## Commentary & Perspective

## An Important Contribution to Our Understanding of the Performance of the Current Generation of Metal-on-Metal Hip Replacements

Commentary on an article by A.J. Hart, MA, MD, FRCSG(Orth), et al.: "Which Factors Determine the Wear Rate of Large-Diameter Metal-on-Metal Hip Replacements? Multivariate Analysis of Two Hundred and Seventy-six Components"

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It is hard to overstate the importance of implant retrieval analysis in the development of successful orthopaedic devices. Given the enormous complexity of the musculoskeletal system, no amount of preclinical testing, joint simulation, and analytic modeling can fully predict the performance of orthopaedic implants. Despite the application of the most sophisticated methodologies available during the 1990s when so-called alternative bearings were being developed for total hip arthroplasty, there was insufficient information to predict, among other things, squeaking of ceramic-on-ceramic bearings and the adverse local tissue reactions that have been widely reported in association with metal-on-metal bearings. Implant retrieval analyses provide important and unique insights into the in situ performance of orthopaedic devices and provide critical clues into mechanisms of failure and success, the latter being determined by postmortem retrieval analyses. The findings from implant retrieval studies also provide the necessary end points for implant designers to develop preclinical testing models. Biomechanical testing, joint simulations, and analytic modeling will only be predictive of implant performance if the failure mechanisms, or end points, of the testing and modeling are congruent with the failure mechanisms observed on retrieved devices.

The study by Hart et al. is an important contribution to our understanding of the performance of the current generation of large femoral head metal-on-metal devices. The large number of components analyzed in this study adds considerably to the utility and generalizability of their findings. The authors point out that the extant implant retrieval literature for contemporary large femoral head metal-on-metal devices is limited to the analysis of components obtained from only sixty-nine patients. In order to provide the statistical power necessary for a multivariate statistical analysis of factors that may contribute to failure, it is necessary to have relatively large numbers of implants available for study. This has been particularly challenging in the United States because of the litigation environment.

The salient finding of this study is that the presence of edge-loading is the most important factor responsible for the variation of wear rate in the retrieved devices. Another important finding was that there was a strong positive correlation between blood metal levels and wear rate. Both of these observations are quite useful. The minimization of edge-loading becomes an important design criterion for the development of improved implants and the development of protocols replicating such adverse conditions in hip simulations that can be used in preclinical testing. Furthermore, it is informative for the surgeon regarding component positioning. Metal testing can be a useful adjunct in postoperative monitoring of patients with metal-on-metal bearings since there is no other noninvasive methodology to determine bearing surface performance; unlike the situation with ultra-high molecular weight polyethylene bearings, radiographs are not helpful in the assessment of wear of metal-on-metal bearings.

In addition, the observation that 69% of the failures had an acetabular cup inclination angle of  $\leq 55^{\circ}$  is a key finding. Even though this does not take into account components that may be malpositioned by virtue of suboptimal anteversion and/or impingement, it does suggest that factors other than acetabular component orientation are responsible for failure in a substantial number of patients. Also yet to be fully explained are failures for pain in the setting of relatively low wear rates and relatively low blood metal ion levels. A plausible hypothesis is that such pain may develop in individuals who are hypersensitive to the metal debris generated from these implants. Detailed correlative histopathological information would be helpful in addressing this hypothesis.

As the authors point out, the contact areas of metal-on-metal modular junctions can undergo tribocorrosive processes that can also be an important source of debris that can contribute to failure. This factor was not addressed in the study and is a potential explanation for the presence of a substantial number of failures associated with components demonstrating relatively low wear rates. For example, the study by Garbuz et al.<sup>1</sup>, comparing blood metal levels in patients with metal-on-metal hip resurfacing and patients with metal-on-metal stemmed total hip replacement, noted higher blood metal levels in the total hip replacement group. This implicates the modular metal-on-metal contact areas as an important source of metal debris. An additional factor that could explain the variability in the performance of these devices that may not be reflected in the measured wear rate relates to the presence

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or absence of protective graphitic tribochemical reaction layers<sup>2</sup>. Factors that contribute to the formation and stability of such layers have yet to be delineated and are likely to provide an important insight into the clinical performance of these bearing services.

It is hoped that the London Implant Retrieval Centre, which is funded in large part by an industry consortium of nine manufacturers, will serve as a model for the future. Clearly, the entire orthopaedic device industry, the orthopaedic surgery profession, and, most importantly, the orthopaedic surgery patient will benefit from a deeper understanding of the mechanisms of failure. This can only be accomplished by studies that have access to large retrieval cohorts and are adequately funded to analyze sufficient numbers and types of implants to provide statistical power. Future studies integrating the findings on the retrieved devices with imaging, histopathologic, serologic, genomic, proteomic, and epidemiologic parameters will provide deeper insights into implant failure mechanisms and potentially lead to novel biomarkers of implant performance and improved implant materials and designs.

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