



■ HIP

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.

There is widespread concern regarding the incidence of adverse soft-tissue reactions after metal-on-metal (MoM) total hip replacement (THR).¹⁻³ These changes have been described by various authors as pseudotumours,⁴ aseptic lymphocytic vasculitis-associated lesions (ALVAL)^{5,6} and metallosis.⁷ In a previous study we have used the umbrella term 'adverse reactions to metal debris' (ARMD) to encompass these conditions and to show that the incidence of pathological changes was attributable to the MoM bearing surface.⁸ We found an incidence of failure secondary to ARMD of 3.2% in patients with the Articular Surface Replacement (ASR; DePuy, Leeds, United Kingdom) resurfacing and of 6% in those with the ASR THR (DePuy). No failure was seen of this type in those with a Birmingham Hip Resurfacing (BHR; Smith and Nephew, Warwick, United Kingdom).

The results suggested that soft-tissue reactions were more likely to develop in association with accelerated wear of metal prostheses, and that the ASR device was more susceptible to accelerated wear compared with the BHR. These conclusions were in agreement with those from other centres.^{9,10} Factors linked to accelerated wear in resurfacing components include a smaller diameter of the bearing,¹¹ suboptimal orientation of the acetabular

component¹² and reduced acetabular cover.^{13,14} We initially attributed the increased rate of failure observed in patients with the ASR THR to the greater proportion of women in the ASR THR group (male:female, 40:60), believing that the smaller mean size of the bearings led to increased surface wear of the bearing and an increased likelihood of ARMD.

Since the above study⁸ was published, the overall failure rate of the ASR bearing has increased significantly. We have observed a disproportionate increase in the failure rate of the ASR THR in men. This phenomenon did not appear to be fully explained by the orientation of the acetabular component, the size of the bearing or the volumetric wear of the bearing surfaces.

Our aims therefore were: 1) to update data on the metal ions in ASR patients; 2) to update the failure rates of the ASR secondary to ARMD; and 3) to investigate the disparity in the failure rate between the THR and resurfacing groups despite the identical bearing surfaces.

Patients and Methods

Implants. Both the ASR hip resurfacing and THR systems use an identical cobalt (Co) chromium (Cr) acetabular component. The bearing surfaces of the femoral components are also of CoCr and are produced to the same geometrical and material specifications. The 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 co-ordinate 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, Carlisle, 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 $\mu\text{g/l}$ (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 $\mu\text{g/l}$. 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 $\mu\text{g/l}$ versus 2.55 $\mu\text{g/l}$, $p = 0.018$, and whole blood Co 3.20 $\mu\text{g/l}$ versus 2.10 $\mu\text{g/l}$, $p = 0.011$; 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 mm^3 to 95.5 mm^3 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

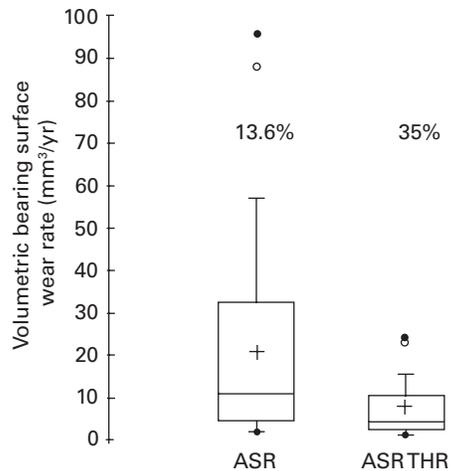


Fig. 1

Bar chart showing the volumetric wear rates of the implants retrieved secondary to adverse reaction to metal debris (ARMD) failure. The percentage values refer to the number of patients in each group who were found to have blood values of Co and Cr lower than the figure of $7 \mu\text{g/l}$ suggested by the Medicines and Healthcare products Regulatory Agency.¹⁸ Box lengths represent the interquartile range, the horizontal lines within the boxes the median value and mean (ASR, Articular Surface Replacement; THR, total hip replacement).

