MINI-SYMPOSIUM: HIP REPLACEMENT

(iv) The science of metal-on-metal articulation

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Summary In recent years there has been renewed interest in metal-on-metal (MOM) bearings for both total hip replacement and surface replacement hip arthroplasty. Short-term clinical results have been encouraging; with low wear rates and few prostheses requiring revision. This review concentrates on the factors that affect the wear of all metal devices such as specification of the alloy, processing techniques, head diameter, clearance between the components, lubrication regime, loading and surface finish. The concerns associated with MOM bearings are also discussed. These include wear particle release and dissemination, and elevated metal ion levels, which may lead to cytotoxicity, hypersensitivity and genotoxicity.

Introduction

The majority of the 800,000 total joint replacements (TJRs) performed worldwide each year are hip replacements and comprise a metal femoral head articulating on an ultra-high molecular weight polyethylene (UHMWPE) acetabular cup. The biological response to UHMWPE wear particles, generated at the articulating surfaces, leads to the production of inflammatory cytokines, bone resorption and eventual osteolysis. A revision operation is then required, which has implications for both the patient and the healthcare provider whilst the ageing population becomes more active and lives longer, an increasing number of prostheses are being implanted into younger patients. Consequently, implant longevity has become more important. The management of an arthritic hip in young active patients represents a challenge to the orthopaedic surgeon. Average survivor rates for males under 55 years fall as low as 70\% at 10 years for conventional hip arthroplasty. Metal-on-metal (MOM) articulations have been seen as one potential solution to the problems associated with UHMWPE-induced osteolysis. The observation that a small number of patients with first-generation MOM prostheses exhibited good clinical and radiographical results after 20 years in vivo led to the development of second-generation MOM hip prostheses, and in 1988 the Metasul prosthesis was...
introduced into clinical practice. This comprised of a cobalt chrome alloy femoral head articulating on a cobalt chrome alloy acetabular cup. Over 200,000 Metasul combinations have been implanted to date. Short-term clinical performance has been encouraging; with low wear rates, and few prostheses requiring revision. However, long-term clinical performance is as yet unknown.

Hip resurfacing offers an alternative for younger more active patients, as it has many theoretical advantages over conventional THR, including femoral bone preservation, reduced risk of dislocation and increased range of movement that can benefit this particular group of patients. The results of the early hip resurfacing prototypes using non-MOM articulations did not meet expectations and early failures were seen as a result of cup loosening and femoral collapse. Recently, several MOM hip resurfacing prostheses have been reintroduced with improved design and manufacturing. The early clinical results of these new MOM resurfacing prostheses are encouraging, and as a result this type of prosthesis is gaining popularity with patients.1

Wear performance

A low wear rate is believed to be critical for extending the implant life of a prosthetic joint, and wear volumes produced by MOM articulations have been estimated to be 40–100 times lower than metal-on-polyethylene bearings.2 The wear of MOM prostheses is known to be highly dependent upon the materials, tribological design and finishing technique. Clinical studies of retrieved first and second-generation MOM hip prostheses have shown linear penetrations of approximately 5 μm/year.1 This is equivalent to a wear volume of approximately 1 mm³/year, two orders of magnitude lower than conventional polyethylene acetabular cups. The wear of hard-on-hard bearings such as MOM hip prostheses has two distinct phases. An initial elevated bedding in wear period occurs during the first million cycles or first year in vivo. This is followed by a lower steady-state wear period once the bearing surfaces have been subjected to the self-polishing action of the metal wear particles, which may act as a solid-phase lubricant.3 Hip-joint simulators have generally shown steady-state wear rates to be lower than those reported in vivo.4.5 Wear simulators represent ideal articulation conditions during the walking cycle. The reality in vivo may differ markedly in terms of surface finish, fluctuations in load, and range of motion. The difference between low in vitro wear in simulators and in vivo wear has been investigated through studies with elevated loads, stop/start motion,5,6 and different kinematics.7,8 These studies have shown that changes in tribological conditions resulted in an increase in wear rates. These factors together with the effect that head diameter and diametral clearance have on the wear of MOM hip prostheses will be discussed in more detail below.

