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Metal-on-metal bearing in hip prosthesis generates 100-fold less wear debris than metal-on-polyethylene

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Aseptic loosening due to osteolysis in total hip replacement has been related to wear debris released from prosthetic components. Retrospective long-term observations of patients with the metal-on-metal prosthesis has shown long-term survivorship and good mechanical performance. Thus, the new and modified metal-on-metal prosthesis has been introduced on the market. Historical clinical data from the 1st generation metal-on-metal hip prosthesis may not be relevant for the 2nd generation of metal-on-metal hip prosthesis. Therefore, preclinical testing of the prosthesis must be conducted before clinical evaluation.

We assessed the tribological performance of the metal-on-metal prosthesis versus the metal-on-polyethylene prosthesis introduced on the market as Metasul™ and Protasul™, respectively. In a 12-channel joint simulator, 6 metal-on-metal bearing and 3 metal on polyethylene prostheses were tested, with the same number of corresponding soak controls. The wear was assessed gravimetrically. The "steady-state" wear-rates from the metal-on-metal prosthesis were almost 100 times less than that from the metal-on-polyethylene prosthesis. The tribological wear performance of the metal-on-metal hip prosthetic system is promising.

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In total hip replacement, polyethylene debris has been thought to play a key role in osteolysis. A positive correlation has been reported between the amount of polyethylene debris and the degree of osteolysis (Willert 1977, Amstutz et al. 1992, Kadoya et al. 1998, Oparaugo et al. 1998). The consensus of a study group concerning the metal-on-metal hip prosthesis system was that factors implicated in failures of 1st generation metal-on-metal devices were neck-socket impingement and high frictional-torque with higher loosening and infection rates (Amstutz and Grigoris 1996, Schmalzried et al. 1996). Moreover, there were concerns about unknown factors such as metal sensitivity, toxicity and carcinogenic potential. Analysis of the metal-on-metal hip prosthesis, retrieved after 20 years in service, has demonstrated negligible surface wear and minimal amounts of metallic particles in the peri-implant tissues (Müller 1995, Schmalzried et al. 1996, Weber 1996). This has given rebirth to the 2nd generation metal-on-metal bearing arthroplastic concept with improved bearing tolerances (Müller 1995).

The historical data about metal-on-metal bearing implants cannot be translated to the new metal-on-metal bearing systems, because several features have been changed. Many studies have reported changes in prosthetic design, materials and fixation, which have led to catastrophic clinical results (Ohlin 1990, Engestaeter et al. 1996, Nilsen and Wiig 1996, Livingston et al. 1997, Graeter and Nevins 1998). Therefore, there is a need for combined preclinical and clinical studies before their general use. In this preclinical study, we tested the tribological wear performance of the metal-on-metal prosthesis compared to metal-on-polyethylene.

Material and methods

The metal-on-polyethylene systems, Protasul, with 28 mm CoCr heads and polyethylene cups (2.5 Mrad/N_2 sterilized) and the metal-on-metal bearing systems, Metasul, 28 mm CoCr head/CoCr cup combinations (gamma-sterilized) were

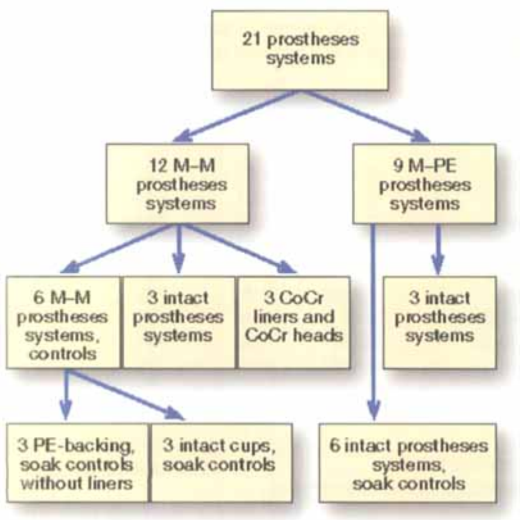

Figure 1. Study design and summary of metal-on-metal bearing (M-M) and metal-on-polyethylene (M-PE) implants tested in wear and control categories in the hip-simulator.

received from Sulzer Inc., Winterthur, Switzerland. The implants were tested in 2 phases: phase 1 was 0–5 million cycles (Mc), followed by a 4-week gap (Christmas period) and phase 2 was 5–10 Mc. Phase 1 used 6 (3 each of wear and soak) CoCr heads on polyethylene cups and 6 CoCr heads on Metasul cups (with PE backing). Phase 2 continued with the 3 CoCr/PE combinations and 3 of the Metasul combinations and the other 3 Metasul liners were made removable from their PE (Figure 1). Phase 2 tested the same number of corresponding soak controls.

