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*Title Page (with full author details)

Cross-sectional imaging should not be rationed in patients with metal-on-metal Articular Surface Replacements

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To the Editor,

I read the recent study by Connelly *et al*. with interest [1]. The high short-term failure rate of metal-on-metal hip arthroplasty (MoMHA) has led to almost all patients requiring regular surveillance. However surveillance regimens are variable and do not reflect the best evidence [2]. Furthermore there are numerous important questions which must be answered so we can modify follow-up protocols accordingly and make them clinically and cost-effective [2-4]. The authors of the present study had access to a large prospective multicenter database, which included patients with the recalled metal-on-metal Articular Surface Replacement (ASR) hip system. This database provides a useful resource to answer some of the important clinical questions around the investigation and management of MoMHA patients with this particular device, and the authors have subsequently written a number of papers using this dataset. However it is important to keep in mind that the questions posed must be clinically relevant. I would argue in this particular study of ASR XL implants by Connelly *et al*. [1] the research question is not clinically relevant, as is the case for their other recent paper on ASR hip resurfacings [5].

The ASR XL system has the highest revision rate of any total hip arthroplasty device that I am aware of over recent years. Langton *et al*. reported it to be 49% at 6 years back in 2011 [6]. Current registry data from Australia and the United Kingdom consistently report 10 year revision rates for the ASR XL system of between 44% and 46% with the ASR hip resurfacing also performing very poorly [7, 8]. Both these registries have shown a gradual and steady increase in revision rates over the 10 years for ASR devices, rather than an initial high short-

term revision rate followed by a plateau. These observations are consistent with the patterns seen in 10 to 15 year outcomes for non-ASR hip resurfacings and non-ASR total hip arthroplasties, although these other devices have not failed at such a spectacular rate as the ASR [9-11].

Thankfully the ASR device was recalled by the manufacturer back in 2010 and is no longer implanted. However there has been substantial medico-legal implications with the device manufacturers paying billions of dollars in compensation to patients with failing ASR implants [12]. For these reasons it has been recommended since 2012 that all patients with ASR XL and ASR hip resurfacing implants require annual investigation, which should include cross-sectional imaging in all cases [13].

It is therefore unclear why the studies by Connelly *et al*. have investigated how to rationalize the use of MARS-MRI imaging in this group of patients with high risk withdrawn implants [1, 5]. The main reason they state relates to the extra cost of these investigations, however I would propose that this can largely be ignored given the catastrophic failure of this implant design and the need to first protect our patients from future problems. Furthermore the authors claim that the algorithm they developed was “highly sensitive and specific”, and that it “outperformed existing national guidelines” [1]. From the data presented I would question these bold statements. Although the sensitivity presented for the devised algorithm was 86% for detecting adverse local tissue reaction (ALTR) on MARS-MRI for the ASR XL, this is simply not good enough given everything we know about ASR implants and the significant implications of missing ALTR in this high-risk population. I propose that most patients with these devices still in-situ would not consider these results from targeted cross-sectional imaging acceptable.

The authors have used the area under the curve (AUC) to assess the discriminatory ability of their new algorithm (AUC of 50% = a non-discriminatory algorithm; AUC of 100% = algorithm with perfect discrimination). Whilst their new algorithm had the highest AUC of the other guidelines assessed, it was still only 63% [1]. This does not therefore represent a clinically useful algorithm, especially given the context of the clinical problem. Furthermore the confidence intervals for the AUC associated with the new algorithm actually overlap with those from the two other sets of guidelines assessed, therefore the authors cannot claim any superiority of their algorithm over existing guidance. Interestingly in both studies the authors have knowingly compared their algorithm in ASR patients to the non-ASR MoMHA guidance published by the MHRA, rather than using the ASR specific MHRA guidance, which exclusively recommends cross-sectional imaging in all cases. This therefore makes both the current study and their previous study unnecessary [1, 5].

In light of the high revision rate of ASR implants, the widely publicized manufacturer recall, the related medico-legal issues, coupled with the ever increasing revision rate in arthroplasty registries, I would urge clinicians reading these two articles by Connelly *et al*. to continue to follow-up patients with the ASR device on a regular basis. This follow-up must include regular cross-sectional imaging, given blood metal ions alone are not adequate in this patient population with Connelly *et al*. themselves reporting that blood metal ions only have a sensitivity of between 69%-75% for identifying ALTR on MARS-MRI [1]. Finally, care should be taken when embarking on future studies to ensure the research questions set are clinically relevant.

References

1. Connelly JW, Galea VP, Laaksonen I, Matuszak SJ, Madanat R, Muratoglu O, Malchau H. Indications for MARS-MRI in Patients Treated With Articular Surface Replacement XL Total Hip Arthroplasty. *J Arthroplasty* 2018; doi: 10.1016/j.arth.2018.04.021.

2. Matharu GS, Mellon SJ, Murray DW, Pandit HG. Follow-Up of Metal-on-Metal Hip Arthroplasty Patients Is Currently Not Evidence Based or Cost Effective. *J Arthroplasty*. 2015;**30**(8):1317-1323.

3. Matharu GS, Judge A, Eskelinen A, Murray DW, Pandit HG. What is appropriate surveillance for metal-on-metal hip arthroplasty patients? A clinical update. *Acta Orthop* 2018; **89** (1): 29-39.

4. Matharu GS, Eskelinen A, Judge A, Pandit HG, Murray DW. Revision surgery of metal-on-metal hip arthroplasties for adverse reactions to metal debris: A clinical update. *Acta Orthop*2018; **89** (3); 278-288.

5. Connelly JW, Galea VP, Matuszak SJ, Madanat R, Muratoglu O, Malchau H. Indications for MARS-MRI in Patients Treated With Metal-on-Metal Hip Resurfacing Arthroplasty. *J Arthroplasty* 2018; **33**(6): 1919-1925.

6. Langton DJ, Jameson SS, Joyce TJ, Gandhi JN, Sidaginamale R, Mereddy P, Lord J, Nargol AV. Accelerating failure rate of the ASR total hip replacement. *J Bone Joint Surg Br*. 2011;**93**(8):1011-1016.

7. Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty. Annual Report 2017. https://aoanjrr.sahmri.com/annual-reports-2017

8. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 14th Annual Report. 2017. http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2014th%20Annual%20Report%202017.pdf

9. Langton DJ, Sidaginamale RP, Avery P, Waller S, Tank G, Lord J, Joyce T, Cooke N, Logishetty R, Nargol AV. Retrospective cohort study of the performance of the Pinnacle metal on metal (MoM) total hip replacement: a single-centre investigation in combination with the findings of a national retrieval centre. *BMJ Open*. 2016;**6**(4):e007847.

10. Matharu GS, Nandra R, Berryman F, Judge A, Pynsent PB, Dunlop DJ. Risk factors for failure of the 36 mm metal-on-metal Pinnacle total hip replacement system: a retrospective single-centre cohort study. *Bone Joint J*. 2017; 99-B(5): 592-600.

11. Matharu GS, Judge A, Murray DW, Pandit HG. Prevalence of and risk factors for hip resurfacing revision: a cohort study into the second decade after the operation. *J Bone Joint Surg Am* 2016; **98** (17): 1444-1452.

12. https://www.nytimes.com/2013/11/20/business/johnson-johnson-to-offer-2-5-billion-hip-device-settlement.html

13. MHRA. Medical Device Alert: all metal-on-metal (MoM) hip replacements. MDA/2012/036. 2012. https://www.gov.uk/drug-device-alerts/medical-device-alert-metal-on-metal-mom-hip-replacements-updated-advice-with-patient-follow-ups.