Tribology of metal-on-metal bearings

The tribology of MOM bearings is dependent on many factors including metallurgy, the design of the prosthesis and its geometry, the lubrication of the surfaces, the loading regime and the kinematics that the prosthesis is subjected to.

Metallurgy

It has long been recognised that cobalt chromium molybdenum (CoCrMo) alloy represents the preferred material for MOM hip prostheses. However, the use of wrought or cast materials, with or without heat treatment, and low (<0.05% w/w) or high (>0.2% w/w) carbon content alloys have been fiercely debated. The effects that these variations in material have on the wear rate and hence the production of wear particles and release of metal ions, have been widely studied. Both processing method and carbon content have an effect on the micro-structure of the CoCrMo alloy. The distribution of the carbides in low and high carbon content CoCrMo alloys differs, with the high carbon content alloys demonstrating a biphasic structure, which is comprised of small grains of CoCrMo surrounded by embedded hard, scratch-resistant carbides which restrict the grain size.3 The low carbon content alloys comprise a single-phase structure with larger grains than the high carbon alloys, probably due to the absence of carbides. The low carbon content alloys have decreased hardness due to the lack of carbides. Wrought high carbon content CoCrMo alloys differ, with the high carbon content alloys demonstrating a biphasic structure, which is comprised of small grains of CoCrMo surrounded by embedded hard, scratch-resistant carbides which restrict the grain size.3 The low carbon content alloys comprise a single-phase structure with larger grains than the high carbon alloys, probably due to the absence of carbides. The low carbon content alloys have decreased hardness due to the lack of carbides. Wrought high carbon content CoCrMo alloys have a fine distribution of small carbides. High carbon content cast alloys exhibit large blocky carbides. Low carbon content alloys produce significantly higher wear rates than high carbon content alloys in both simple configuration wear tests and hip-joint wear simulator tests.3,4,9 Hence, the pairing of low carbon cups with low carbon femoral heads is not recommended. High carbon/ high carbon pairings show the lowest wear rates in hip-joint simulator tests.4,9 Dowson et al.10 compared the wear rates of cast and wrought CoCrMo
alloys with and without various heat treatments. These authors reported no significant differences between the wear volumes of the wrought and cast high carbon CoCrMo materials. However, the wrought material exhibited a slight, non-significant advantage over the as cast material. Heat treatments and hot isostatic pressing have been shown to have little effect on the wear rate of MOM hip prostheses.10

Design and geometry

The effect of head diameter and diametral clearance will be considered here. Head diameter is becoming increasingly important as MOM resurfacing prostheses gain popularity with surgeons and younger patients. This type of prosthesis has the advantage of conserving bone on the femoral side, is less invasive and may 'buy time' until a total hip arthroplasty is necessary. Resurfacing prostheses cover the femoral head and therefore have large diameter femoral components, the average being in the region of 54 mm. Smith et al.11 considered the effect of increasing head diameter on the wear of MOM hip prostheses. These authors tested 16, 22.225 and 28 mm diameter CoCrMo alloy femoral heads against CoCrMo alloy acetabular cups in a hip-joint simulator and found that with increasing head diameter, volumetric wear rate increased firstly and then decreased. Wear volumes were highest for the smallest diameter heads, at 4.85 and 6.30 mm³/10⁶ cycles, respectively, for the 16 and 22.225 mm diameter heads. There was a marked decrease in wear exhibited by the 28 mm diameter heads, with bedding in wear of 1.60 mm³/10⁶ cycles and a steady-state wear of 0.54 mm³/10⁶ cycles. Dowson et al.12 also investigated the effect of increasing head diameter on the wear of MOM bearings, testing 36 mm conventional hip prostheses, and 54 mm diameter resurfacing prostheses in a hip-joint simulator. Stable run-in surfaces were established quickly as the head diameter increased from 28 to 36 mm and then to 54 mm. In agreement with previous studies,11 as head diameter increased wear volume decreased markedly, with steady-state values of 0.17 mm³/10⁶ cycles for the 54 mm diameter bearings.12 The bedding in wear rates for all prostheses were substantially higher at 3.23 mm³/10⁶ cycles for the 54 mm bearings.

