The Hip Society: Optimizing Management of Patients with Metal-on-Metal Hips: Understanding and Applying the Best Evidence into Practice

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Since 1996 more than 1,000,000 metal-on-metal (MoM) hip arthroplasty bearing couples have been implanted across the United States and throughout the world [1]. Unfortunately, these MoM bearing couples have not fared as well as metal-on-polyethylene or ceramic-on-polyethylene couples. Adverse local tissue reactions (ALTR) are increasingly recognized as a mode of failure with MoM bearings. Failures of MoM articulations have been described as catastrophic, causing tremendous soft tissue damage and requiring extensive reconstructive procedures. These types of catastrophic failures have markedly curtailed the utilization of MoM bearing couples. Perhaps one of the most pressing questions facing orthopaedic surgeons throughout the world is the appropriate evaluation and treatment of patients who have had MoM hip arthroplasty or resurfacing procedures.

Clinical Evaluation

The clinical follow-up of patients who have undergone primary total or resurfacing hip arthroplasty with MoM bearings commences no differently than evaluation for patients who have undergone hip arthroplasty with metal- or ceramic-on-polyethylene articulations. Patients who report pain and discomfort in their arthroplasty may have either extrinsic or intrinsic causes. Careful evaluation is mandatory. All extrinsic causes of pain must be excluded. Perhaps, one of the most significant causes of extrinsic pain is spinal disease. Therefore, patients should undergo careful evaluation to exclude spinal causes of pain such as stenosis, disc herniation, spondylolysis or spondylolisthesis. General physical conditions such as femoral or inguinal hernias may also cause significant groin pain that maybe misconstrued as hip disease. Vascular or neurological causes of pain should be excluded. Malignancy or metastases may also represent a cause of pain and discomfort. Metabolic bone diseases such as Paget's or osteomalacia may cause symptoms similar to failed arthroplasty. Finally, complex regional pain syndrome or psychological disorders should be excluded. In summary, when patients present with a painful THA all extrinsic causes must be excluded. With respect to intrinsic causes of hip pain one must never forget that the failure of ingrowth represents a significant cause of failure, particularly in large head MoM THA. Most importantly, one should never forget infection as a diagnosis of exclusion. Instability and/or subluxation must be ruled out as well as periprosthetic fracture. Other causes of pain and discomfort intrinsic to the hip involve trochanteric bursitis, early iliopsoas tendonitis, or piriformis syndrome. It is only when all of these causes are eliminated that one should consider adverse local tissue reaction has an etiology of pain and discomfort.

Complete History

A complete history is essential to evaluate all patients who have undergone hip arthroplasty. The temporal onset, duration, severity, location, and character of the pain help narrow the differential diagnosis. A history of delayed wound healing or pain after dental or gastrointestinal procedures raises suspicion 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 be helpful in assessing potential hypersensitivity reactions. Furthermore, a thorough review of systems should be noted for any potential systemic symptoms.

Physical Examination

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 elicit pain, as reproduction of pain on active hip flexion and passive hip extension may suggest iliopsoas tendinitis. Abduction strength must be assessed. A comprehensive neurovascular examination is necessary to rule out neurogenic and vascular causes of pain.

Radiographic Evaluation

A critical review of serial plain radiographs should be performed, 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 acetabular components positioned with a high inclination angle have been shown to demonstrate elevated serum and joint fluid levels of metal ions and increased wear secondary to edge loading [2], it is important to measure the acetabular component orientation in both planes including abduction angle relative to the pelvic horizontal on AP view.

ESR/CRP and Hip Aspiration

In contrast to metal-on-polyethylene (MoP) THA, where elevation of both erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) have specificity for infection as high as 0.93 [3], interpretation should be done with caution with MoM hips as elevated ESR/CRP have been reported in non-infected cases of ALTR. Synovial fluid white cell counts >3,000 WBC/mL combined with predominantly polymorphonuclear cells (PMNs, >80%) have been reported to have the highest accuracy and sensitivity for infection in MoP THA [4]. However, these parameters may not be applicable in MoM hip arthroplasty as ALTR proven to be culture negative may have white cell counts >3,000 WBC/mL combined with >95% PMNs. 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 and the predominance of monocytes should warrant further investigation.

