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# Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging[1]

This standard is issued under the fixed designation F2978; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide describes the recommended protocol for magnetic resonance imaging (MRI) studies of patients implanted with metal-on-metal (MOM) devices to determine if the periprosthetic tissues are likely to be associated with an adverse local tissue reaction (ALTR). Before scanning a patient with a specific implant, the MR practitioner shall confirm that the device is MR Conditional and that the scan protocol to be used satisfies the conditions for safe scanning for the specific implant. This guide assumes that the MRI protocol will be applied to MOM devices while they are implanted inside the body. It is also expected that standardized MRI safety measures will be followed during the performance of this scan protocol.

1.2 This guide covers the clinical evaluation of the tissues surrounding MOM hip replacement devices in patients using MRI. This guide is applicable to both total and resurfacing MOM hip systems.

1.3 The protocol contained in this guide applies to whole body magnetic resonance equipment, as defined in section 2.2.103 of IEC 60601-2-33, Ed. 3.0, with a whole body radiofrequency (RF) transmit coil as defined in section 2.2.100. The RF coil should have quadrature excitation.

1.4 The values stated in SI units are to be regarded as standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use. The user may consider all precautions and warnings provided in the MR system and hip implant labeling prior to determining the applicability of these protocols.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

A340 Terminology of Symbols and Definitions Relating to Magnetic Testing

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *IEC Standard:*[3]

IEC 60601-2-33, Ed. 3.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2010

## 3. Terminology

3.1 *Definitions—For the purposes of this standard the following definitions shall apply:*

3.1.1 *Magnetic Resonance Imaging (MRI)*—diagnostic imaging technique that uses static and time varying magnetic fields to provide tomographic images of tissue by the magnetic resonance of nuclei.

3.1.2 *MR - Conditional*—an item that has been demonstrated to pose no known hazards in a specific MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, *dB/dt* (time rate of change of the magnetic field), radiofrequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required (Practice F2503).

3.1.3 *Metal-on-Metal (MOM) hip replacement*—a hip arthroplasty device in which the articulating surfaces of the femoral head and the acetabular cup are fabricated from metal.

## 4. Summary of Protocol

4.1 Surface coil fast spin echo (FSE) sequences of the affected hip in three planes and a larger field-of-view (FOV) short tau inversion recovery (STIR) sequence to include both

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, P.O. Box 131, CH-1211 Geneva 20, Switzerland, http://www.iec.ch.

hips and the surrounding pelvis are recommended. A large FOV sequence of the entire pelvis should be included to assess for remote causes of pain, such as pelvic or sacral fractures, which may be referred to the hip.

4.2 With regards to the FSE surface coil imaging, an intermediate echo time, water-sensitive fast spin echo technique is effective in highlighting osteolysis and detecting wear-induced synovitis. The fluid-sensitive inversion recovery sequence helps outline fluid collections and will demonstrate the presence of marrow edema in the setting of implant loosening or peri-prosthetic fracture (1).

4.3 Modifications of standard pulse sequence parameters should be applied when imaging in the presence of metallic implants. Options available to reduce susceptibility artifacts on routine clinical scanners include increasing the amplitude of the readout gradient by the use of a wider receiver bandwidth and thinner slices (2, 3). Decreasing voxel size by the use of a high-resolution matrix will increase spatial resolution and trabecular detail in the face of the susceptibility artifact. However, these techniques will also decrease the signal-to-noise ratio. Orienting the frequency encoding direction along the long axis of the prosthesis can also be effective in decreasing artifacts but may not be feasible (4). In addition, view-angle tilting (VAT) gradients can be applied, which applies a section-selection gradient during the signal readout (5).

4.4 Techniques to avoid when imaging in the presence of metal include imaging at high field strengths, use of frequency-selective fat suppression and use of gradient echo sequences. Susceptibility artifact is directly proportional to the main magnetic field ($B_0$); therefore, imaging at field strengths greater than 1.5 T should be avoided when possible. When fat suppression is required, inversion recovery sequences are preferred over frequency-selective fat suppression techniques, as they are less susceptible to magnetic field inhomogeneities. Standardized gradient echo imaging should be avoided, as these sequences lack the 180° refocusing pulse of spin echo sequences, resulting in rapid dephasing of spins and large areas of signal void in the presence of metal.

