Joint Implant Surgery & Research Foundation
Chagrin Falls, Ohio, USA

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee Meeting

June 28, 2012

Metal (MoM) Bearings Questions and Discussions

An Interview Facilitated by Timothy McTighe

Timothy McTighe Dr. HS (hc)

- Executive Director, JISRF
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- Member Society of Biomaterials
- Member International Society for Technology in Arthroplasty

Timothy McTighe was present on June 28, 2012 for the FDA Advisory Committee Meeting on Metal -on- Metal Bearings. As part of the ongoing dialogue, JISRF has decided to conduct an interview on this day's activities and publish this interview in its July edition of the Reconstruct Review.

JISRF published an interview on May 31, 2010 on the subject of MoM with eleven surgeons and their comments can be viewed at: http://www.jisrf.org/activities/052010.htm

As we all know there is considerable debate and concern with the postoperative adverse reactions that we are seeing world wide with the use of MoM bearings. JISRF has conducted this interview with six highly respected surgeons and one world class Tribologist based off the discussions held at the recent FDA Device Panel Meeting.

Advisory Committee Member:

Michael B. Mayor, MD

- William N. and Bessie Allyn Professor of Orthopaedic Surgery,
- The Geisel School of Medicine at Dartmouth
- Adjunct Professor of Engineering
- Michael.B.Mayor@Dartmouth.edu

Presenter at Panel Meeting:

Bernard N. Stulberg, MD

Lutheran Hospital
Cleveland, OH

Professional Societies

- American Academy of Orthopaedic Surgeons
- American Orthopaedic Association
- American Association of Hip and Knee Surgeons
- Hip Society
- Knee Society
- International Society for Technology in Arthroplasty
- Orthopaedic Research and Education Foundation

Special Interests

Repair of failed or infected joint replacements and complex hip and knee replacements.

In Attendance at Panel Meeting:

Thomas K. Donaldson, MD

Donaldson Research Center
Colton, CA
- Private practice since 1991
- Board Certified Orthopedic Surgeon who has been in practice in the Inland Empire.

Affiliations
- Director and Founder of DARF
- American Academy of Orthopaedic Surgeons
- American Association of Hip and Knee Surgeons
- Joint Implant Surgery & Research Foundation
- American Medical Association
- San Bernardino County Medical Society

Ian C. Clarke, PhD

Donaldson Research Center
Colton, CA
- Professor in the Joint Research Center at Loma Linda University
- CO-Director, DARF
- CO-Director of Basic Science, JISRF
- CO-Assistant Editor, Reconstructive Review, JISRF

Community Total Joint Surgeons:

John Keggi, MD

Community Orthopaedic Surgeons: Orthopaedics New England
Middlebury, CT
- Attending Orthopaedic Surgeon
- Waterbury Hospital, Waterbury, Connecticut
- New Milford Hospital, New Milford, Connecticut
- St. Mary's Hospital, Waterbury, Connecticut (Courtesy Staff)

Lou Keppler, MD

St. Vincent Charity Medical Center
Cleveland, OH
- Co-Director, The Spine and Orthopedic Institute
- Orthopedic Surgeon
- Member JISRF Clinical/ Surgical Advisory Panel and Tissue Sparing Implant (TMI™) Study Group

Ed McPherson, MD

L.A. Orthopedic Institute
Los Angeles, CA
- Director of Orthopedic Surgery
- Member JISRF Clinical/ Surgical Advisory Panel and Tissue Sparing Implant (TMI™) Study Group

The Original 8 Questions from the FDA to the Advisory Panel:

