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COMMENTARY
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Safety Issue of Hip Resurfacing, A Commentary

McTighe T [1], Acknowledgments to: Clarke I, Lazennec J

I had the pleasure of attending the recent International Society For Technology in Arthroplasty (ISTA) Annual Meeting held in Vienna, Austria September 30 - October 3, 2015. This years President was Robert M. Streicher, PhD supported by Program Director Joseph Fetto, MD. They along with their entire educational team put on an excellent symposium.

For those that are not acquainted with this group I encourage all that are interested in joint replacement to take time next year to join Stephen Murphy, MD, who will be hosting, as the 2016 President, the annual meeting in Boston.

One session that I particularly enjoyed was the session on Friday afternoon titled Hip Arthroplasty in the Patient Under 50: Long Term Clinical Series Moderated by Thomas Gross and Koen de Smet. There were twelve excellent papers presented in this session on results with Hip Resurfacing Arthroplasty. In fact, if one had only heard those papers and new nothing about the recent controversy one would wonder why more Resurfacing was not being done today! This leads into our Commentary on "Safety Issue of Hip Resurfacing."

Hip Resurfacing (HR) development of the 1970s was an attempt to address the failures of conventional cemented stems. Those early HR designs failed because problems with maintaining bone under the resurfaced femoral head, and loosening of the socket with substantial acetabular bone loss. However technology, knowledge and surgical techniques have evolved over the past 45 years. The more recent designs like the Birmingham Hip Resurfacing (BHR) focused on metal to metal bearing surfaces. These devices are under attack and maybe they should be. However, lets not ignore the significant amount of information and potential improvements in both design technology and surgical techniques that have come about over the past few years.

The Medical Healthcare Products Regulatory Agency (MHRA June, 2015) warned of higher risks with 46-48mm sizes of BHR hip resurfacing arthroplasty (HRA). For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where edge-wear became a risk occurred at 65-66º, revealing an insignificant difference with respect to diameters.

This warning brings with it a level of confusion and implies that the critical factor is small sizes (46-48) when in fact the real risk is not the size of the implant but the inclination (position) of the implant.

Our lead paper in this edition is titled "Margin-of-safety Algorithm Used with EOS Imaging to Interpret MHRA Warning for 46-48mm MOM Arthroplasty" authored by Clark and Lazennec.

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The level of evidence in this paper brings about some very significant findings. "For the 46mm and 48mm cups highlighted in the MHRA alert, the critical cup inclinations where

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edge-wear became a risk occurred at 65-66°, revealing an insignificant difference with respect to diameters. The MOS-algorithm also indicated that lower lateral-inclination angles were particularly beneficial, i.e. a 46mm cup positioned at 50° inclination would exhibit a higher margin of safety than either 48mm or 50mm sizes positioned at 55° inclination. This evidence supported clinical studies that recommended BHR cup inclinations of 50-55° or lower as optimal for reducing metal-ion concentrations."

Was the MHRA alert released without all the factors being properly reviewed and expressed? Does this alert cloud the issue of risk factors? Does this alert bring more attention to the legal community that may act hastily causing more concern; anxiety and expense to a heath care community already under attack? Does this alert provide clearly defined guidelines as to when surgical intervention should be considered?

I suggest not, however, our featured paper (Clark and Lazennec) provides an algorithm that can provide a simple and reproducible tool to help guide surgeons on how the MHRA warning may affect their clinical outcomes.

Over the years we have seen that when new designs come to the general market if the surgeon and companies do not fully understand the design principles and the required technique to ensure proper indications, implant position and precautions, patients are at risk.

Papers presented at the 2015 ISTA Meeting demonstrated that MOM HR works well in the hands of the "Experts." This then raises the question do the "Experts" always tell the truth when they are proclaiming excellent results how do we judge? Full disclosure of potential conflicts is our best practice for this concern.

Do we need Expert HR Centers?

How do we define Expert HR Centers?

How do we define Expert HR surgeons?

Who and what criterion defines the expert surgeons who are permitted to perform HR?

Will manufactures support HR technology that is plagued with current financial risks?

Should we be advocating for an indemnification from the patient that since he or she is part of the decision making process they lose their rights for punitive damages in cases of clinical failure?

The question raised now is who should decide on what and when to use. There has been debate that maybe only those that do a significant amount of any given procedure should be able to use or do the procedure. Then there is the argument of some type of additional training process or certification should entitle the surgeon to have access to this technology. If that route is taken who decides? Does the training come from industry, from CME activities, from Professional Societies from additional Fellowships or from an honest discussion between patient and surgeon with full disclosure on the merits and risks of the procedure along with a full discussion of the training of the individual experience the surgeon has with this technology. One would think this happens as a matter of routine practice.