4.5 Table 1 outlines a suggested protocol for imaging MOM hip arthroplasty using a 1.5 Tesla (T) clinical scanner (6).

4.6 Multi-acquisition variable-resonance image combination (MAVRIC SL) is a new technique that results in an image with markedly reducd susceptibility artifact (7-9). Early studies have demonstrated decreased image distortion at the bone-implant interface and improved detection of peri-prosthetic osteolysis and synovitis when compared to conventional fast spin echo techniques (10). A recently reported study of patients with either MOM resurfacing or MOM total hip arthroplasty demonstrated synovitis using the MAVRIC sequence in 77.4% of resurfacing arthroplasty and 86.2% of total hip arthroplasty (THA) hips (11). For imaging MOM arthroplasty, the use of a MAVRIC sequence is recommended in at least one plane (coronal or axial) when this sequence is available. Specific parameters are listed in Appendix X2. With regards to timing, this protocol has been successful in assessing patients for both immediate and delayed complications, including fracture, nerve impingement and tendon tears in the immediate postoperative period, and adverse tissue reactions, infection and potential loosening in the later postoperative period (6, 12-14).



**TABLE 1 Suggested Protocol for Metal-on-Metal Hip Arthroplasty Imaging at a 1.5 T MRI Scanner** $^{A,B}$

| Timing Parameters | Axial FSE/TSE | Coronal FIR | Coronal FSE/TSE | Axial FSE | Sagittal FSE/TSE |
|---|---|---|---|---|---|
| Coil | Body Coil | Body Coil | Surface Coil | Surface Coil | Surface Coil |
| TR, msec | 4,500 - 5 500 | 4,500 | 4,500 - 5,800 | 4,500-5,500 | 5,500-6,500 |
| TE, msec | 21.4 - 32.0 | 18 | 24 - 30 | 24 - 30 | 23 - 30 |
| TI, msec | . . . | 150 | . . . | . . . | . . . |
| Number of echoes | 16 - 20 | 7 - 9 | 10 - 20 | 10 - 20 | 14 - 20 |
| BW, kHz | 83 - 100 | 83 - 100 | 83 - 100 | 83 - 100 | 83 - 100 |
| FOV, cm | 32 - 36 | 34 - 36 | 18 | 17 - 19 | 18 - 20 |
| Matrix | 512 × 256 | 256 × 192 | 512 × 352 | 512 × 256 - 288 | 512 × 352 |
| Slice thickness, mm | 5 | 5 | 4 | 4 | 2.5 - 3 |
| Interslice gap, mm | 0 | 0 | 0 | 0 | 0 |
| Number of averages | 4 | 2 | 4 - 5 | 4 - 5 | 4 - 5 |
| No phase wrap | yes | yes | yes | yes | yes |
| Swap phase and frequency | yes | yes | yes | yes | yes |
| Variable BW | yes | yes | yes | yes | yes |
| Frequency direction | anterior to posterior | right to left | right to left | anterior to posterior | anterior to posterior |

[A] *Abbreviations:*
BW – bandwidth.
FIR – fast inversion recovery.
FOV – field of view.
FSE – fast spin echo.
TSE – turbo spin echo.
KHz – kiloHertz.
TE – echo time.
TI – inversion time.
TR – repetition time.

[B] Depending on the MRI system, the BW may be reported as half-bandwidth (maximum frequency), so a reported BW of 62.5 is actually acquired at 125 Hz over the entire frequency range. For Table 1, to convert to Hz/pixel when implementing 512 frequency encoding steps, use the following formula: (kHz x 2000)/512.