1. Please summarize the key differences, if any, between US and Outside the United States (OUS) practice which should be taken into account when reviewing/interpreting the data, and which impact the ability to extrapolate OUS data to the US population, including differences in patient population, surgeon experience/preference/technique, and the devices themselves.
2. Based on published registry reports as well as information presented to the Panel today, please discuss the additional data fields which would be appropriate (and practical) to add to existing hip implant registries or include in new registries being developed.
3. For patients who have received a MoM Total Hip Replacement, but are asymptomatic please discuss the optimal follow-up regimen (s) based on current available information.
4. For patients who have received a MoM Total Hip Replacement, but are symptomatic please discuss the optimal follow-up regimen (s) based on current available information.
5. For patients who have received a MoM Total Hip Resurfacing System, but are asymptomatic please discuss the optimal follow-up regimen (s) based on current available information.
6. For patients who have received a MoM Total Hip Resurfacing System, but are symptomatic please discuss the optimal follow-up regimen (s) based on current available information.
7. For patients being considered for primary hip arthroplasty, please discuss:
   a. Patient or population characteristics which are more likely to achieve the most favorable outcome and/or for whom the risks most likely outweigh potential benefits with a
      i. MoM THR System
      ii. MoM Resurfacing System
   b. Pre-operative laboratory or imaging tests which should be considered in identifying appropriate candidates for MoM THR/ MoM Resurfacing System.
8. Please discuss the key information which should be conveyed to physicians and/or patients as part of product labeling for MoM hip systems, including
   a. Contraindications
   b. Warnings
   c. Precautions
   d. Directions for Use
   e. Outcomes Data
   f. Other

The following is going to be a brief review of the historical development of metal on metal bearings so we might better understand how and why we ended up in our current situation. Remember those that don't remember the past often are doomed to repeat it.

Historical Review of MoM Bearings

1930's Phillip Wiles from the UK designed and inserted the first THA. Prior to this date, prosthetic replacement surgery was of the hemi-arthroplasty type with only one arthritic surface being replaced and the results were unsatisfactory.

George Kenneth McKee

GK McKee was a trainee with Wiles and following his appointment as Orthopaedic Surgeon in Norwich, England, began development of total hip replacement designs. He developed various uncemented prototype total hip replacements in the 1940's and 1950's. McKee presented his results to the BOA meeting in Cambridge in 1951. The results in those early days were initial relief of pain followed by loosening and mechanical failure. Haboush introduced polymethylmethacrylate for fixation of hip endoprosthesis in 1953 and Charnley popularized this use of bone cement. McKee's cement fixed McKee-Farrar THR from 1960 was the first widely used and successful THR. This THR had a Thompson stem, a chrome cobalt metal on metal articulation and both the acetabular and femoral components were fixed with cement.

Peter Ring

Peter Ring from Redhill, Surrey, provided the next development in hip arthroplasty. He distrusted bone cement and developed a self locking total hip replacement for uncemented fixation.

Professor Sir John Charnley

Professor Sir John Charnley was convinced that the metal on metal articulation of the McKee joint was unsatisfactory. He performed experiments to show that the McKee joint had a high frictional torque in the laboratory and he predicted that this frictional torque would eventually loosen the fixation of the McKee components in their bony bed.

He was convinced that the natural elastohydrodynamic lubrication with synovial fluid could not be used to reduce the frictional torque of the metal on metal articulation and he began his search for self lubricating bearings.

This search took him into the field of polymers and his first attempt at hip arthroplasty in the early 1950's was a Teflon on Teflon bearing used as a resurfacing for the arthritic femoral head and acetabulum. Unfortunately the Teflon on Teflon bearings wore out within two years.

Sivash Stem 1960s

SRN Stem 1970s

The Sivash hip was the first C.C. head with a titanium stem "constrained socket".

Eventually lead to the development of the S-Rom® Stem System.

Derek McMinn FRCS

Dr. Derek McMinn qualified from St. Thomas's Hospital in London. Practicing as a Consultant Orthopaedic Surgeon since 1988, his special interest has been joint reconstruction surgery.

He always loved taking on the challenge of patients with complex hip and knee problems - complexities that often demanded improvisation and innovation. The stemmed reconstruction acetabular cup for the grossly deficient socket is one of his innovations.

His pioneering of the Birmingham Hip Resurfacing has revolutionized the management of hip arthritis in young active patients. In addition to his busy private practice, he works part-time in the UK National Health Service at the Royal Orthopaedic Hospital, Birmingham.

