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The Clinical Implications of Metal Debris Release from the Taper Junctions and Bearing Surfaces of Metal on Metal Hip Arthroplasty. Part One: joint fluid and blood metal ion concentrations.

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The Clinical Implications of Metal Debris Release from the Taper Junctions and Bearing Surfaces of Metal on Metal Hip Arthroplasty.

Part One: Joint Fluid and Blood Metal Ion Concentrations.

Abstract

The influence of metal debris exposure on the subsequent immune response and resulting soft tissue injury following metal on metal (MoM) hip arthroplasty is poorly understood. Some reports have suggested that debris generated from the head neck taper junction is more destructive than equivalent doses from metal bearing surfaces. We investigated the influence of the source and volume of metal debris on Cr and Co concentrations in corresponding blood and hip synovial fluid samples and the observed agglomerated particle sizes in excised tissues using regression analysis of prospectively collected data. A total of 199 explanted MoM hips were analysed to determine rates of volumetric wear at the bearing surfaces and taper junctions. Multiple regression statistical modelling suggested that a greater source contribution of metal debris from the taper junction was associated with smaller aggregated particle sizes in the local tissues and a relative reduction of Cr ion concentrations in the corresponding synovial fluid and blood samples. Metal debris generated from taper junctions appears to be of a different morphology, composition and therefore, potentially, immunogenicity to that generated from bearing surfaces. This may provide some understanding of the increased incidence of soft tissue reactions reported in patients implanted with THRs compared to patients with hip resurfacings.

Introduction

The host immune response to particles generated by orthopaedic devices is largely determined by the composition, morphology and volume of the debris.[1] Cobalt chrome (CoCr) metal on metal (MoM) hip prostheses in general wear at much lower rates than metal on polyethylene (MoP) devices and the particles released into the body are smaller. For this reason, MoM hips were reintroduced in an attempt to reduce the incidence of component loosening secondary to macrophage mediated osteolysis seen in association with polyethylene debris.[2]
Unfortunately it is now recognised that metal debris, specifically chromium (Cr) and cobalt (Co) in ionic or particulate form, is linked to a spectrum of macroscopic pathologies which have been grouped under the umbrella term "adverse reactions to metal debris" (ARMD).[3]

We have previously published our experience with a cohort of patients implanted with ASR (Articular Surface Replacement (Depuy, Indiana)) resurfacing and ASR total hip replacements (THRs).[3] These devices utilise identical bearing surfaces (the surfaces of the head and cup) in terms of materials and sizes but with the THR there is an extra metallic interface: the head-neck taper junction. We found that, compared to the ASR resurfacing patients, the ASR THR patients experienced double the failure rate of their devices secondary to ARMD. We also found that those reactions tended to be of greater severity in terms of the extent of tissue necrosis. Paradoxically, the THR patients had been exposed to, on average one third the total volume of CoCr debris as the resurfacing patients.[3]

We therefore hypothesised that debris released from taper junctions of MoM THRs is different to bearing debris in terms of size and composition, with taper debris more representative of the base alloy. We examined this hypothesis by comparing tissue samples and blood and joint synovial fluid Co and Cr concentrations in patients with MoM THRs (with a taper junction formed of a male titanium alloy taper with a female CoCr surface) with patients implanted with MoM resurfacings (no taper).

Methods

We have been conducting a prospective investigation of the failure of MoM hip prostheses since 2008. Patients who experience failure of these devices at our centre routinely undergo pre-revision blood and hip joint synovial fluid Co and Cr metal ion measurement. Tissue samples excised at revision surgery from multiple sites surrounding the prosthesis are analysed by a pathologist with extensive experience in MoM cellular responses using published methodology.[4] Explanted prostheses undergo analysis of the bearing and female taper surfaces to determine the amount of material loss, in volumetric terms, which has occurred in vivo.[3]

Given that seven variables in total were being investigated (see table 1), a number of which were categorical and potentially the subject of bias, we believed that we would need over 80 complete data sets in each of the resurfacing and THR groups to derive meaningful results. Approximately 40 to 50 complete data sets were received per year of the study, therefore a four-year cut off was agreed upon. The study obtained ethical approval from Durham and Tees Valley 2 local research ethics committee and was sponsored by Newcastle Upon Tyne Hospitals Trust. Only contemporary MoM prostheses were included, meaning that all metal components were manufactured from the same medical grade high carbon content with the same base CoCrMo medical grade alloy. There were however differences in the manufacturing processes, which are described in table 2.