Additional prototype sequences are in development and will become available for such imaging including slice encoding for metal artifact correction (SEMAC), which is a variant of the VAT principle that adds additional phase-encoding steps in the slice dimension (9, 15). Currently, a commercially available sequence applies the SEMAC principle and is termed the WARP sequence, which is a high bandwidth protocol that includes the VAT technique (16).

## 5. Significance and Use

5.1 Magnetic resonance imaging is ideally suited to image MOM hip arthroplasty due to its superior soft tissue contrast, multiplanar capabilities and lack of ionizing radiation. MR imaging is the most accurate imaging modality for the assessment of peri-prosthetic osteolysis and wear-induced synovitis (17-19).

5.2 Before scanning a patient with a specific implant, the MR practitioner shall confirm that the device is MR Conditional and that the scan protocol to be used satisfies the conditions for safe scanning for the specific implant.

5.3 This guide can be used to identify the following adverse events.

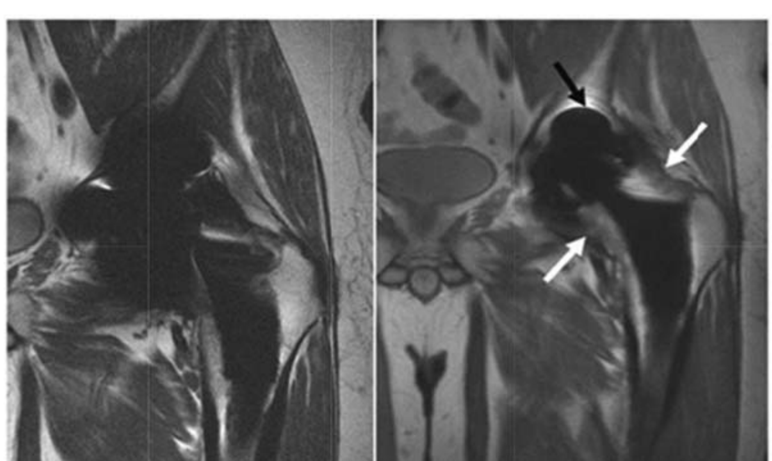
5.3.1 *Osteolysis*—Magnetic resonance imaging is superior to conventional radiographs and CT in the assessment of peri-prosthetic osteolysis and has been shown to be the most accurate method to locate and quantify the extent of peri-prosthetic osteolysis (17, 18). On MR imaging, osteolysis appears as well marginated intraosseous intermediate to slightly increased signal intensity lesions that contrast with the high signal intensity of the intramedullary fat. A characteristic line of low signal intensity surrounds the area of focal marrow replacement, distinguishing the appearance of osteolysis from tumoral replacement of bone or infection (20).

5.3.2 *Component Loosening*—While the data are preliminary, MR imaging can identify circumferential bone resorption that may indicate component loosening. Loosening may result from osteolysis, circumferential fibrous membrane formation or poor osseous integration of a non-cemented component. On MR imaging, component loosening typically manifests as circumferential increased signal intensity at the metallic-bone or cement-bone interface on fat-suppressed techniques (19). The finding of circumferential fibrous membrane formation or osteolysis also indicates potential loosening; this is in contrast to a well-fixed component, with high signal intensity fatty marrow directly opposed to the implant interface.

5.3.3 *Wear-Induced Synovitis*—Magnetic resonance imaging is the most useful imaging modality to assess the intracapsular burden of wear-induced synovitis surrounding MOM arthroplasty (21). Preliminary data indicate that the signal characteristics of the synovial response on MR imaging correlate with the type of wear-induced synovitis demonstrated on histology at revision surgery (22). Low signal intensity debris is suggestive of metallic debris on histology. Mixed intermediate and low signal debris correlates with the presence of mixed polymeric (polyethylene and/or polymethyl methacrylate) and metallic debris at histology. Magnetic resonance imaging can demonstrate decompression of synovitis or fluid into adjacent bursae, such as the iliopsoas or trochanteric bursa, which can present as soft tissue masses or with secondary nerve compression. On occasion, wear-induced synovitis can result in a chronic indolent pattern of erosion of the surrounding bone, even in the absence of focal osteolytic lesions (6).