MoM Interrogatories by McTighe

Question 1

This was a significant challenge by FDA to ask 22 members of the Advisory Committee for Orthopaedics and Rehabilitation Devices (all with varied backgrounds and experiences to attempt to develop a consensus regarding these nine questions. How did you feel about the challenge and do you feel the panel came together with a consensus about the questions posed by FDA?

Dr. Mayor: As a product of two twelve hour days, stirring together a mix of presentations from FDA and invited proponents and skeptics, I saw the response of the panel, an amalgam of remarkable diversity and expertise, to be a very substantial consensus. It allowed orthopaedic clinicians, radiologists, epidemiologists, toxicologist/ pharmacists, industry and consumer interests to pool their perspectives and convictions toward a well supported overview of the history, evolution and current challenges confronting FDA, the scientific and clinical community, patients and the public.

Question 2:

To Donaldson and B. Stulberg, both of you have performed Hip Resurfacing (HR) and I believe you have used different devices. Can you explain your interest in HR and what was your decision making for device selection?

Dr. Donaldson: Living in southern California near Dr. Amstutz, I was well indoctrinated in the enamor of hip resurfacing. I have utilized the Conserve-Plus(Wright Medical), Burmingham (Smith and Nephew) and was involved in the IDE study utilizing the Recap(Biomet-not FDA approved) hip resurfacing. Clearly the reported data supports the Burmingham above the others in outcomes and this is my resurfacing implant of choice.

Dr. Stulberg: I have used resurfacing Arthroplasty in my practice in a very specific and somewhat limited group of patients since 2002– Mostly male, and mostly under the age of 50. I began as part of the CORMET IDE, and with the exception of a few BHRs, my experience has been primarily with the Cormet device. My results are included in those reported as part of the IDE study and published results, demonstrating the importance of technique and patient selection. In the population I selected they have worked well, despite the fact that the instrumentation for the early patients was rudimentary. Currently I do not perform resurfacing Arthroplasty but refer those interested and appropriate patients to one of my partners who use the BHR exclusively.

Question 3:

To all of our surgeons: It seemed to me that part of the market selection for MoM bearings had very little to do with the alternative selection for a new bearing surface. What I mean to say is the HR group desired to save bone in the younger more active patient primarily and the THA group wanted large head diameters to reduce hip dislocations. Comments?

Dr. Mayor: Both surface replacement and stemmed total hips are inspired by dual desires; a consuming interest in minimizing the generation of particulates and minimizing the incidence of post-arthroplasty dislocations. In conversation with my clinically active colleagues they assert they were driven by both considerations in inseparable combination. Having both surface replacement and stemmed approaches offered the full spectrum of treatment modalities to solve both problems in a wide variety of patients.

Dr. Donaldson: Hip Resurfacing is appealing for the bone preserving nature of the procedure. The metal on metal articulation seemed to be the solution for the previous failed metal on polyethylene attempts for hip resurfacing. The large ball metal total hip alternative was initially meant to be a solution in the case of a neck fracture from hip resurfacing. The large ball alternative to hip resurfacing quickly took center stage and hip resurfacing was left for a much smaller select group of patients. No surgeon was disappointed in the overnight elimination of the dislocation risk!

Dr. Stulberg: I agree with Dr. Mayor, that both desires were part of the discussion with young patients undergoing THA. Please remember that some of the usage was driven by the availability of the devices. Resurfacing with MoM bearings was largely an IDE option ONLY for patients between 2000 and 2005, while several manufacturers offered

large head MoM THA in 2003. As interest in larger head devices to prevent dislocation became of interest across all bearing surface types, it was natural that the use of larger head diameters offered in MoM Arthroplasty would be part of that discussion.