Wear Analysis. Explanted prostheses were analysed using a coordinate measuring machine (Legex 322; Mitutoyo, Halifax, United Kingdom). Wear analysis involves the calculation of the total amount of material that has been removed from the components in vivo. This material loss can be expressed in volumetric terms either as “total volumetric wear (in mm^3)” or this total value can be divided by the number of years in vivo to provide a mean “volumetric wear rate” (expressed in mm^3/year). The accuracy of such methods has been validated and is of the order of $0.5mm^3$ per component for bearings and $0.2mm^3$ for tapers.[5] Throughout this paper, wear rates refer *only to volumetric CoCr material loss*. For resurfacings, “total volumetric wear rates” refer to the bearing surface wear rates (combined head and cup volumetric wear rates). For THRs, "total volumetric wear rates" refer to the combined wear rates of the head, the cup *and the female taper surface*.

Assessment of metal particle load in tissues. Previous authors have concluded that average particle sizes released from MoM hips range from about 30 to 100 nm.[6] To our knowledge however it is unclear whether it is the size and morphology of particles in solution, or the particles which aggregate and are deposited in local tissues, which are the determinants of the subsequent immune response. As the primary purpose of this paper was to establish relative differences in the periprosthetic environment related to variations in wear rates and the source of wear, we believed it was legitimate for this study to report the size of precipitated, aggregated particles as graded under light microscope examination. This was assessed by the method used to assess tissue iron overload in liver biopsies (see table 3).[7] We have described these approaches in detail in an earlier paper which focused on the cellular response involved in the ARMD spectrum.[4]

Joint fluid Co and Cr concentrations. Prior to revision surgery, joint fluid was extracted under local anaesthetic in order to rule out infection and to analyse the Co and Cr concentrations using the same technique and equipment as previously described in the collection of blood specimens.[3] Samples did not undergo acid digestion prior to analysis.

Macroscopic revision findings. The amount of fluid observed at revision was categorised as described in our previous publication: 0 - no abnormal fluid; 1 - small amount of abnormal fluid; 2 - copious amounts of abnormal fluid; 3 - fluid under pressure/fistulation of fluid.

Statistical analysis. Initially, the distribution of blood and joint Co and Cr concentrations, as well as volumetric wear rates from the bearing and taper surface were examined using the Shapiro-Wilk test. All values were determined to be non-parametrically distributed ($p<0.001$ for all tests) and were therefore log normalised. A number of multiple regression models (including stepwise and hierarchical approaches) were constructed in order to investigate whether any differences in the outcome variables were brought about due to differences in the source of the metal debris (table 1).

As can be seen in figure 1, taper debris, generated from a smaller surface interface than that of the bearing surfaces, was generally of lower magnitude. To account for this, the proportion of the total volumetric wear rate that was contributed by the taper surface was calculated. For example, if the total wear rate was 10mm^3/year and the taper wear rate was 1mm^3/year then the value entered into the regression model was 0.1. Statistical analysis was carried out using Minitab v17 (Coventry, UK). There is limited evidence on this subject but we believed it reasonable to include patient age and sex for all analyses (metal ions are excreted renally; renal function may decline with age[8] and some authors have noted a link between patient sex and ion concentrations.[9]) The observed particle grade in retrieved tissues was also included, as the surface area of agglomerated particles may affect rate of ionic release secondary to corrosion.[10] For the joint fluid analysis, fluid grade was included as a variable in order to rule in or out effects secondary to dilution.

Results

A total of 199 hips (116 THRs and 83 hip resurfacings) were analysed which had corresponding blood, joint and tissue samples. Patient demographics, clinical parameters and implant details, are shown in table 4.

Note: The various multiple regression modelling approaches returned consistent findings. The models reported are those that best described the response variables where all the coefficients of the explanatory variables were significantly different from zero with significance drawn at $p < 0.05$. Beta standardised coefficients are reported as "β" with standard error as "SE".

Part 1: Is taper debris associated with different agglomerated particle sizes in retrieved tissues compared to bearing surface wear?

In the ordinal logistic regression model, total wear rate appeared to have the strongest influence on agglomerated particle size (β = 0.339, SE = 0.071 p<0.001), with greater wear rates being associated with larger observed particle sizes. There was a trend towards smaller observed particle sizes when a greater proportion of the total volume of wear was contributed by the taper (β =-0.194, SE = 0.074, $p = 0.014$). These two variables accounted for approximately 21% of the overall variation. Patient sex, age, device type and fluid grade were not found to be significant factors. As can be seen in figure 2, smaller particle grades were associated with larger Co:Cr ratios in the corresponding joint fluid samples. In other words, smaller agglomerates of particles were more likely to be associated with Co rich joint fluids.

