The Bearing Dilemma in 2012: What Are We to Do?

New information is changing the decisions orthopaedic surgeons make

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New materials and better information on the way older materials perform are having a significant impact on joint replacement—particularly for total hip arthroplasty (THA). At The Hip Society/American Association of Hip and Knee Surgeons 2012 Specialty Day program, William J. Maloney III, MD, brought “The Bearing Dilemma in 2012” into sharp focus, with panelists focused on the evolution of polyethylene bearings, the use of ceramic-on-ceramic (CoC) bearings, and the controversy over metal-on-metal (MoM), and a series of audience response questions.

Polyethylene: Then and now

According to A. Seth Greenwald, DPhil (Oxon), of Orthopaedic Research Laboratories, early use of ultra-high–molecular-weight polyethylene resulted in wear as an inescapable consequence of in vivo femoral articulation. The debris created set off a chain reaction, resulting in osteolysis, bone loss, and ultimately THA failure.

As a result, multiple attempts were made to reduce wear and improve materials. “The most important—and perhaps overlooked—manifestation was the influence of gamma radiation in an air environment as an end-point sterilization process,” noted Dr. Greenwald. Early research found that increasing the radiation dosage not only reduced wear, but also created free radicals, which led to oxidative degradation—an issue that initially was not fully appreciated.

“Along the way, a new generation of polyethylene alternatives emerged, whose common denominator was an appreciation of the importance of increased cross linking while minimizing oxidative degradation to reduce wear,” said Dr. Greenwald. The first generation of contemporary cross-linked polyethylenes began to emerge in 1997, and subsequent variations have eliminated gamma irradiation as an end-point sterilization technique, but has now been incorporated into the manufacturing process.
In measuring the performance of these new materials, Dr. Greenwald looked at three factors: crack initiation, crack propagation, and abrasive wear.

“How well can the material inhibit a potential crack—arising from a stress concentrator within the acetabular shell locking mechanism or an imperfection in the material—and prevent it from starting and spreading?” he asked.

Crack propagation refers to the spread of the crack through the component. “Fatigue crack propagation resistance of these materials decreases with increased cross linking and may not be suitable for orthopaedic components where high cyclic stresses are involved,” he said.

Abrasive wear is the third mechanism that influences the performance of these materials. Pointing to the interaction between radiation dose level and wear, Dr. Greenwald noted “a significant improvement of the wear rate and corresponding minimization of the osteolytic response by comparison to what we have called conventional polyethylene.”

He pointed to the increasing dominance of cross-linked polyethylene and the disappearance of conventional polyethylene in orthopaedic hip implants. “The take-home messages are these,” he concluded. “Abrasion is the primary polyethylene damage mode in THA designs. Midterm reports indicate that advanced cross-linked polyethylenes significantly improve wear performance in THA, reducing the onset of osteolytic processes. Gamma irradiation has shifted from being the final sterilization mode to being part of the manufacturing process. Going forward, component placement will play an increasingly important role to ensure the longevity of these materials.”

Examples of highly cross-linked polyethylene liners that failed and had to be removed and replaced. Larger image

Courtesy of A. Seth Greenwald, DPhil (Oxon), Orthopaedic Research Laboratories, Cleveland, Ohio

The case for ceramics

As Carsten Perka, MD, of Berlin’s Center for Musculoskeletal Surgery, Charité University Hospital, pointed out, “Biologic problems related to wear debris have stimulated interest in alternate surfaces. Although the new polyethylenes appear to be a significant improvement, they are not perfect. Ceramic has the lowest wear of all our experience to date.”

Dr. Perka noted that ceramics are extremely hard, scratch-resistant, and biocompatible; they also offer a low coefficient of friction, superior lubrication, and lower wear rates in comparison
to other THA bearing surfaces. More than 7 million ceramic devices have been implanted to date.

“There’s one more important issue,” he continued. “Bigger heads do not increase the wear rate. And sometimes there’s another advantage—durability. Ceramic seems to be more stable than we expect. With today’s more active patient and lifestyle, we must look at long-term survival rates, and ceramic performs very well.”

But, he acknowledged, concerns about squeaking and fracture risk continue. Although the causes may be multifactorial, Dr. Perka said that surgical technique could contribute to the problems. “The implantation technique of ceramic components is less forgiving compared to other bearings. From my point of view, prevention is the goal, and that is the surgeon’s responsibility to avoid component malpositioning and mismatch between the head size and the cup size.

“Squeaking only occurs if the friction in the joint articulation is sufficient to excite vibrations to audible magnitudes, due to loss of lubrication,” he continued. “Based on the literature, other risk factors for squeaking include component malpositioning, edge loading, impingement, and wear debris.”

The risk of fracture is greatest within the first year after surgery. Estimates of femoral head fracture risk range from 0.03 percent to 0.05 percent, while the risk of fracture of the ceramic acetabular insert is even lower—0.013 percent to 0.017 percent.