Dr. Keggi: Both HRA and THA surgeons and patients were interested in large heads for stability and what was subjectively described as a more natural hip motion of an anatomically sized head. While some surgeons moved to the direct anterior approach to reduce dislocations, others adopted MoM to reduce dislocations associated with the posterior approach. HRA does also have the advantages of bone preservation and a higher tolerance for activity compared to THA, but these are only currently achievable with a MoM construct as well. Overall, MoM was the only available material combination for either HRA or THA that could meet those particular goals in certain settings.

Dr. McPherson: I have a very healthy revision practice, and the major influences for me to change were the frequent cases of massive osteolysis and pelvic bone destruction that occurred in poly metal THAs, as early as 8 to 10 years! At the same time, hip dislocation was still a significant problem in both young and older populations. For me, I chose the large diameter metal-metal THA, which for me solves both problems, [if] the hip is correctly positioned and hip offset is optimized. Even though there has been a pushback with metal-metal technology, I remind you that there is still no perfect bearing construct. All have an Achilles heel. Don't throw out the baby with the bath water. There are surgeons out there that can make a metal-metal THA work well, very well.

Question 4: (for Dr. Clarke)

Dr. Clarke as one of the leading experts in Tribology you and your staff have conducted many wear studies on MoM bearings. I can recall in one such study that I participated with you and Dr. Bowsher we did a study on off the shelf HR MoM system. I believe that was the first time an off the shelf device was tested. Can you please describe what the typical process was for companies looking for testing data to submit for their 510K applications?

Dr. Clarke: With regard to tribology studies, our standard test suitable for submission to various regulatory bodies has been our 5 million load cycles under standard simulator test mode in which we report the volumetric wear rates of balls and cups along with the morphology of the CoCr wear debris from run-in to steady-state wear phases. Now with the analytical tools in the DARF Center we can provide dimensional studies via a precision CMM tool, roughness studies by white-light interferometry and wear analyses by SEM and EDS imaging.

Question 5: (for Dr. Clarke)

Dr. Clarke, one of the findings in our study seemed to support your labs findings with other MoM bearings, that regardless of carbon content, regardless of manufacture, regardless of head diameter 1 out of 6 samples in the wear testing met with break away or run away wear. Is my recollection correct and can you briefly review this finding? Second part of this question, why was this finding not recognized as a red flag to clinical application on MoM bearings?

Dr. Clarke: This question of breakaway wear in MoM bearings has been a confounding phenomenon (estimated to be 20% of our MoM wear samples) since we first published this finding (Anissian et al, 1999). During one such breakaway event during a lab visit, Dr. Donaldson made his historic comment that he "hoped none of his patients would get such MoM bearings". We have noted the same breakaway wear phenomenon from virtually all laboratories that publish their MoM wear rates. There is no information on this confounding MoM problem in national or international standards. It has taken more than 12 years for this phenomenon to be recognized and discussed at the national level. Indeed, this topic just came up for discussion at a recent meeting of the ASTM organization (Section F04.22).

The overall challenge appears to be that a) our societies, industry and regulatory bodies are very slow to react to information that does not fit into conventional thinking and b) most test labs work to established standards and regulatory guidelines (ASTM, ISO) such that there is no incentive to perform studies 'outside-the-box'. In other words, we are boxed in by the need to perform to standard

guidelines, thereby hoping to readily obtain regulatory approvals.

Question 6:

Many have suggested that if the US had a Joint Registry like the ones in Australia or the U.K., we could have reduced our exposure to the current clinical situation we find ourselves in. I question the logic of that statement since both the U.K. and Australia have well regarded Joint Registries and they find themselves in the same clinical situation. Any comment from our panel members?

Dr. Keggi: The US registry is just getting underway and our practice and our institution are pleased to be participating in the early phases. It will be critical in a market the size of ours to identify problems as quickly as possible for poorly performing implants or techniques in order to improve care and avoid problems for patients who are otherwise generally well-served by newer technologies as they emerge. A US registry would not have necessarily spotted MoM problems sooner. In this country the vast majority of hip resurfacings were carried out with well-performing implants. Europe and Australia had a broader experience that included higher percentages of the implants that ultimately prompted concern. MoM THAs were performed in the US with a wider variety of implants compared to HRA. US surgeons were quick to report their experiences with MoM THA as the problems emerged and a registry would not have acted any more quickly, I believe. A US national registry will still have numerous benefits for all parties as long as we understand its limitations and work to be a consistent as possible in data collection and follow up.