The implants were run in a multi-station (Figure 2) servo-hydraulic hip simulator (Shore Western Manufacturing Inc, Monrovia, CA) under the PAUL load-profile, which is a physiological walking simulation with continuous cyclic motion and loading (2kN peakload; 1Hz). The prostheses were mounted in dynamic and static stations. Bovine serum (70 mg/mL protein concentration, Hyclone Inc., Logan, UT) was used as lubricant with 10% volume additives (sodium azide and EDTA) to prevent microbial growth and minimize calcium phosphate formation on the implant surfaces. Lubricant temperatures were monitored twice a day (19°–24 °C). Lowering the room's temperature prevented high temperature in the lubricant, which can cause higher precipitation, changes in protein molecules and lubrication properties. The

Figure 2. A station in the hip joint-simulator.

CoCr heads were cleaned and weighed while still mounted on their taper-cones to avoid metal-transfer problems created by dismantling. Wear was assessed by weight-loss techniques at intervals of approximately 500,000 cycles. An unmounted, untested 32 mm CoCr ball was used as a weight-control in all cleaning procedures and weight-measurements.

Volumetric wear-rates were calculated to compare the amount of wear debris produced by the implant materials of different densities (CoCr 8.3 mg/mL; polyethylene 0.936 mg/mL). Gravimetric wear-assessment of implants with polyethylene components requires concomitant implants for soak control studies, since there will be weight-changes created by fluid absorption into the polyethylene material. The control soak-cups were dynamically loaded in bovine serum identical to the wear cups to monitor fluid absorption.

Results

The PE-backed CoCr liners used in phase 1 had weight gains (serum absorption) larger than their corresponding soak-control cups. The compara-

Summary of metal-on-metal and metal-on-polyethylene prosthetic system wear and other data. The high level of CL in liners is probably due to the extreme low amount of wear

ID No.	Simulator	Implants	No.	R^2	W (mg/Mc)	95%CL
W1	Wear-stations	Metasul heads	6	0.443	0.7	27
W2	Wear-stations	Metasul cups	3	0.38	0.91	48
W3	Wear-stations	Metasul CoCr liners	3	0.109	0.29	100
W4	Wear-stations	PE cup (CoCr heads)	3	0.962	10.32	7
W5	Wear-stations	CoCr heads (PE cups)	2	0.409	0.24	53
S1	Soak-stations	Metasul PE sleeves	3	0.449	0.75	39
S2	Soak-stations	Metasul cup (CoCr+PE)	3	0.69	2.04	20
S3	Soak-stations	HB1 Co Cr Control head	1	0.121	0.03	NA
S4	Soak-stations	PE Cups	6	0.683	0.64	16

Soak-stations are controls
R^2 R squared (regression coefficient)
W (mg/Mc) mean wear-rate (mg weight-loss per million cycles)
95% CL 95% confidence limits expressed as percentage of mean wear-rate
NA not applicable

tive wear measurements could be made only in phase 2, in which three Metasul liners had been made removable from their PE-backing. This represented the "steady-state" wear-phase (Schmalzried et al. 1998a). The Metasul system averaged a weight loss of 0.70 and 0.29 mg/Mc (0.084 mm^3/Mc and 0.035 mm^3/Mc) for heads and liners, respectively (Table). We also noted that one of the CoCr heads (metal-on-polyethylene) had large weight variations. These were considered unreliable data and were excluded from the set. The stable weight-loss trend for the two remaining CoCr heads averaged 0.24 mg/Mc (0.03 mm^3/Mc; Table). The Metasul heads wore 2.4 times more than their CoCr liners (metal-on-metal bearing) and 3 times more than the CoCr heads in the metal-on-polyethylene system. ANOVA statistics showed that the Metasul heads had significantly ($p = 0.004$) higher wear rates than the other CoCr components (Table).

For polyethylene cups bearing on CoCr heads in the Protasul system, the linear wear-trend from 5.15 million to 10 million cycles averaged 10.32 mg/Mc in weight-loss (Table). Adjusting for the corresponding polyethylene soak control-cups which gained 0.64 mg/Mc (6.8% of the gross-wear), the net polyethylene weigh loss was 10.96 mg/Mc (11.70 mm^3/Mc). The absorption-gain in the removable polyethylene-backing was 0.75 mg/Mc (Table). The Metasul wear-cups (PE-backing intact) showed a 0.91 mg/Mc weight gain, compared to the 2.04 mg/Mc weight gain in the corresponding Metasul soak control-cups. Subtracting soak-controls from wear-cups would have created an apparent net weight loss of 1.13 mg/Mc. The weight variation in the control CoCr head averaged 0.047 mg (SD 0.136) during this test period.

Discussion

We found that the metal-on-metal bearing system generated 100-fold less volumetric wear than the conventional metal-on-polyethylene system. This is significantly lower than the wear rate from ceramic-on-polyethylene systems which have been giving a wear reduction of about 2-fold (Clarke and Gustafson 1996, Clarke et al. 1996). Thus, the metal-on-metal bearing system confers a significant reduction in volume of particulate material shed into the periprosthetic tissues. In this study, the Protasul heads (metal-on-polyethylene) and the Metasul heads (metal-on-metal bearing) wore at the rate of 0.24 and 0.70 mg/Mc, respectively. The Metasul steady-state wear-rates from 1 to 10 million cycles were encouragingly low in the simulator studies, i.e., 0.035 and 0.085 mm^3/Mc for CoCr liners and heads, respectively, and 0.12 mm^3/Mc in combination. However, there was an increase in wear of nearly 3 times for Metasul heads, compared to Protasul heads in vitro.