Part 2: Is taper debris associated with different metal ion concentrations in the joint fluid compared to bearing surface wear?

Joint fluid Cr. In the best fitting regression model, total wear rate was the dominant variable (β = 0.716, SE = 0.05, $p < 0.001$). A greater proportion of wear contributed by the taper was associated with a significantly lower joint Cr concentration (β = -0.107, SE = 0.050, $p = 0.03$), as was male sex (β = -0.150, SE = 0.047, $p = 0.002$). These two variables however added relatively little to the R^2 value derived from total wear rate on its own (R^2=58% versus R^2=55%). Fluid grade, device type, agglomerated particle size grade and patient age were not found to be significant.

Joint fluid Co. In the best fitting regression model, a greater proportion of taper wear was not associated with a significantly higher Co concentration. Total volumetric wear rate (β = 0.703, SE = 0.060, $p < 0.001$), fluid grade (β = 0.112, SE = 0.04, $p = 0.05$) and female sex (β=0.114, SE = 0.055, $p = 0.040$) were the only variables significantly associated with greater Co concentrations.

Part 3: Is taper debris associated with different metal ion concentrations in the blood compared to bearing surface wear? (unilateral patients only)

Blood Cr. A greater proportion of taper wear was associated with a lower blood Cr concentration (β = -0.128, SE = 0.037, $p = 0.003$). As with the joint fluid model, the dominant variable to explain blood

Cr concentrations was clearly total volumetric wear rate (β = 0.874, SE = 0.041, $p < 0.001$). Female sex was associated with greater Cr concentrations (β = 0.095, SE = 0.037, $p = 0.045$), as was fluid grade (β = 0.082, SE = 0.038, $p = 0.031$). The presence of the ASR resurfacing device was associated with lower Cr concentrations (β = -0.148, SE = 0.037, $p < 0.001$). However, the proportion of taper wear, female sex and the presence of the ASR resurfacing device added relatively little to the R^2 value derived from total wear rate on its own (R^2=80% versus R^2=76%). Particle size and patient age had no significant effect.

It was observed that as total wear rates increased, the ratio between the joint fluid Cr concentrations and the equivalent Cr concentrations in blood samples also increased. This implied that Cr was retained in the joint. To investigate this a further regression analysis was performed on joint Cr:blood Cr ratio versus combined wear rates and particle sizes. The equation for this model was as follows: JointCr:bloodCr=1.58+0.06*particle grade+0.57*logtotalwearrate(R^2=24%,$p<0.001$). This confirmed that as wear rates increased, joint Cr concentrations became proportionately larger than the blood Cr concentration. This effect was not seen with Co (figure 3).

Blood Co. A greater proportion of taper wear was not significantly associated with a higher blood Co concentration. Only total volumetric wear rate (β = 0.927, SE = 0.039, $p < 0.001$), the ASR resurfacing device (β = -0.162, SE = 0.042, $p < 0.001$) and fluid grade (β = 0.130, SE = 0.036, $p < 0.001$) were found to be significant variables. Again, the full best fitting regression model provided only a marginal increase in the power of the model to explain the variation in blood Co compared to total volumetric wear rate on its own (R^2=82% versus R^2=78%).

Having established that particle size and joint fluid grade had minimal impact on measured blood Cr and Co concentrations, we then drew from a larger database of results from the Northern Retrieval Registry[i], which conducts wear analysis on explants retrieved from external hospital trusts across the United Kingdom. These datasets do not typically include joint fluid/particle observations but the advantage of this further analysis was to allow us to select only unilateral Pinnacle devices thereby eliminating the potential confounding effect of wrought versus as cast CoCr components (table 2). This left us with 107 explanted 36mm diameter Pinnacle wear results with corresponding blood Cr and Co results from patients whose sex and age were known (see table 5). Regression models which were constructed using this patient data set alone confirmed the results reported above. For blood Cr, the best fit model (R^2=70%) showed that the dominant variable was once again total volumetric wear (β = 0.719, SE = 0.057, p <0.001) and that the proportion of wear volume contributed by the taper was inversely related to blood Cr (β = -0.269, SE = 0.057, p <0.001). Patient age and sex were both non-significant.

For blood Co, again the total rate of volumetric wear was the most important variable (β = 0.882, SE=0.052, p <0.001), again the taper contribution was insignificant (p=0.249) and increasing age was associated with greater Co concentrations (0.151, SE = 0.050, p = 0.003). Female sex was found to be insignificant. The overall power of the model was 75% (p<0.001).

