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Information Statement

Current Concerns with Metal-on-Metal Hip Arthroplasty

The American Academy of Orthopaedic Surgeons gratefully acknowledges the work of the Association of Hip & Knee Surgeons in the development of this information statement. It is an educational tool based on the opinion of the authors and not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Metal-on-metal (MoM) bearings were reintroduced over the last two decades because of their lower volumetric wear rates in comparison to conventional metal-on-polyethylene bearings.[1] This has the potential to substantially reduce wear-induced osteolysis as the major cause of failure. Other proposed advantages of MoM hip arthroplasty include greater implant stability, and bone conservation (for hip resurfacings). It has been estimated that since 1996 more than 1,000,000 MoM articular couples have been implanted worldwide. However, with increasing clinical experience, the national joint registries have recently reported the failure rate of total hip arthroscopy (THA) with MoM bearings to be 2-3 fold higher than contemporary THA with non-metal-on-metal bearings.[3,4] Moreover, adverse periprosthetic tissue reactions involving the hip joint have emerged as an important reason for failure in MoM patients.

The information provided in this white paper is intended as an aid to the orthopaedic surgeon in the assessment and management of patients with metal-on-metal bearings. It is recognized that each patient may have specific circumstances or features that require individualized approaches, and this document is not intended to be proscriptive in any fashion. In addition, it is recognized that there is insufficient high quality evidence in this area to develop a formal guideline based on a systematic review of the literature. Thus, a document based on a consensus of experienced practitioners is in order given the state of the published literature.

Adverse Local Tissue Reaction Risk Stratification Algorithm for Evaluating Patients with Metal-on-Metal Hip Arthroplasty

A painful MoM hip arthroplasty has various intrinsic and extrinsic causes (**Table 1**). As in all painful THA,[5] a thorough clinical history, a detailed physical examination, as well as radiographic and laboratory tests are essential to delineate potential cause(s) of pain in patients with MoM hip arthroplasty. A systematic risk stratification recommendation, for multiple modes of failure including adverse local tissue reactions, based on the currently available evidence is presented here to optimize management (**Tables 2, 3, 4**). The algorithm presented in this review will continue to develop as further evidence becomes available. For patients who have a stemmed total hip or surface replacement device that has been recalled by the manufacturer, this risk stratification scheme still applies. In addition, the surgeon should inform the patient about the recall and direct them to information from the manufacturer (on its website) regarding the recall and suggested follow up.

Table 1: Extrinsic/Instrinsic to the Hip

Extrinsic to the Hip	Intrinsic to the Hip Intracapsular/Implant-Related:
• Peripheral vascular disease	• Infection
• Hernia (femoral, inguinal)	• Loosening
• Peripheral nerve injury (e.g. sciatic, femoral, meralgia paresthetica)	• Instability/Subluxation
• Malignancy or metastases	• Periprosthetic fracture
• Metabolic bone disease (e.g. Paget's disease, osteomalacia)	• Adverse soft tissue reaction
• Complex regional pain syndrome	• Extracapsular:
• Psychological disorder	• Trochanteric bursitis
• Peripheral vascular disease	• Iliopsoas tendonitis

Table 2: MoM 'Low' Risk Group

'Low' Risk Group Stratification	
Patient Factors	• Low activity Lefel Patient
Symptoms	• Asymptomatic (including no systemic or mechanical symptoms
Clinical Examination	• No Change in Gait (i.e. No Limp, No abductor weakness) • No Swelling
Implant Type	• Small Diamerter Femoral Head (<36mm) Modular Mom THA; hip resurfacing in males <50 with OA
Radiographs (2 views ± Serial for Comparison when available)	• Optimal Acetabular Cup Orientation • No Implant Osteolysis/Loosening
Infection Work-Up (ESR, CRP, ± Hip Aspiration)	• Within Normal Limits
Metal Ion Level Test (if available)	• Low (<3 ppb)
Cross-Sectional Imaging (if available) These studies include MARS MRI; Ultrasound or CT when MRI contraindicated or MARS protocol not available.	• Within Normal Limits
Treatment Recommendation	• Annual Follow Up

Table 3: MoM 'High' Risk Group

'High' Risk Group Stratification	
Patient Factors	• Female with Dysplasia (for Hip Resurfacing) • High activity level patient
Symptoms	• Symptomatic • Severe Local Hip and/or mechanical Symptoms • Systemic Symptoms
Clinical Examination	• Change in Gait (i.e. Limp). Abductor weakness • Swelling
Implant Type	• Large diameter femoral head (≥36mm) Modular or Non-modular MoM THA • Recalled MoM Implant
Radiographs (2 views ± Serial for Comparison when available)	• Suboptimal Acetabular Cup Orientation • Implant Osteolysis/Loosening
Infection Work-Up (ESR, CRP, ± Hip Aspiration)	• Within Normal Limits
Metal Ion Level Test	• High (>10 ppb)
Cross-Sectional Imaging (MARS MRI; Ultrasound or CT when MRI contraindicated or MARS protocol not available)	• Presence of Abnormal Tissue Reactions *with* Involvement of Surrounding Muscles and/or Bone • Solid lesions • Cystic Lesions with Thickened Wall • Mixed Solid and Cystic Lesions
Treatment Recommendation	• Consider Revision Surgery

