



Metal-on-Metal Total Hip Arthroplasty: Current Recommendations and Lessons Learned

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Abstract

Metal-on-metal (MoM) hip arthroplasty was re-popularized in the 1990s to resolve osteolysis and wear associated with metal-on-polyethylene products. Despite early success, registries began reporting high failure rates due to adverse reactions to metal debris (ARMD), manifesting as pseudotumors, hip effusions and osteolysis. Evaluation includes clinical exam, advanced imaging, and blood metal ions and infectious markers. This review provides physicians with an evidence-based update on the 1) clinical workup and management of patients with existing MoM implants, 2) risk and prognostic factors associated with suboptimal results and 3) the precipitating events and lessons learned applicable to future orthopedic prosthesis.

Background

Complications associated with metal-on-metal (MoM) hip implants have been documented since the 1950s when the first generation of MoM implants was introduced. [1] Unfavorable outcomes such as prosthetic loosening, metallic debris, and metal hypersensitivity resulted in a shift to using polyethylene implants in the mid 1970s. [2] However, polyethylene wear-induced osteolysis and loosening called for an improved prosthetic. [3] Thus, in the late 1990s, second-generation MoM devices were re-introduced with the rationale of producing less wear and dislocation due to thinner cups and larger heads. [1,4] Ear-

ly clinical trials and hip simulations in the early 2000s showed excellent outcomes resulting in the massive implantation of over a million MoM hips worldwide. [2] Despite preliminary success, international registries began detecting higher than acceptable revision rates and complications later in the decade, and voluntary recall by several manufacturers (Table 1). [4] The high failure rates of MoM implants is caused by the release of metal ions secondary to mechanically induced corrosion. [5] The generation of metal ions triggers the secretion of cytokines leading to the

Table 1. Recall dates of MoM hip replacement systems by manufacturer

Hip Replacement System	Manufacturer	Date of Recall
Durom Acetabular Component	Zimmer	July 22, 2008
ASR XL Acetabular	DePuy	August 24, 2010
R3 Metal Liners, R3 Acetabular Cup	Smith & Nephew	June 13, 2012
Rejuvenate, ABG II Modular	Stryker	July 6, 2012
Biomet M2a Magnum Hip	Zimmer Biomet	February 9, 2015
Profemur Z Hip Stem, Profemur Neck Varus/ Valgus CoCr	Wright/ Microport	November 15, 2016

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Level of Evidence: V

formation of pseudotumors and other adverse local tissue reactions (ALTR). [5] Joint failure associated with pain, large sterile effusions of the hip and/or macroscopic necrosis/metallosis are consequences of adverse reaction to metal debris (ARMD). [6] While rare, systemic toxicity associated with blood metal ions can result in hypothyroidism, tinnitus, neurosensory deficits and cardiomyopathy. [7]

The monitoring and management of patients with problematic MoM requires a step-by-step algorithmic approach including history and physical, blood metal ions (Co, Cr), and imaging (radiography, ultrasonography, and MRI). Optimal management requires evaluating specific patient and implant risk factors on a case-by-case basis. Current studies evaluating revision outcomes have identified specific surgical approaches and factors associated with improved results. MoM implants are now rarely used, however, many patients have a MoM prosthesis that requires surveillance or revision.

Orthopedic registries, retrieval analysis, and collaboration between surgeons have been essential to understanding MoM failures. We continue to examine the deficits in the surveillance and market clearance of MoM implants to understand and learn from past mistakes. The focus of this review is to provide physicians with an evidence based update on the 1) clinical workup and management of MoM total hip arthroplasty, 2) patient and implant risk factors associated with suboptimal results and strategy for improved revision outcomes, and 3) actions that resulted in the widespread introduction and recall of MoM hips and the lessons learned that can be applied to the novel orthopedic prosthesis in the future.