Dr. Mayor: It seems fundamental that registries for prosthetic implants are a basic necessity. Are registries a perfect form of monitoring? No. What are their faults? To properly reflect the performance of any class of implants the design of the registries is critical. Participation needs to be as broad as possible, and sufficiently "granular" to clearly spot the devices going in and coming out, reflecting right/left specificity and with a broad reach to capture data from a mobile population. That said, the users of the registries will have to set thresholds that determine performance figures which may fall out of acceptable bounds. Durable devices whose revision is accomplished reasonably readily with good outcomes post-revision, with long-term function both before and after revision are not the same as those with short time-spans to a significant incidence of revision and whose revision is tortuous, difficult and with unpredictable outcomes.

Dr. Stulberg: I think that registry information has been useful, but there are a number of ways to get good information about the performance of an operation that are not registries, and there are differing populations of surgeons and patients in each of our environments. Failure of an operation is usually multifactorial, patient, technical and device issues playing in to that failure. Finding ways of measuring each of those factors over a broad population rapidly, is challenging, for all countries. IDE studies for very new or for potentially high-risk devices, are costly and time consuming, but provide data that is important to the safe and effective use of devices. We enjoy the availability of a wide range of products for implantation in the US, and it seems to me that strategies to carefully evaluate device performance in the hands of those who will use them most, not necessarily in the hands of the experts who design or promote the devices, give us the best sense of how valuable that device will be for patient use. I am not certain that any approaches currently offered meet that objective.

Dr. Clark: Your point is well made. Three years ago at the Bristol Hip Meeting, I was advised that MoM THA devices were no longer being used in the UK. However they were still being used in the USA at that time. In the history of the ASR resurfacing device, the Australians first blew the whistle that something was wrong. Then the UK joined in with their data and then the problem came to the USA and then as of the last FDA Panel Meeting, the FDA is currently reviewing all issues related to MoM THA and RSA devices.

Dr. McPherson: The problem with the wear debris inflammatory process whether it is with poly, metal or a future bearing material, is the incubation period. Small scale IDE PMA trials will review results up to perhaps 5 years, but not much longer. When devices are released to the orthopaedic community, these constructs are "truly tested" and adverse wear debris problems come to light. However, these problems often take 5 to 8 years to reveal themselves. The joint registry, like a radar

screen, shows that an attack is coming, but it cannot prevent the launch of the attack. The joint registry just tells us where to focus our efforts.

Dr. Keppler: I do not believe most United States surgeons take into account out-of-United States practices. We do have different patient population expectations. The United States patient population is very consumer-centric. I don't believe that additional data fields need to be added to hip implant registries. I believe that present registries are sensitive enough to indicate relatively early problems developing with any particular implant.

Question 7:

For all surgeons. Do patients still come in asking either HR or THA for MoM, and if yes, how do you advise them?

Dr. Donaldson: Patients do come in asking about hip resurfacing. For the most part patients have heard enough that they want to make sure they are not getting a metal on metal hip. Clearly the younger male still is a candidate for MoM hip resurfacing in my practice. I believe the performance in young males has been outstanding and should be discussed. I do not believe that MoM HR should be used on females despite many successes in my practice to date.

Dr. Stulberg: My experience is similar. There are patients who still want to consider resurfacing, and come to our practice asking if they are candidates. I believe, as does Dr. Donaldson, that there are populations for whom this is an excellent procedure. I refer those as I have mentioned above. I no longer use or advise the use of MoM THA in my patient population.

