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Analysis of 118 second-generation metal-on-metal retrieved hip implants

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Osteolysis is due to particulate wear debris and is responsible for the long-term failure of total hip replacements. It has stimulated the development of alternative joint surfaces such as metal-on-metal or ceramic-on-ceramic implants.

Since 1988 the second-generation metal-on-metal implant Metasul has been used in over 60 000 hips. Analysis of 118 retrieved specimens of the head or cup showed rates of wear of approximately 25 µm for the whole articulation per year in the first year, decreasing to about 5 µm per year after the third. Metal surfaces have a 'self-polishing' capacity. Scratches are worn out by further joint movement. Volumetric wear was decreased some 60-fold compared with that of metal-on-polyethylene implants, suggesting that second-generation metal-on-metal prostheses may considerably reduce osteolysis.

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Osteolysis is due to particulate wear debris[1,2] and is mainly responsible for the long-term failure of total hip replacement (THR).

The Charnley THR has been shown to give satisfactory clinical results with a survival rate of 85% at 20 years. When radiological evidence of loosening was added to that seen at revision operations, 22% of the acetabular and 7% of the femoral components were considered to be unstable.[3] Polyethylene wear was shown to be significantly related to acetabular loosening and resorption of the femoral neck in nearly two-thirds of cemented THRs in patients younger than 20 years at the time of operation.[4]

About half a million polyethylene wear particles are produced at each step due mainly to abrasive wear.[5,6] Contact of particle-laden articular fluid with the surrounding bone could be a key factor in the development of osteolysis. Joint fluid under pressure invades soft tissues and bone and expands the effective joint pace.[7] As a result, activated macrophages may be found in cysts around the prostheses.[8]

It is not only the concentration of accumulated polyethylene particles which affects the amount of osteolysis, but also their capacity for phagocytosis.[9,10] Particles with a critical size of between 0.5 and 10 µm are needed to induce the secretion of interleukin-6 by macrophages in vitro.

It is still unclear as to whether polyethylene or cement debris induces more osteolysis. Severe lysis around a stable uncemented press-fit titanium shell is a clear indication of polyethylene wear.[11] Polymethylmethacrylate (PMMA) cement alone is less harmful if it does not contain radiopaque additives. In vitro, monocytes and macrophages responding to particles of bone cement are capable of differentiation into osteoclastic cells. Their capacity for bone resorption is activated only when radiopaque additives are introduced with the cement particles, with a doubling of the rate for Ba_2SO_4 compared with ZrO_2.[12] Osteolysis therefore has a multifactorial pattern and the biological activity of all possible wear particles has to be considered when introducing new implants.[13]

There have been many attempts to find a solution to the problem of wear. Trials of an improved polyethylene have not been convincing,[14,15] but various types of modified polyethylene are still being developed.[16] The first use of metal-on-metal surfaces was by Wiles[17] in 1938 with a stainless-steel implant. The unsatisfactory results induced McKee to employ cast cobalt alloy. From 1962 onwards metal-on-metal prostheses were increasingly rivalled by the metal-on-polyethylene implant of Charnley. Both prostheses contributed to the success of THR in the 1960s.[18] The better results achieved with metal-on-polyethylene implants almost led to discontinuation of the use of metal-on-metal prostheses.

A long-term study by Jacobsson, Djerf and Wahlstrom[19] confirmed that the 20-year cumulative probability of aseptic survival was 77% for the McKee-Farrar prosthesis and 73% for the Charnley prosthesis. These findings have shed new light on the mechanisms of wear and subsequent osteolysis with metal-on-metal prostheses.

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In 1970, Boutin[20] developed an alternative alumina-on-alumina implant. Although this combination has very low wear and is still used in Europe, its popularity remains limited because of the possible fracture of the brittle components.[21]

Based on their findings of low wear and minimum osteolysis with retrieved Müller-Huggler prostheses, Weber and Fiechter[22] developed a new metal-on-metal implant called Metasul (Sulzer Orthopedics Ltd, Winterthur, Switzerland). This second-generation prosthesis has been used in over 60 000 THRs since 1988.

We now present a critical analysis of the wear pattern observed in the first 118 received implants (heads or cups) that have been collected by the laboratories of Sulzer Orthopedics Ltd.

Materials and Methods

The 118 single metal-on-metal implants (65 heads and 53 cups) retrieved were made of wrought Co-28Cr-6Mo-0.12C alloy (ASTM F-1537/ISO 5832-12); 115 had a diameter of 28 mm and three of 32 mm. Over 80% were uncemented. The mean time of implantation was 22 months (2 to 98).