Clinical Evaluation

It is important to obtain the original surgical date, location, indication, perioperative complications, and make and model of the prosthetic. [8] Patients presenting with hip pain should be asked to characterize the temporal onset, duration, severity, location, and quality of the pain to further qualify the diagnosis. [9] Radiation of pain to the greater trochanter and down the thigh is a common presentation that may result in an antalgic gait. [10] Other symptoms are feeling fullness of the hip, swelling, squeaking, crackling, or clunking with movement of the hip. [9] History of a dermal reaction to metal jewelry has been associated with a greater risk for MoM hip hypersensitivity reactions. [9] History of reduced range of motion (ROM) especially with abduction rarely accompanied by a periprosthetic rash, may indicate a reaction to metal debris. [2] Delayed wound healing, inflammation, and infection are

suggestive of early joint sepsis. [11] Positive findings require further infectious work-up including erythrocyte sedimentation rate and C-reactive protein (ESR/CRP) levels, synovial fluid white cell counts, and cultures. [9] Physical exam includes palpation for soft tissue masses, assessment of active and passive ROM, identification of pain points, and muscle strength in flexion, extension, abduction, and adduction. A comprehensive neurovascular examination is necessary to rule out associated neurogenic and vascular pathologies. [9]

The Role of Blood Metal Ions

a. Recommendations for Blood Metal Measurements

Screening for cobalt and chromium metal ion levels became common around the time the DePuy Articular Surface Replacement (ASR) total hip prosthetics were recalled in August 10, 2010. Initial studies supported using a threshold of 7 ppb as a trigger for further work-up. [12] Recent studies have shown that the cut-off level of 7 ppb has low sensitivity and found that a cut-off of 4.97 ppb provides optimal sensitivity and specificity. [13] There is no ideal threshold of blood metal ions levels used for action because low levels are not specific in detecting ARMD and high levels risk ignoring some cases of ARMD. [14] However, a 7 ppb threshold has been most widely used and consistent with the latest United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) recommendations. [15] In 2017, the MHRA also issued an updated recommendation that female hip resurfacing and males with femoral head implant diameter ≥ 48 mm should undergo lifetime annual serum metal ion screening regardless of symptomology. [16] In contrast, the U.S. Food and Drug Administration (FDA) states that there is insufficient evidence to recommend routine blood metal ion testing for patients with no radiograph evidence or clinical symptoms of failure. [17] A current study showed that annual blood Co and Cr have limited discriminant capacity in diagnosing metallosis and there was no significant increase in metal ions beyond 7 years. [18] In consideration of the current evidence, we suggest using the widely used threshold of 7ppb for initial work-up and discontinuation of routine serum testing for asymptomatic well-functioning implants.

b. Systemic Toxicity

Several case reports were published in the past decade describing systemic toxicity due to metal ion release. [4] Bradberry et al. found that the presentation of MoM systemic toxicity may include hypothyroidism, tinnitus, optic atrophy, sensory deficits, and/or cardiomyopathy, not attributed to other pathologies. [7] Clinical features may develop months to years following original implant placement though revision is generally curative of symptoms.

[7] Gillam et. al found a three-fold increase in rates of hospitalization admission for heart failure post-MOM total hip arthroplasty. [19] However, this topic remains controversial as other studies have found no increased risk for cardiac failure in MOM patients compared to a non-MOM cohort. [20] Zywiell et al. concluded that systemic symptoms were associated with cobalt levels greater than 100 ppb and that systemic toxicity was extremely unlikely in the context of low cobalt levels. [21] We recommend that patients should be revised with urgency when patients present with a failed MoM arthroplasty, systemic symptoms and extremely elevated blood metal ions (>100 ppb). [21]

Role of Advanced Imaging

a. Plain Radiography

Plain radiography to assess component position, loosening, osteolysis, bone quality, and femoral neck erosion due to impingement (Fig 1a,e,f). [22,23] Radiographs are indicated in all symptomatic patients with MoM replacements or resurfacings. [24] Radiographs should be com-