These results are in contrast to those reported for conventional UHMWPE-on-metal hip prostheses, where the wear of the UHMWPE acetabular cups was shown to be proportional to the sliding distance, as predicted by basic engineering principles. Therefore, reducing the femoral head diameter should lead to a reduction in wear volume and extension of prosthesis life. Charnley demonstrated the validity of this relationship and showed that maximum wear life of hip replacements could be achieved by making the head diameter half that of the socket diameter.13 Important additional factors must be considered such as rim impingement and neck strength, and it has been shown that optimal head diameter falls between 20 and 24 mm. The Charnley low friction arthroplasty, appropriately regarded as the 'gold standard' falls within this range at 22.225 mm.

Dowson et al.12 also considered the effect of diametral clearance. The diametral clearance is defined as the diameter of the acetabular cup minus the diameter of the femoral head (Fig. 1). There is a direct relationship between clearance and lubrication, and as MOM bearings are lubrication sensitive, clearance has a direct effect on wear. Dowson et al.12 reported that for both 36 and 54 mm bearings as diametral clearance increased, bedding in wear of the MOM components increased significantly. For the resurfacing components, those couples with smaller diametral clearances (83–129 μm; with a head diameter of 54.5 mm, n = 5) exhibited running in wear rates that were four-fold lower and steady-state wear rates that were two-fold lower, than those components with larger clearances (254–307 μm; with a head diameter of 54 mm, n = 3). However, there does appear to be an optimum band of clearance, which produces favourable wear rates. Farrar et al.14 were the first to show reducing wear rates with reducing clearance down to approximately 80 μm with 28 mm MOM hip prostheses. However, reduction of clearances to below 30 μm caused wear to increase substantially. This was thought to be due

![Figure 1](image-url)
to geometrical errors, which are inevitable with any manufactured part. Where small clearances approached the order of the cumulative geometrical errors, contacts may develop much closer to the equator and the possibility of a local negative clearance exists. These authors found that it was possible to simulate the wear of equatorial bearing devices, such as those described for the pre-1970 McKee Farrar and Ring prostheses, with modern MOM prostheses in a hip simulator by having negative or very low clearances. During testing these devices with low clearances reached approximately 20,000 cycles, and exhibited extremely high wear, before seizing completely.

**Lubrication**

MOM hip prostheses can be lubricated in three ways; boundary lubrication, mixed lubrication and full fluid-film lubrication, either alone or in combination. Lubrication is generally related to friction and wear and hence can play an important role in wear of particle generation in MOM bearings. Lubrication is dependent upon the viscosity of the lubricant, the sliding speed, the radius of the femoral head, clearance and surface roughness of the components. The lubrication analysis carried out by Jin et al. in 1997 first highlighted the importance of both head diameter and radial clearance on the lubrication of MOM hips. One of the experimental methods of studying lubrication is through measuring friction. The coefficient of friction is commonly plotted against the Sommerfeld parameter, which is the product of the velocity, viscosity of the lubricant and the radius of the femoral head, divided by the load. This type of plot is called a Strubeck curve and an idealised form is depicted in Fig. 2. The trend of the curve indicates the modes of lubrication. The initial flat section of the curve indicates boundary lubrication and substantial contact between the surfaces of the hip prostheses. The falling trend in the Strubeck curve indicates mixed lubrication in which the load is carried partly by contact between asperities on the joint surfaces, and partly by the lubricating fluid. The rising trend of the curve indicates full fluid-film lubrication in which the load is fully supported by the lubricant and surface asperity contact is minimal. Theoretical analysis of the mode of lubrication can be made by calculating the ratio of effective lubricating film thickness in hip prostheses to composite surface roughness of the femoral head and acetabular cup. This is known as the lambda ratio, $\lambda$. A $\lambda$ value greater than three indicates that full fluid-film lubrication is likely to be prevalent in the joint. Mixed lubrication is indicated when $\lambda$ is between one and three, and boundary lubrication when $\lambda$ is less than or equal to one. In general, as the $\lambda$ ratio increases wear decreases for MOM joints, with joints operating under boundary lubrication having the highest wear rates and joints operating under full fluid-film lubrication having the lowest. Smith et al. demonstrated this in their study on the effect of head diameter on lubrication, where head diameters of 16 and 22.225 mm were shown to have contact between the bearing surfaces at all times during the simulator tests, and hence a boundary lubrication regime was found to be prevalent. Alternatively, a mixed lubrication regime involving significant asperity contact may have prevailed. As head diameter increased to 28 mm a mixed lubrication regime was found to be prevalent; however, as only limited asperity contact occurred occasional fluid-film lubrication was indicated. As further increases in head diameter occur to 36 mm and beyond, the lubricating film alleviates metallic contact between the articulating surfaces and the volumetric running in wear and steady-state wear fall dramatically. As head diameter increases, the articulation is more likely to promote fluid-film lubrication and the benefits to the joints are subsequently seen in the wear characteristics.

