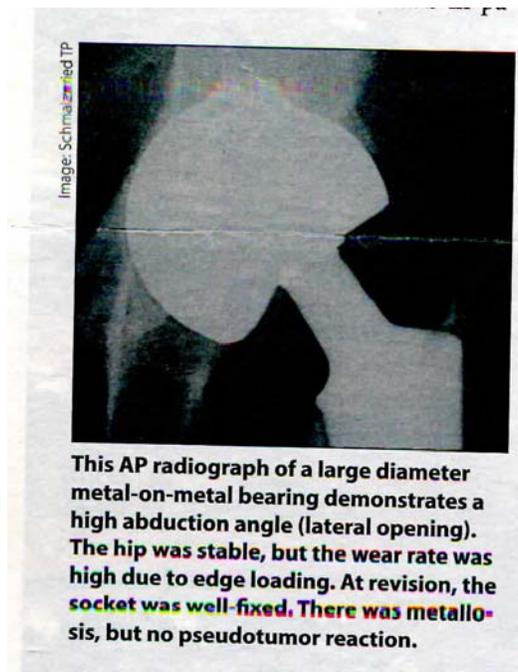


Patients with metal-on-metal hips being contacted after UK officials issue alert

By early May, many patients affected by the alert had already been contacted by their hospitals. A Scottish orthopedic surgeon said the alert was expected.

Orthopedic surgeons in the United Kingdom are contacting patients and starting to follow them up after the Medicines and Healthcare products Regulatory Agency issued a medical device alert requesting they further investigate the cause of pain in their patients with painful metal-on-metal hip arthroplasties or resurfacings.

“I think everyone has been expecting it. For several years now surgeons have been coming across a small number of patients with painful resurfacings but whose X-rays were quite normal,” **Edward R. Dunstan, FRCS (Orth)**, an orthopedic consultant at Queen Margaret Hospital in Dunfermline, Scotland, said.



This AP radiograph of a large diameter metal-on-metal bearing demonstrates a high abduction angle (lateral opening). The hip was stable, but the wear rate was high due to edge loading. At revision, the socket was well-fixed. There was metallosis, but no pseudotumor reaction.

Dunstan has studied chromosomal aberrations and metal-ion levels in patients with metal-on-metal arthroplasties, but does not perform resurfacings. He estimated that perhaps 40,000 U.K. patients have had their hips resurfaced to date. The follow-up being requested will be challenging, he said.

“The problem is going to be trying to identify all the patients,” Dunstan told *ORTHOPEDICS TODAY*, explaining that to reduce long surgical waiting times in the United Kingdom, patients are often referred out of area or have their procedures performed privately.

Scope of problem

In fact, Dunstan wondered whether the effort to find all of the affected patients in the wake of the alert might reveal an even greater than expected problem surrounding metal-on-metal hip surgery.

“Patients are not routinely followed up [on] in the United Kingdom, I’m afraid,” he said.

As an anecdote, he said the last follow-up a relative of his, who had after undergoing metal-on-metal resurfacing surgery in 2003, was at 6 weeks postoperatively. He said his relative was recently contacted by the independent treatment centre where his surgery was performed and is among the many patients in the United Kingdom and worldwide who are doing well following metal-on-metal arthroplasty.

Toward an early revision

The April 22 medical device alert [MDA/2010/33] was generated by reports that the Medicines and Healthcare products Regulatory Agency (MHRA) received about revisions of these implants involving soft tissue reactions, which may be associated with unexplained hip pain.

“The MHRA established a Joint Working Group to study the association between metal-on-metal hip replacements and soft tissue injury and to produce advice and guidance for the Health Services based on the results. The MHRA issued guidance on the management of patients with metal-on-metal hip replacements in the form of a Medical Device Alert to all surgeons. Any patients who are affected by those recommendations will be contacted by their surgeon,” an MHRA spokesperson told *ORTHOPEDICS TODAY*.

The text of the alert explains it is not a recall affecting all U.K. patients with a metal resurfacing arthroplasty and the goal is an early revision of poorly performing metal-on-metal hip replacements, which “should give a better revision outcome,” MHRA officials wrote in the alert.