There needs to be a balance between the designers, the developers, the distributors and all guided by the Professional Educational and Scientific Societies. When this breaks down we then see the government and legal sharks jump into the mix. In my opinion, bias as it is, I believe we can continue to make improvements in design, material and surgical technique however, I do not believe our government or our insurance industry has the same focus. Their focus is to say this technology is now a commodity and there is no difference between devices or training. They are trying to bring both surgeons and designers down to the lowest common denominator and say there is no difference so all-pricing for both should be at a commodity price point. Example: An active 65-year-old male on Medicare cannot sit with his surgeon to decide what type of implant is best for him. Lets say both surgeon and patient wish to use a ceramic on ceramic bearing or a Metal on Metal HR. Can he in the U.S. pay the cost differential and have the technology of his choice? The answer is no it is against the law. We need to fight to maintain the authority that medical decisions are a joint decision process between surgeon, patient and supported by proper medical societies.

The clinical evidence is in and clearly demonstrates that current HR can be done safely when there is full understanding of the design principals and the required technique to ensure proper implant position.

Clarke and Lazennec's paper supports what we already know that surgical prosthetic placement is the major criteria for good outcomes. A small cup correctly placed can be better for the patient than a large cup incorrectly placed.

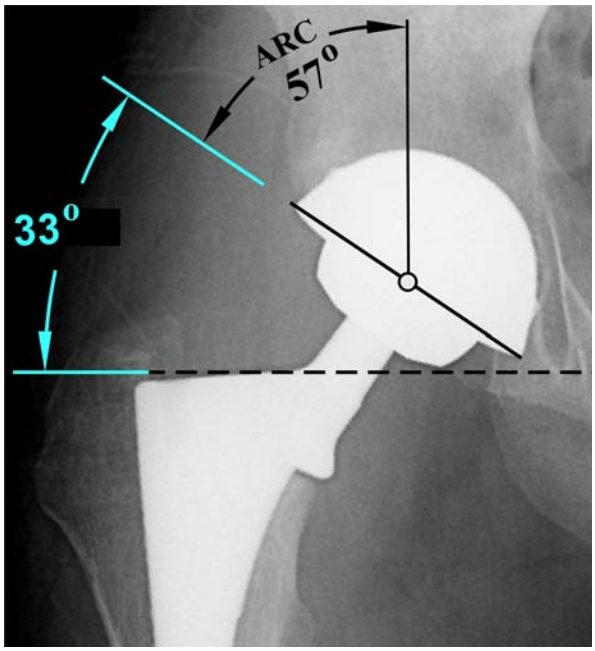

Fig. 1. 38mm M2a (Biomet, Warsaw IN)

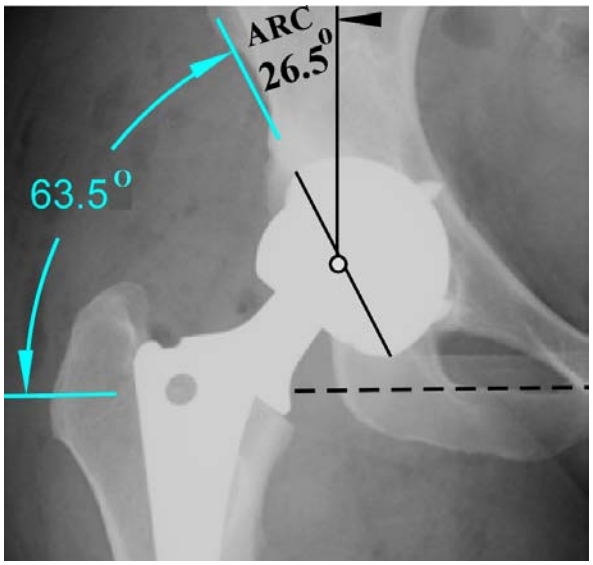

Fig. 2 36mm Pinnacle (Depuy, Warsaw IN).

A simple case survey (using the ARC parameter) illustrates the difference in cup coverage due to the angle of lateral inclination. A 33°-inclined cup allows for ARC-coverage of 57° whereas a 63.5°-inclined cup reduces the ARC-coverage to 26.5°. Case-1 had a 38mm M2a (Biomet, Warsaw IN) and case-2 had a 36mm Pinnacle (Depuy, Warsaw IN). Patient-1 was a 17-year-old male revised after 7 years for hip pain and a noisy bearing but with notably low metal ions. Patient-2 was a 51-year-old female revised at 5 years with a painful hip and high metal ions. Such case analyses are quite complex and the surgeon needs a simple instrument to isolate the effects of cup design, diameter and inclination in deciding whether edge wear should be a real consideration. It may be that the MOS-algorithm can serve as that instrument.