Table 4:MoM 'Moderate' Risk Group

'Moderate' Risk Group Stratification	
Patient Factors	• Male or Female • Dysplasia (for Hip Resurfacing) • Moderate activity level patient
Symptoms	• Symptomatic • Mild Local Hip symptoms (e.g. Pain, Mechanical symptoms) • No Systemic symptoms
Clinical Examination	• Change in Gait (i.e. Limp). No abductor weakness • No Swelling
Implant Type	• Large diameter femoral head (≥36mm) modular or non-modular MoM THA • Recalled MoM Implant • Hip Resurfacing with Risk Factors (Female with Dysplasia) • Modular neck device
Radiographs (2 views ± Serial for Comparison when available)	• Optimal acetabular cup orientation • No Implant Osteolysis/Loosening
Infection Work-Up (ESR, CRP, ± Hip Aspiration)	• Within Normal Limits
Metal Ion Level Test	• Moderately Elevated (3-10 ppb)
Cross-Sectional Imaging (MARS MRI; Ultrasound or CT when MRI contraindicated or MARS protocol not available)	• Presence of abnormal tissue reactions without Involvement of Surrounding Muscles and/or Bone • Simple Cystic Lesions or Small Cystic Lesions Without Thickened Wall
Treatment Recommendation	• Follow Up in 6 months
Revision Surgery	• Consider Revision Surgery if symptoms progress, Imaging Abnormality Progresses and/or Rising Metal Ion Levels over 6 Months

Clinical Evaluation

A complete history is essential to evaluate patients with MoM hip arthroplasty. The temporal onset, duration, severity, location, and character of the pain help narrow the differential diagnosis. A history of delayed wound healing, pain after dental or gastrointestinal procedures all hint of joint sepsis. Other symptoms such as a feeling of swelling or fullness about the hip, and mechanical symptoms of crepitus, clicking or squeaking should be elicited. A clinical history of metal allergy manifested as a dermal reaction to metal jewelry may also be helpful in assessing potential hypersensitivity reactions. Furthermore, a thorough review of systems should be noted for any potential systemic symptoms.

Comprehensive neurovascular examination is necessary to rule out neurogenic and vascular causes of pain. Inspection of the skin should note previous scars and signs of infection. Careful palpation should be performed around the hip to detect any soft tissue mass. Range of motion should be examined to determine the positions that may elicit the patient's pain, as reproduction of pain on active hip flexion and passive hip extension may suggest iliopsoas tendinitis. Abduction strength must be assessed.

Radiographic Evaluation

After a complete history and physical examination, evaluation of a MoM hip arthroplasty should follow with a critical review of serial plain radiographs, focusing on signs of implant-related complications such as loosening or osteolysis particularly in retro-acetabular, ischial and pubic regions. For hip resurfacing implants, the presence of radiographic sign of impingement (an indentation typically located in the lateral or anterolateral aspects of the femoral neck) should be noted. As the acetabular components with high inclination angle have been shown to demonstrate elevated serum and joint fluid levels of metal ions and increased wear secondary to edge loading,[6] it is important to measure the acetabular component orientation in both planes including abduction angle relative to the pelvic horizontal on anteroposterior view. A shoot-through lateral is also helpful is assessing acetabular component anteversion.

ESR/CRP and Hip Aspiration

In contrast to metal-on-polyethylene (MoPE) THA, where elevation of both erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) have specificity for infection as high as 0.93,[7] interpretation of elevated ESR and CRP should be done with caution in MoM hip arthroplasty patients as elevated ESR/CRP have been reported in non-infected cases of adverse soft tissue reactions. Synovial fluid white cell count greater than 3,000 WBC/mL combined with predominant polymorphonuclear cells (>80%) has been reported to have the highest accuracy and sensitivity for infection in MoPE THA.[8] However, these parameters may not be applicable in MoM hip arthroplasty as adverse soft tissue reactions (proven to be culture negative) often have white cell counts greater than 3,000 WBC/mL combined with >95% polymorphonuclear cells. Although manual cell count should be obtained as tissue debris in suspension may lead to falsely elevated automated cell counts, no absolute quantity of cells can be suggested at this time. However, the higher the number of cells, predominance of monocytes, would warrant further investigation.

