier with the preserved bone stock (Yoon et al. 1998, Sedel 2000, Tateiwa et al. 2008, Hannouche et al. 2011). The fracture rates of modern alumina ceramic bearings have been reported to be as low as 1 in 25,000 (Nizard et al. 2005, Tateiwa et al. 2008, Jeffers and Walter 2012).

Hip simulator studies on CoC bearings have consistently shown very low wear rates (Nevelos et al. 2001, Rieker et al. 2001, Tipper et al. 2002, Stewart et al. 2003), but this has not been reflected by the long-term retrieval analyses (Nevelos et al. 1999, 2001, Prudhommeaux et al. 2000, Affatato et al. 2012). It must be understood, however, that retrieval studies are performed on joints that have failed, not well-functioning joints, so this does not give information on the larger proportion of successful CoC THRs. There have only been a few long-term retrieval analyses of explanted CoC bearings (Nevelos et al. 1999, 2001, Prudhommeaux et al. 2000) and even fewer retrieval analyses of modern CoC bearings (Affa-

tato et al. 2012). With the excellent clinical survivorship of the modern implants (Jeffers and Walter 2012), failed first-generation CoC bearings may well have to be studied to more fully understand the in vivo tribology.

The aim of this study was to investigate the wear patterns, the surface properties, and friction and lubrication regimes in 9 explanted first-generation alumina CoC bearings. The tribological data from this study are likely to represent the worst case scenario, which can be used for comparison in future retrieval studies featuring modern CoC bearings.

Material and methods

9 CoC prostheses were explanted at Glenfield Hospital in Leicester between 1998 and 2003. All of them were Mittelmeier Autophor CoC THRs that had been implanted in the 1980s through an anterolateral approach. The implant consisted of an externally threaded truncated cone socket made of monolithic alumina ceramic, which was screwed into an under-reamed acetabulum to articulate with a 32- or 38-mm modular head on a fenestrated cementless cobalt-chrome alloy stem. The ceramic components were "BIOLOX" alumina ceramic material with a mean grain size of 4.2 μm and a density of 3.94 g/cm^3.

The prostheses were from 3 men and 6 women with a mean age of 48 (22-60) years at implantation. The reasons for hip arthroplasty were primary osteoarthritis (7 cases), osteoarthritis secondary to developmental dysplasia (1 case), or osteoarthritis secondary to slipped upper femoral epiphysis (1 case). Six 32-mm and three 38-mm alumina ceramic heads had been implanted with an appropriately matched threaded ceramic acetabular component. The indication for revision surgery was aseptic loosening, which occurred after an average of 16 (range 7–20) years. None of the hips had dislocated prior to revision surgery and none of the patients had reported any squeaking.

Analysis

All implants were disinfected in a 10% solution of Gigasept for 48 h, then rinsed in tap water. This was followed by rinsing in distilled water and they were finally left to dry. After cleaning, the joints were stored individually in Ziploc bags.

Surface characterization

Nine explanted joints were analyzed visually to determine the obvious areas of wear. A Zygo NewView 100 non-contacting profilometer was then used to measure the 3D surface roughness profiles (S_{rms}, S_a, and S_{sk}) of the femoral heads and acetabular cups of these 9 explanted joints to characterize microscopic wear. The 10× lens with 2× zoom was used, giving an area of view of 0.366 × 0.274 mm. 10 measurements were taken on both a "roughened" area and a "smoother" area on each component to give comparative readings.

S_a is the arithmetic roughness of a surface over the full area of view. Srms is the root mean square of the surface roughness, otherwise known as the standard deviation of the data (treating a surface as a continuous stream of dimensional data). S_a and S_{rms} are very similar in magnitude but S_{rms} has a more rigorous statistical basis. S_{sk} is the skewness and indicates whether the roughness is due to peaks (resulting in a positive skewness) or troughs (leading to a negative skewness) on the bearing, the latter having better wear properties.

Contact-mode atomic-force microscopy (TopoMetrix Explorer SPM) was used to produce a topographical map of the surfaces of 6 alumina femoral heads from bearing couples MF, DD, JF, DAS, RL, and JL. The geometry of the other bearings and/or the presence of the femoral stem prevented images from being taken on the remaining heads and all the acetabular cups. The head surfaces that were investigated were imaged using an Si_3N_4 cantilever with a tip radius of curvature of < 50 nm and a scan frequency of 1 Hz. As with the Zygo surface roughness measurements, the images were taken on both an unworn area and a worn area. Both 100-μm^2 and 20-μm^2 images were acquired.