However, modern manufacturing and finishing techniques allow MOM bearings to be super-polished to achieve very low surface roughness $R_a$ values. If surface asperities remain absent during articulation, the tendency towards higher $\lambda$ ratios and full fluid-film lubrication will increase.

Diametral clearance also has an important effect on lubrication. It has been shown that the mean lubricant film thickness due to elastohydrodynamic action is strongly influenced by both increases in head diameter and decreases in

![Figure 2 Strubeck curve indicating modes of lubrication.](image-url)
clearance. Dowson et al.\textsuperscript{12} demonstrated that by increasing head diameter to 54 mm, decreased the volumetric wear of MOM articulations, but if clearance was optimised further reductions in wear could be achieved (Fig. 3). For the older designs of surface replacement prostheses the $\lambda$ ratio was between one and two, indicating a mixed lubrication regime. However, as prosthesis design was improved and clearances optimised, the $\lambda$ ratio approached three, indicating that full fluid-film lubrication was possible in these newer devices (Fig. 3). These studies clearly demonstrate the benefits of optimising the design of MOM hip prostheses, and that improvements in design such as optimising clearances for surface replacement prostheses and improving surface finishes of all components can have a significant effect on the wear of MOM devices.

**Kinematics and load**

There has been a consistent trend for in vitro simulator wear rates to be lower than those reported in in vivo studies. The effects of kinematics and load have been studied by Firkins et al.\textsuperscript{9} and Williams et al.\textsuperscript{7}, respectively. Firkins et al.\textsuperscript{9} compared the wear of MOM hip prostheses in two different hip simulators with different kinematic inputs. One simulator had three independent input motions, which produced an open elliptical wear path with a low level of eccentricity. The other simulator had two independent input motions, which produced an open elliptical wear path but with greater eccentricity. The two simulators had been shown to produce similar wear rates for UHMWPE acetabular cups.\textsuperscript{17} However, when MOM hip prostheses were tested the simulator, the wear path with greatest eccentricity produced a wear rate that was 10-fold greater than the simulator with three independent motion inputs. In vitro simulations apply standard patterns of motion to the prostheses, whereas a more extensive range of activities and motions are applied in vivo. This was confirmed by Bowsher et al.\textsuperscript{8} who developed a severe simulator testing method for MOM hip prostheses that incorporated fast jogging cycles. These authors reported a nine-fold increase in steady-state wear rates for the simulator testing that incorporated these fast jogging cycles compared to normal walking gait simulations.

