The performance of metal-on-metal hip replacement bearings has received public and scientific scrutiny related to ion release, metal sensitivity and pseudotumors.1–3 The following information is provided to assist surgeons in their choice of the proper bearing for each patient.

1. Safety

• In January, 2008, an MHRA (Medicines and Healthcare products Regulatory Agency) Expert Advisory Group observed, “There is no evidence that increased levels of cobalt and chromium ions are associated with any clinical effects.”4

• Metallic debris can be present in the body even with non-metal-on-metal surfaces.5,6

• From 1998 to 2009, manufacturer data combined with FDA MAUDE (Manufacturer and User Facility Device Experience) reports, indicates a .17% adverse event rate with metal-on-metal constructs.7,8 Biomet’s adverse event rate is lower than the industry rate.

  • 844,983 metal-on-metal units implanted (manufacturers include Biomet, Zimmer, DePuy and Wright Medical)8
  • 1,448 total adverse events reported (implant and non-implant related)7
  • .17% adverse event rate7

  Biomet® M2a™ Acetabular Units Reports (1999–2009):
  • 112,412 M2a™ units implanted9
  • 63 total adverse events reported (implant and non-implant related)8
  • .056% adverse event rate9

• DePuy Orthopaedics has announced that FDA’s Orthopaedic and Rehabilitation Devices Panel has recommended approval of the Pinnacle® CoMplete™ Acetabular Hip System. “The panel saw testimony that included study results comparing the safety and efficacy of the ceramic-on-metal implant to that of a DePuy metal-on-metal implant. Those results reportedly showed no significant difference in adverse events, revision rates or survivorship over a 2-year period.”10

2. Benefits of Modern Metal-on-Metal Bearings

• Metal-on-metal bearings have a potential maximum range-of-motion exceeding 160 degrees versus 131 degrees with polyethylene bearings.9,11

• Large-diameter heads have been shown to reduce risk of dislocation.12–14

• Larger metal-on-metal heads have less volumetric wear, on average, than smaller metal-on-metal heads.15,16 Additionally, large-diameter metal-on-metal heads have demonstrated 98% less wear than polyethylene in bench testing.9

3. Not all Metal-on-Metal Designs are the Same

Adverse event data must be carefully assessed, as they include not just metal-on-metal total hips, but resurfacing. Additionally, the data includes adverse events unrelated to the bearing surface.

• It’s important to note the differences between metal-on-metal total hip replacement and metal-on-metal hip resurfacing.

  • De Haan et al. noted “Malpositioned [resurfacing] components may cause symptoms due to prosthesis-bone impingement, soft-tissue impingement or painful local tissue reactions due to the high rate of wear of the metal bearing undergoing edge-loading…”17

  • Metal-on-metal resurfacing exhibits different and additional modes of failure. Studies have shown that femoral neck fractures are a concern of metal-on-metal hip resurfacing.18,19

• Regarding the recall of Zimmer’s Durom® cup, the “Background on Durom® Cup Status” stated, “Zimmer is taking this voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component…”20 Additionally, Long et al. noted that early loosening was due to the flared cup design.21 It’s important to reinforce that the metal-on-metal bearing surface was not mentioned as a concern.
• Biomet’s M²a-Magnum™ Total Hip Replacement System is engineered to provide strong, stable fixation by means of Biomet’s clinically proven PPS™ Porous Plasma Spray22 and four paired sets of peripheral fins. Additionally, the M²a-Magnum™ System has provided a 99.2% survivorship rate at three years.23
• According to an Urgent Field Safety Notice regarding DePuy’s ASR™ Systems, “Recent analysis of datasets from these sources suggests a higher than expected revision rate for the DePuy ASR™ Articular Surface Replacement and ASR™ XL Monoblock Metal-on-Metal System…” Component loosening, component malalignment, infection, pain, fracture, dislocation and metal sensitivity are identified as reasons for revision within the datasets. DePuy emphasizes that surgical technique, especially cup positioning, and patient selection are essential to achieve optimal implant performance and survivorship.24
• DePuy’s ASR™ XL System and Biomet’s M²a-Magnum™ System are both monoblock metal-on-metal systems. However, there are key design differences between the products:
  • M²a-Magnum™ shells are fully hemispherical, ASR™ XL shells are not.25
  • The M²a-Magnum™ System provides a closed-back head design while the ASR™ XL System has an open back.25
  • The diametral clearance of the M²a-Magnum™ System is 150–300 microns compared to 70–100 microns with the ASR™ XL System.25
• Cup design may potentially affect performance.

The following quotes are from papers that were presented on metal-on-metal constructs at the 2010 AAOS meeting:
• “The device providing the smallest acetabular coverage arc was associated with the highest metal ion levels.”26
• “There was a highly significant inverse correlation between CPR [cup to rim] distance and metal ion levels…”26
• “The greater the coverage angle provided by the acetabular component, the greater the tolerance to suboptimal position.”26
• “Our overall results suggest that the reduced arc of cover of the 4g cup has led to an increased failure rate secondary to the increased generation of metal debris.”27

4. Importance of Cup Positioning
• Steps can be taken to minimize the potential for metallic debris generation and ion concentration. Metal-on-metal cups that are malpositioned have significantly higher concentrations of metal ions than cups that are positioned properly.17
• Malik et al. have noted, “We consider the optimum cup inclination to be 40 degrees as this allows a margin of error of up to 5 degrees for surgical placement, which would maximize cup inclination at 45 degrees.”28

All bearing couples come with unique benefits and potential risks. Cup placement, construct design and patient selection may play important roles in the outcomes of metal-on-metal implants. The benefits and potential clinical advantages, as well as the risk, of these devices are important to weigh when considering alternative bearing options. Biomet offers multiple alternative bearing solutions such as the M²a-Magnum™ Large Metal Articulation, C³a-Taper™ Ceramic-on-Ceramic and E1™ Antioxidant Infused Technology which provides wear rates similar to metal-on-metal.9

The package insert contains further information on risks and indications. Visit biomet.com to view the risk information for Biomet total joint implants.

References
8. OSMA Amended Petition for Downclassification of Metal-on-Metal Implants (August 2009).


20. Background of Durom® Cup Status (July 2008).


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