Accelerating failure rate of the ASR total hip replacement

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There is widespread concern regarding the incidence of adverse soft-tissue reactions after metal-on-metal (MoM) hip replacement. Recent National Joint Registry data have shown clear differences in the rates of failure of different designs of hip resurfacing. Our aim was to update the failure rates related to metal debris for the Articular Surface Replacement (ASR). A total of 505 of these were implanted.

Kaplan-Meier analysis showed a failure rate of 25% at six years for the ASR resurfacing and of 48.8% for the ASR total hip replacement (THR). Of 257 patients with a minimum follow-up of two years, 67 (26.1%) had a serum cobalt concentration which was greater than 7 μg/l. Co-ordinate measuring machine analysis of revised components showed that all patients suffering adverse tissue reactions in the resurfacing group had abnormal wear of the bearing surfaces. Six THR patients had relatively low rates of articular wear, but were found to have considerable damage at the trunion-taper interface. Our results suggest that wear at the modular junction is an important factor in the development of adverse tissue reactions after implantation of a large-diameter MoM THR.
head (ASR XL head) attaches to a titanium alloy Corail or S-ROM stem (both DePuy) through a CoCr taper junction. The tapers are produced in two sizes: 11/13, compatible with the S-ROM stem, and 12/14, compatible with the Corail stem. Each is available with a varying offset. The tapers are machined to a tolerance of a maximum of 13 μm out-of-roundness (manufacturer’s data). They remain fixed to the femoral heads during explantation.

Our patients were taken from a single-surgeon prospective study of the ASR bearing surface which was begun in 2004. There were 418 ASR surface replacements and 87 ASR THRs, of which 30 bearings were on Corail stems and 57 on S-ROM stems. These patients have been described in detail previously.8,15 They were followed up at six weeks, three months and annually thereafter unless complications developed. The outcome was evaluated using the Harris hip score16 and the University of California, Los Angeles (UCLA) activity score.17

Since the introduction of the Medicines and Healthcare products Regulatory Agency guidelines,18 which recommend that all symptomatic patients with a MoM joint should undergo analysis of blood metal ions, a mass screening programme for all patients with MoM bearings was initiated at our centre. At the time of writing, 409 ASR patients have given samples, of whom 149 have given repeat samples with the aim of carrying out annual tests on all patients and more frequent testing for patients with increased levels.

Failure of the joint secondary to ARMD was recorded. The diagnosis was based on the clinical history, the findings at revision and the histological analysis of excised tissue. Any evidence of sepsis, such as positive cultures, grossly increased inflammatory markers in the blood or histological evidence of infection, precluded the diagnosis of ARMD. A raised concentration of Co or Cr in the whole blood or serum was not a prerequisite for the diagnosis since there have been reports of tissue destruction in association with normal surface wear.19

**Analysis of explants.** All the ASR components which were revised underwent volumetric wear analysis of the bearing surfaces and internal surfaces of the tapers using a coordinate measuring machine (Legex 322; Mitutoyo, Hampshire, United Kingdom) with an accuracy of 0.8 μm. Volumetric and maximum linear wear rates were calculated using Matlab software (MathWorks, Natick, Massachusetts) based on a previously validated programme.20 In order to provide graphical representation of the wear at the taper junctions, the co-ordinate measuring machine was used to perform several out-of-roundness traces at height intervals of 0.5 μm on the internal surface of the tapers. The latter was also analysed by SEM (FEI XL30 ESEM-FEG; Philips, Eindhoven, The Netherlands) with microanalysis capability (EDX) (Quantax; Rontec, Carlise, Massachusetts) working in a high vacuum at 25 kV.

**Statistical analysis.** Due to the non-parametric nature of the data, Spearman’s rank analysis was used to analyse relationships between variables and Mann-Whitney U tests were used to determine significant differences between groups. Significance was set at p < 0.05.

**Results**

**Mid-term CoCr levels.** There were 257 patients with unilateral ASR resurfacings and THRs who had a minimum follow-up of two years. Of these, 67 (26.1%) were found to have blood levels of Co or Cr which were greater than 7 μg/l (the figure quoted in the Medicines and Healthcare products Regulatory Agency guidance to guide clinicians in the identification of a poorly performing bearing surface) and 30 (11.7%) had concentrations greater than 20 μg/l. This is a level above which patients were found to have gross macroscopic metallosis at revision in the study of De Smet et al.,21 findings which agree with our observations.

