Metal release from total hip articulations in vitro

Substantial from CoCr/CoCr, negligible from CoCr/PE and alumina/PE

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We used a hip joint simulator to compare the metal release from CoCr/CoCr, CoCr/PE, and alumina/PE total hip articulations. The metal release was quantified by analyzing the Co, Cr, and Ni contents of the bovine serum lubricant used with atomic absorption spectroscopy. CoCr/CoCr articulations released substantial amounts of metal, whereas CoCr/PE was equal to the control, alumina/PE, in that metal release was negligible. The metal release was in accordance with the known clinical wear rates of CoCr/CoCr articulations. The largest dimensional changes occurred in polyethylene cups, the penetrations of CoCr heads to the polyethylene cups being twice that of the alumina head, which is consistent with clinical experience. The research on the wear behavior of different materials, aiming to find a prosthesis with negligible wear, needs to be continued. Due to the substantial metal release, the CoCr/CoCr articulation is hardly the final solution of the wear problem in total hip arthroplasty.

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The revival of the metal-on-metal articulation, in which a femoral head made of CoCr alloy articulates against an acetabular cup made of the same alloy, has been justified by the satisfactory long-term results of the old CoCr/CoCr prostheses. In the papers on contemporary CoCr/CoCr prostheses (Schmidt et al. 1996, Streicher et al. 1996, Weber 1996, Semlitsch and Willert 1997), the fact that the linear wear in CoCr/CoCr articulations, 2–20 μm/year, is low compared to that of polyethylene cups articulating against CoCr heads, 100–300 μm/year, is repeatedly emphasized.

The present study focuses on the metal release from total hip articulations. The metal release from CoCr/CoCr articulations was compared to that from CoCr/PE articulations in a wear test done with an established hip joint simulator (Saikko et al. 1992). An alumina/PE articulation served as a control.

Material and methods

Specimens

The femoral heads and acetabular cups were randomly chosen from the hospital supplies. All components came from the same company (Sulzer). Joints 1 and 2 were similar CoCr/CoCr joints, and joints 3 and 4 were similar CoCr/PE joints. The CoCr heads in joints 1, 2, 3, and 4 were similar. Joint 5 was an alumina/PE joint, the polyethylene cup being similar to those of joints 3 and 4.

The heads had a nominal diameter of 28 mm. The CoCr cups were polyethylene cups with a CoCr inlay. They had a nominal outside diameter of 48 mm, were non-metal-backed and were fixed to the simulator with acrylic bone cement. The CoCr, polyethylene, and alumina materials were in accordance with ISO 5832/4, ISO 5834/1 and 2, and ISO 6474 standards, respectively. In the CoCr alloy, the carbon content was 0.2% and the proportion Co/Cr/Ni was 62/28/1.

Simulator

The five-station hip-joint simulator has been described in detail elsewhere (Saikko et al. 1992). Basically, the machine simulates level walking. It includes flexion-extension motion of 60°. The vertical component of the joint load was stationary, relative to the cup. The plane of the rim of the cup was placed at an angle of 45 degrees to the horizontal flexion-extension axis. At the neutral position of the flexion-extension cradle, the neck axis of the head was at an angle of 30° to the vertical. The femoral head-holder made of stainless steel and the taper-fit interface were isolated from the lubricant with a layer of silicone. The cup-holder, made of acrylic, functioned also as the lubricant receptacle.

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The 5 total hip joints were tested simultaneously under identical conditions. The test frequency was 1.1 Hz. The lengths of extension and flexion phases were 2/3 and 1/3 of the cycle time, respectively, and during extension, the load was on (3.5 kN), and during flexion, the load was off (zero).

