FDA Safety Communication: Metal-on-Metal Hip Implants

U.S. Food & Drug Administration

Date Issued: Jan. 17, 2013

Audience:

- Orthopaedic surgeons
- Health care providers responsible for the ongoing care of patients with metal-on-metal hip implants
- Patients who are considering or have received a metal-on-metal hip implant

Medical Specialties: Orthopaedics, General Medicine, Family Practice, Radiology, Radiologic Technology, Clinical Laboratory Managers and Directors

Device:
Metal-on-metal hip implants consist of a ball, stem and shell, all made from cobalt-chromium-molybdenum alloys.

There are two types of metal-on-metal hip implants [1]:

- Traditional total hip replacement systems
- Resurfacing hip systems

Purpose: In February 2011, the FDA launched a metal-on-metal hip implant webpage [2]. The FDA is providing updated safety information and recommendations to patients and health care providers. This new information is based on the FDA's current assessment of metal-on-metal hip implants, including the benefits and risks, the evaluation of the published literature, and the results of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting.

Summary of Problem and Scope:
Metal-on-metal hip implants have unique risks in addition to the general risks of all hip implants [3].

In metal-on-metal 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 around the implant, which may cause damage to bone and/or soft 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 (a surgical procedure where the implant is removed and another is put in its place). Some of the metal ions released will enter the bloodstream and travel to other parts of the body, where they may cause symptoms or illnesses elsewhere in the body (systemic reactions).

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. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles.

Recommendations for Orthopaedic Surgeons:

Before Surgery

- Select a metal-on-metal hip implant for your patient only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system (metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic or ceramic-on-metal). Factors to consider include the patient's age, sex, weight, diagnosis, and activity level.
    - Note that a 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems.
- Inform patients about the benefits and risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Also discuss the patient's expectations and review the potential complications of surgery with a metal-on-metal hip implant.
- Pay close attention to patient populations for which metal-on-metal hip systems are contraindicated. Be aware of the risk factors that may predispose a device to excess wear and early failure.

Additional information on the FDA's recommendations for orthopaedic surgeons before, during and immediately following metal-on-metal hip replacement surgery can be found in Information for Orthopaedic Surgeons [4].

Patient Follow-Up

- Follow-up of asymptomatic patients with metal-on-metal hip implants, including physical examinations and routine radiographs, should occur periodically (typically every 1 to 2 years). If the hip is functioning properly, the FDA does not believe there is a clear need to routinely perform additional soft tissue imaging or assess metal ion levels in the blood.
- Be aware that there are certain patients who are at risk for increased device wear and/or adverse local tissue reactions (ALTR) and should be followed more closely. They may include:

    - Patients with bilateral implants
    - Patients with resurfacing systems with small femoral heads (44mm or smaller)
    - Female patients
    - Patients receiving high doses of corticosteroids
    - Patients with evidence of renal insufficiency
    - Patients with suppressed immune systems
    - Patients with suboptimal alignment of device components
    - Patients with suspected metal sensitivity (e.g. cobalt, chromium, nickel)
    - Patients who are severely overweight
    - Patients with high levels of physical activity.
- Pay close attention to signs and symptoms that may be associated with metal-on-metal hip implants. Please see the website for a list of common ALTRs and systemic symptoms/complications [4].
- Conduct a thorough evaluation if a patient with a metal-on-metal hip experiences local symptoms such as pain or swelling at or near the hip, a change in walking ability or a noise from the hip joint more than three months after metal-on-metal hip implant surgery.
- Follow symptomatic patients with metal-on-metal hip implants at least every 6 months.

Additional information on the FDA's recommendations for patient follow-up can be found in Information for Orthopaedic Surgeons [4].

For additional information regarding soft tissue imaging or assessing metal ion levels, please review the FDA's recommendations below.

Imaging
For some symptomatic patients with metal-on-metal hip implants, additional diagnostic imaging is required to assess and diagnose soft tissue findings surrounding the implant. Please be aware of the FDA's recommendations:

- Consider the benefits and risks of using different types of diagnostic imaging procedures (e.g. MRI with metal artifact reduction, CT, or ultrasound) as well as the availability of specialized radiology expertise when determining the most appropriate imaging modality for each patient.

If you determine that an MRI of a metal-on-metal hip implant patient is appropriate, the FDA recommends the following:

- Consult with the radiologist to evaluate the benefits and risks of utilizing MRI with metal artifact reduction;
- Review the available device-specific labeling from manufacturers for MRI Conditions; and
- Inform the MRI site that the patient has a metal-on-metal hip implant.

For additional information on the FDA's recommendations about imaging a patient with a metal-on-metal hip implant, please see Imaging Evaluation [5].

Assessing Metal Ion Levels
Some patients with a metal-on-metal hip implant may have elevated metal ion levels (e.g. cobalt and/or chromium) in their bloodstream. Several factors can impact the accuracy, reproducibility, and clinical interpretation of metal ion test results. Please be aware of the FDA's recommendations:

- The FDA does not believe there is a clear need to routinely check metal ion levels in the blood if the orthopaedic surgeon feels the hip is functioning properly and the patient is asymptomatic.
- Patients with metal-on-metal hip implants who develop any symptoms or physical findings that indicate their device may not be functioning properly, should be considered for metal ion testing.
- If measuring metal ions, consider obtaining and following serial measurements (using the same sample type, the same measurement method, and preferably the same laboratory) in determining metal ion levels in symptomatic patients.
- At this time, the FDA is not recommending a specific metal ion level as a trigger for revision or other medical intervention. The metal ion concentration values, including increases in metal ion levels over time, should be considered in addition to the overall clinical scenario including symptoms, physical findings, and other diagnostic results when determining further actions.