Friction testing

Friction tests were performed on 5 of the bearing couples (MF, DD, JF, DAS, and JL) to determine the lubrication regime under which they were operating during the walking cycle. It was not possible to perform friction tests on all of the joints, due to either the external diameter of the acetabular cups being too large for the simulator or the presence and attachment of the original femoral stem. The prostheses were inverse anatomically mounted with the acetabular component orientated 33° to the horizontal using a specially built holder (this was to place the load vector in the same position as would be found in the body with an acetabular cup inserted at 45°). The components were positioned in the friction rig to allow either a "worn" area or an "unworn" area to be tested.

In the friction simulator, a servo-hydraulic cylinder provided a dynamic loading cycle with maximum and minimum loads set at 2,000 N and 100 N. A simple harmonic oscillatory motion of ± 24° was applied to the femoral head in the flexion/extension plane. The period of motion was 1.2 s. The simulator comprised a low-friction carriage into which the acetabular cup was placed and an upper moving frame into which the femoral head was fixed. The acetabular carriage was supported by externally pressurized bearings, which ensured a very low-friction axis about which the carriage could rotate due to the frictional torque generated between the bearing surfaces. Friction in the external bearings was at least 2 orders of magnitude lower than the friction in the prostheses, which ensured that the measured frictional torque was accurate This rotation was resisted by a Kistler piezoelectric transducer, which was calibrated to measure torque. The frictional torque, load, and angular displacement were measured throughout each cycle. The frictional torque was converted to friction factor, f, using

the equation below (Unsworth 1978):

$$f = T/rL$$

where T is the frictional torque between the bearing surfaces, r is the radius of the femoral head, and L is the axial load applied. An average friction factor was taken of 3 runs from the high-load stage of the loading cycle (equivalent to the stance phase of walking).

To determine the lubrication regime, several viscosities of lubricant were tested to enable a Stribeck curve to be generated. The Stribeck curve plots the measured friction factor against Sommerfeld number, z, defined below:

$$z = \eta ur/L$$

where η is the lubricant viscosity and u is the entraining velocity of the bearing surfaces. A decreasing friction factor with increasing Sommerfeld number indicates a mixed lubrication regime, a rising friction factor with increasing Sommerfeld number indicates full-fluid film lubrication, and boundary lubrication is shown as a flat trendline with no dependence of friction factor on Sommerfeld number (Unsworth 1978, Dowson 2001).

Two different lubricating fluids were used in these tests; carboxymethyl cellulose (CMC) solutions and bovine serum. This was done to allow comparison between the fluids and to determine the effects of the introduction of proteins to the lubrication of the CoC joints. Both the CMC fluids and the bovine serum were prepared to different viscosities to allow for the generation of Stribeck plots. The different viscosities of the CMC solutions were 0.001 Pa s $< \eta < 0.103$ Pa s and the different viscosities of bovine serum were 0.001 Pa s $< \eta < 0.105$ Pa s (as measured on a Ferranti-Shirley cone-on-plate viscometer).

Diametral clearances

The diametral clearances of all the joints that underwent friction tests were measured on the Mitutoyo 3D Euro-C-A544 coordinate measuring machine (CMM). The CMM is a device with 3 axes of motion. It was used to measure the geometrical features using a moveable probe. Selected points were measured on the test piece by the probe, which provided the coordinates relative to a fixed point on the machine. Twenty points were measured on each of the friction-tested heads and cups, and the best circles fitted. This allowed calculation of the diametral clearances.