Sensitivity and Specificity of Metal Ion Levels in Predicting MoM Failure

Metal ions are released from the bearing surfaces and from modular connections by virtue of mechanically assisted crevice corrosion (MACC). Metal ion levels are influenced by factors such as the implant type, implant materials and design, diameter of the bearings, and positioning of the implant. In 2010, the British Medicine and Healthcare Products Regulatory Agency issued a safety alert pertaining to all types of MoM hip implants and recommended cross sectional imaging studies in patients with either cobalt or chromium ion levels above 7 parts per billion (ppb or µg/l). Read the MoM Device Alert at:
https://www.gov.uk/drug-device-alerts/medical-device-alert-metal-on-metal-mom-hip-replacements-updated-advice-with-patient-follow-ups

More recently, the sensitivity and specificity of the 7 ppb cut-off level has been reported to be 52% and 89%, respectively,[9] indicating that the 7 ppb has relative poor ability to identify MoM failures. The lowering of the cut-off level to 5 ppb increases the sensitivity to 63% and lowers specificity to 86%. In measuring trace metals cobalt and chromium with concentrations in the parts-per-billion range, the risk of contamination is a major technical challenge. Adherence to stringent protocols is required from specimen collection to sample introduction to the analysis.[10] While metal ion levels are a useful diagnostic test for assessing MoM hip arthroplasty, its role is limited to being an important adjunct to systemic clinical assessment and other investigative tools. Therefore, metal ion levels alone should not be relied on as the sole parameter to determine clinical recommendation for revision surgery. Furthermore, the correlation between cobalt or chromium serum, blood or synovial fluid levels, and adverse local tissue reactions observed at the time of revision surgery is incompletely understood[11]. In addition, the interpretation of metal ion levels is confounded in patients who have other Co- and Cr-containing metallic implants, particularly bilateral MoM total hip or surface replacements. In light of the current limitations of the metal ion levels in guiding surgical intervention, research efforts are currently underway to identify diagnostic tests, such as biomarkers in synovial fluid that would be helpful in detecting periprosthetic necrosis prior to the occurrence of significant adverse local tissue reactions.

Ultrasound & Magnetic Resonance Imaging

As ultrasound is not affected by metal artifacts,[12] ultrasound is a useful tool to detect the presence of a soft-tissue mass adjacent to MoM implant.[13] It can differentiate solid lesions from cystic lesions, and can also be used to guide biopsy and aspirations. Ultrasound has been used to screen a large number of asymptomatic MoM patients in order to establish prevalence of asymptomatic pseudotumours.[14] However, this imaging technique remains operator dependent, and its utility may be limited in evaluating the deep structures.

Metal artifact reduction sequence magnetic resonance imaging (MARS MRI) has the capacity to produce high-resolution images of the periprosthetic tissues in patients with MoM hip arthroplasty. Image distortion due to susceptibility artifact generated by the ferromagnetic property of the cobalt-chromium implant is reduced with various modification of pulse sequence.[12] Modified MRI has been demonstrated to be the most accurate test to detect the wear-induced synovial response predating the presence of osteolysis on radiographs or standard MRI.[15] MARS MRI is an important cross sectional imaging modality in detection of adverse local soft tissue reactions. MRI can delineate anatomical extension boundaries of periprosthetic fluid collections and solid masses, as well as detection of any compression of juxtaposed neurovascular structures, which is of particular importance in pre-operative planning. It also allows evaluation of the surrounding soft tissue envelope such as the integrity of hip abductor and gluteal musculature. Therefore, early application of MRI may be an important tool that allows early detection of adverse soft tissue reactions. As wear-induced synovitis has been observed in both symptomatic and asymptomatic MoM patients, a prospective study is currently underway to monitor these patients longitudinally. Metal artifact reduction technique continues to be refined with development of new imaging optimization protocols. Therefore, the utility of MARS MRI in evaluating patients with MoM hip arthroplasty is likely to have an increasing role in the clinical decision-making process.

Frequency of Follow Up

The frequency of follow up examinations needs to be tailored to the individual patient based on the risk stratification category and intervening clinical course. Annual follow up is recommended for patients with a MoM total hip or surface replacement arthroplasty. Patients in the moderate risk category and patients electing to forego surgery in the high risk category should be followed at 4 to 6 months intervals. Follow up evaluation should include a careful history and physical and plain radiography. In addition, the orthopaedic surgeon should consider repeat MARS-MRI testing and metal ion analysis, depending on the individual patient's signs, symptoms, radiographs and clinical course.

Implant Retrieval Analysis

For those patients who undergo revision surgery of their metal on metal bearing, it is recommended that the implant be evaluated at a center experienced in implant retrieval analysis of such devices. The mechanism of failure of the hip reconstruction can be ascertained by a gross and microscopic evaluation of the implant in concert with clinical, radiographic and histopathologic findings. Delineating the mechanism(s) of failure will provide valuable information to surgeons, manufacturers and implant designers

Summary

There should be a low threshold to perform a systematic evaluation of patients with MoM hip arthroplasty as early recognition and diagnosis will facilitate the initiation of appropriate treatment prior to significant adverse biological reactions. A painful MoM hip arthroplasty has various intrinsic and extrinsic causes and a systematic treatment approach based on the currently available data is presented to optimize management of MoM patients. The risk stratification algorithm presented will continue to develop as further evidence become available providing additional insights. While specialized tests such as metal ion analysis are useful modalities for assessing MoM hip arthroplasty, over-reliance on any single investigative tool in the clinical decision-making process should be avoided. Future research focusing on validation of the current diagnostic tools for detecting adverse local tissue reactions as well as optimization of MoM bearings and modular connections to further diminish wear and corrosion is warranted.

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