For additional information on the FDA's recommendations on metal ion test methods, selecting a test lab and interpreting test results, please see Metal Ion Testing [5].

Device Revision
The decision to revise a metal-on-metal hip implant should be made in response to the overall clinical scenario. In case of adverse local tissue reactions (ALTR), revision of a metal-on-metal hip implant may have a worse prognosis than revision of other types of bearing surfaces.

In selecting components for revision:

- Consider the benefits and risks of all bearing surfaces for each patient.
- Check the specific device labeling for compatibility of device components.
- If a patient is suspected to have developed metal sensitivity, carefully select the materials of the revision components (potentially avoiding materials with nickel or chromium).

For additional information, please review the FDA's considerations on device revisions [6], which includes our recommendation for a retrieval analysis of every failed metal-on-metal hip implant.

Summary of FDA Recommendations for Orthopaedic Surgeons

	Symptomatic Patients	**Asymptomatic Patients**
Regular Clinical Evaluation	At least every six months	Typically at least once every 1 to 2 years
Soft Tissue Imaging	Consider the benefits and risks of MRI, CT and ultrasound for each patient.	Not necessary if you feel the hip is functioning properly.
Metal Ion Testing	Consider monitoring serial metal ion levels. Currently, the most reliable test results are available for cobalt in EDTA-anticoagulated blood*. In repeat tests, use same sample type, measurement method and preferably the same laboratory.	Not necessary if you feel the hip is functioning properly.

*For chromium testing, a validated method that resolves potential interferences must be used. Please review FDA's recommendations for chromium testing [5].

Recommendations for Health Care Providers:
Metal-on-metal implant patients with systemic symptoms are more likely to visit their primary care practitioner than their orthopaedic surgeon, which makes it important for all health care providers to be aware of metal ion adverse events that may occur in metal-on-metal hip implant patients. Based on case reports, these events may include:

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

Patients with systemic findings that are thought to be related to a metal-on-metal hip implant should be advised to follow-up with his or her orthopaedic surgeon to determine the appropriate course of action.

For additional information, please review the FDA's considerations to Health Care Professionals [7].

Recommendations for Patients Considering Hip Implants:

- Be aware that every hip implant has benefits and risks.
- Discuss your options for hip surgery with your surgeon.

A list of some questions to ask your orthopaedic surgeon can be found in Patients Considering a Metal-on-Metal Hip Implant [8].

Recommendations for Patients with Metal-on-Metal Hip Implants:

- If you are not having any symptoms and your orthopaedic surgeon believes your implant is functioning appropriately, you should continue to routinely follow-up with the surgeon every 1 to 2 years.
- If you develop new or worsening problems such as pain, swelling, numbness, noise (popping, grinding, clicking or squeaking of your hip), and/or change in your ability to walk, contact your orthopaedic surgeon right away.
- If you experience changes in your general health, including new or worsening symptoms outside your hip, let your physician know you have a metal-on-metal hip implant.

Additional information for patients with a metal-on-metal hip can be found in Patients who have a Metal-on-Metal Hip Implant [9].

FDA Activities:
The FDA is committed to providing reliable safety recommendations to patients and health care providers about the utilization of these devices. Recent activities include:

1. On May 6, 2011, the FDA instructed manufacturers of metal-on-metal total hip replacement (THR) systems to conduct postmarket surveillance study [10] of these devices. Five manufacturers currently market metal-on-metal hip implants in the U.S. and all five have approved postmarket surveillance study plans. Data from these studies will provide patients and health care providers with additional information about the safety profiles of the implants, including the effect of metal ion concentrations in the bloodstream.
2. On June 27-28, 2012, the FDA convened the Orthopaedic and Rehabilitation Devices Panel [11] of the Medical Devices Advisory Committee to seek expert scientific and clinical opinion on the benefits and risks of metal-on-metal hip systems. Information from this panel meeting has helped form these recommendations.
3. On January 17, 2013 the FDA issued a proposed order [12] requiring manufacturers of metal-on-metal total hip replacement systems to submit premarket approval (PMA) applications. Metal-on-metal total hip replacement systems were evaluated under the 510(k) premarket notification program. Metal-on-metal total hip replacement systems were marketed in the U.S. prior to 1976 legislation that gave the agency premarket authority over medical devices. As “preamendment devices,”

they were designated as Class III (higher risk) devices but were regulated under the 510(k) premarket notification program.

Additional information on FDA ongoing activities are provided in FDA's Role and Activities [13].

Other Resources:
For additional resources, see Metal-on-Metal Hip Implants: Other Resources [14].

Reporting Problems to the FDA:
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with a metal-on-metal device, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [15]. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements [16] should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations. [16]

Reports to the FDA about adverse events related to metal-on-metal hip systems include, but are not limited to: pain, malposition, adverse local tissue reaction, metallosis, hypersensitivity (allergy), loosening, and dislocation.

To help us learn as much as possible about the adverse events associated with metal-on-metal hip implants, please include the following information in your reports, if available:

- Date of implantation
- Date of implant removal (if applicable)
- Clinical cause for revision (if available)
- System components affected by the adverse event.

Contact Information:
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) via e-mail at DSMICA@FDA.HHS.GOV [17] or by phone: 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

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Links:

[1] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241601.htm
[2] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm
[3] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241604.htm
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[6] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241667.htm#3
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[12] https://www.federalregister.gov/articles/2013/01/18/2013-01006/effective-date-of-requirement-for-premarket-approval-for-two-class-iii-preamendments-devices
[13] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241769.htm
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