Concerns about Metal-on-Metal Hip Implants

All artificial hip implants carry risks including wear of the component material. Metal-on-metal (MoM) hip implants have unique risks in addition to the **general risks of all hip implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241594.htm#risks)**.

In MoM hip implants, the metal ball and the metal cup slide against each other during walking or running. Metal can also be released from other parts of the implant where two implant components connect. Metal release will cause some tiny metal particles to wear off of the device into the space around the implant. Wear and corrosion at the connection between the metal ball and taper of the stem may also occur. Some of the metal ions (e.g. cobalt and chromium) from the metal implant or from the metal particles will enter the bloodstream.

Orthopaedic surgeons take several precautions before and during hip replacement surgery to try to optimize the way in which the ball and socket rub against each other so that fewer wear particles are produced. However, there is no way to fully avoid the production of some metal particles.

Different people will react to these metal particles in different ways. At this time, it is not possible to predict who will experience a reaction, what type of reaction they might have, when the reaction will occur, or how severe the reaction will be.

Over time, the metal particles around some implants can cause damage to bone and/or tissue surrounding the implant and joint. This is sometimes referred to as an “adverse local tissue reaction (ALTR)” or an “adverse reaction to metal debris (ARMD).” Soft tissue damage may lead to pain, implant loosening, device failure, and the need for revision surgery (the old device is removed and replaced with another one). Patients with a progressing ALTR may be considered for earlier revision to prevent extensive damage to bone, muscle and nerves.

International regulatory agencies have issued alerts and safety communications related to MoM hip implants.

- In April 2010, the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) issued a **medical device alert (/ucm/groups/dts-bs/documents/medicaldevicealert/con079162.pdf)** that included specific follow-up recommendations for patients with MoM hip replacements. The recommendations included blood tests and imaging for patients with painful MoM hip implants. In February 2012, MHRA published a medical device alert and updated it in **June 2012 (/ucm/groups/dts-bs/documents/medicaldevicealert/con155767.pdf)** with advice on the management and monitoring of patients with MoM hip systems.
- In May 2012 Health Canada issued a **public health communication (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/_2012/metal_implant_pc-cp-eng.php)** to orthopaedic surgeons and patients regarding MoM hip implants.
- The Therapeutic Goods Administration of Australia published their **safety information (http://www.tga.gov.au/hp/information-devices-mom-hip-implants.htm)** for healthcare professionals on MoM hips in September 2012.

There are also reports in orthopaedic literature, data from international orthopaedic implant registries and presentations from professional/scientific meetings that have increasingly noted complications and potential problems of early failure of MoM hip systems, often requiring revision surgery. Much of the available data are from countries outside the U.S., and the data may not be directly applicable to the experience in the U.S. For example, some of the devices available outside of the U.S. are not marketed in the U.S. For this reason, recommendations from international regulatory agencies may not necessarily apply to U.S. patients with MoM hip systems.

If patients with MoM hip implants develop any **symptoms that may indicate that their device is not functioning properly (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241594.htm#risks)**, it is very important for them to make an appointment with their orthopaedic surgeons promptly for further evaluation. Aside from a physical exam of the hip, the orthopaedic surgeon may consider several tests to evaluate these symptoms including:

- Using a needle to remove fluid from around the joint (joint aspiration)
- Soft tissue imaging
- Blood tests, including checking levels of metal ions in the blood

Patients who receive MoM hip implants should also pay close attention to changes in their general health including new or worsening symptoms outside their hip. If they are referred to a doctor to evaluate new conditions, they should let their physician know they have a MoM hip implant. T here have been some case reports and articles in the medical literature that suggest patients with a MoM hip implant may have certain symptoms or illnesses elsewhere in the body (systemic reactions). These include:

- General hypersensitivity reaction (skin rash)
- Cardiomyopathy
- Neurological changes including sensory changes (auditory, or visual impairments)
- Psychological status change (including depression or cognitive impairment)
- Renal function impairment
- Thyroid dysfunction (including neck discomfort, fatigue, weight gain or feeling cold

At the current time, there is not enough evidence to support the routine need for checking metal ion levels in the blood or soft tissue imaging if patients with MoM hip implants have none of the signs or symptoms described above and the orthopaedic surgeon feels the hip is functioning properly. The FDA is recommending that asymptomatic patients with MoM hip implants continue to follow-up with their orthopaedic surgeon every 1 to 2 years to monitor for early signs of change in hip status.

More in Metal-on-Metal Hip Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm)

The Hip Joint (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241593.htm)

Hip Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241594.htm)

Metal-on-Metal Hip Implant Systems (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241601.htm)