Lubricant

Sterile filtered adult bovine serum Sigma B-2771 was used as lubricant. The test was stopped for serum retrieval and specimen-cleaning at 0.28, 0.83, 1.37, 1.66, 2.29, 2.82, and 3.21 million cycles. Before each stage, 20 mL of serum was pipetted into each test station. Evaporation during the test was compensated for by Milli-Q-grade distilled water. During the stops, the specimens and their holders were rinsed with a jet of Milli-Q-grade distilled water. The total volume of fluid retrieved from each test station was 100 mL, consisting of the serum used and the rinse water. It was assumed that the retrieved fluid contained all the metal released from the joint. The serum was not in contact with any metallic surfaces other than those of the heads and cups.

Third body particles

At 2.82 million cycles, 10 mg of bone cement particles were applied between the heads and cups. The particles were produced with a fine, carefully cleaned file. The bone cement contained barium sulfate.

Atomic absorption spectroscopy (AAS)

In AAS, all the metal in the sample is dissolved, and so particles are not distinguishable from ions, but the total metal content is quantified. Before the sample was taken, the fluid was thoroughly shaken. For statistical purposes, three analyses were done for each element from each 100 mL lot. Since AAS is expensive and laborious to use, the 0.83 and 1.37 million cycle samples were combined, as also were the 2.29 and 2.82 million cycle samples. Microwave digestions were done in a CEM MDS-2000 oven equipped with a pressure-control unit. A Varian 400P spectrometer with D_2 background correction was used for graphite furnace atomic absorption analyses. The acid used in digestion was HNO_3 (65%, E. Merck, suprapur), and water used for solutions was purified in a Milli-Q reagent grade water system (Millipore). The digestions were carried out in closed Teflon PFA 100 mL vessels. The sample volume was 3 mL and the acid volume was 10 mL. Samples were digested at a pressure of 590 kPa for 1 h. After digestion, the resultant solution was diluted with Milli-Q water. The digested samples were stored at room temperature in bottles made of high-density polyethylene. The digested samples were analyzed for Co, Cr, and Ni. The instrument parameters are given in the Table. A $Pd(NO_3)_2$ matrix modifier was used to analyze Co and Ni, because it improved the signals significantly. Background correction was used to determine Co and Ni, but not Cr, because Cr was analyzed, using a wavelength at which the D_2 background correction was not effective. In the unused serum, the Co, Cr and Ni contents did not exceed detection limits, which were 5 μg/L for Co, and 10–15 μg/L for Cr and Ni.

Instrument parameters in atomic absorption spectroscopy

Element	Wavelength (nm)	D_2	Ashing temp. (°C)	Atomization temp. (°C)
Co	240.7	yes	750	2400
Cr	357.9	no	1000	2600
Ni	232.0	yes	800	2500

Roundness measurements

After the test, the roundness of the heads and cups was measured with a Talyrond apparatus. The roundness was not measured before the test, because of the risk of scratching the metallic bearing surfaces. The measurement plane was the equator on the heads, and the 45° of latitude on the cups. The measurements of the cups were used to the estimate linear wear.

Scanning electron microscopy (SEM)

After the test, the articulating surfaces were characterized with a scanning electron microscope.

Results

Test

The frictional heat usually kept the lubricant bulk temperature close to the body temperature. Protein precipitation was observed in all joints during the test. Within two days of the start, the serum usually turned dark grey in joints 1 and 2, but in joints 3, 4, and 5, it turned creamy white. On joints 1 and 2, tenacious calcium phosphate deposits from serum lubricant were observed outside the contact area. In joint 2, the frictional torque became, suddenly, at 1.66 million cycles, so high that there was visible movement between the CoCr inlay and its polyethylene backing, so the test was not continued with this joint. In the other four joints, the 3.21 million cycle test was uneventful. In joint 1, the bone cement particles had a repairing effect: the articulating surfaces were smoother at 3.21 million cycles than at 2.82 million cycles. After the application of the bone cement particles, no increase

