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Submission: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

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Respondent's details

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Respondents

Tom Joyce is a biomedical engineer with almost 20 years of experience specialising in the design, testing, analysis and evaluation of artificial joints including hips, knees, shoulders and fingers. He works extensively with industry and clinicians in order to inform and improve future designs of artificial joints. He currently supervises a number of projects around hip joint failure including: ex vivo analysis of failed resurfacing hip prostheses; improving the metal-on-metal hip prosthesis – a study of failures and wear mechanisms; investigation of failed lower limb arthroplasties; and 'when technology fails patients': engaging with stakeholders on metal-on-metal hip joint failures. He has taken part in recent investigative media programmes highlighting problems with metal-on-metal hip failure, these include Dispatches and Newsnight in the UK, Primetime in Ireland, Four Corners in Australia and Kontant in Denmark.

Dave Langton is an orthopaedic research registrar who researches metal-on-metal hip prostheses. He has worked alongside Mr Antoni Nargol, consultant orthopaedic surgeon, who implanted a large cohort of DePuy ASR resurfacing and total hip replacements. With seminal publications in key orthopaedic journals Dave has moved forward understanding of the performance and failure modes of metal-on-metal hip prostheses.

Scope

Our submission to the Committee focuses on failed metal hip implants, which intersects with our areas of expertise. We will concentrate on:

i) engineering analysis of failed metal-on-metal hips. We have examined components from almost 950 failed hip components and published much of our data. We are the only independent centre in the UK, and probably the world, undertaking such extensive research. We were the only research

group in the world to publish critical data on the DePuy ASR metal-on-metal hip prior to its worldwide recall in August 2010.

ii) Metal ion testing. Much of our research has been informed by data from metal ion testing. We believe such data gives crucial insights which can be used to enhance patient care and safety. We have access to the largest independent metal ion database in the world.

Responses to the Consultation

The committee will be asked to discuss the following as it pertains to these devices in the U.S. population: Device mechanisms of failure, metal ion testing, imaging methods, local and systemic complications, preoperative and postoperative patient risk factors, as well as clinical follow-up considerations for patients with MoM hip systems (total and resurfacing).

1. Device mechanisms of failure

We believe that mechanisms of failure are related to metal wear debris and the adverse reactions this debris causes [1]. Indeed, we were the group to define the term Adverse Reactions to Metal Debris (ARMD) [1] which is now widely recognised and used. Much of this wear debris originates from the articulating surfaces (indeed this is the dominant source in hip resurfacing). We have shown and quantified this wear in a number of scientific publications. Initially we measured wear depths [1, 2] and we currently employ a high precision co-ordinate measuring machine to determine wear volumes [3-5]. In an early paper of ours we showed that failed metal-on-metal hip resurfacings had roughened in vivo, thus operating under boundary lubrication where metal-to metal contact would be expected and metal debris created with every step [6]. In large head metal-on-metal total hip replacements an additional source of metallic wear debris is the taper junction, where the femoral head attaches to the femoral stem. We are the only group to be able to quantify the wear volume from such taper connections and our results have recently been published [7].

The only way that we were able to definitively identify the mechanism of failure has been through an analysis of failed hip prostheses [1-7]. Examination of explanted joints that have failed or caused problems in the body is one of the most valuable sources of data about how and why implants fail – they can be thought of as the ‘black box’. Unfortunately, conservation of the failed joint itself is not required and many are simply thrown away. We call for the conservation and analysis of explanted joints to be made mandatory. This analysis should be undertaken by independent, not-for-profit experts. Such a move might be facilitated by the establishment of a national explant retrieval centre and the

committee should consider putting in place consultations for how such a centre could be managed and funded. One option might be a universal tariff on all new joints. Another option would be that a charge is made to the manufacturer for each joint examined – in this way manufacturers would be additionally encouraged to design and produce joints with the greatest longevity.

2. Metal ion testing

Much of our research has been massively informed by metal ion testing [1, 5, 8, 9]. We have published more papers on blood metal ion data involving more subjects than any other group in the world. Indeed our first paper, and the first in the world to indicate problems with the DePuy ASR hip was based on metal ion data [9]. We went on to show and explain differences in performance of competitor designs of metal on metal resurfacings [8]. We are not alone in claiming that metal ion testing serves as an excellent surrogate for in vivo wear of metal-on-metal hips [10].

We have carried out more revision of metal-on-metal joints secondary to ARMD than anywhere else in the world. Also we have detailed histologically the condition in more cases than anyone else in the world [11].

Current guidelines from the UK suggest that additional clinical investigation be undertaken on patients with metal-on-metal hips if their metal ion levels are greater than 7µg/l [12]. Based on our extensive clinical database we suggest that this should be reduced to 5µg/l.

References

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