Metal Ion Levels

One mechanism that leads to metal ion release from bearing surfaces and modular connections is by virtue of mechanically assisted crevice corrosion (MACC). Metal ion levels are influenced by implant type, implant materials and design, diameter of the bearings, and positioning of the implant. In 2010 in the United Kingdom, the 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 g/l). More recently, the sensitivity and specificity of the 7 ppb cut-off level has been reported to be 52% and 89%, respectively [5], indicating that 7 ppb has relative poor ability to identify MoM failures. The lowering of the cut-off level to 5 ppb increases the sensitivity to only 63% and lowers specificity to 86%. Furthermore, the correlation between cobalt or chromium serum, blood, or synovial fluid levels and ALTR observed at the time of revision surgery is incompletely understood [6].

The diagnosis of adverse reactions to metal debris in MoM hip arthroplasty is a multifactorial process. A variety of factors should be taken into consideration including symptoms, component position, component design, abductor weakness, mechanical symptoms as well as diagnostic factors including ultrasound or MARS MRI. While metal ion levels are a useful diagnostic test for assessing MoM hip arthroplasty, their role is limited to being an important adjunct to systemic clinical assessment and other investigative tools. Ion levels are just one factor in the evaluation and should not be relied upon solely to determine the need for revision surgery.

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 marked adverse local tissue reactions.

Advanced Imaging Studies - Ultrasound

As ultrasound is not affected by metal artifacts [7], it can be a useful tool to detect the presence of soft-tissue masses adjacent to MoM implants [8]. It can differentiate solid lesions from cystic lesions, and can also be used to guide biopsies and aspirations. Ultrasound has been used to screen a large number of asymptomatic MoM patients in order to establish the

prevalence of asymptomatic pseudotumors [9]. However, this imaging technique remains operator-dependent and its utility may be limited for evaluating the deep structures.

Advanced Imaging Studies - Metal Artifact Reduction Sequence Magnetic Resonance Imaging (MARS-MRI)

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 properties of the cobalt-chromium implants is reduced with various modifications of pulse sequence [7]. 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 [10]. MARS MRI is an important cross-sectional imaging modality for the detection of adverse local soft tissue reactions. It can delineate anatomical extension boundaries of periprosthetic fluid collections and solid masses, as well as detect of any compression of juxtaposed neurovascular structures, which is of particular importance in preoperative planning. It also allows for the evaluation of the surrounding soft tissue envelope such as the integrity of the hip abductor and gluteal musculature. Therefore, 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, prospective studies are 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 or resurfacing hip 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, physical examination, 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.

Recalled Device

The risk stratification scheme still applies, whether for stemmed total hip arthroplasty or hip resurfacing replacement. Additionally, the patient should be informed about the recall and directed to information from the implant manufacturer (e.g. website) regarding the recall and suggested follow-up.

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 mechanisms 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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Disclosures

Consulting/Royalty payments have been received directly related to products discussed. Some products pictured have not been approved by the U.S. Food and Drug Administration. The DePuy ASR and the Zimmer Durom have been voluntarily recalled by the manufacturers. Recommendations evolve with increasing knowledge and experience.

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Risk Stratification for Patients with Metal-on-Metal Hip Arthroplasty

Criteria	Low	Moderate	High
Patient factors	• Low activity level	• Moderate activity level • Male or female with dysplasia (for resurfacing)	• High activity level • Female with dysplasia (for resurfacing)
Symptoms	• Asymptomatic	• Symptomatic • Mild local (pain)/mechanical • No systemic	• Symptomatic • Severe local (pain)/mechanical • Systemic
Clinical examination	• No change in gait (no limp) • No abductor weakness • No swelling	• Change in gait (limp) • No abductor weakness • No swelling	• Change in gait (limp) • Abductor weakness • Swelling
Implant characteristics	• Small diameter (≤36mm) modular MoM THA • Resurfacing in males younger than 50 with OA	• Large diameter (≥36mm) modular or non-modular MoM THA • Recalled implant • Modular neck device • Resurfacing with patient risk factors (female with dysplasia)	• Large diameter (≥36mm) modular or non-modular MoM THA • Recalled implant
Radiographic evaluation	• Optimal cup orientation • No osteolysis or signs of loosening	• Optimal cup orientation • No osteolysis or signs of loosening	• Suboptimal cup orientation • Implant osteolysis or loosening
Infection work-up	• Within normal limits	• Within normal limits	• Within normal limits
Metal ion test level	• Low (<3 ppb)	• Moderate (3-10 ppb)	• High (>10 ppb)
Cross-sectional advanced imaging	• Within normal limits	• Presence of abnormal tissue reactions without involvement of surrounding muscles and/or bone • Simple cystic lesions or small cystic lesions without thickened wall	• 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	• Annual follow-up	• Follow-up in 6 months • Consider revision surgery if symptoms progress, imaging abnormality progresses, and/or rising metal ion levels over 6 months	• Consider revision surgery