Results

Surface analysis

3 femoral heads showed stripe wear and the remaining 6 bearings showed varying degrees of roughened or darkened areas. 2 of the 3 acetabular components of the bearings with stripe wear showed evidence of rim wear. However, there were minor scratches on the rim of most of the acetabular components, possibly resulting from retrieval of the bearings. There
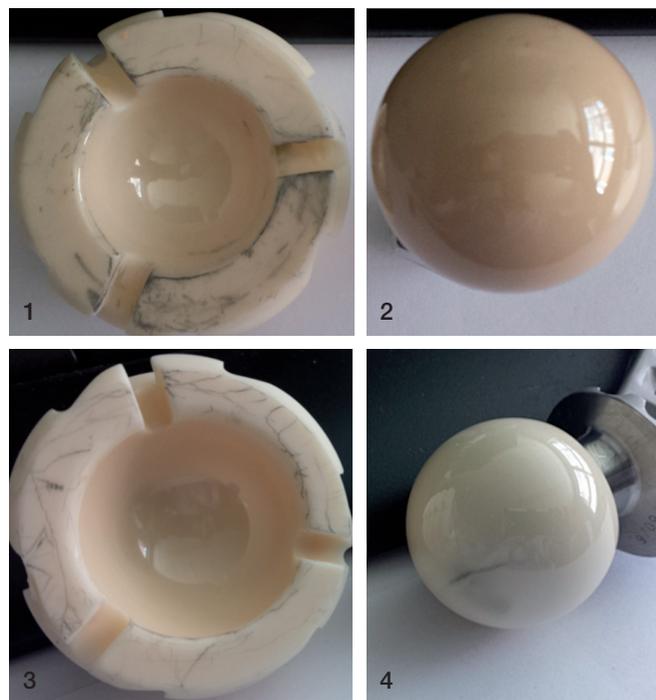
Figure 1. Typical bearings illustrating minimal wear at the cup periphery (1), minimal wear on the femoral head (2), minimal wear at the center of the cup and rim wear peripherally (3), and stripe wear on the femoral head (4).

are no accepted ways of describing wear patterns on retrieved bearings. We described the wear as being predominantly central or peripheral (Figure 1).

Demographic data and the patterns of wear on the femoral head and acetabular components are summarized in Table 1.

Surface topography of the femoral heads and acetabular cups showed that the unworn areas had a very smooth surface, but the roughened and areas with stripe wear had more peaks and troughs, as shown in Figure 2.

Six femoral heads (bearings MF, DD, JF, DAS, RL, and JL) were also imaged using the AFM. Images were taken of the smooth areas, darkened areas, rough areas, and areas with stripe wear. The increasing severity of wear on the bearings is illustrated in Figure 3.

These images showed that the smooth areas were flat and even, displaying just a few incidences of granular pullout resulting in fewer and smaller pits. The majority of these pits were 0.2–0.3 μm in depth and 2 μm wide. The darkened, roughened areas and the areas showing stripe wear showed higher peaks and valleys with more substantial granular pullout, and also some material deposition. In the roughened areas, the pits were up to 1μm deep and 10 μm wide. Areas of stripe wear showed pits measuring 1 μm deep and 15 μm wide.

The surface topographical and AFM observations of these first-generation bearings suggest that the wear process is a continuum with the initially smooth bearings experiencing granular pullout, to produce roughened areas.

Table 1. Demographic data on patients and on wear patterns in femoral head and acetabular components

A	B	C	D	E	F	G	H	I
MF	74	OA	1988	2000	12	32	Peripheral and central	Peripheral and central
BW	72	OA	1985	2001	16	32	Peripheral	Peripheral
NM	85	OA	1986	2000	14	38	Central stripe wear	Central and rim wear
DD	83	OA	1983	2001	18	32	Periphery	Peripheral
JF	85	OA	1984	2002	18	32	Central stripe wear	Central and rim wear
DAS	70	OA	1983	2002	19	32	Peripheral	Central
RL	51	SUFE	1982	2002	20	38 (skirted head)	Central stripe wear	Central, NO rim wear
CT	78	OA	1984	2003	19	38	Peripheral	Peripheral
JL	62	DDH	1991	1998	7	32	Central	Central