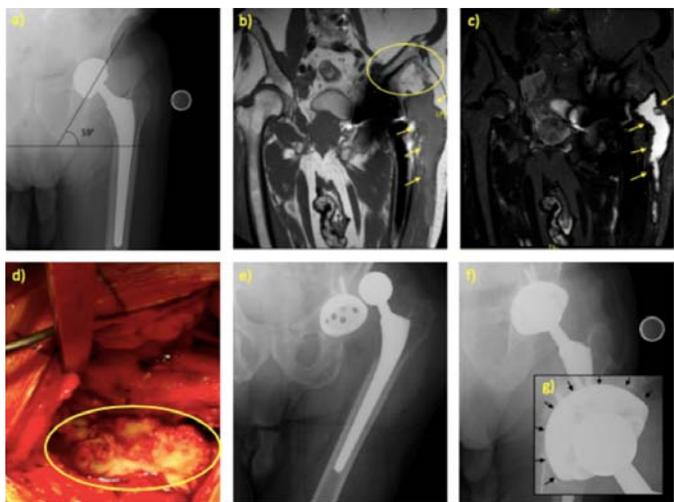


Figure 1. 82-year-old patient with a well-functioning left total metal on-metal Biomet M2A hip implanted in 2005. Patient presents in 2018 with pain, “fullness of hip” and clicking for the past 3-5 months. The work-up included elevated ESR/CRP and elevated cobalt and chromium levels. We present a series of radiographs and MRI images in Figures 1a-f describing his clinical management. a) Plain radiographs show no acute disease with inclination angle of 59°. The patient required revision of the cup, liner, and head. b) T-1 weighted MRI reveals substantial abductor muscle damage (yellow circle) and pseudotumor of the left hip that overlying the quadriceps muscles (marked by yellow arrows). c) T-2 weighted MRI reveals the borders of the saturated pseudotumor (marked by yellow arrows). d) Intra-operative image reveals large pseudotumor that extends superficially (yellow circle). e) The same patient dislocated 4 months after revision likely secondary to abductor muscle damage. The stem was well ingrown. f) The patient was unstable after reduction and converted to a Biomet Freedom Constrained Liner. g) We suspect failure of osseointegration into the porous cup evidenced by a continuous 1 mm lucent (marked by arrows).

pared to evaluate osteolysis and component loosening. [4] Additionally, it is important to assess for osseointegration of the implant as metal ions induce local inflammation and excessive fibrous tissue formation that may prevent osteoblasts from anchoring the implant with strong bone growth (Fig 1g). [25]

b. Ultrasonography

Ultrasound may be utilized for initial evaluation of the soft tissues due to its low cost, safety, and easy accessibility. [24] Literature supports the efficacy of ultrasound in detecting tendinous pathologies and periarticular fluid collections. [26] Unlike MRI, ultrasound is not susceptible to metal artifact distortion and has few contraindications. [4] However, ultrasound is operator dependent, requiring expert interpretation, and is limited in sensitivity and evaluation of deeper structures. [27] It is also more challenging to compare serial ultrasounds for surveillance. [26] In practice, ultrasound is generally utilized as an initial screening tool and may serve as a valuable supplement to more definitive modalities. [4]

c. MARS-MRI

With the introduction of metal artifact reduction sequence (MARS), MARS-MRI is the most sensitive and specific modality for diagnosing MoM hip pseudotumors. [28] MARS-MRI can assess for extracapsular and extrinsic cause of hip pain, such as iliopsoas tendonitis, bursitis, nerve compression, and spine pathology as well as abductor muscle integrity. [27] Beyond detection, an expert musculoskeletal radiologist can use MARS-MRI to characterize the location, size, and quality of soft tissue masses and joint effusions (Fig 1b,c). [22] Pandit et al. found that the two most common imaging abnormalities were either a cystic mass, lateral or posterior to the joint or a mainly solid mass, lying anteriorly and involving the psoas muscle. [29] However, the presence of a pseudotumor may be equally likely in a painful hip compared to a well-function hip and is not necessarily an indication for revision surgery. [30] For monitoring, MRI is crucial in collaboration for second opinions and evaluating pseudotumor size progression and invasion of adjacent neurovasculature. Additionally, rapid muscle atrophy due to an accelerated metal-wear induced inflammation is associated with worse revision outcomes and long-term prognosis compared to non-MoM cohorts. [29] Serial MRI can detect sensitive changes in soft tissue pathology and guide surgeons in performing timely revisions that may preserve abductor muscle and patient mobility. [31]

Associated Risk Factors

a. Patient Risk Factors

Liow et al. state that female gender, dysplasia, metal

hypersensitivity, and low body mass index are associated with increased failure rates of MoM hips. [2] Kovovich et al. also reported increased wear and local tissue reactions associated with bilateral implants, high dose corticosteroid therapy, renal insufficiency, metal sensitivity, severe obesity, and high activity. [4] A retrospective analysis by Amstutz et al. reported equal outcomes in male and female hip implants when other risk factors were removed. A recent study of 661 patients found no association between activity level and survivorship and recommended that patients may continue full activity in well-functioning metal hip replacements. [32] With the existing controversy in patient risk factors, further clarification is needed to supplement the management of MoM patients.

