

METAL-ON-METAL

What are the indications for MOM surfaces in total hip arthroplasty (THA) today?

Dr. Barrack: My major interest in MOM is for hip resurfacing. Many patients want to avoid a traditional THA. Most MOM total hips that I perform are in patients who otherwise would be candidates for hip resurfacing but have a specific contraindication and prefer the THA option that is most similar to resurfacing.

Dr. Schmalzried: As Dr. Barrack points out, in the United States, hip resurfacing is currently available only with MOM bearings.

Dr. Cuckler: My indications for MOM include the need for a reconstruction requiring enhanced stability (dislocation resistance), anatomic factors that render ceramic-on-ceramic or cross-linked polyethylene articular couples suboptimum (the very small acetabulum; the individual with a high body mass that might increase the risk of ceramic fracture), and, of course, a highly wear-resistant couple.

Dr. Jacobs: Although I don't use MOM bearings, I could see that one might consider a MOM bearing to gain the benefits of a very large head in terms of achieving hip stability.

I would also refer to the Academy's recent technology overview, which was done based on systematic review of the literature through the Council on Research, Quality Assessment, and Technology. They have done an excellent job reviewing the literature to provide high-quality evidence for clinical decision making. Clinicians should pay a lot of attention to those systematic reviews, which minimize bias.

Dr. Maloney: I think the indications for MOM are declining as we get more comfortable with highly cross-linked polyethylene in high-activity patients and have more concern about adverse tissue reactions associated with MOM articulations.

Dr. Rothman: My bottom line is that there isn't any indication for MOM. It's hard for me to justify either part of the combination – resurfacing or MOM arthroplasty – when you look at the large databases. According to the Australian registry data for 2008, for example, MOM has the highest rate of revision.

Dr. Goldberg: Can you envision a different articulating surface using different metallurgy that might in fact ultimately create a situation where you wouldn't have the problem of ion wear or other problems we see?

Dr. Jacobs: That certainly is a possibility. We have made progressive improvements in polyethylene over the course of decades, and there is no reason we cannot also do so with MOM bearings. Just because the current technology might be associated with high debris release in certain situations, that doesn't mean that improvements in MOM bearing surfaces will not yield improved results.

Dr. Schmalzried: Accumulating data indicate that component position and an aberrant wear mechanism are responsible for the adverse local tissue reactions that occur with MOM bearings. The role of increased lateral opening angle has been repeatedly demonstrated in peer-reviewed publications, but many surgeons are still unaware – and insufficiently critical – of their own implant positions. Less well-recognized is the role of version, particularly combined with anteversion, especially in resurfacing. Retrieval analyses indicate that, independent of the degree of bearing wear, corrosion and corrosion products drive the more severe local reactions with tissue necrosis and pseudotumor formation.

Dr. Maloney: I don't believe improved metallurgy will solve this problem. The metallurgy has gone through several iterations in the last two decades. The current problem probably relates to edge loading, and it is associated with suboptimal implant position. Even in the best surgeon's hands, implant positioning will not always be perfect and a small percentage of adverse tissue reactions can be expected.

Dr. Barrack: Much of the negative data is based on suboptimal designs that have been removed from the market, and a disproportionate amount of focus has been placed on negative data from a single center. In both patient selection and component insertion, MOM has a smaller margin of error than other combinations. Surgeons who are not confident in their ability to consistently position the components

should stay away from this procedure. With the right patients and a correctly performed procedure, however, the results can be truly remarkable.

Dr. Goldberg: *If a patient has an MOM surface, how should he or she be monitored?*

Dr. Barrack: If a patient has a well-positioned, well-fixed implant of average size or larger, monitoring should be similar to THA. Patients with components in a suboptimal position should be followed more frequently and any patients who develop symptoms such as swelling or signs of nerve compression should have advanced imaging (ultrasound or magnetic resonance imaging [MRI] with specific sequences) and metal ion levels.

Dr. Schmalzried: I agree that no additional monitoring is needed for the asymptomatic patient. The evaluation of a painful hip with an MOM bearing is similar to any other. Don't forget the basics – is it infected? Is it loose? Is there a soft-tissue issue such as iliopsoas bursitis or tendinitis? Obtain radiographs in multiple planes.