A Case
B Age
C Primary Diagnosis
  DDH: developmental dysplasia of hip
  OA: osteoarthritis
  SUFE: slipped upper femoral epiphysis;
D Year implanted
E Year of revision surgery
F Time to revision, years
G Head size, mm
H Main area of wear on femoral head [a]
I Main area of wear on cup [a]
[a] Central was the inner 50% of the bearing and peripheral was the remainder of the bearing.
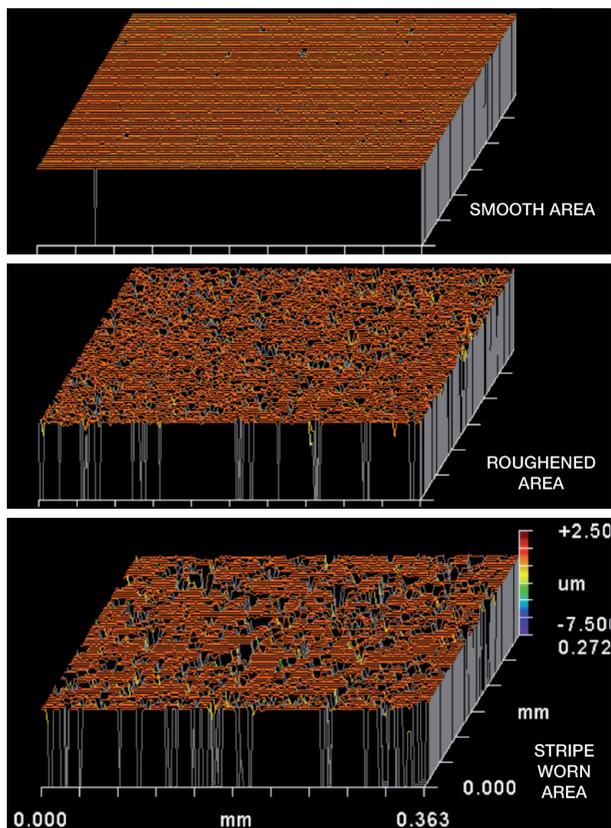
Figure 2. Surface topography of femoral head on smooth (top panel), roughened (middle panel), and stripe-worn areas (bottom panel). The graphs have the same scales on the x- and y-axis as the graph at the bottom with stripe wear.

Wear analysis

The linear and volumetric wear was not measured for two reasons. Firstly, in the majority of cases (all but one joint), the CMM was not able to define the unworn surface. Secondly, if the unkown surface was able to be measured, the analysis software failed to create the surface image to then give a wear value.

Microscopic wear was assessed by quantifying the surface roughness of the acetabular components and femoral heads. The mean surface roughness data for the femoral head and acetabular components from the worn and smooth areas are illustrated in Tables 2 and 3.

The smooth areas on the acetabular and femoral components showed surface roughness of 0.01 μm, which is similar to the 0.005-μm surface roughness of newly manufactured ceramic bearings (Prudhommeaux et al. 2000).

The areas of stripe wear on the femoral heads showed higher surface roughness than the minimally worn areas for both Srms and Sa parameters (Mann-Whitney U tests; 0.645 vs. 0.289 and 0.402 vs. 0.156, respectively; p = 0.04 and p = 0.02). All the worn areas showed negative skewness, which leads to a better bearing surface since the peaks have worn down.

