Information for Our Patients Regarding Metal-on-Metal (MoM) Hip Replacements

The American Association of Hip and Knee Surgeons, The Hip Society and the American Academy of Orthopaedic Surgeons

Concerns have been raised regarding the safety of metal-on-metal hip replacements. Recently, one specific type of implant was voluntarily recalled from the United States market. The purpose of this statement is to inform and educate our patients, and the public at large, about the issues surrounding metal-on-metal hip replacements.

1. What are the concerns?

While the vast majority of patients who have hip replacements have experienced excellent results and are quite pleased with their surgery, some hip replacements fail. Hip replacements can fail because of various reasons, such as the implants become loose in the bone, the hip comes out of the socket (dislocation), the joint becoming infected and the surface of the joint replacement wears out. The debris generated by wear of the joint replacement can damage the surrounding bone and soft tissues (muscles, tendons, ligaments, and hip capsule). The surface of the hip joint replacement consists of a ball and a socket. The most common type of surface is a metal ball on a plastic liner within a metal socket. Other types of surfaces include a ceramic head on a ceramic liner, a ceramic head on a plastic liner and a metal head on a metal liner. A metal head on a metal liner is referred to as a metal-on-metal (MoM) hip replacement.

Some recent scientific studies have reported a higher than expected failure rate of a specific metal-on-metal (MoM) hip replacement design. These systems have been voluntarily recalled by the company because of unexpectedly high failure rates. The specific type of MoM hip implants that have been recalled are the ASR ™ XL Acetabular System and the ASR ™ Hip Resurfacing system manufactured by DePuy Orthopaedics, Inc. (Warsaw, Indiana), a Johnson & Johnson company.

It is important to note that the majority of patients who have MoM hip replacements have done well. Studies of other types of MoM hip replacements show very good results and low failure rates. Also, all types of hip replacements can have wear-related problems.

2. Who is affected?

Any patient who has a MoM hip replacement could potentially be affected; however, patients with the DePuy ASR™ designed hip replacement may be at greater risk. While we do not know the exact number of MoM hip replacements performed in the United States to date, during a 12-month period from 2005 to 2006, nearly 40,000 MoM hip replacements were performed in the United States. This is estimated to be approximately 32% of all hip replacements performed in the country during that timeframe. We believe that usage has declined since that time period.

3. How do these implants fail?

Like all types of hip replacements, MoM hip replacements can fail because of infection, the hip coming out of the socket and loosening of the implant in the patient's bone. While all hip replacements generate some amount of wear debris from the joint surface, the wear and corrosion of the metal components of the MoM replacement can cause an "adverse local tissue reaction (ALTR)" which damages the surrounding bone and soft tissues. The patient may have pain and swelling due to such damage. The amount of metal debris generated may be influenced by specific designs of the hip replacements, how the socket is placed in the bone and individual patient factors. In a few very rare patients, metal debris from the hip caused illness throughout the body.

4. When should a patient with a MoM hip replacement be concerned or seek evaluation by their orthopaedic surgeon?

Unexplained pain, swelling, or the onset of a limp can be associated with failure of any hip replacement, including MoM hips. These or any other new symptoms occurring around a previously pain-free joint should alert the patient to see their orthopaedic surgeon for evaluation. Patients can find out from their orthopaedic surgeon the name of

the specific company which manufactured their hip implant; these companies often have information available to patients on their websites.

5. How should patients be evaluated if they have a MoM hip replacement?

Your orthopaedic surgeon may evaluate you and your MoM hip replacement by:

- Obtaining a medical history
- Performing a physical examination
- Reviewing x-rays of your hip
- Ordering advanced imaging studies of the hip to look for fluid and tissue abnormalities
    - Ultrasound
    - Computed Tomography scan (CTscan)
    - Magnetic Resonance Imaging (MRI) with special techniques that reduce the interference from metal implants
- Routine blood tests may be ordered to evaluate for
    - Possible infection
    - Blood metal ion levels

Typically, an orthopaedic surgeon would take all the information available from the patient's history, physical examination, imaging studies (x-ray, CT, MRI, ultrasound, etc.), and laboratory tests to advise the patient on an appropriate treatment plan.

6. How valuable is blood testing of metal ions?

Blood levels of metal ions can be measured and can reflect how much wear (and corrosion) of the MoM joint replacement is occurring. Patients who have high wear and/or corrosion will generally have higher levels of metal ions. This, in and of itself, does not always indicate the need for additional surgery. Rather, the level of metal ions would be another piece of information that would be used by an orthopaedic surgeon in making a recommendation to the patient.

Patients can have repeat testing of the level of metal ions in their blood to find out if the level is stable, decreasing, or increasing. High, but stable, metal ion levels may be a cause for concern. An increasing level of metal ions may also be a cause for concern and may mean the hip is not functioning as expected. It is also necessary to note that metal ion level testing may not be available in some laboratories, may not be covered by insurance, and has not been standardized among different laboratories, possibly making the results difficult to understand. Blood metal ion testing requires an exacting technique to minimize contamination and inaccurate results.