Orthopedic departments and surgeons, hospital medical directors and others have been asked to perform annual follow-ups for 5 years in asymptomatic patients and more frequently in symptomatic patients. In appropriate patients, blood metal ion measurements and cross-sectional imaging should be performed, the U.K. health officials noted.

BOA, British Hip Society documents

The British Orthopaedic Association (BOA) and the British Hip Society (BHS) have issued a five-page document to help orthopedic surgeons interpret the alert and another document with advice for patients affected.

In the surgeon’s document, officials from the BOA and BHS, including John Skinner, chair of the Expert Advisory Group for the BHS, BOA, National Joint Registry for England and Wales, and MHRA, wrote, “The key points are that excellent results are reported with metal-on-metal hip resurfacing arthroplasty and total hip replacement from many centers. It is accepted that metal-on-metal bearings have a higher incidence of painful joints. There are a small, but significant number of patients who develop pain and significant tissue damage.

“It is felt that pain with metal-on-metal bearings should be investigated as we are still uncertain which patients are likely to progress or develop serious soft tissue reactions.”

Next steps

The MDA and BOA/BHS documents provided information for U.K. surgeons about the alert or to contact laboratories that can perform the requested analysis of blood, synovial fluid and urine samples to identify for trace elements.

At press time, no medical agencies outside the United Kingdom, including the FDA, had issued any similar alerts.

Dunstan, whose preferred hard-on-hard hip coupling is ceramic-on-ceramic, he said he found the information in the alert useful.

U.S. reaction

At a May 6 press conference in New York, **Edwin P. Su, MD**, of the Hospital for Special Surgery, discussed how important proper patient selection and precise surgical technique are to obtaining the best resurfacing results and mitigating the risks of adverse tissue reaction or revision surgery. His preferred patients are usually younger males with good bone stock and a diagnosis of osteoarthritis.

Small components and malignment can be problematic, said Su, who has performed more than 1,300 hip resurfacings. “While some implants do perform better than others, good outcomes with hip resurfacing will most often be achieved by an experienced surgeon who has received excellent training and who is careful in selecting appropriate patients,” he said.

When asked about the MHRA alert at the press conference, Joseph M. DeVivo, president of Smith & Nephew Orthopaedics, maker of the Birmingham Hip Resurfacing (BHR), a widely used metal-on-metal resurfacing prosthesis, noted the document casts some general concern about using metal-on-metal implants, but does not speak specifically to BHR.

“BHR specifically has its clinical data that stand on their own and has not produced the type of concern that competitive, either resurfacing devices or, for that matter, a general big, metal-head metal-on-metal has. So we understand the concern and it is our intention to stand on the data that the device has created in multiple worldwide sources,” DeVivo said.

Shortly after the alert was issued the American Association of Hip and Knee Surgeons e-mailed a copy of it to their members, but it did not take a position on the issues it raised. – *by Susan M. Rapp*

References

For a copy of the alert: www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON079157

For a copy of the BOA/BHS advice to surgeons and patients: www.boa.ac.uk/en/news/whatsnew

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PERSPECTIVE

The MHRA warning is reasonable considering that the risk of an adverse local tissue reaction (ALTR) is estimated between 1% and 9%. The follow-up procedure and diagnostic testing are similar to what I do in my practice. As stated in the MHRA alert, the majority of patients implanted with metal-on-metal hip replacements has well-functioning hips and are thought to be at a low risk of developing serious problems. If the joint is painless and the patient has satisfactory function, the risk of any problem is low. However, persistent pain should be investigated in any joint arthroplasty. Potential causes include low grade infection and aseptic loosening, as well as ALTR.

The alert does not detail the role of radiographs, which are a key component in my evaluation. There are numerous scientific reports indicating that the risks of higher wear, higher ion levels and ALTR are increased when the acetabular component abduction angle (lateral opening) is greater than 50°. There is some evidence that increased combined anteversion is also a risk factor. Radiographs can also identify loose components. For several reasons, monoblock cobalt chromium acetabular components (as used in resurfacing) may not osseointegrate as reliably as modular titanium alloy components.

In my experience, when the components are well-positioned and well-fixed, the risk of ALTR is zero.

-Thomas P. Schmalzried, MD

Medical Director of the Joint Replacement Institute

ORTHOPEDICS TODAY Editorial Board Joint Reconstruction Section Editor