Friction and lubrication regime analysis

This was only possible for the five 32-mm bearings (MF, DD, JF, DAS, and JL). The bearings were positioned within the holders in an attempt to obtain measurements with contact over a smooth area (position 1) and then a rough area (posi-
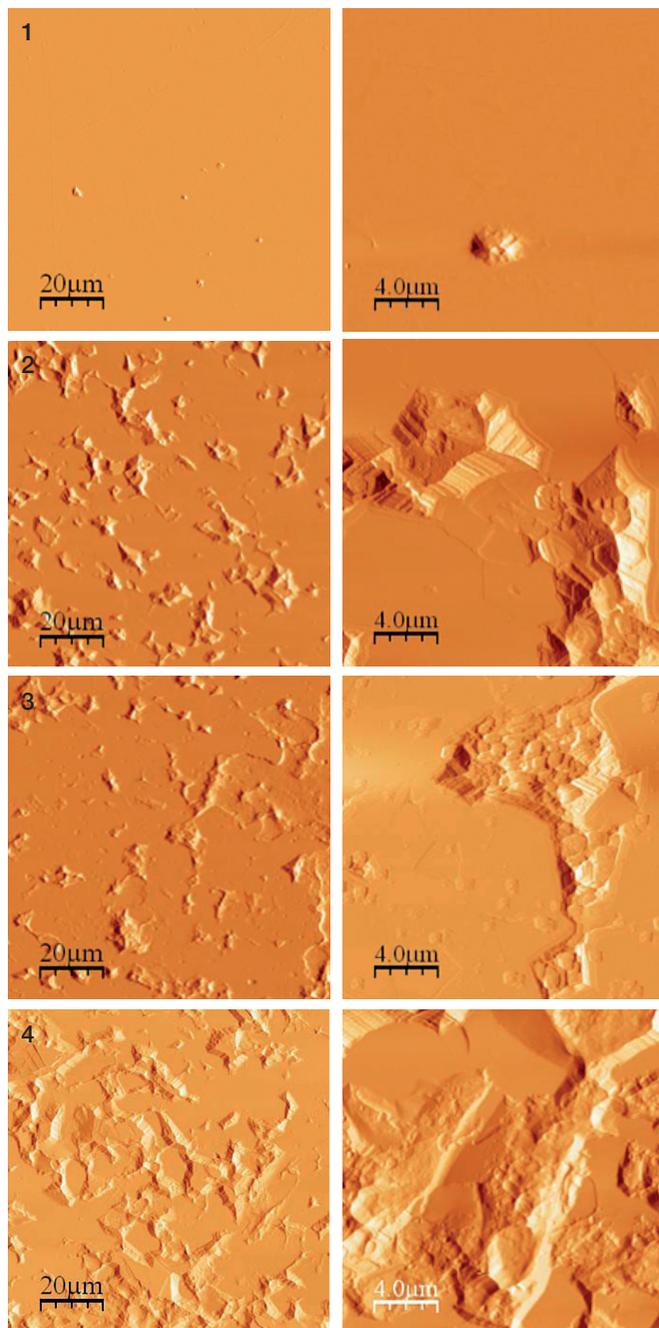
Figure 3. Atomic-force microscope images of smooth areas (1), darkened areas (2), roughened areas (3), and stripe-worn areas (4) of femoral heads, all at 2 magnifications.

tion 2), using both CMC fluids and CMC with bovine serum as the lubricants. It was challenging to pair the smooth and roughened areas of the joints, but the trend was that the friction factor was higher over the roughened areas. The damaged explanted joints produced similar friction (bearings MF, DD, and JF) or lower friction (bearings DAS and JL) when bovine serum was used as lubricant. Higher friction was observed when CMC fluids were used as lubricant. The areas

of stripe wear gave similar friction to the roughened areas of other joints.

The lubrication regime was inferred from the Stribeck plots of bearing couples (Figure 3). The explanted joints tested operated in a mixed/boundary lubrication regime with a decreasing friction factor observed with increasing Sommerfeld number.

Diametral clearances

This was performed on the 5 joints that underwent friction analysis, with a view to explaining the performance, and the results are illustrated in Table 4. The majority of bearings had diametral clearances of more than 100 μm. One of the joints (MF) had a far larger diametral clearance of 463 μm and friction tests had to be abandoned due to high friction developed by this joint. We also noted that most of the bearing surfaces of both the head and the cup were roughened.

Discussion

Wear patterns

After a mean of 16 years in vivo, only 33% (3/9) of the femoral heads showed evidence of stripe wear and 2 of 3 of the matching acetabular cups showed rim wear, suggesting that edge loading may have been a mechanism of stripe wear. The other bearings showed minimal wear, with areas of darkening and roughening only.

The general pattern of wear appears to have been less severe than in the retrieval analyses of similar bearings that have been published (Nevelos et al. 1999, 2001, Prudhommeaux et al. 2000, Affatato et al. 2012). In a retrieval analysis of 11 Autophor THRs after a mean period of 9 years, the majority of the bearings had stripe wear (6/11) or severe wear (4/11) (Nevelos et al. 1999). Similar wear patterns were observed by Prudhommeaux and colleagues with stripe wear (5/11) and severe wear (2/11) present on the retrieved Ceraver-Osteal bearings after a mean period of 11 years (Prudhommeaux et al. 2000). More recently, Affatato et al. (2012) showed that stripe wear was present on 16/20 retrieved second-generation CoC bearings after a mean of 13 years.