Of these 257 patients, the ASR THR patients (n = 51) had a significantly higher median concentration of Co in serum and whole blood than the ASR resurfacing patients (n = 206) (serum Co 3.78 μg/l versus 2.55 μg/l, p = 0.018, and whole blood Co 3.20 μg/l versus 2.10 μg/l, p = 0.011; Mann-Whitney test for non-parametric data).

**Bearing diameter and metal ion concentrations.** In the resurfacing group, there was a significant trend for ion concentrations to decrease as bearing diameter increased (Spearman’s rank correlation = -0.135, p < 0.001). This was in contrast to the ASR THR group in which ion levels showed a non-significant increase as bearing diameter increased (Spearman’s rank correlation = 0.105, p = 0.414).

**Revisions.** The most common finding at revision was a joint effusion in association with varying degrees of soft-tissue necrosis. Gross macroscopic metallosis was often encountered as well as a few solid or cystic masses described as pseudotumours.

**ASR resurfacing ARMD failures.** At the time of writing there were 57 failures in the ASR resurfacing group. Volumetric wear rates ranged from 2.30 mm³ to 95.5 mm³ per year (Fig. 1). Thus all ASR resurfacing patients who developed ARMD had implants with wear greater than would be expected in pain-free patients with well-functioning prostheses.22 Kaplan-Meier analysis showed survival of 75% at six years for the resurfacing group as a whole (Fig. 2).

**ASR THR ARMD failures.** There were 25 ASR THR ARMD failures with 14 in the S-ROM group and seven in the primary ASR THR Corail group. A further four patients developed ARMD after conversion of a primary ASR resurfacings to an ASR THR (Corail) following early fracture. Kaplan-Meier analysis showed an implant survival of 51.2% at six years for the ASR THR group as a whole (Fig. 2) with 21 of the failures in patients in whom the acetabular components were placed in zones 1, 2 or 323 (Table I).

**Bearing diameter and failure rates.** As bearing diameter increased, ARMD revision rates decreased in the resurfacing group (Fig. 3). The same pattern was seen in the ASR THR patient group; however, of the four THRs with bearing sizes ≥ 55 mm, there were two ARMD failures.
secondary to taper failure (50%). In the equivalent resurfacing group, there was only one failure in 35 patients (2.9%).

The volumetric articular wear rates of the failed ASR THRAs ranged from $1.27 \text{ mm}^3$ to $24.08 \text{ mm}^3$ per year (Fig. 3). In six patients wear was found to be less than $3 \text{ mm}^3/\text{year}$. Maximum wear depths measured in the tapers of these six patients were found to be greater than 15 $\mu\text{m}$ (15 to 78) in each case. Therefore in these cases the loss of material was not from the articulating surface but from the taper (Fig. 4). Of the ASR THR ARMD patients, nine were found to have blood and serum concentrations of Co and Cr lower than the threshold level of 7 $\mu\text{g/l}$ suggested by the Medicines and Healthcare products Regulatory Agency.\textsuperscript{16}

The maximum linear wear depths from the internal taper junctions of the femoral components from ARMD patients are shown in Figure 5. A single unused (contaminated during operative procedure) femoral component was available for examination. It was found to have a maximum out-of-roundness of 5 $\mu\text{m}$ and therefore matched the specification provided by the manufacturer. Volumetric loss from the tapers retrieved from ARMD patients varied from 0.07 $\text{mm}^3$ to 3.0 $\text{mm}^3$.
Discussion

In the light of an increasing number of reports of soft-tissue reactions in peri-prosthetic tissues, there are concerns about the continued use of MoM bearings. Our previous study implied that excessive metal wear was the basic cause of these adverse reactions rather than an idiopathic response to a well-functioning prosthesis. These findings were consistent with those from other centres. While excess wear of the articular surface appeared to explain all of the resurfacing failures at our centre, in this study we have observed a number of patients with relatively well-positioned resurfacing head THRs who have experienced ARMD with apparently well-functioning bearing surfaces. In each of these considerable damage was identified at the taper junctions.