Dr. Perka noted that in some cases, particularly in patients who require a large range of motion, ceramic bearings would not be the best choice. He also advised surgeons to “pay attention to the type of ceramic that you use” because registry data lump together all forms of ceramics.

In conclusion, he said, “The selection of a bearing surface should consider factors such as the patient’s age and activity level. I believe that ceramic-on-ceramic is an attractive option for the young, active patient, in part due to the high wear resistance. But these bearings are less forgiving than the highly cross-linked polyethylenes; the implant position is crucial and fewer head and liner options are available.”

**Waning enthusiasm for metal**

“In the United Kingdom,” reported John Skinner, MBBS, FRCS (Eng), FRCS (orth), “We seem to be in the bleak of winter with MoM bearings. We had the euphoria and the excitement of hip resurfacing; we’ve seen early problems with fracture; we’ve seen these overcome by some using large diameter metal bearings, only to have our enthusiasm wane as we hear about adverse reactions.”

Dr. Skinner, of the London Implant Retrieval Center, noted that metal hip resurfacing accounted for 10 percent of the UK market at one point and that MoM implants were used in approximately 35 percent of THA surgeries in the United States.
But the retrieval center currently has approximately 1,000 failed MoM bearings. “That’s a lot of anguish and heartache for surgeons and a lot of problems for patients,” he said.

“When metal bearings fail, the potential for necrosis—tissue and cell death—could be in muscles, nerves, or bone. These cases are rare, and the metal might not come from the bearing but by galvanic corrosion from the stem, but no matter where it comes from, the damage can be quite extensive,” Dr. Skinner continued.

Late in 2010, the Medicines and Healthcare products Regulatory Agency (MHRA), the British equivalent of the U.S. Food and Drug Administration, issued a device alert, recommending that all patients with MoM hip implants should be followed for at least 5 years. The alert also recommended testing patients for the level of metal ions in their bloodstreams to help identify those at risk. “The MHRA said that 7 parts per billion (ppb) was an unusually high number in well-functioning bearings,” explained Dr. Skinner, “but it was never a cut-off level indicating that these implants need to be revised.”

He pointed out that metal ion levels are exceptionally low in patients with well-functioning hip implants; more than 90 percent of these patients have just 2 ppb. Based on an analysis of 660 patients with MoM bearings who had either well-functioning implants or revision surgery, a team of researchers from the United Kingdom and Finland found that using 7 ppb as a revision marker had 50 percent sensitivity and 90 percent specificity. At 25 ppb, specificity approaches 100 percent, while at 2 ppb, specificity was less than 50 percent.

“What this tells me is that there will never be a metal ion concentration that we’ll be able to ‘hang’ revision on,” said Dr. Skinner. He recommended using a metal artifact reduction sequence to identify hip implants that require revision. He also recommended that orthopaedic surgeons follow the guidelines of the British Hip Society and stop using large-head MoM bearings.

“No matter how well they’re positioned, they have a higher-than-expected incidence of failure,” he said. With regard to hip resurfacing, he noted that despite registry data showing high revision rates, “in high volume surgeons, hip resurfacing has fantastic results—particularly in patients younger than age 55.”

In conclusion, Dr. Skinner made the following recommendations:

- Follow patients with MoM bearings carefully; symptoms of pain and limp are very important.
- Blood tests to measure metal ion levels are useful but revision decisions should not be based on them alone.
- Eliminate all other possible causes for pain prior to performing revision surgery, even in patients with MoM implants.
- Metal artifact reduction series are very useful, and magnetic resonance imaging can be used to identify possible tissue damage.
• Hip resurfacing in younger patients—when performed by high-volume surgeons—generally has good results.
• Stop using large diameter MoM implants.

Disclosure information: Dr. Greenwald—DePuy, A Johnson & Johnson Company; Smith & Nephew; SBI; Maxx Health; DJO Surgical; Nuvasive; Synvasive; TJO; Acumed, LLC; Ranier; Japan Medical Materials; Integra; ConforMIS; Seminars in Arthroplasty; Journal of Arthroplasty; Orthopedics; Orthopedics Today; Video Journal of Orthopaedics; Journal of the Korean Orthopaedic Association; Journal of Orthopaedic Surgery (Asian Pacific Orthopaedic Association); Hospital for Special Surgery Journal; Dr. Perka—Smith & Nephew; Aesculap/B.Braun; Zimmer; DePuy, A Johnson & Johnson Company; Biomet; AO Publishing; German Orthopaedic and Trauma Society; Dr. Skinner—funding for retrieval analysis through the London Implant Research Centre supplied by Biomet; DePuy, A Johnson & Johnson Company; Mathys Ltd; Smith & Nephew; Zimmer; Stryker; Finsbury; Dr. Maloney—Wright Medical Technology, Inc.; Zimmer; Abbott; Gilead; ISTO Technologies; Johnson & Johnson; Merck; Moximed; Pfizer; Pipeline Orthopaedics; TJO; Journal of Orthopaedic Research; Journal of Orthopaedic Science

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The Current Climate (Pie charts)

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