The linear wear was not measured for technical reasons. In previous retrieval analyses, the linear wear has ranged from 42 to 1,821 μm on the femoral side and from 20 to 559 μm on the acetabular side (Nevelos et al. 1999, Prudhommeaux et al. 2000).

The microscopic wear measurements from these previous studies showed surface roughness (Ra) of 0.1–0.21 μm on areas of stripe wear and 0.01–0.03 μm on areas of minimal wear (Nevelos et al. 1999, Affatato et al. 2012). The surface roughnesses of both the smooth areas and areas of stripe wear were higher in our series, but 3-D measurement of roughness was used rather than the 2-D measurement used in previous retrieval analysis. The former has been shown to be more representative of the surface properties and may

Table 2. Surface roughness of femoral heads for smooth and rough areas according to the presence/absence of stripe wear

Wear pattern	Area on head	S_{rms}(SD)/µm	S_a (SD)/µm	S_{sk}(SD)/µm
Stripe (n = 3)	Rough	0.645 (0.285)	0.402 (0.246)	−4.053 (1.381)
	Smooth	0.010 (0.002)	0.008 (0.002)	−1.881 (1.592)
Minimal (n = 6)	Rough	0.289 (0.057)	0.156 (0.043)	−6.130 (1.36)
	Smooth	0.011 (0.002)	0.008 (0.001)	−4.235 (3.578)

S_a, S_{rms}, and S_{sk} are the 3D expressions for surface roughness.

Table 3. Surface roughness of acetabular components for smooth and rough areas

Wear types	Area on cup	S_{rms} (SD)/µm	S_a (SD)/µm	S_{sk} (SD)/µm
Minimal (n = 9)	Rough	0.151 (0.059)	0.062 (0.020)	−8.79 (5.680)
	Smooth	0.014 (0.002)	0.010 (0.002)	−2.89 (2.701)

S_a, S_{rms}, and S_{sk} are the 3D expressions for surface roughness.
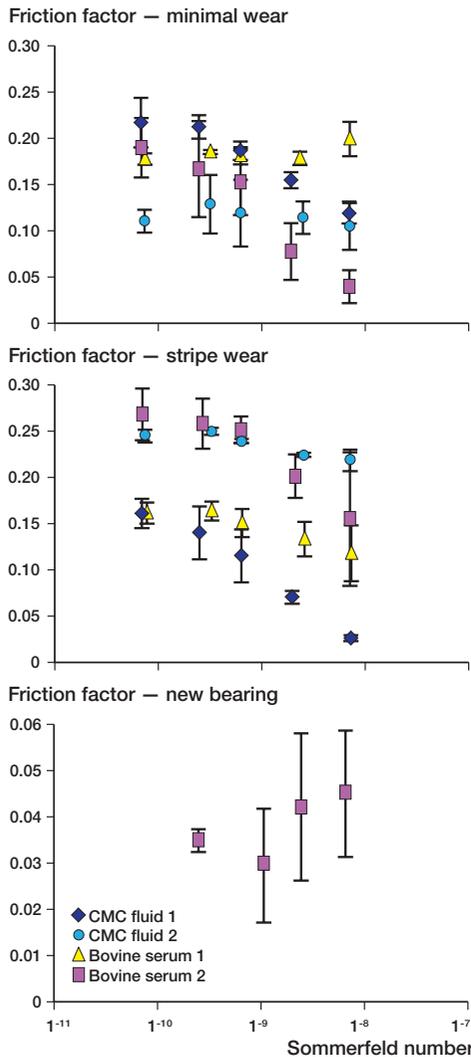
Figure 4. Stribeck plots of bearings with minimal wear and stripe wear, and of a newly manufactured bearing.

Table 4. Diametral clearances of bearings that were friction-tested

Bearing	Diameter (µm)				Diametral
	1	2	3	Average	clearance (µm)
Head MF	31.885	31.885	31.879	31.883	463
Cup MF	32.341	32.358	32.338	32.346	
Head DD	31.999	32.002	32.000	32.000	116
Cup DD	32.113	32.119	32.117	32.116	
Head JF	31.932	31.931	31.930	31.931	171
Cup JF	32.096	32.106	32.103	32.102	
Head DAS	31.984	31.978	31.984	31.982	133
Cup DAS	32.116	32.115	32.113	32.115	
Head JL	32.006	32.004	32.003	32.004	105
Cup JL	32.108	32.108	32.110	32.109	

give a better indication of the actual wear process (Zecchino 2003).