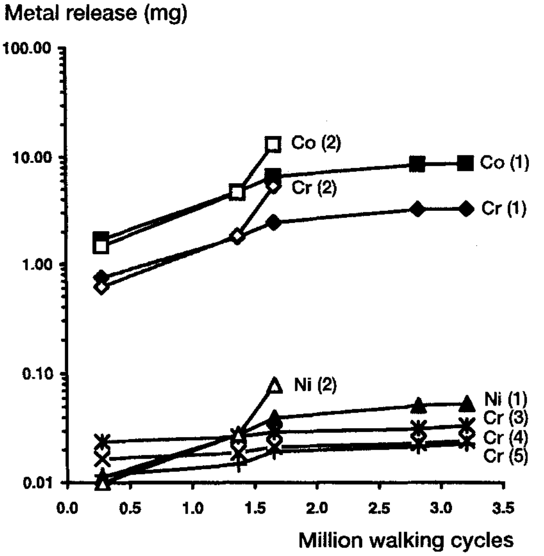

Figure 1. Variation of metal release from articulations with number of walking cycles in hip simulator wear test. Note logarithmic scale of vertical axis.

from the body temperature level occurred in the lubricant of joints 1 and 5, but in joints 3 and 4, the lubricant temperature was about 50 °C.

AAS

The metal content analyses of serum lubricant permitted calculation of the total metal release (Figure 1). Each point was calculated using the average of the three measurements. The repeatability was good, the average standard deviation of the three measurements being 2.3%. The metal releases of Co and Cr were greatest from joints 1 and 2. The total metal release (Co + Cr + Ni) from joint 1 was 12.0 mg after 3.21 million cycles, and from joint 2, 18.6 mg after 1.66 million cycles. A marked increase in Co, Cr and Ni release occurred in joint 2 when it was damaged. Up to 1.37 million cycles, the metal releases from joints 1 and 2 were similar. In joint 1, the application of the bone cement particles virtually stopped the metal release. In lubricants of joints 3, 4, and 5, the Co and Ni contents did not exceed the detection limits, but small amounts of Cr were always detected.

Roundness measurements

The roundness of the heads measured reflected the original roundness, since the measurement track crossed only the fringes of the worn area. In all heads, the deviation from roundness was below the 5 μm limit specified in the ISO 7206-2 standard. Unfortunately, the measurements over the worn area, which could have been used to estimate linear wear, gave unreliable results because the track crossed the taper-fit bore. On the cups, the measurement track crossed the center of the wear 'pit'. The estimates of linear wear in cups 1 to 5 were calculated to be 0.01, 0.01, 0.17, 0.16, and 0.07 mm, respectively.

Figure 2. SEM from articulating surface of head 1.

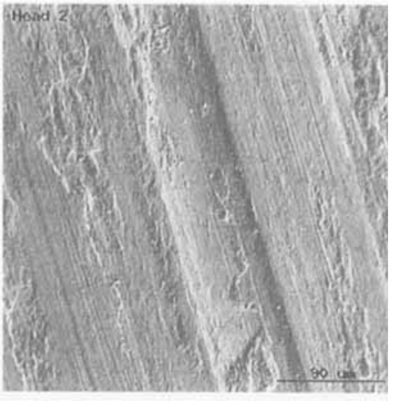

Figure 3. SEM from articulating surface of head 2. Note rougher appearance compared with head 1.

SEM

In joints 1 and 2, grooving of the articulating surfaces occurred, but in joint 1, the surfaces were much smoother than those in joint 2 (Figures 2 and 3). Typical appearances of head 3 and the corresponding cup are shown in Figures 4 and 5. Some acrylic particles adhered to heads 3 and 4 (Figure 6). On heads 3, 4, and 5, streaks were found in the flexion-extension direction. The streaks were probably calcium phosphate, since Ca and P peaks were detected in them by energy dispersive spectrometry.

Discussion

Metal release from implants occurs in the form of both ions and particles. Ion release is caused by corrosion, and particle release by wear. All implant alloys

Figure 4. SEM from articulating surface of head 3.

