September 29, 2010

Metal Ion, Radiological and Cross-Sectional Testing Protocols

Guidance for the ASR™ XL Acetabular System/DePuy ASR™ Hip Resurfacing System Recall

On August 24, 2010, DePuy Orthopaedics, Inc. issued a voluntary recall of all ASR products. Since the recall, DePuy has received inquiries from surgeons concerning how to evaluate patients who received an ASR product. This update is designed to provide information related to frequently asked questions, and should not preclude any other routine clinical evaluation or treatment.

We hope this information assists you in the evaluation and treatment of your ASR patients. This information is not meant to substitute for the exercise of your own medical judgment.

MHRA Device Alert

In the recall communication, DePuy outlined that patients should be followed as per the May 25, 2010 UK Medicines and Healthcare Products Regulatory Agency (MHRA) Device Alert, which states:

- Follow up all patients implanted with ASR acetabular cups at least annually for five years postoperatively. Beyond five years, follow up in accordance with locally agreed protocols.
- For patients who are symptomatic or implanted with a cup angle greater than 45°, particularly where a small component has been implanted:
    - Consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scans
    - If metal ion levels in whole blood are elevated above 7 parts per billion (ppb) for either metal ion, a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
    - If MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses, then revision surgery should be considered.

The following provides information on how to meet the MHRA follow-up recommendations.

Whole Blood Collection Suggestions

At the evaluation visit, if the patient is symptomatic or if you or the patient has concerns about the hip, blood metal ion testing (cobalt and chromium in whole blood) should be considered.

Patients should be advised to refrain from taking mineral supplements, vitamin B-12 or vitamin B complex at least three days prior to specimen collection.

Cobalt and chromium in whole blood will need to be drawn at a LabCorp Patient Service Center. When sending patients to LabCorp, please provide the following information:

- **Patient's name**
- **Patient's address**
- **Patient's date of birth**
- **DePuy ASR Claim number**

- **Billing Account Number: 13103875**
- **Panel code: 284418** (Cobalt and chromium in whole blood)
- **Surgeon's first and last name**
- **Surgeon's fax number** (results will be faxed to this number)
- **Surgeon's LabCorp account number** (if available)

Results may be reported in different units. Please note the following are equivalent:
1 ppb = 1 µg/l = 1 ng/ml

To find the closest lab please visit: www.labcorp.com. If there is no LabCorp Patient Service Center in the area, patients should be directed to Quest Diagnostics with a detailed prescription containing:

Special Miscellaneous test: Cobalt and chromium in whole blood

To find the closest laboratory or Patient Service Center visit: www.questdiagnostics.com

Radiological Protocol Suggestions

1. X-rays should be obtained on an annual basis or as per standard of care
2. All efforts should be in place to have consistency of positioning in each view which could be reliably used to compare with previous radiographic exams in order to assess any radiographic changes since the original procedure.
3. Views for plain x-rays:
    a. AP-Pelvis (centered at symphysis pubis)
    b. AP-Hip (at hip joint center)
    c. Cross table lateral
4. If using digital radiographs, it is recommended to have the image size at 1:1 to facilitate any linear dimension analysis.
5. Radiographic signs of interest:

While we encourage you to familiarize yourself with the available medical literature on the subject, our current understanding of potential radiographic signs of interest discussed in the literature is as follows:

- Interface implant-bone demarcations
- Periprosthetic osteolysis lesion(s)
- Femoral neck narrowing (resurfacing)
- Acetabulum inclination angle subtended by a horizontal reference line delineated by interobturator line tangent to inferior aspect of both obturator foramen and a line through the open face of the acetabulum.
- Hip joint center relative to vertical line through tear-drop and a horizontal reference line, i.e. intraobturator line.
- Acetabulum coverage (superior-lateral and inferior-medial)
- Visible changes from previous radiographs

Additional Cross-sectional Imaging Suggestions

Magnetic Resonance Imaging (MRI)

MRIs should be ordered as MRI with metal artifact reduction sequences (MARS) to reduce the size and intensity of magnetic field distortion created by the implant

Patient Position
Supine, feet first
Position pelvis in the centre of body matrix coil (top of prosthesis at top of coil)
Landmark at centre of coil

Machine Settings
Machine settings are specific to each MRI scanner. The manufacturer of the MRI scanner should be contacted to identify the appropriate settings for the metal artifact reduction sequence (MARS). The MARS order provided by the surgeon to radiology should include "MARS fast spin echo" or "MARS turbo spin echo" to reduce artifacts.

MRI Findings
MRI findings should be correlated with clinical examination. MRI may demonstrate changes that appear to correspond to macroscopic surgical findings (soft-tissue necrosis, abnormal masses, sterile fluid collections and bone necrosis).

MRI Signs of Interest

While we encourage you to familiarize yourself with the available medical literature on the subject, our current understanding of potential MRI signs of interest discussed in the literature is as follows:

- Periprosthetic soft tissue mass with no hyperintense T2W fluid signal or fluid-filled peri-prosthetic cavity
- Peri-prosthetic soft tissue mass/fluid-filled cavity or lesions with either of following:
    - Muscle atrophy (fatty infiltration) or edema in any muscle other than short external rotators or
    - Bone marrow edema: hyperintense on short inversion recovery sequence (STIR)
    - Fluid-filled cavity extending through deep fascia
- Tendon defect and/or avulsion, intermediate T1W soft tissue cortical or marrow signal

Fluid collections are usually well circumscribed and best seen on T2-weighted sequences. Cores have signal intensities similar to that of bladder fluid, while the pseudocapsules appear hypointense to skeletal muscle and often feature areas of no signal.

Soft-tissue masses are more solid and best seen on a T2-weighted sequence. They may appear less circumscribed than the fluid collections and may have no obvious capsule and can characterize loss of muscle definition and tissue planes.

Ultrasound

Ultrasound can be used when a MARS MRI is not available. Ultrasound should be performed by staff experienced in conducting musculoskeletal ultrasound scans. Ultrasound findings should be correlated with clinical examination; these may demonstrate changes that appear to correspond to macroscopic surgical findings (soft-tissue swelling, abnormal masses, fluid collections, muscle or tendon abnormalities and bone necrosis).

Patient Position
Supine and lateral decubitus

Probe Placement
To obtain sagittal oblique images place probe parallel to long axis of femoral neck.

To obtain additional images, place probe anteriorly, posteriorly and directly laterally to femoral neck.

Ultrasound Findings
Any abnormality needs to be examined in multiple planes. Examination includes inspection of the psoas muscle. Use probes of varying frequency depending on the size of the patient.

Ultrasound Signs of Interest
While we encourage you to familiarize yourself with the available medical literature on the subject, our current understanding of potential ultrasound signs of interest discussed in the literature is as follows:

- Extra-articular fluid collection
- Fluid collections (identified as hypoechoic areas in soft tissues)
- Solid or cystic masses

These suggestions are based on the attached published literature references. These articles provide more information related to the MARS MRI and ultrasound techniques and the findings related to soft tissue reactions around hip replacements. Medical practice is constantly evolving, so there may be new suggestions regarding imaging techniques in the future. Any updated suggestions or guidances will be found on the DePuy website, www.DePuy.com. If you have additional questions, please contact DePuy's Scientific Information Office at 888-554-2482.

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