Hip simulator studies tend to underestimate the wear rates, and substantial differences have been found between the wear of alumina CoC hip joints in vivo and the wear found in standard simulator tests (Stewart et al. 2003). Ex vivo specimens (retrieved during revision surgery) have shown wear rates of about 1 mm³/year, stripe wear on the head with surface roughening, intergranular fracture, and wear debris from 10 nm to 1 µm in size. In contrast, standard simulator studies have shown wear rates of less than 0.1 mm³/106 cycles, with only relief polishing wear of the alumina ceramic (Nevelos et al. 2001, Rieker et al. 2001, Tipper et al. 2002, Stewart et al. 2003). Recently, Affatato et al. (2012) suggested that the wear in alumina-alumina bearings in association with a loose acetabular component may be variable in pattern, and may partially explain why the wear of a ceramic head in vivo may be greater than that seen after in vitro testing of well-functioning joints.

Friction and lubrication regimes of the bearing couples

This is the first retrieval analysis on CoC bearings to describe friction and lubrication regimes. All the friction tests showed higher friction than expected with CoC joints. Scholes and Unsworth (2000) tested 28-mm diameter CoC joints with both CMC fluids and bovine serum, and they found very low friction factors such that they operated close to full-fluid film lubrication, as illustrated by the lowermost Stribeck plot in Figure 4. The joints as manufactured were capable of working with minimal contact between the ceramic surfaces, and this resulted in low friction. These joints were, however, tested as received (immediately after manufacture) and their surfaces were considerably smoother than the ones reported in this study.

The damage apparent on the explanted joints created a far higher degree of friction, and these joints appeared to be working within mixed/boundary lubrication, resulting in considerable contact between the bearing surfaces. When bovine serum was used as the lubricant, it is likely that a protein layer formed on the bearing surfaces. When testing the joints as manufactured, Scholes and Unsworth (2006) discovered that this protein layer resulted in an increase in the friction factor developed because the protein adsorption disrupted the fluid film lubrication to give higher friction. In the current study, however, no fluid film lubrication was found, so this protein layer resulted in similar or lower friction since the shear stress of the proteins was lower than that of unlubricated ceramic. Thus, the damaged explanted joints produced similar or lower friction using bovine serum as the lubricant than when using CMC fluids, and this may have been due to protein-protein contact producing lower friction than ceramic-on-ceramic contact.

It appears that as the ceramic bearings get worn and roughened, the friction in the joint increases and mixed/boundary lubrication predominates. Synovial fluid would then play a more important role in reducing friction. It is difficult to tell how often CoC bearings exhibit fluid film lubrication in vivo, as although hip simulator studies have shown these joints to work close to full-fluid film lubrication during the standard gait cycle, this is only part of the daily activities that an artificial joint will encounter. Other activities such as stair climbing or rising from a sitting position are also common activities that have not been measured.

Clearances of the bearing couples

The clearances of the joints were less than ideal for fluid film lubrication. It is generally recommended that 40–100 μm diametral clearance is optimum (Mabuchi et al. 2004, Nizard et al. 2005, Hannouche et al. 2011). All the bearing couples had diametral clearances of more than 100 μm and one of them with marked roughening (MF) had a diametral clearance of 463 μm. Such large clearances hinder any fluid film lubrication from being generated, to help reduce friction.

Even with less than ideal clearances in a CoC bearing with higher ceramic grain sizes and reduced density, minimal wear was seen on most of the bearings. One can reasonably expect wear to be less with modern ceramics, which are manufactured with optimal clearances and improved material properties.

Conclusions

With the increased longevity of implanted CoC bearings and the inability of current simulators to reproduce hip movements during everyday activities other than just the natural walking cycle, we will have to rely on small retrieval analyses from older CoC bearings to learn about failure of these THRs. High diametral clearances, higher than expected friction, and mixed/boundary lubrication regimes prevail in the retrieved joints. However, these first-generation CoC bearings still showed less severe wear patterns in the long term compared to previous retrieval analyses. The improvements in ceramic manufacture are likely to result in improved survivorship of modern CoC-bearing THRs.

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