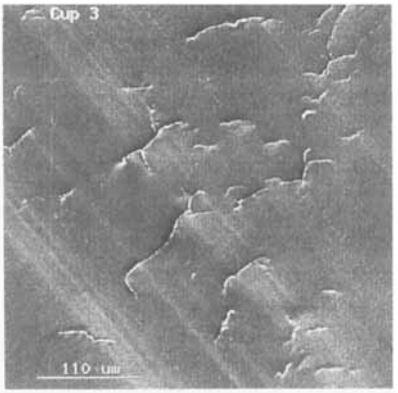

Figure 5. SEM from articulating surface of cup 3.

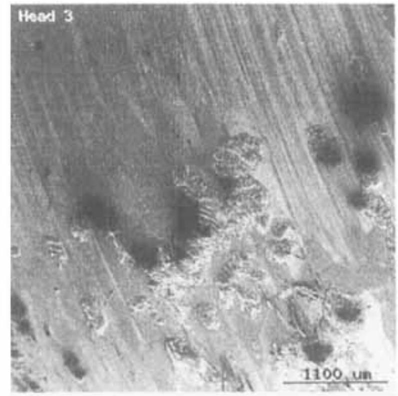

Figure 6. SEM from articulating surface of head 3 showing acrylic particles.

release ions (Steinemann 1980). Laboratory studies have shown that articulation may cause increase in metal ion release, which is attributable to the removal of the passive oxide layer of the metallic bearing surface (Davidson and Kovacs 1989).

When a metallic surface articulates against a counterface made of the same alloy, wear is inevitable, because the lubrication conditions in vivo are not good enough to prevent true metal-metal contact (Walker and Gold 1971, Streicher et al. 1996). The number of metal particles released from CoCr/CoCr articulations appears to be lower than the number of polyethylene particles removed from polyethylene cups, and so the biological reaction to wear particles could be reduced. However, it is possible that metal particles are more harmful than polyethylene particles, due to their shape and smaller size (Pazzaglia et al. 1987). CoCr particles are known to be toxic (Haynes et al. 1993) and conducive to infection (Cordero et al. 1994), induce proliferation of macrophages (Howie 1990), damage macrophages (Rae 1975) and fibroblastic cells (Maloney et al. 1993), reduce the amount of bone (Goodman et al. 1995), and cause malignant tumors in rats (Lewis and Sunderman 1996). The health risk from metal release has been debated. It has even been suggested that CoCr particles could be carcinogenic (Gillespie et al. 1996).

Polyethylene particles are chemically passive under in vivo conditions, but metal particles are not, since they release ions due to corrosion (Shahgaldi et al. 1995). The effective surface area releasing ions increases substantially when wear particles are generated. The typical rate of CoCr wear particle production ranges from 1 to 5 mm^3 per year (Kothari et al. 1996, McKellop et al. 1996). There are billions of metal and polyethylene particles per gram of tissue adjacent to failed hip prostheses (Margevicius et al. 1994).

The average rate of metal release from CoCr/CoCr joint 1 was 3.7 mg per 1 million cycles. This corresponds to 0.4 mm^3/year, as 1 million cycles in the simulator was assumed to correspond to 1 year in vivo, and the density of CoCr was assumed to be 8.33 mg/mm^3. The value is about the same as in the retrieved McKee-Farrar prostheses with the lowest volumetric wear rates (Kothari et al. 1996, McKellop et al. 1996). The damage to CoCr/CoCr joint 2 resulted in steep increases in Co, Cr, and Ni contents of the serum lubricant. In joint 1, the test was uneventful, and the metal contents remained lower. In joint 5, the metal contents were negligible, as can be expected from an alumina/PE joint. The metal contents were negligible also in the CoCr/PE joints 3 and 4.

