

Understanding Metal-on-Metal Hip Implants

Hip replacement is an option to help reduce hip pain and restore movement for patients who are no longer obtaining pain relief from nonsurgical treatments. Following is information about hip replacement, including the types of hip replacement and special considerations with metal-on-metal hip replacements.

The Hip Joint

The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the thigh bone (femur) rotates within the curved surface of the acetabulum (see Illustration 1).

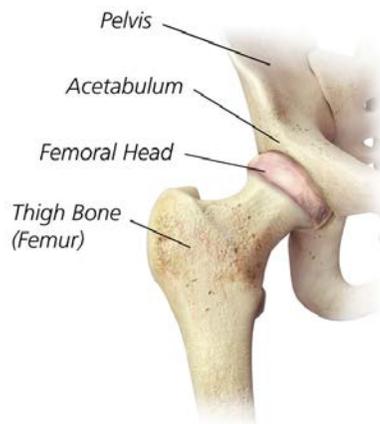


Illustration 1: The healthy hip



Illustration 2: Hip replacement

Severely diseased or damaged hip joints may be replaced with implants, which typically consist of a metal stem, a femoral head (ball) and a liner that fits into a cup. The metal stem is inserted into the femur (thigh bone) and the cup is anchored into the pelvis. The femoral head, which is attached to the top of the stem, then rotates within the liner that is inserted into the cup as shown in Illustration 2.

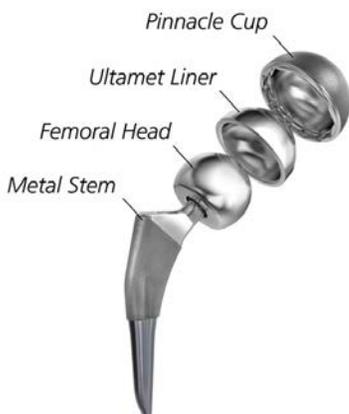


Illustration 3: Hip replacement with the PINNACLE Cup and ULTAMET liner

With “modular” metal-on-metal hip implants, both the head and the liner are made of metal. While no longer widely used, a potential benefit of metal-on-metal systems is that they allowed for larger femoral heads to be used that provided greater function and a lower risk of dislocation.¹ Illustration 3 shows an example of a metal-on-metal hip from DePuy.

Wear Debris from Metal-on-Metal Implants

All implants, no matter what materials are used, experience wear over time. The body’s immune system responds to the debris from this wear, and this can sometimes cause the need for a further surgery. With metal-on-metal implants, the wear debris can either be in the form of metal particles or metal ions that pass through the blood stream on their way to being excreted from the body. These particles are typically so small that they can only be seen with a microscope.

While metals such as cobalt and chromium are essential to normal functioning of the body, the levels of these metals may be increased in patients with metal joint replacements. There is no definitive data linking a particular level of metal ions in the blood to occurrence of problems in the hip joint.

Concerns have been expressed about whether ions in the blood might have “systemic effects”, or effects in parts of the body other than the hip joint. The U.S. Food and Drug Administration (FDA) has stated that “presently, the FDA does not have enough scientific data to specify the concentration of metal ions in a patient’s body or blood necessary to produce adverse systemic effects.”² Further, according to the FDA,

¹ Berry et al., Effect of Femoral Head Diameter and Operative Approach on Risk of Dislocation After Primary Total Hip Arthroplasty; *The Journal of Bone & Joint Surgery*, 2005; 87:2456-2463.

² FDA: Metal-on-Metal Hip Implants:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm>. Accessed March 2016.

“Based on the limited number of case reports in published literature, the true incidence or prevalence of adverse systemic effects from MoM [metal-on-metal] hip implants is not known at this time.”³

The metal particles and ions released by hip implants have not caused problems for the vast majority of patients, but a limited number of patients have been reported to have an adverse reaction to them. It is important that patients promptly follow up with their surgeon if they are experiencing any symptoms. Routine check-ups on for people with implanted hips are recommended regardless of whether they are having symptoms.

Metal-on-Metal Patient Follow-Up Guidance

Regulatory authorities and orthopaedic associations in some countries have published guidance on the follow up of patients with metal-on-metal implants. This guidance varies among countries and regions around the world and often applies to all metal-on-metal implants, regardless of manufacturer. DePuy recommends that all patients with a joint replacement follow up with their surgeon as directed. The frequency of follow up visits will be determined by the surgeon based on local guidance, the physician’s clinical protocol, and the needs of the individual patient.

DePuy’s Modular Metal-on-Metal Hip Replacement

The PINNACLE[®] Acetabular Cup System is a modular hip replacement system from DePuy with femoral head and liner options that are made from materials such as ceramic or a type of plastic called polyethylene. The metal-on-metal liner option for PINNACLE, which was known as ULTAMET[®] Metal-on-Metal Articulation, was available for use until August 31, 2013⁴ when the company discontinued it due to changing surgeon preferences.

ULTAMET Metal-on-Metal is backed by a strong record of safety and effectiveness in reducing pain and restoring mobility for patients suffering from chronic hip pain. The company continues to monitor current data about the performance of ULTAMET Metal-on-Metal from a variety of sources, including data from national joint registries⁵, medical literature, company-sponsored clinical trials and adverse event reports.

Important Safety Information

The performance of a hip replacement depends on the patient’s age, weight, activity level, among other factors. Each patient considering a hip replacement should consult with a surgeon to determine the best implant option for his or her health condition.

About DePuy

DePuy is the oldest orthopaedic device manufacturer and has been a leader in the orthopaedic industry for decades. Our mission is to develop products and technologies that help patients who have been affected by pain, disability and a loss of mobility return to their daily activities.

³ FDA: Metal-on-Metal Hip Implants:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm>. Accessed March 2016.

⁴ For more information, please visit : http://www.depuy.com/sites/default/files/metal_liner_press_statement_final_5-16-3013.pdf

⁵ Annual reports for the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) and for the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) can be found here: UK NJR <http://www.njrcentre.org.uk/njrcentre/default.aspx>; AOA NJRR <http://aoanjrr.dmac.adelaide.edu.au/>