In the symptomatic MOM hip patient, a cobalt or chromium ion level (whole blood or serum) of greater than 10 parts per billion suggests an aberrant wear mechanism. Ultrasound, computed tomography, or MRI can be used to look for a fluid collection, cystic/solid mass, or so-called pseudotumor.

Dr. Maloney: I know of no data that dictate a specific follow-up protocol. I would recommend routine clinical and radiographic follow-up annually. If the patient is symptomatic, I would suggest an MRI to look for soft-tissue and/or an abnormal fluid collection around the hip. Others have used ultrasound. Finally, a hip aspiration would be performed for fluid analysis and culture.

Dr. Jacobs: I have the luxury of having a lab in the next building where it's not particularly difficult or expensive to get accurate metal ion levels. I have found these levels to be very helpful in managing and monitoring these patients.

The challenge is to make metal ion analyses more readily available to the practicing orthopaedic surgeon who may not have access to such a lab.

Dr. Goldberg: *Let's turn to those pseudotumors – aseptic lymphocytic vasculitis-associated lesions (ALVAL), or as Dr. Schmalzried calls them, adverse local tissue reactions (ALTR). What do you think is the etiology and how should we treat it?*

Dr. Rothman: I have a nonscientist's view of ALVAL. I don't think the lines between metal sensitivity, lysis, and pseudotumor are completely understood. In one sense, it almost doesn't matter if these are separate processes. They are all destructive processes that will destroy the hip.

Dr. Barrack: ALVAL is a spectrum of adverse tissue reactions to metal debris. Most often it is a reaction to excessive metal debris from edge loading due to suboptimal component positioning. More rarely it may represent an allergic or hypersensitivity reaction to a normal level of metal ions. It has many clinical manifestations, including pain alone, fluid collections alone, solid mass formation (pseudotumor), and rarely, tissue necrosis.

Dr. Schmalzried: I don't quite agree with that, ALVAL is a histologic diagnosis with criteria defined by Willert and colleagues. The salient stimulus does not appear to be metal wear particles, because this histology has been observed and reported in hips without MOM bearings. The list of potential stimuli include metal ions and other corrosion products. The issue of true "hypersensitivity" continues to be debated.

Dr. Maloney: I think we are seeing a spectrum of soft-tissue reactions that range from a foreign body reaction leading to a pathologic response similar to polyethylene and localized bone reabsorption to cellular necrosis secondary to toxicity. Whether there is a hypersensitivity reaction or not, I think remains to be sorted out. But I do agree that it doesn't matter; these adverse tissue reactions are occurring at a percentage that's not insignificant, and, if severe, will lead to soft tissue destruction. In those cases the hip is not salvageable.

Dr. Jacobs: As Tom said, ALVAL is not really a diagnosis but a histologic description. Whether the local tissue reaction will be toxicity, osteolysis, or a delayed-type hypersensitivity response will depend on the dose and distribution of the debris that is generated, plus the individual susceptibility of the host. We still haven't defined the exact role that metal hypersensitivity plays in this phenomenon; research in this area is ongoing.

Dr. Goldberg: *What should clinicians be wary of regarding the issue of hypersensitivity in general with MOM implants?*

Dr. Jacobs: I am getting more and more referrals about this issue. In general, clinically significant metal hypersensitivity in well-functioning metal-on-polyethylene implants is very rare. A subpopulation of patients with MOM bearings – and it's hard to quantify the magnitude of that group – may have metal hypersensitivity. The bulk of the clinical problems that we are seeing today, however, have to do with component malpositioning in certain designs, leading to excessive wear and debris release, leading to soft-tissue reaction. In turn, this excessive debris leads to an adverse local tissue reaction. Whether we will observe a similar phenomenon with increasing frequency in longer-term follow-up of well-positioned components remains to be seen.

Dr. Cuckler: Pseudotumors are the result of adverse wear due to either component malposition or pseudo subluxation. The particular wear debris response in MOM is associated with tissue necrosis and high levels of a variety of inflammatory cytokines that lead to osteolysis, loosening and tissue destruction. This, however, is not identical to the hypersensitivity reaction, which is a T-cell mediated immune response to ion release.