Dr. McPherson: Right now, more patients are coming in and asking not to have a metal-metal bearing. In Los Angeles, my patients value quality of life such that they want to enjoy all that our state has to offer. Stability still is a major concern to patients and me. Therefore, I will utilize a large diameter metal-metal THA if the patient understands that I need to monitor serum metal ion levels [and] the patient understands that I may have to change that bearing if serum metal levels are too high (i.e. bad bearing mating or runaway wear). If not, my go to bearing is a dual articulation bearing.

Dr. Keppler: At the present time, I would not recommend metal-on-metal total hip replacement system or metal-on-metal resurfacing system to any of my patients.

Dr. Keppler: Contraindications to metal-on-metal are obviously those patients who had a metal sensitivity or women of childbearing ages. Warnings would include the potential for abnormal wear with the increase in heavy metal ions and the possible systemic side effects from this abnormal ion levels. Additional warnings would include the potential for early failure and the need for revision, the potential local damage to soft tissues and bone associated. Standard total hip precautions would pertain to metal-on-metal hip systems. But additional precautions relative to recommended monitoring of heavy metal ions may also be included. Direction for use should include the manufacturer's biomechanical studies which include the biomechanically optimal position of placement as well as safe zones for acceptable function. Unsafe zones need to be clearly identified. Outcome data obtained either through the use of the product outside the United States or from IDE data should be included in produce information. Specifications with respect to the handling of any retrieved devices should be included such that these devices are available for study.

Question 8: (for Dr. Clarke)

Dr. Clarke was there an over valuation or justification by the theory of MoM with fluid-film lubrication and if yes, how did this misdirect our attention?

Dr. Clarke: It was much more than just what fluid-film theory had to offer, which most surgeons don't really buy into in any case. There were i) publications in JBJS reporting on 20 to 30-year follow-ups with successful MoM cases like the McKee-Farrar, ii) there was what was seen as break-through technology for resurfacing concepts using the thin CoCr cups and iii) there was virtually 100% surgeon buy-in that the large-diameter femoral head replacements would banish the related problems of cup placement with its triad of risks (impingement, subluxation and dislocation). Also just ahead of clinical studies of the highly-crosslinked

polyethylenes, there was iv) a realization of the debris-driven osteolysis problem in the earlier generation of polyethylene cups. It is also to be noted that there were plenty of red flags regarding the toxicity Co and Cr and published case reports on 'pseudotumors' with McKee-Farrar devices in the 1970's. So yes there was a very strong redirection of interest into the MoM technology.

Question 9:

With metal ion testing it was recommended that once a patient was symptomatic ion levels should be monitored. My question is, should ion levels be evaluated from a baseline of preoperative levels and monitored say at one year and two years to help establish a baseline comparison for different devices?

Dr. Keggi: At this moment there is not a benefit to pre-operative testing. The run-in period is approximately one year for most MoM bearing pairs but we are only beginning to accumulate data specifically related to the trunnion interface and modular junctions. To this end, periodic post-op monitoring can be valuable clinically and scientifically. Clinically, we obtain ion levels at one year post-op and at intervals thereafter depending on the results, clinical symptoms (if any) and MRI findings. Routine MRI screening of asymptomatic MoM patients is not common presently, but MRI scanning of patients with a history of rising levels or of symptoms is indicated to detect pseudotumors or large fluid collections that may represent complications of the MoM construct.

Dr. Mayor: There certainly could be a valid scientific argument made about the value of that data, but would those measures accrue any value to any individual patient? The recommended ion level that would trigger clinical concern has been pretty thoroughly vetted, resulting in recommendations that levels much above 5 to 7 micrograms per liter should focus clinical attention on that patient's implant, with rising levels bringing more concern to bear. It would be useful to know when the "bedding in" phase of implant wear faded to a steady state, but it would not be of such great usefulness to any individual patient to seriously effect decision-making.