Revision was for recurrent dislocation (24%), loosening of the stem (17%), loosening of the cup (28%) and other reasons such as infection or ectopic ossification in 31%.

We used a co-ordinate measuring machine with a resolution of less than 1 μm to determine the wear of the components. Measurements were made every 7.5° on 12 concentric circles (577 measurements for each component). Wear is defined by the maximum deviation from ideal sphericity. This method gives values for the highest local wear for a component. The volumetric wear of the components was calculated by the method of Willert et al.[23]

Results

Linear and volumetric wear. We found two patterns of wear, a moderate rate of between 20 and 80 μm/year and a low rate below 20 μm/year (Fig. 1). The five components with moderate rates of wear were revised for mechanical reasons, three for recurrent dislocation, one for tilting of the cup and one for a 'squeaking hip'.

The mean annual rate of wear in vivo was found to decrease with the time from insertion. For the entire implant the rate was 25 μm/year for the first year and about 5 μm per year after the third year (Fig. 2).

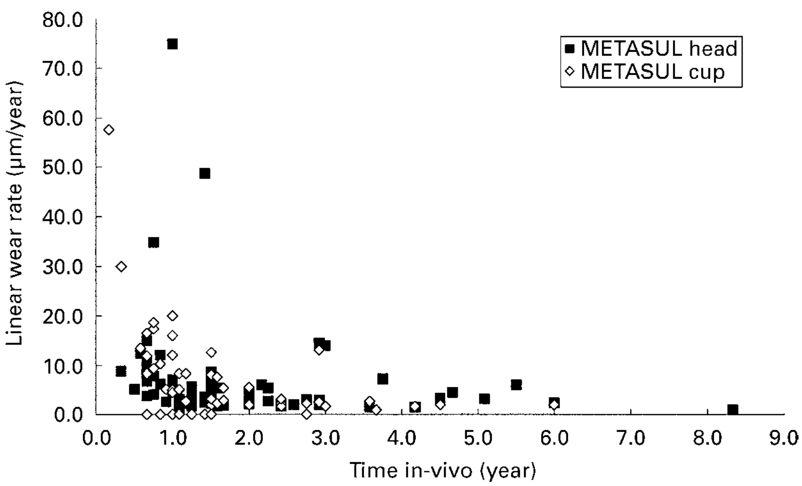

Fig. 1

The rate of maximum wear for the head or cup in vivo related to the time of implantation for the 118 components.

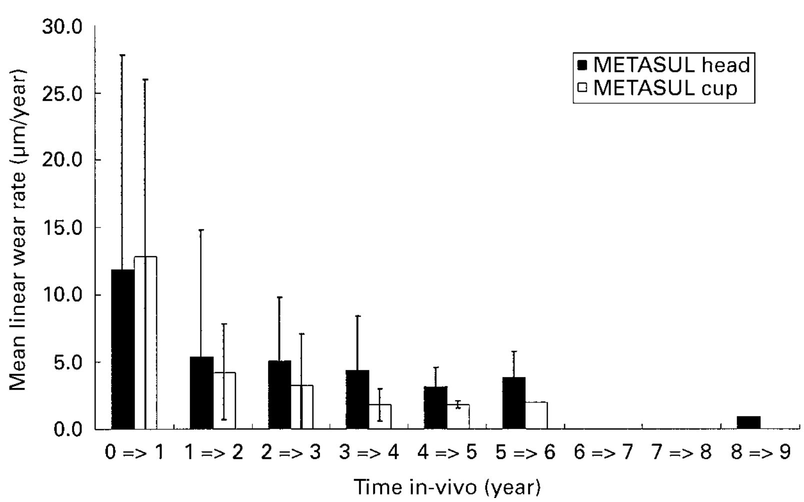

Fig. 2

The annual mean rate of maximum wear for the head or cup in vivo related to the time of implantation for the 118 prostheses. One standard deviation is shown.

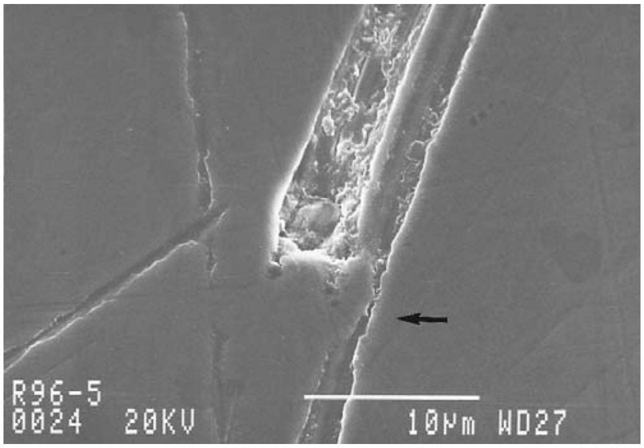

Fig. 3

Scanning electron micrograph of a typical worn surface of a second-generation metal-on-metal implant. The polishing effect is indicated by the arrow.