Only linear wear rates are reported in the papers on contemporary CoCr/CoCr prostheses (Schmidt et al. 1996, Streicher et al. 1996, Weber 1996, Semlitsch and Willert 1997). However, it is the amount of debris generated that is important in regard to the long-term performance of the prosthesis. As the linear wear rate is low compared to polyethylene, there is a deceptive impression that the number of wear particles is negligible. For example, a linear cup wear of 10 μm corresponds to a wear volume of 1.2 mm^3 (Dowson et al. 1993). If the particles are globules with 1 μm diameter, 1.2 mm^3 of debris consists of 2.4 billion particles! Based on the roundness measurement, the estimate of the linear wear rate of cups 1 and 2 was a few μm/year, which is within the range reported for retrieved contemporary CoCr/CoCr prostheses, 2–20 μm/year (Semlitsch and Willert 1997).

Although it is not claimed that the seizure type of damage of joint 2 would be likely to take place in vivo, it should be noted that, in engineering practice, seizure is avoided by explicitly using dissimilar material combinations. Seizure typically occurs when metal slides against a similar counterface under questionable lubrication conditions. In the prosthetic hip, the lubricant is not optimal and cannot be influenced at present. One of the main advantages of the metal on plastic and ceramic on plastic sliding combinations, in general, is that they work satisfactorily even without lubrication. There was no obvious difference between joints 1 and 2 or between the test conditions which would explain the marked difference in their wear behavior. The difference in the clearance was small, 0.08 vs. 0.09 mm. It is possible that the CoCr/CoCr articulation is susceptible to damage in a simulator, but difficult to say whether this has practical significance. In McKee-Farrar prostheses, very high friction was sometimes observed (Walker and Gold 1971) but, in that case, it was due to equatorial contact, caused by inadequate manufacture tolerances.

Bone cement particles between the articulating surfaces were not harmful in regard to metal release. In joint 1, the particles virtually stopped the metal release by acting as a polishing medium smoothing the asperities formed in earlier articulation, which was easily discerned with the naked eye. Polishing is a process in which the smoothing occurs not through the removal of the peaks of the surface roughness, but through the melting of the surface in the micro range, so that the 'peaks' fill the 'valleys' (Burkart and Schmotz 1981). No material is removed. The observation is consistent with the reported self-healing characteristic of CoCr/CoCr articulations (McKellop et al. 1996). In joints 3, 4 and 5, the metal release before and after the addition of bone cement particles was negligible.

CoCr/PE was equal to alumina/PE, as in both of them the metal release was negligible. This is in accordance with clinical studies. In patients with CoCr/PE prostheses, the serum or blood Co and Cr content is elevated only when the stem is loose (Kreibich et al. 1996) indicating that the articulation is not a significant source of metal release. Using inductively-coupled plasma mass spectroscopy, Davidson and Kovacs (1989) observed Co and Cr release from CoCr heads articulating against polyethylene cups in a simple simulator with Ringer's solution, as the lubricant, and bone cement particles caused an increase in Co and Cr release. The differences in the results between the study by Davidson and Kovacs and the present one may be attributed to the difference in lubricants. In fact, the Cr release measured by Davidson and Kovacs was not much higher than that measured from joints 3, 4, and 5 in the present study, 10–20 μg/L, but since joint 5 was an alumina/PE joint, and since the Co content did not exceed the detection limit, these small amounts of Cr hardly came from the CoCr heads. They may have come from the polyethylene cups, since chromium, originating in the manufacturing processes, has been detected in unimplanted polyethylene cups (Meldrum et al. 1993).

The present simulator results on CoCr/CoCr wear are in good agreement with those of earlier simulator studies (Rae 1979, Medley et al. 1996, Streicher et al. 1996), although there were differences in the prosthetic designs and simulators.

We conclude that CoCr/CoCr articulations release substantial amounts of metal, but CoCr/PE and alumina/PE articulations do not. Due to the substantial metal release, more studies are needed on the biological effects of CoCr particles.

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