Dr. Stulberg: I think a single baseline postoperative value is probably sufficient. We measured levels extensively and serially in patients undergoing uncemented arthroplasty, in the 1980s and found that preoperative and 1 year studies were useful, but earlier postoperative studies often reflected metal debris from other sources (such as surgical instruments). Elevated levels occurred only with device failure. As a monitoring tool, one would be concerned only if there were an increase in levels over a steady-state, baseline value. I think that a single specimen, measured by a vetted laboratory, and collected in a standardized fashion, would be sufficient for most patients, and I would repeat those studies only if symptoms raised concern for device related complications. As long as the initial specimen was at least 1 year following implantation I would find it a believable baseline. While a preoperative value might be of scientific interest, we really are only interested in what happens to that patient after the device is implanted.

Dr. McPherson: Preoperatively, most experts would agree that serum cobalt and chrome levels are going to be near normal range and it is not worth the cost to society to measure all patients preop. As Ian Clark and Tom Donaldson have shown, run in wear lasts for about one million cycles. This takes 1-2 years depending on patient activity level. Therefore for me the earliest time to measure serum ion levels would be at three years. I want to point out that I do not solely rely on serum ion levels. If the patient complains of new onset pain or starts to limp, I immediately start an evaluation to assess for toxic reactive synovitis. Also, the serum level of ions that we consider as "toxic" is still fuzzy. Like poly debris, some patients can tolerate a higher debris load than others.

Dr. Keppler: For asymptomatic patients, ion studies are drawn as a baseline. The patients are counseled relative to their ion studies and based on the results of that study additional studies may be recommended.

Question 10:

Dr. Goodman raised a good question during one of the sessions on cost concerns with obtaining MRI's for all patients (potential 750,000) symptomatic and asymptomatic. I believe the Panel was instructed not to consider cost as part of any recommendation to FDA. Do you agree cost consideration should not be part of any health care discussion.

Dr. Keggi: Clinical testing protocols should rely primarily on sound reasoning and data and should be aimed at producing results that are useful for decision-making. Unselective MRI scanning of all MoM patients would be excessively expensive and would not help the decision-making process. So, I this case, the cost is a factor to reasonably consider. A bigger cost of unselective testing is the "Cascade Effect" where testing produces falsely- or insignificantly positive results that oblige more invasive testing and/or procedures and which in turn, ultimately, cause complications. We must consider all of the implications of policy recommendations and strive to avoid the unintended consequences.

Dr. Mayor: My sense is that it is absurd to think we can act responsibly and ignore the cost of any of our recommendations, particularly if that cost seems to approach astronomical levels. Beyond the simple issue of monetary burden, the logistics of getting MRI imaging with special protocols to suppress metal artifact is daunting, at least, or prohibitive in real terms. It would be interesting to see a rigorous cost/benefit analysis generated to better assess the impact of such an effort.

Dr. Stulberg: To be fair, the FDA may have been asking for a full accounting of the scientific validity and reproducibility of using MRI on the entire patient population, so as not to confuse the issues of cost and practicality with the actual ability of the test to be applied across a broad range of practice environments predictably. I agree with Dr. Mayor that it would irresponsible for a formal recommendation to skirt the issues of the financial and logistical burdens this would place on the health care system.

Dr. McPherson: I feel strongly that the cost burden to society is a major concern, as our health care budget will soon exceed 20% of GDP. If we mandate an expensive monitoring process for a procedure, this is to me an unacceptable burden to the healthcare budget. One of two things must happen. Either we abandon the procedure because it is cost prohibitive, or we find an algorithm that is practical and economical. It is my duty as a surgeon to make sure that this decision stays within the orthopaedic community and does not fall into the hands of a governmental bureaucratic committee.

Dr. Keppler: For patients who are symptomatic, MRI examination is performed. If joint effusion exists, then revision is typically recommended. If patients are asymptomatic, metal study, after ion study is obtained and is not thought to represent a significant elevation patients are re-studied in one year. If a significant elevation in ions is noted on the baseline study, more frequent follow up is recommended. If patients are significantly symptomatic, revision surgery is typically recommended.

Question 11: (for Dr. Clarke)

Dr. Clarke, you and Dr. Donaldson have an FDA contract I believe to analyze MoM brands (BioMet, DePuy, S&N, and Zimmer) with diameters 28 mm to 54 mm. Is this a retrieval study or a wear study?