b. Implant Risk Factors

Large femoral head sizes have been associated with higher fretting and failure rates of metal hip arthroplasty. [33] Wear in the trunnion-head modular interface, known as trunnionosis, is a common mechanism of failure and affected by larger femoral head sizes increasing torsional forces at the trunnion. [33] Retrieval studies have found that increased femoral head diameter in THA produce increased fretting while corrosion is associated with length of implant time. [34] Early corrosion has also been associated with certain implants such as the Stryker Rejuvenate modular-neck stem design. [35] Flexural rigidity of the neck, trunnion length, trunnion diameter, and taper angle all affect the force distribution at the taper junction. [33] Weiser et al. recommend minimizing femoral head sizes, utilizing more rigid stems and trunnions, and meticulous cleaning and firm head impaction to reduce the risk of trunnionosis. [36] Additionally, edge loading accelerates wear rate as high inclination angles ($>55^\circ$) result in elevated contact pressure at the articulating surface, which was found by Hart et al. to be the most important predictor of wear rate (Fig 1a and Fig 2a). [37,38] Compared to the ASR hip re-

surfacing, ASR total hip arthroplasty has higher risk for development of moderate-to-severe pseudotumors. [39] Additionally, a contact patch edge to rim (CPER) distance of less than 10 mm has been correlated with edge-loading and excessive wear (Fig 2b). [40] Due to the variability in implant design, consideration of implant components and risk factors improves patient specific care.

Revision Surgery

Symptomatic patients with pseudotumors that are solid, large, invasive, and destructive of soft tissue and bony structures require timely revision surgery. [41] In contrast, asymptomatic patients with normal imaging and blood ion levels (<4.5 ppb) most likely do not require revision and can be conservatively monitored. [41] However, patients with MoM implants require more robust guidelines for management. Liow et al. conclude that poor revision outcomes are seen in patients with prerevision radiographic loosening, solid lesions/abductor deficiencies on MRI, and high grade intra-operative tissue damage. [42] Matharu et al. suggest a posterior surgical approach when possible, revision of all MoM hip components, and use of a large diameter (>36 mm) ceramic-on-polyethylene or metal-on-polyethylene articulations to optimize revisions. [43] The hip anatomy should be reconstructed properly as Garcia-Rey et al. concluded that abductor muscle weakness is one of the greatest risk factors for dislocation. [44] Limited revision by conversion to dual mobility in MoM patients with cups in good position and condition have had positive early outcomes. [45] Straightforward patients may be revised with bearing replacements of the acetabular shell and metallic head. [46] However, complicated patients with severe metallosis of the acetabular cavity may require revision with pelvic plating. [47] Pseudotumors that invade soft tissue may require assistance from vascular surgeons for excision while bony osteolysis and trunnionosis may require custom implants and femoral stem replacement. [48] It is important to monitor patients for osseointegration of the implant pre- and post-revision as cellular damage secondary to metallosis can disrupt osteoblast function and bone growth (Fig 1g). [25] Wyles et al. found a high infection rate associated with revision of failed MoM hip replacements, especially in patients presenting with ARMD pre-revision. [49] Thus, post-operative patients should be monitored carefully for short-term infection and long-term complications. We need further reports from multi-center studies and retrospective registry cohorts to establish definitive thresholds for revision, modifiable intra-operative factors, and prognostic risk factors. [41]

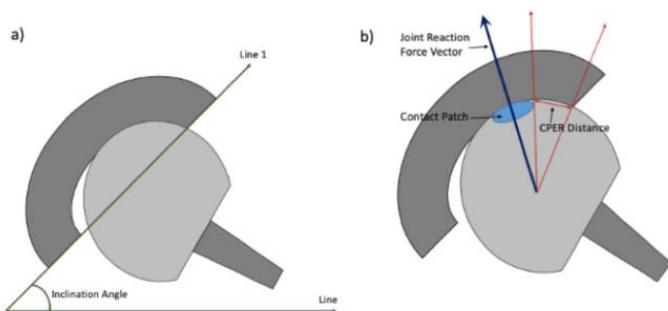


Figure 2. a) Illustration of inclination angle determined by angle between Line 1 (drawn across rim of the cup) and Line 2 (a horizontal reference across ischial tuberosities). b) Illustration of contact patch edge to rim (CPER) Distance. Joint reaction force vector represents balance of moment arms of body weight and abductor tension.