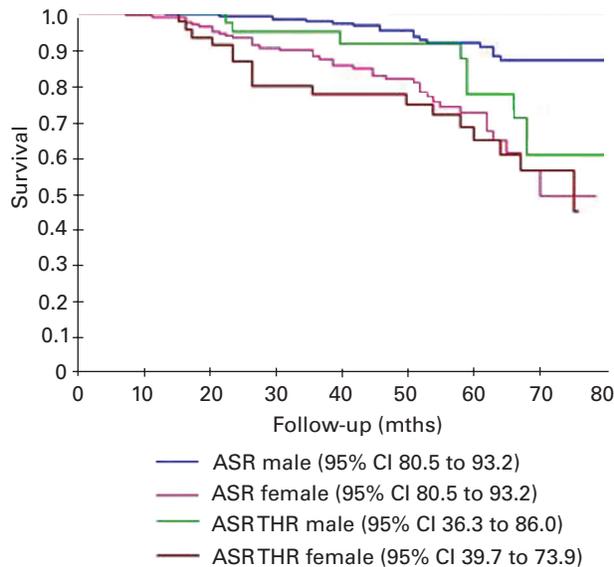


Fig. 2

Kaplan-Meier implant survival analysis of all patients divided into subgroups according to gender and type of arthroplasty. Only failures secondary to adverse reaction to metal debris (ARMD) are included (ASR, Articular Surface Replacement; THR, total hip replacement; CI, confidence interval).

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 THRs ranged from 1.27 mm^3 to 24.08 mm^3 per year

Table I. Position zones of the acetabular component derived from a two centre study on levels of metal ions in 585 cases and a volumetric wear assessment of failed metal-on-metal joints from a regional centre for implant retrieval. Zone 1 corresponds to the lowest ion levels and lowest bearing surface wear. Zones 2 and 3 are 5° expansions around and incorporating zone 1^{20,23}

Acetabular component position zone	Inclination ($^\circ$)	Anteversion ($^\circ$)
1	40 to 50	10 to 20
2	35 to 55	5 to 25
3	30 to 60	0 to 30
4	> 60	> 30
5	< 60	> 30
6	> 60	> 30

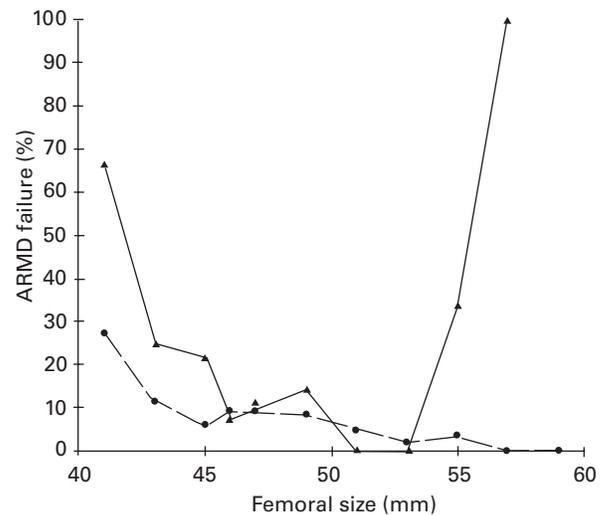


Fig. 3

The revision rates secondary to adverse reaction to metal debris (ARMD) at the time of writing. The black line represents total hip replacement patients and the broken line the Articular Surface Replacement resurfacing patients.

(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.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 mm^3 to 3.0 mm^3 .