The study by Firkins et al.\textsuperscript{9} applied different swing phase loads in two different simulators, and hence the differences in wear rates may have been due to the application of different loads rather than differences in kinematics alone. Williams et al.\textsuperscript{7} investigated the effect that swing phase load exerted on the wear of MOM hip prostheses. These authors investigated a number of different load conditions, including a low swing phase load (100N), a swing phase load as recommended by ISO14242-1 (280N), and a small (100N) negative load applied during the swing phase, which caused separation of the head and insert. The latter is referred to as micro-separation, and simulates the effects of joint laxity that occurs after surgery. When micro-separation was introduced into the simulation testing of alumina ceramic-on-ceramic hip prostheses it was found to increase wear rates to clinically relevant levels, produce wear patterns similar to those observed in vivo, in the form of a wear stripe on the femoral head, and produce clinically relevant wear particles.\textsuperscript{18} It was found that increasing the swing phase load from 100 to 280N in the same hip-joint simulator increased the wear of MOM hip prostheses by over 10-fold. Introducing micro-separation to the gait cycle of the simulation increased wear further, and a wear stripe was observed on the femoral heads, accompanied by rim damage on the acetabular cups. It was also found that increasing the swing phase load from 100 to 280N led to higher coefficients of friction and the authors postulated that the significant increase in wear may be attributed to the dependence of MOM bearings on fluid-film lubrication conditions. During testing with low swing phase loads the fluid film will be allowed to replenish during the swing phase, resulting in lower friction and wear, but this effect will be smaller during testing with higher swing phase loads. This was consistent with the results of stop-start simulator testing,\textsuperscript{6} where the intermittent motion caused breakdown of the protective fluid film resulting in higher wear rates. During micro-separation conditions, fluid-film replenishment would have been improved because of increased...

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\caption{The effect of radial clearance (half of diametral clearance) upon lubrication and $\lambda$ ratio in metal-on-metal total hip implants and resurfacing prostheses (ASR, DePuy Int.).}
\end{figure}
fluid entrainment during the swing phase; however, any benefit would soon be overwhelmed by the high stresses generated when the head contacted the insert rim at heel strike. There have been no reports of wear stripes on retrieved MOM explants; however, this may be due to the self-polishing mechanism of the metal components that occurs during gait. Williams et al. suggest that microseparation should not occur with every step as it does in the hip simulator and this may be sufficient to mask stripe wear in vivo. Factors that cause rim contact such as malpositioning of the acetabular cup or joint laxity producing micro-separation of components may elevate wear in vivo. Therefore, additional care may be required with the surgical techniques and fixation of MOM bearings compared to polyethylene-on-metal couples.

Concerns

Although MOM hip prostheses produce significantly lower wear rates than conventional UHMWPE-on-metal couples, and 10-fold lower wear rates than highly crosslinked UHMWPE-on-metal hip prostheses, there are concerns associated with these bearings. Wear particles have been reported to be in the nanometer size range, an order of magnitude smaller than UHMWPE particles. Therefore, despite a lower wear volume than UHMWPE bearings the number of particles produced are estimated to be greater, possibly between one and ten million particles per step. These small particles have the potential to distribute throughout the body via the lymphatic system, with particles found in the lymph nodes, liver, spleen and bone marrow. As MOM hip prostheses are indicated for younger more active patients these particles, and the potential effect that these ions have on cells and tissues, elevated ion concentrations have been reported in both the blood and urine of patients with metallic implant components. In addition, contrary to what might be expected, there is no conclusive evidence that ion levels fall in vivo after the bedding in period of the MOM prostheses, during which wear of the prostheses are higher. Cobalt and chromium ions have high toxicity, and there are very real concerns about the effects of sub-lethal doses of metal ions, which have been shown to cause DNA damage. This damage takes the form of chromosome aberrations and chromosome translocations. Over long periods of exposure the worry is that this will lead to the development of certain types of cancer, such as leukaemia and lymphoma. In animal models elevated levels of cobalt, chromium and nickel have been correlated with increased carcinoma rates. However, reports in the literature of malignancies developing after total hip or knee replacement surgery are exceedingly rare. Out of eight epidemiological studies on the relative risk of cancer after TJR, only one study looked specifically at MOM implants. This study did not find an increased risk of cancer development in the subjects receiving MOM hip prostheses compared to those receiving metal-on-polyethylene hip prostheses. However, all the studies to date have been substantially underpowered in terms of patient numbers required to show a difference between the two prosthesis types.