Dr. Clarke: Actually the DARF Center has two FDA contracts, one for wear assessment in MoM explants and one for pre-clinical studies of MoM wear, as related to ASTM test methods (ASTM section F04.22).

Question 12: (for Dr. Clarke)

I also believe you have a contract to develop a clinically relevant adverse test for MoM devices in hip simulators? Do you believe it is possible to develop a predictive model to predict clinical failure?

Dr. Clarke: Turning that statement around, one can see that it would be impossible to devise a relevant pre-clinical test for a device if there was no prediction on which failure mechanisms would arise in its future. Thus I believe that it is entirely feasible, once we understand the MoM wear mechanisms that occur in vivo, it will be possible to devise a physiologically-relevant set of wear tests. I would also predict that this MoM know-how will aid our understanding of how to test the

polyethylene and ceramic bearings and produce more clinically-relevant tests for those devices also.

Question 13:

One final question to all. Today, if you personally needed a hip arthroplasty at your age, activity and current knowledge, what bearing material would you pick?

McTighe: I will start this answer off by saying I would be happy to have any of our surgeon panel members do my hip. I would not want a HR, I have never been impressed with this procedure. I would want a bearing that at 60 years of age would last me my life time (20 years). I think a ceramic head 36mm on a highly cross link polyethylene acetabular component that allows 6mm to 8mm of poly thickness.

Dr. Keggi: If I were involved in contact sports or still ran marathons, I would still choose a resurfacing. Having hung up my running shoes for lower impact exercise, I prefer a ceramic-on-ceramic construct. Presently, alumina COC is the only fully ceramic couple available in the US and it performs very well. I look forward to the availability of Delta COC in the US which will perform even more reliably.

Dr. Mayor: I'm 74, will be 75 in October. I manage a thirty acre woodlot and burn several cords of wood each winter, which I fell, limb, buck, split, stack and move prior to ignition. My father did the same to beyond 85 years of age, and died six weeks short of his 100th birthday. My right hip is not at risk, as it bears no weight with an above knee amputation distal to it. I'd select a surgeon skilled in THR from an anterior approach, and request a moderately cross-linked poly liner articulating against a ceramic head. I'd prefer a ceramic head with a titanium sleeve factory inserted. I would not choose an anti-oxidant additive, but would request a polyethylene with few or no free radicals residual to any cross-linking process.

Dr. Stulberg: I agree with Dr. Mayor. I'd pick a surgeon skilled in THA, in an environment he/she controlled well, using his/her favorite approach, and would ask for an uncemented titanium implant, HA coated on the femur, with a ceramic head appropriately sized to allow 6-8mm of highly cross-linked UHMWPE – and no bigger than 36 mm. At my age and golfing skill level that will easily last me 40 years.

Dr. Donaldson: Tim without a doubt today, I would still consider a hip resurfacing, however as a total, ceramic on vitamin E polyethylene. If we had 36 ceramic on ceramic I might go down that avenue but I don't think the thin delta shell is finalized!

Dr. McPherson: I have been using metal-metal THA constructs routinely since 1998. I follow my patients regularly, and I feel comfortable with my outcomes. If I needed a total hip today, I would have the following construct:

- Metal-metal THA with Magnum (Biomet) monolithicall metal cup
- Cementless proximal porous short stem with restoration of hip offset (or slightly increased if needed)
- A meticulous surgeon who understands prosthetic femoral acetabular impingement and would sculpt (with osteotomes) my acetabulum and proximal femur to eliminate hip levering. An adept surgeon is the most important part of the success equation

Of course I would be awake with a spinal. I would have mirrors or a live camera feed so that I could "make suggestions" during the procedure! (lol).

Dr. Keppler: Currently on all THA I use a neck sparing short curved stem with either a 36mm ceramic or chrome cobalt femoral head on highly cross linked polyethylene and certainly would choose this approach for myself.