7. What treatment can be done for a patient with a failed MoM Hip Replacement?

Revision hip surgery (re-do hip replacement) can be performed in patients with failed MoM hip replacements. The exact type of surgery needed will depend on the type of implant and whether the bone and soft tissues have been damaged. Currently, there are limited published results of revision surgery for patients with MoM hips. Results of revision surgery may depend on the degree of damage to the bone and soft tissues from the MoM implant as well as patient characteristics. If in doubt, patients are encouraged to seek a second opinion.

8. Can orthopaedic surgeons predict who is at risk for problems with a MoM hip replacement?

At this time there are no tests which can predict if a patient who has a MoM hip replacement will have problems. Some studies suggest that patients who have smaller-sized balls and sockets or less than optimal alignment of their socket may be at increased risk to develop an adverse local tissue reaction.

9. Are there any issues with women of childbearing age who have a MoM hip replacement?

There is limited information on women who have had MoM hip replacements and then became pregnant; some data suggests that metal ions can cross the placenta. The effect of such metal ions on the fetus is unknown.

10. Why were MoM Hips designed?

MoM hip replacements were designed to solve problems which were seen with other types of hip replacements and to create a hip replacement which was more durable than the metal-on-plastic hip replacements available at the time. Moreover, MoM allowed the use of larger metal balls (larger diameter femoral heads) which improved the stability of the hip joint and made it harder for the patient to pop the hip out of the socket (dislocate the hip). Dislocation is the most common complications following hip replacement surgery.

11. What other types of hip replacements are available to patients?

Hip replacements can be performed with a joint surface which is not metal-on-metal. Such hip replacement would include: metal-on-polyethylene (metal femoral head on a plastic liner), ceramic-on-polyethylene (ceramic femoral head on a plastic liner) and ceramic-on-ceramic (ceramic femoral head on a ceramic liner). The most common type of hip replacement performed is metal-on-plastic.

12. Why did the United Kingdom issue a Medical Device Alert and what did it say?

With the use of a national joint replacement registry, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom identified a higher than expected rate of failure with some MoM hip replacements. In April of 2010, they issued a medical device alert and recommended that all patients with MoM hip replacements have a physical examination and x-ray evaluation on a yearly basis for the first five years after the hip replacement was performed. For patients with symptoms, blood testing of metal ion levels and advanced imaging with MRI or ultrasound were recommended. If metal ion levels were greater than 7 parts per billion for either chromium or cobalt, the recommendation was for repeat blood testing three months later.

13. What is the U.S. orthopaedic community doing to help patients understand the issues with MoM hip replacements?

The orthopaedic community is continuing to perform research on MoM hip replacements, and to work on educating patients and surgeons regarding concerns related to them.

Furthermore, the American Joint Replacement Registry has recently been established. Some surgeons currently participate in registries that track the performance of devices and patient outcomes.

14. What is the American Joint Replacement Registry?

The American Joint Replacement Registry (AJRR) was incorporated in 2009 to serve as a national center for data collection and research on total hip and knee replacements. Such data will benefit patients and society at large by allowing early identification of implants that are not performing as expected. The benefit of registries is evident from the United Kingdom, where problems with the DePuy ASR™ implant was identified. For further information please see: www.orthodoc.aaos.org/ajrr.

15. Who is the American Association of Hip and Knee Surgeons?

The American Association of Hip and Knee Surgeons (AAHKS) is a not-for-profit professional organization of hip and knee surgeon specialists. The organization was founded in 1990 and currently has 1,500 surgeon members. The mission of the AAHKS is to advance and improve hip and knee patient care through leadership in surgeon education, patient advocacy, and supporting research. For further information please see www.aahks.org.

16. Who is the Hip Society?

The Hip Society is a not-for-profit professional organization of hip surgeons whose mission is to advance knowledge and understanding of how the healthy hip functions, as well as how diseases can affect the hip. The Hip Society provides a forum to stimulate the exchange of knowledge in these areas, with the hopes of advancing the currently available treatment options.

17. Who is the American Academy of Orthopaedic Surgeons?

With nearly 36,000 members, the American Academy of Orthopaedic Surgeons (www.aaos.org) or (www.orthoinfo.org) is the premier not-for-profit organization that provides educational programs for orthopaedic surgeons and allied health professionals,

as well as champions the interests of patients, and advances the highest quality musculoskeletal health. Orthopaedic surgeons and the Academy are the authoritative sources of information for patients and the general public on musculoskeletal conditions, treatments, and related issues.

18. Whom can you contact for further information?

The best source of information for patients is their orthopaedic surgeon. We encourage all patients with questions to contact their orthopaedic surgeon. The AAHKS, The Hip Society, and the AAOS can provide educational information regarding MoM hip replacements, but cannot provide medical advice to patients.

DISCLAIMER: The purpose of this document is to provide information about metal-on-metal hip replacements. This document is not a source of medical advice and concerned patients should see their orthopaedic surgeon for evaluation.

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