Metal sensitivity is also a potential problem. Metal ions, whether produced secondary to wear debris or via corrosion can initiate a hypersensitivity response. A delayed cell-mediated response, or delayed-type hypersensitivity response can occur, in which cytokines are released by T-lymphocytes and increased activation of macrophages is seen, which may result in T-cell mediated periprosthetic osteolysis. Many metals can initiate a hypersensitivity response, the most common is nickel followed by cobalt and chromium. Therefore, with the well-documented elevation of cobalt and chromium ions in patients with MOM hip implants, there is a theoretical risk of developing hypersensitivity reactions. Recently, an immune response exclusively associated with second-generation MOM hip prostheses, has been described. Histomorphological changes suggest a type of hypersensitivity reaction to the all-metallic implants. The hypersensitivity hypothesis was further strengthened by the observation that these patients experienced early clinical failure at 11–60 months (mean 29 months), and the fact that patients who received a second MOM prosthesis did not experience any relief of symptoms. Conversely, patients who received either metal-on-polyethylene or ceramic-on-polyethylene couples reported that their symptoms completely disappeared. In a control group of patients with joint prostheses not containing cobalt, chromium or nickel these signs of an immunological reactions were absent. Reports of this type of reaction are becoming increasingly common, however, more research is needed in this area. It is not known whether these patients experience prosthesis
failure because of a pre-existing metal sensitivity, or whether metal sensitivity develops because of a high wearing bearing and elevated metal ion levels. Theoretically, there would be an increased probability of developing hypersensitivity to elevated metal ion levels, and hence an increased risk of implant failure. Recently, Park et al. reported a 6% incidence of early onset osteolysis, which was associated with a delayed-type hypersensitivity response to metal in patients who received second-generation MOM hip prostheses. Interestingly, these authors reported that 8/9 patients with early osteolysis were hypersensitive to cobalt, with only two patients eliciting a hypersensitive reaction to nickel. It has previously been reported that nickel is a potent sensitiser, with crossreactivity to cobalt being common. This is the first report to link cobalt hypersensitivity with early failure of MOM hip prostheses. However, the study by Park et al. used patch testing to determine metal hypersensitivity, which has certain limitations when used as a method to determine deep-tissue hypersensitivity. Patch testing involves exposure to the allergen for short periods of time, whereas the patient experiences constant exposure to the orthopaedic implant. In addition, there is a lack of knowledge about, and availability of, appropriate metal challenge agents. No suitable standardised battery of relevant metals currently exists and there are also concerns that patch testing could induce hypersensitivity in a previously insensitive patient. To date, standardised effective testing methodology for the clinical determination of hypersensitivity reaction to metal implants has not been well established, since the methods are labour intensive and clinically unpopular. Hallab et al. described several methodologies for the diagnosis and detection of metal hypersensitivity in patients that have metal implants. These authors recommend a combined approach using three in vitro immunological assays to measure several components of lymphocyte activation in order to provide a technique better able to diagnose hypersensitivity responses to metals. Activated lymphocytes (CD4 T helper cells) slow their rate of migration, begin to proliferate, and release various cytokines. The three assays include lymphocyte proliferation or lymphocyte transformation assays (LTA), lymphocyte migration inhibition assays and cytokine profiling of responding T cells. It is clear that there is a need for a prospective study in which a large group of patients with MOM bearings are evaluated with multiple in vitro hypersensitivity assays such as migration inhibition assays and proliferation assays, in order to investigate the relationship between metal hypersensitivity, osteolysis and prosthesis failure.

The current generation of MOM implants have only early and mid-term results available, with no long-term results published as yet. Therefore, although MOM bearings may be considered a viable alternative to either polyethylene or ceramic implants, outstanding and unresolved issues continue to exist with this prosthesis type, as they do with the alternatives.

References


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