Few patients appear to develop ARMD with a well-functioning prosthesis and this is consistent with the idea that 'sensitive' or 'allergic' patients are the exception rather than the rule. Patients who have undergone THR may be labelled allergic if the bearing surfaces of retrieved explants are examined, found to be normal, and the taper damage is not investigated. Often little or no metal debris is found in the capsular tissue in these cases and a heavy lymphocytic infiltrate with lymphoid neogenesis is present. In these instances an incorrect diagnosis of 'metal allergy' can easily be made. At our centre we have analysed a variety of MoM devices from over 100 patients from different centres and we have yet to encounter a patient who has developed ARMD in the absence of abnormal wear of the articular surface or taper junction. It is our belief that the concept of 'allergy' in this field of orthopaedics remains unproven and is not a unique condition to be looked upon differently in terms of diagnosis or treatment. Patients who quickly develop a lymphocyte-dominated soft-tissue reaction to a
relatively small concentration of metal debris have similar macroscopic and microscopic tissue appearances to those who develop pain a number of years after surgery and are found to have been exposed to massive concentrations of metal debris. All ARMD patients at our centre who underwent in vivo tests of metal allergy including lymphocyte transformation studies did not have excessive lymphocytic reactivity to Co or Cr ions. Our results agree with those of Kwon et al.8,25 Garbuz et al26 recently found that the serum levels of Co and Cr in patients with a large-diameter Durom (Zimmer, Warsaw, Indiana) THR were increased to a much greater extent than in those who received a Durom resurfacing. As in our study, the bearing surfaces of the resurfacing and THR systems were identical. They found a disproportionate increase in the concentrations of Co relative to Cr. In our study, we observed a similar phenomenon, with a significantly higher Co concentration in the ASR THR patients compared with the ASR resurfacing patients. In our ASR resurfacing patients, the median level of Co was found to decrease as the femoral diameter increased. The reverse was true in the THR patients. We speculate that this may have been due to increased mechanical stress on the tapers as the bearing diameter increased.

The catastrophic failure rates of the ASR bearing surface can largely be explained by the design of the acetabular component and its predisposition to edge wear.13,14,27 ASR acetabular components of smaller size are particularly vulnerable to this process because of their reduced arcs of cover.12 However, smaller acetabular components, when used in a THR system, have an even greater rate of failure secondary to ARMD than resurfacing devices of the same size. The contrast in performance between large ASR resurfacing acetabular components and their stemmed equivalents is even sharper. Seven large acetabular components were implanted in the THR group. They had a diameter of ≥ 60 mm, which is the threshold size that we have previously shown to be more resistant to the effects of the position of the acetabular component in terms of bearing surface wear.12 Three have failed secondary to ARMD within five years. In two of the cases the acetabular components were optimally positioned and the volumetric articular wear rates were relatively low, as were the corresponding ion levels. In both of these cases, however, there was marked taper damage. By contrast, there were 35 equivalent-sized acetabular components used as pure resurfacing devices. All remain in situ except for one which failed because of avascular necrosis. We believe that the generation of metal debris from taper junctions explains the poor performance of the larger sized THR joints and also the increased failure rates of the smaller sizes relative to the pure resurfacings. The out-of-roundness traces show consistent patterns of localised taper damage adjacent to taper areas which have retained their manufacturing form. The patterns of material loss suggest that the tapers have been splayed open by mechanical forces. We speculate that the trend for the use of larger diameter, harder-wearing bearing surfaces without a compensatory change in taper morphology28 has culminated in the clinical outcomes described in our report. In our total explant collection we have observed severe taper damage with a number of commercially available MoM devices from around the world, including the 36 mm Pinnacle system (DePuy), the Adept (Finsbury/DePuy, Leatherhead, United Kingdom) and the Birmingham (Smith and Nephew) femoral components. We therefore do not believe that this is a problem specific to the ASR. The latest National Joint Registry Annual Report suggests that we are correct in this assumption.29 In conclusion, no resurfacing patients in our study who experienced ARMD were found to have a well-functioning bearing surface or metal ion levels which were lower than the median levels for the group as a whole. Six ASR THR patients had failed joints which had relatively little measurable wear from the articulating surfaces. These prostheses were found to have significantly worn taper junctions. We believe that abnormal wear at the head-neck junction may be a major contributing factor to the development of ARMD in MoM THRs using bearing diameters of 36 mm and greater. We advise surgeons to have a high index of suspicion of ARMD in well-positioned MoM THRs even in the absence of elevated levels of metal ions. Asymptomatic patients may have severe soft-tissue destruction, a fact which has been reported in other centres.29 Surgeons need to be aware of potential taper damage when revising failed MoM joints and the trunion and internal surface of the tapers should be carefully inspected. Consideration should be given to the use of ceramic revision heads which have an internal titanium sleeve to protect the ceramic material.
Further opinion

A further opinion by Professor I. Learmonth is available with the electronic version of this article on our website at www.jbjs.org.uk/education/further-opinions

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References