Dr. Goldberg: *What do you do for patients who have a clinically significant pseudotumor?*

Dr. Rothman: We are pretty aggressive about changing the bearings to a more traditional bearing. I think we are revising them sooner rather than later.

Dr. Maloney: I don't like the term pseudotumor because that implies some type of cancerous lesion. When patients have a symptomatic soft-tissue mass or fluid collection, I think they should be revised. Of course, first you want to rule out infection.

Dr. Cuckler: The true prevalence of the pseudotumor phenomenon is not known. Surgeons choosing a MOM prosthesis must be aware that certain risks are associated with every articular couple; there is no perfect hip replacement.

Dr. Goldberg: *Our patients are saying, "I'd like this new hip resurfacing procedure because I can do more." What do you think are the indications and contraindications for surface replacement arthroplasty?*

Dr. Maloney: You could argue that a small group of men under the age of whatever you want to pick – 60, 55, 50 – who are high-activity patients, may be reasonable candidates for resurfacing. But you could also do conventional THAs, and our data for patients younger than age 50 show negligible wear with highly cross-linked polyethylene. I think a well-done THA will allow the patient to do everything that a well-done resurfacing does, probably with slightly less risk of failure over the first decade.

Dr. Cuckler: I still regard resurfacing as an alternative to conventional "big-ball" MOM THA that requires continued long-term follow-up to validate this procedure as the preferred reconstruction for the young, active patient. Resurfacing is more technique-sensitive than THA, but in the hands of a surgeon with sufficient experience, appears to produce results at intermediate follow-up equivalent to conventional MOM THA.

Dr. Rothman: I think if you took your strongest rationale for resurfacing, it's hard to defend. One broad meta-analysis found the failure rate was twice as high for surface replacement in half the time. The failure rate was, I believe, 3 percent at 4 years for surface replacement versus 1 percent at 8 years for

total hips. That's such a dramatic difference that it's hard for me to justify to a patient the theoretical advantages of resurfacing.

Dr. Barrack: Less than 15 percent of patients with osteoarthritis of the hip are good candidates for resurfacing, but these are the most active, highest demand group of patients. The best indication is a relatively young, active patient with good bone stock, minimal deformity, average or greater head size, and the need or desire to maintain a high activity level at work and/or in recreation.

Dr. Goldberg: *One reason we are having this roundtable was the British alert. Do we have a moral and ethical obligation to inform patients about that alert?*

Dr. Maloney: If I had a large MOM practice, I would send my patients a letter saying that there has been increasing concern over a small number of patients who appeared to be having an adverse tissue reaction to MOM bearings. If they were having any problems whatsoever, I would like to see them in the office. I don't want to sound alarm bells, but I do want to let MOM patients know that if they are having any clinical symptoms, they should be evaluated.

Dr. Rothman: I would also warn potential patients interested in MOM that there are elevated risk factors associated with that choice.

Dr. Schmalzried: The narrow perspective of the alert should be recognized. It's true that MOM implants are associated with a higher risk of ALTR and the community should be aware of this. The alert, however, should not be used as an overall assessment of the efficacy of MOM bearings in THA or resurfacing, as that would require analysis of the benefits as well as the risks.

Dr. Cuckler: Critics of MOM articular couples usually conveniently ignore shortcomings in other alternative bearing surfaces – squeaking, fracture, stripe wear, run-away wear, and the unknown long-term performance of highly cross-linked polyethylenes. There is no perfect THA materials combination!

Dr. Jacobs: It is reasonable and ethical to inform patients of this alert and to provide context on what it actually means. The concerns expressed in the alert were precipitated largely by the under-performance of certain MOM systems relative to others. Informing patients of this alert is a good starting point for a frank conversation with the patient about the pros and cons of MOM, in keeping with the spirit of the informed consent.

For more information on metal-on-metal hip devices, including links to the UK's Medicines and Healthcare Products Regulatory Agency's alerts, passouts from the 2010 AAOS/Orthopaedic Research Society workshop on hypersensitivity and biomaterials, and the studies cited in this roundtable, refer to the online version available at www.aaosnow.org.

Disclosure information:

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