We have reported scattered results with high variability about the mean. Too small implant numbers, and a limited detection level are common weaknesses in such studies. This is not unique in our study and the majority of investigators who have done tribological experiments have experienced the same limits (Medley et al. 1996). Nevertheless, the liner/head wear ratio in our study was 40%, which complies well with clinical reports (Rieker et al. 1998). Linear wear measurements of metal-on-metal bearing versus metal-on-polyethylene systems have predicted wear reductions in the range of 50–150 times, using dimensional techniques such as contour-measurement methods (Streicher et al.1996, Rieker et al. 1998).

To reduce the serum degradation and calcium coating on the implant's surface which, in turn, would increase the surface roughness and ultimately the wear ratio, it was necessary to keep the lubricant temperature lower than the body temperature. Adding EDTA to the lubricant reduced the calcium-coating phenomena but the focal frictional heat generation caused serum degradation and probably calcium-coating. Throughout this study, attention was paid to the serum temperature, chamber replenishment rates and color of the serum, looking for any signs which would indicate abnormally high wear rates of the Metasul implants. Other investigators have noted the effects of high frictional torques and grey discoloration of the serum confounding the results (Saikko et al. 1998). However, we did not observe such phenomena in this study. It may be that experimental differences, such as the volume of lubricant and the lubricant's temperature, between the simulator studies accounted for the differing reports. We found excellent tribological performance of the metal-on-metal bearing system according to the volumetric wear of both metal-on-metal and metal-on-polyethylene prosthetic systems.

It is important to note that the factors which influence the fate of an implant include: 1) material of the prosthesis and amount of wear, 2) fixation and load sharing of the implant, 3) surgeon-related factors, and 4) patient-related factors. In this study, we have shown that the amount of the volumetric wear in metal-on-metal bearing is much less than with the metal-on-polyethylene prosthesis system measured by weight loss. It should be noted that the results of a joint simulator study of a prosthesis describe tribological properties while a radiostereometry (RSA) study shows micromotion of the prosthetic system, which reflects only the implant's fixation and stability in vivo. Reports on anyone of these factors alone cannot predict the final outcome of THR. Long-term randomized multi-center clinical studies in combination with retrieval analysis should provide the investigators with accurate information about these factors. A combined joint simulator and RSA study may offer a short-cut for evaluation and prediction of the fate of the new prosthesis, covering to a certain extent both surgeon- and patient-related factors.

The total Metasul wear was almost 1 mg/Mc, with the heads contributing 71% of that volume. 1 million cycles in a hip-joint simulator has been compared to 1 year of prosthetic use by the patient. However, a recent study (Schmalzried et al. 1998b) indicated that more active patients accumulated up to 3.5 million cycles per year (the maximum rate was seen in an athletic 72-year-old man). Therefore, in the active patient averaging 3.5 Mc/year, this could represent a bioburden of metallic wear in the order of 3 mg/year, while in the patient with low level activity, it is close to 1 mg/year. Serum and urine analyses in THR patients with a 1st generation metal-on-metal prosthesis showed that cobalt and chromium levels were increased 4-fold, when comparing metal-on-metal bearing to metal-on-polyethylene systems (Jacobs et al. 1996a, b). Investigators who study the toxicological importance of trace elements such as Co, Cr and Mo should be aware that the CoCr/polyethylene prosthetic system can release 25% of the metallic wear burden of the metal-on-metal bearings, as has been shown in this study. Although the metal-on-metal prosthesis eliminates the concerns over polyethylene particulate disease, it introduces other concerns due to metallic corrosion products and wear particles in patients (Black 1996, Bouchard et al. 1996). While there are concerns about unknown factors, such as metal sensitivity toxicity, carcinogenic potential, because of non-uniformity of evaluation and incomplete follow-ups, the usefulness of the 1st generation metal-on-metal bearing data is difficult to assess (Amstutz and Grigoris 1996, Black

1996, Schmalzried et al. 1996) and their relevance is uncertain. The metallic ion can be dissolved in body fluid and eliminated from the patient's body while the polyethylene wear cannot. Which one of these particles, metallic or plastic, is more harmful to the host is a question for future biocompatibility investigations and cannot be accurately answered by a tribological study.

The results of our laboratory experiments with the Metasul hip prosthetic system is promising. At the Karolinska Hospital, we have initiated both an in vitro biocompatibility analysis and a prospective randomized clinical study. These will focus on implant migration assessed by radiostereometry and monitor the serum and urine levels of ionic Co and Cr, for comparison with our simulator studies.

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