According to the formula of Willert et al,[23] the volumetric wear volume after the run-in period was estimated to be 0.3 mm^3/year.

Wear pattern. Figure 3 shows the typically worn surfaces of the metal-on-metal implants, common to all specimens. There are two types of scratch: relatively large, with a width and depth of about 5 µm and a length of about 3 mm, and minor, which are 'polished' large scratches due to the remarkable ductility of the cobalt alloy. The latter were observed in the first generation of McKee-Farrar and Müller-Huggler prostheses.[24]

Discussion

Wear rate of the metal-on-metal retrieved implants. The linear rate of wear of 5 µm per year is at least 20 times less than that of prostheses with a polyethylene cup. The volumetric rate of wear of 0.3 mm^3 per year is at least 60 times less than the clinical volumetric wear rate measured for prostheses with a polyethylene cup (17.9 mm^3/year) because of the smaller clearance of the metal-on-metal implant.[25]

Four of the prostheses with a moderate rate of wear were unstable and this affected the geometry of the implant. This is some ten times higher than that for typical metal-on-metal implants, but much less than for the polyethylene in metal-on-polyethylene or ceramic-on-polyethylene prostheses.

In the fifth retrieved specimen with a moderate rate of wear the 'squeaking' may have been due to a partial deficiency of lubrication allowing some resonance or slip-stick mechanisms (instability in frictional behaviour) to occur. A 'squeaking' articulation was simulated in vitro with a Charnley pendulum by running the articulation with insufficient lubrication.

Biological activity of metal wear particles. Willert and Semlitsch[26] found that the cellular reaction to metal wear particles was always lower than that to bone-cement particles. The low metal content in the tissues surrounding a metal-on-metal implant was found to correspond to the wear measurements. In most cases the tissue content of PMMA is much greater than that of metal.

Doorn et al[27] found that the metal wear particles from McKee-Farrar and Metasul implants had a smaller diameter (<0.1 µm) than polyethylene particles from conventional implants (about 0.5 µm). Although the metal-on-metal implants have a lower volumetric wear, the calculated number of wear particles is higher than for the same volume of polyethylene wear. The granulomatous inflammatory reaction and the presence of foreign-body giant cells, however, were less pronounced around the metal-on-metal implants. This paradox may be explained either by the excretion process observed for Co and Ni components[23] or by the smaller size of metal particles (<0.1 µm). Green et al[9] have shown that only polyethylene particles of a defined size (0.5 to 10 µm) can induce secretion of interleukin-6 in macrophages with the subsequent formation of granuloma and hence osteolysis.

The actual metal ion concentration of the biologically active elements Cr and Ni was calculated to be much less than the results of atomic absorption spectral analysis suggested at first sight. It has been shown that Cr is bound in insoluble compounds and that Co and Ni were eliminated by natural excretion.

There has also been interest in the distant reactions of the resorbed and, in some cases, excreted metal ions.[25] Elevation of urinary Co in patients with CoCr alloy implants has been reported to be between 5 and 22 µg/l for porous Austin-Moore prostheses, but this was transient.[28] In comparing patients having a metal-on-metal implant with those with a ceramic-polyethylene prosthesis containing no cobalt, Brodner et al[29] found a mean level of Co of 1.1 µg/l after one year in the metal-on-metal group, which was significantly higher than that in the control group, which had a median below the detection limit of 0.3 µg/l. This was confirmed by Jacobs et al[30] who analysed the concentration of Co and Cr in the serum and urine of two groups of patients with metal-on-metal implants followed up for over 20 years. The measured Co concentration in the serum was 0.9 µg/l.

Hildebrand et al[31] studied body fluids and local tissue samples from patients before and after removal of devices such as intramedullary nails, plates and screws. They found that all the implants had large areas of corrosion. The metabolism and liberation of the corroded metal ions differed. Ni and especially Cr were observed as extra- and intracellular precipitates whereas Co seemed to be bound to tissue in an unprecipitated form. In view of their number, the length of time of implantation and the few reports of adverse effects, the impact of high levels of metal ions on the body may be questioned. The effect of an excessive intake of Co in the body is unclear. In an experimental study on rabbits, Goodman et al[32] showed that the presence of Co-base alloy particles may inhibit bone growth, and Allen et al[33] reported that Co was toxic to osteoblast-like cell lines and inhibited the production of type-I collagen, osteocalcin and alkaline phosphatase.

