



Is there a Future for Metal on Metal Hips?

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Total hip replacement (THR) is one of the most successful interventions in the medical field. Long-term success of a hip replacement is primarily dependent on the wear characteristics of the bearing surfaces used. The association between wear debris, particularly polyethylene particles, and aseptic loosening has driven the search for bearing surfaces with lower wear, the logic being that reducing wear would reduce future revision burden. Metal on metal (MOM) bearing surfaces were introduced as an alternative in particular for use in the young and active patients, due to their perceived advantages of low wear. In addition, relatively large head size meant that the dislocation risk was reduced. Two types of joint replacements with MOM bearing surfaces are available: MOM hip resurfacing (MOMHR) and MOM total hip replacement (MOMTHR). MOMHR a bone preserving procedure tends to replicate normal hip biomechanics but carries the risk of fracture neck of femur as the native femoral neck is preserved during surgery. Therefore MOMTHR was introduced as it nullifies this risk. The uptake of these two types of implant designs has been rapid and more than half a million MOM hips have been implanted worldwide over the last 10 years. The contemporary MOM designs are made up of high carbon content Cobalt-Chrome (Co-Cr) alloy.

Currently there are two clinical aspects of MOM hips which will decide the future of these implants. First is the risk of fracture neck of femur with hip resurfacing [1] and second is the abnormal soft tissue reaction that is seen in some patients with MOM hips [2]. The issue of the fracture seems to be primarily associated with surgical technique, i.e. disruption of the blood supply to the femoral head during surgery if the surgeon is not careful and with meticulous technique, in most series the incidence is well below 1%. However, the incidence of abnormal soft tissue reactions is worryingly on the rise. These soft tissue reactions can be of solid, cystic or mixed nature. Various names such as cysts, bursae, metal reactions, metal sensitivity, ALVAL (aseptic lymphocytic vasculitis associated lesions) [3], ARMD (adverse reactions to metal debris), ALTR (adverse local tissue reaction) and pseudotumour have been used to describe them. Pseudotumour by definition is an enlargement that resembles a tumour, resulting from inflammation, fluid accumulation, or other causes and this term will be used in this editorial. They can cause a spectrum of damage ranging from a small indolent cyst or mass to local invasion with substantial soft tissue and sometimes extensive bone destruction. The typical presentation is pain in the groin or hip region but they may also present as a mass, nerve damage, vascular claudication, spontaneous (pathological) fracture or dislocation or with a clunking hip. The systemic consequences of high cobalt levels (arthroprosthetic cobaltism) have been reported in patients presenting with a variety of symptoms ranging from neurological (tinnitus, vertigo, convulsions), cardiological (cardiomyopathy) to endocrine (hypothyroidism) dysfunction.

Diagnosis of these abnormal soft tissue reactions can be difficult at times. A high degree of suspicion and awareness is needed. Typically, plain radiographs are normal although in some cases they may show neck narrowing and focal osteolysis. Cross-sectional imaging is essential to establish the extent and nature of the pseudotumour. Ultrasound is probably the most sensitive but is user dependent. Computed tomography (CT) or magnetic resonance imaging (MRI) suffer from metal induced artefacts and may miss small lesions.

The histological features are those of extensive necrosis and an inflammatory response [4] dominated by macrophages and lymphoid cells, including lymphocytes, plasma cells and lymphoid aggregates; the latter is commonly termed ALVAL. Blood concentrations of metal ion levels have been used as a surrogate marker of wear associated with MOM hips. Inductively coupled-plasma mass spectroscopy (ICP-MS) is the preferred technique to assess metal ion levels. Metal ion levels from laboratories are either expressed as micrograms per litre ($\mu\text{g/l}$) or nanomoles per litre (nmol/L). MHRA (Medical and Healthcare Products Regulatory Agency) recommends either cobalt or chromium ion levels above seven $\mu\text{g/l}$ as abnormal although some patients with lower levels can still present with a pseudotumour [5]. The metal ion levels tend to be low in patients with problems following MOMTHR as compared to those with problems following MOMHR.

The cause of pseudotumour is multifactorial. Most are associated with appreciable wear of the components with evidence of edge-loading and high levels of metal ions in the blood and the joint or cyst fluid. Well-functioning MOM hips need fluid lubrication. Under edge-loading conditions, this lubrication fails which is usually associated with massive wear which can have local toxic effect. The main damage is caused by very large numbers of very small cobalt chrome wear particles, rather than ions. The size of the particles tends to vary between 30 nm-500 nm. The wear particles are ingested by macrophages and, once in the acidic environment of the phagolysosome, corrode and release ions. The cobalt ions within the cells kill them. The particles are then released and can be taken up by and kill more cells. The on-going cell death and release of intracellular constituents and metal ions causes the extensive necrosis. However not all cases are associated with high levels of wear or metal ions. In this small proportion of cases a delayed hypersensitivity (type IV) reaction may be the cause. Bilateral MOM hips are more likely to have pseudotumours than unilateral, suggesting that some individuals can tolerate a certain level of metal wear debris. The origin of wear particles is the bearing surface for the MOMHRs while it is primarily the trunion-taper interface for the MOMTHR.

The incidence of pseudotumours varies in different series, in part because of different definitions of the lesion, different methods of imaging and different lengths of follow-up. In our practice the incidence of revision for pseudotumour was between 1% and 2% when we first described it. The incidence appears to increase with time. In our series at 8 years the incidence is 4% with other series reporting significantly higher incidence. One particular type of MOM hip

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implant (ASR, DePuy, Warsaw, USA) is reported to have failure rate of 25% at six years for the resurfacing and of 48.8% for the ASR THR [6].

The risk of developing a pseudotumour is related to patient selection, surgical execution and implant design. The patient related factors that increase the risk include female gender, history of hip dysplasia and in women age less than 40. The incidence in men is low. Differences in bone size and native anatomy are thought to be principal factors for this observed difference. Probably the most important surgical factor related to pseudotumour is acetabular component mal-orientation which increases the risk of edge-loading [7]. The design of the implant has a profound effect on wear and the incidence of pseudotumour. The ASR has been shown to have a high incidence even in men. For the majority of the other devices the incidence has been generally low and of the same degree. An important factor contributing to the wear rate is the internal socket geometry. The inside of a conventional socket tends to be hemispherical, subtending an angle of 180° while the inside of a resurfacing sockets subtend an angle between 160° and 170°. Other important risk factors include the thickness of the socket, the design of the socket rim, the clearance, and the metallurgy.

The concept of metal-on-metal hip resurfacing remains good and should not be discarded because of problems related to pseudotumour formation. A young and active male patient less than 55 years old without history of hip dysplasia seems to be the ideal candidate for offering this intervention. MOMTHR should not be used until more evidence is available about the incidence, and aetiology of pseudotumour formation in these patients. As pseudotumours appear to be a reaction to metal wear debris so new articulations, without

metal, need to be developed and assessed. There are still unanswered questions and these will decide the fate of MOM hips. The key areas of research are likely to be in the field of aetiology of pseudotumours, their natural history, change in incidence of pseudotumours with time and long-term genotoxic and carcinogenic effects of metal particles. In addition, how to monitor the patients with metal-on-metal hips and when to revise these hips are two areas of on-going debate.

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