Lessons Learned and Future Recommendations

MoM bearings were re-introduced in hip arthroplasty with the hope of addressing the consequences of polyethylene wear, hip dislocation and osteolysis. [50] Initial clinical evidence and laboratory evidence were promising as early in vitro simulations showed significantly reduced wear of tested MoM hip prosthetics (1 mm³/million cycles, compared to wear of metal-on-polyethylene prosthetics, 30-100 mm³/million cycles). [51] These findings instigated a widespread, mass implantation of MoM hips with disastrous outcomes. Thus, we realize that preclinical testing, joint simulation, and analytic modeling are insufficient in predicting the performance of orthopedic implants. [52] Hart et al. highlight precipitating factors including false confidence from hip simulations, immaturity of national registries, late implementation of implant retrieval centers, and inadequacy of clinical follow-up studies. [53]

a. *The Role of Registries*

The joint replacement registries of Australia, England, and Wales first established higher failure rates in MoM hips, resulting a massive recall of ASR and ASR XL metal implants by Depuy, Johnson and Johnson in 2010. [53] The detection was too late to prevent the ensuing catastrophe, leading us to question the efficacy of such registries. Retrospectively, we realize that National Joint Registry of Wales and England, established in 2002, had relatively poor compliance and consent, and immaturity in dealing with failed implants at the time. [53] Registries are also unable to predict or prevent the poor implants from entering markets and are limited to monitoring and reacting failing products. [54] Maturing registries today have implemented mandatory compliance from practicing surgeons and improved protocols for safety measurements. [54] The U.K developed improved guidelines for the introduction of new prosthesis in response and Tucker et al. suggested that a standing committee and universal protocol should oversee the introduction and performance of existing and new implants. [54]

b. *Implant Retrieval*

The integration of implant retrieval centers was essential to identifying the mechanisms of failure of MoM hip implants. With the increased compliance of surgeons, current studies have identified mechanical components, surrogate markers such as blood metal ions, and positional factors associated with failed implants. [53] The role of retrieval analysis in our management of MoM hips suggests that early retrieval protocols should be in place prior to the introduction of novel orthopedic implants.

c. *Recommendations for Regulation*

Beyond surveillance, we must assess the regulatory en-

ties and barriers in place to prevent the entry of suboptimal products. Though it is important to foster medical innovation, patient safety was severely compromised with metal hip prostheses. [55] Upon investigation, Howard et al. found that many companies bypassed the FDA premarket approval (PMA) market clearance pathway with a less stringent 510(k) pathway, using existing but outdated metal hip predicates. [55] We now realize that the 510(k) pathway is insufficient for the evaluation of high risk orthopedic prostheses. [55] Additionally, they found that FDA post-market surveillance was insufficient and more stringent, longer duration post-approval studies should have been mandated in metal hip implants. [55] Finally, certain manufacturers withheld failed FDA approvals and continued to market their products in other countries. [55] Thus, Howard et al. conclude that regulatory approval information should be made accessible to all stakeholders including surgeons, patients, and hospital administrators in the future. [55] Upon investigation of the protocols in place, it is evident that regulatory bodies need to serve a more involved and robust role in the assessment of novel orthopedic prosthesis.

Summary

Currently, we recommend a step-by-step algorithmic approach with clinical exam, serum studies, and imaging for evaluating MoM patients. [8] Inconsistent practice between different orthopedic centers calls for further international guidance and multi-disciplinary panels to improve consensus in decision making. [56] We hope that the integration of more mature registries and retrieval centers with updated regulatory protocols can prevent the massive implantation of suboptimal prosthetics in the future. While the use of total metal hips is now largely outdated, the lessons we learned can be widely applied to prevent a similar catastrophe from occurring again. [53]

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AUTHOR DISCLOSURES

- The authors declare that there is no conflict of interest in connection with this submitted article.

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