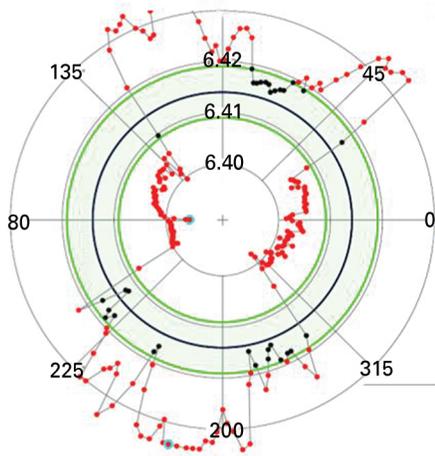


Fig. 4a

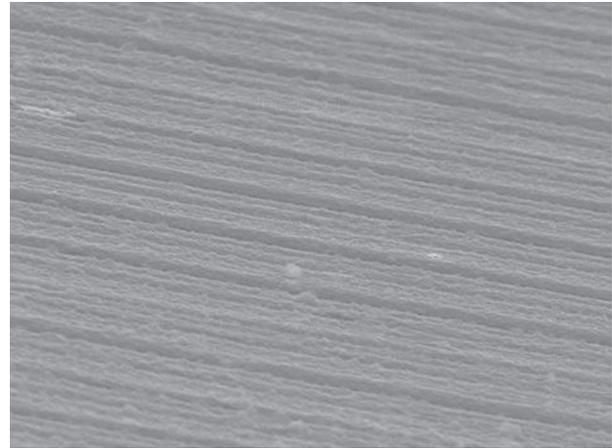


Fig. 4b

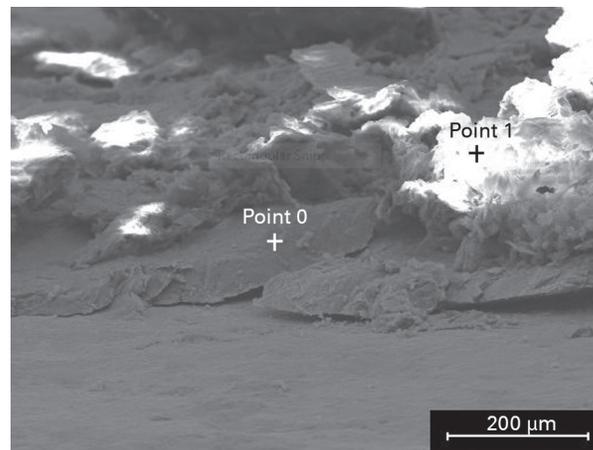


Fig. 4c

Figure 4a – an out-of-roundness trace of a retrieved 11/13 taper sleeve from an Articular Surface Replacement XL femoral component. There are two largely undamaged areas which correspond to the anterior and posterior scalloped areas of the S-ROM stem with which it was coupled. Adjacent to these areas there is marked abnormality of the taper surface with wear depths reaching 40 μm . Figure 4b – scanning electron microscopy (SEM) image of the areas with no surface change. The manufacturing form has been retained and the elemental composition is as expected. Figure 4c – SEM image of the worn areas. The manufactured form has been lost and there are chromium, phosphate and titanium rich deposits (points 0 and 1) implying corrosion.

Discussion

In the light of an increasing number of reports of soft-tissue reactions in peri-prosthetic tissues,^{4,7} 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.⁸ These findings were consistent with those from other centres.⁸⁻¹⁰ 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 centres²⁴ 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

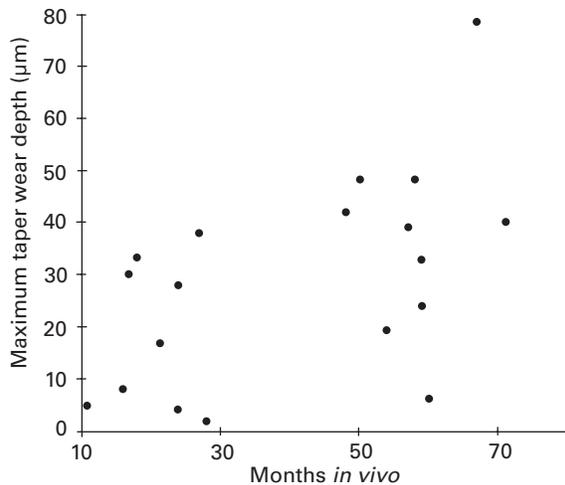


Fig. 5

Scattergraph showing the maximum wear depths of the internal surfaces of the femoral components exhibiting adverse reactions to metal debris which appear to be related to the length of time *in vivo* (Spearman rank correlation = 0.530, $p < 0.001$).

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.²³ All ARMD patients at our centre who underwent *in vitro* tests of metal allergy including lymphocyte transformation studies did not have excessive lymphocytic reactivity to Co or Cr ions.⁸ 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,²⁴ 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.²⁸

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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