5.3.4 *Infection*—In the setting of infection, the synovium often demonstrates a hyperintense, lamellated appearance with adjacent extracapsular soft tissue edema. These appearances help to distinguish the synovial pattern of infection from wear-induced synovitis, although aspiration is still required for definitive diagnosis (14). The presence of a soft tissue collection, draining sinus or osteomyelitis further supports the diagnosis of infection on MR imaging.



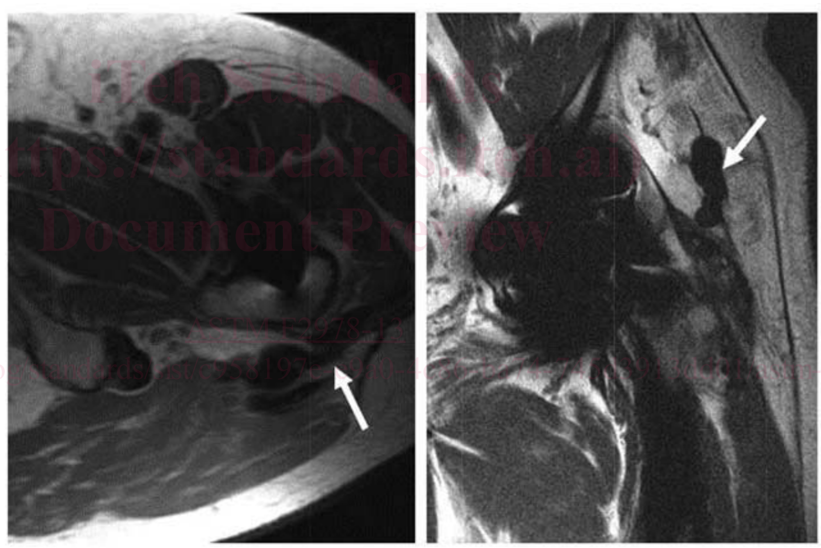


NOTE 1—Note the improved visualization of synovitis (white arrows) and the bone-prosthesis interface (black arrow) on the MAVRIC image. Images courtesy of Dr. Hollis Potter.

**FIG. 1 Coronal FSE (Left) and MAVRIC (Right) Images of a Left MOM Hip Arthroplasty**

NOTE 1—There is focal osteolysis (white arrows) in the greater trochanter, which manifests as well-demarcated intermediate signal intensity, similar to that of skeletal muscle, replacing the normal high signal intensity fatty marrow. Images courtesy of Dr. Hollis Potter.

**FIG. 2 Coronal (Left) and Axial (Right) FSE Images of a Left MOM Hip Arthroplasty**





NOTE 1—Wear-induced synovitis decompresses into the abductor musculature where there is low signal intensity debris (arrow), consistent with metallic debris. Images courtesy of Dr. Hollis Potter.

**FIG. 3 Axial (Left) and Coronal (Right) FSE Images of a Left MOM Hip Arthroplasty**

5.3.5 *Adverse Local Tissue Response*—Adverse local tissue reactions can manifest as synovitis, bursitis, osteolysis and cystic or solid masses adjacent to the arthroplasty, which may be termed pseudotumors (17-19). ALTR can also include the histopathologic feature of aseptic lymphocytic vasculitis-associated lesions (ALVAL), which can be confirmed using histology. A relatively common appearance of joints with ALVAL is expansion of the pseudocapsule with homogenous high signal fluid interspersed with intermediate signal intensity foci. More recent studies suggest that maximum synovial thickness and the presence of more solid synovial deposits highly correlate with tissue damage at revision surgery and necrosis at histologic inspection (12).

## 6. Apparatus

6.1 *MRI Specification*—The MRI apparatus consists of a magnet using whole body RF quadrature excitation (refer to 1.3). Imaging is recommended to be conducted at a magnetic field strength of 1.5 T and should have the capabilities to perform the sequences suggested in 4.5. Higher field open systems, such as 1.0 T and 1.2 T open systems, may also provide acceptable performance provided the protocols are