Carcinogenic risk. Several reports[34-37] have discussed an increased risk for the development of remote tumours of the lymphatic and haemopoietic systems from wear particles. Visuri and Koskenvuo[38] reported a 3.8-fold increase in the rate of leukaemia in patients with McKee-Farrar prostheses compared with those with metal-on-polyethylene implants. The difference, however, was not statistically significant and it was stated that factors other than THR may play a major role in the origin of cancer. A cohort study by Mathiesen et al[39] did not support a carcinogenic role for THR. Like Gillespie et al,[35] they found an increased risk in the first year, but when the second year after implantation was included there was no increase in the number of malignancies. They assumed that these must have been accidental findings in routine testing and not related to any implant. Langkamer et al[40] reviewed the reports of the Bristol Bone Tumour Register on 240 malignant soft-tissue sarcomas; 18 patients had sarcomas in the thigh and four in the soft tissues around a THR. Two of the latter were leiomyosarcomas and two malignant fibrous histiocytomas (MFH). The prostheses were made of stainless steel which contrasts with previous reports of the formation of MFH around cobalt-chrome implants. Hence, no risk factors could be determined.

Despite the evidence that the incidence of malignant tumours after joint reconstruction must be very low,[41] the issue of potential carcinogenesis is still a concern.

Comparison with ceramic-ceramic implants. After its introduction in the 1970s alumina has been used widely for the head to articulate with a polyethylene cup. It has maintained its position despite reports of fractures of the head[42] and has proved successful in reducing the amount of polyethylene wear.[43] The introduction of ceramic-on-ceramic articulating surfaces did not achieve the same success. There are many reports of problems related to the brittle material,[44] insertion and design.[45,46] Studies in France on cemented alumina implants revealed problems of fixation of the acetabular cup and early deterioration of the cement mantle giving rise to third-body wear. Since this wear was attributed to the zirconia particles used to opacify the bone-cement particles and not to the alumina particles, uncemented fixation has been recommended.[47]

In retrieved implants, a rate of wear of 8 μm per year was measured for the cup and head.[48,49]

Alumina particles were found to be widespread in periarticular lymphatic tissues, but the tissue reaction proved to be low. By contrast, zirconia particles produced marked activation of macrophages and an inflammatory reaction.[47] Although alumina wear has been said to be substantially inert,[46] there has been a recent report of a spontaneous fracture of the distal femur in a patient with an uncemented ceramic-on-ceramic THR.[50] Material obtained from the area of fracture showed abundant histiocytes and spectrography revealed concentrations of aluminium ten times higher than those of Co and Cr. The fracture was attributed to the foreign-body reaction to the large amount of ceramic particles and the subsequent osteolysis.[10]

There is also concern about the abrasive potential of these ceramic particles because of their extreme hardness. It is impossible to remove all the ceramic particles, in revision of a failed ceramic-on-ceramic prosthesis, and Kempf and Semlitsch[51] have reported the massive wear of a steel head articulating against a polyethylene cup in such a case.

In addition to the need to inform patients about the potential carcinogenic risks for metal-on-metal implants,[41,52] we recommend that attention be drawn to the impossibility of replacing the ceramic prosthesis with anything other than an implant of the same degree of hardness. This could pose a considerable challenge if a fractured ceramic head damaged the metal Morse taper of the stem.[53] Since a ceramic head should only be used on an intact Morse taper, revision of the stem would then be necessary even if it were absolutely stable.

Conclusions

1) Metal-on-metal implants have a volumetric rate of wear 60 times lower than that of polyethylene implants.
2) In retrieved specimens less osteolysis was observed with metal-on-metal implants, suggesting that the biological response is influenced more by the size of the wear particles than by the total amount of debris. The solubility of metal wear particles could lead to an improved tissue-clearing capacity and might be one explanation for the reduced induction of osteolysis by metal-on-metal implants.
3) There is an increase in the Co concentration in the serum and urine in patients with metal-on-metal implants. No clinical abnormality can be attributed to this finding even after an implantation time of ten years.
4) The rate of wear of the metal-on-metal implants which we studied is lower than that of metal-on-polyethylene implants and therefore the second-generation metal-on-metal implants may increase the survival of THRs. Complete follow-up studies over a period of more than 30 years are necessary, especially for younger patients.

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