Discussion

We conducted this study in order to investigate our suspicion that taper junction debris may be of a different composition to that generated by the bearing surfaces of MoM hips. The main limitation of this study was the use of surrogate measures to gauge the composition and morphology of released debris. We believe we are justified in reporting the surrogate measures of the composition of debris (ie precipitated, agglomerated particulate sizes in retrieved tissue and blood/joint metal ion concentrations) however as these surrogate measures are important clinical outcomes in themselves.

The main findings of this investigation were as follows:

1. As the proportion of wear debris contributed by the taper increased, there was a relative reduction in Cr concentrations in the corresponding blood and joint fluid samples. This implies that taper debris is composed of less Cr relative to bearing surface debris.

2. Agglomerated particulate sizes in tissue samples tended to increase with increases in total wear rates, though tended to be smaller when there was a greater source contribution from the taper. This implies that taper debris may be of a different morphology to bearing surface debris.

3. As bearing surface wear rates increased, joint fluid Cr concentrations rose disproportionately to blood Cr concentrations, implying the accumulation of Cr in the periprosthetic environment with high rates of wear.

4. Patient sex, age and the presence of joint fluid effusions appear to interact affect the body's handling of Cr and Co debris.

Metal on Metal Bearing Surface Wear

The clinical usefulness of medical grade CoCr alloy is due to its hardwearing nature and its resistance to the corrosive effects of the human body. These key properties depend on the alloy's ability to spontaneously generate a Cr oxide passive layer in vivo.[10] In MoM hips, when the femoral head contacts against the cup during activities of daily living, this passive layer is rubbed off to some extent but, in a well-functioning prosthesis, is thought to be rapidly regenerated.[10] Wear rates of MoM joints can in some circumstances be extremely low – as low as reported in the idealised environment of a hip simulator study.[11] Hip simulator studies have shown that the debris generated in such low wearing environments is primarily Cr particulate debris, with only a minority of particles containing Co.[12] Consistent with these findings, numerous blood metal ion studies have shown extremely low blood Co concentrations in patients with well-functioning MoM prostheses[9], indicates that Co release, in ideal situations, is very limited. This was clearly not the case in the majority of the patients in the current study, as evidenced by the gross elevations in blood and joint fluid Co concentrations.

In the current study, as wear rates increased, Co concentrations became larger than the equivalent Cr concentrations in the blood (figure 3). The reverse was true in the joint fluid, where Cr concentrations, in general, became larger than Co as bearing wear increased. Concomitantly, the ratio of joint fluid Cr to blood Cr concentration became larger. Furthermore, as bearing surface wear rates increased, agglomerated particulate sizes in the tissues tended to increase. This observation was consistent with previous simulator studies[13] which showed an increase in particle size as wear rates increased. Taken in combination, these findings imply that larger particles precipitate, become trapped and slowly corrode, producing massive local concentrations of Cr ions in the joint fluid. Co, more soluble, more easily diffuses into the blood stream. The strongest evidence of this effect is the relative clearance rate of the two elements following removal of MoM prostheses.[14]

Davda et al[15] proposed that joint fluids must undergo acid digestion to adequately assess the metal content. While we agree acid digestion may be useful, we believe it is just as useful to gauge the actual periprosthetic exposure to ionic debris with the fluid in its original form. None of the conclusions in this paper would have changed if Davda et al's suggestions had been followed – simply that we are likely to have *under* measured the total concentration of Cr in the hip fluids experiencing very high rates of wear.

Taper Wear

The taper junction, which, in this study featured connections composed of a CoCr head press fit onto a titanium stem, has a smaller surface area and thus material release is generally lower in total volumetric terms.[16] We have previously shown that the CoCr surface in these type of tapers is unable to sustain a Cr oxide layer of sufficient thickness, leaving the underlying bulk alloy vulnerable to wear.[17] Bulk CoCr alloy is composed of material with an approximate Co to Cr ratio of 2.1: 1 by weight.[10] It is likely the absence of this thick oxide layer which leads to the generation of particulate debris which is more representative of the composition of the bulk alloy. Some authors have suggested that elevated Co to Cr in the bloodstream is diagnostic of taper failure and due to preferential leaching of Co secondary to corrosion.[18] But the apparent disproportionate release of Co beyond that present in the alloy appears to be illusory. The observed clinical effect is equally, if not to a greater extent, due to a *reduction in Cr* release from the taper junction (for reasons described above) rather than an increase in Co release secondary to a corrosive mechanism specific to the taper.

Can blood metal ion screening be used to detect taper failure? Using total volumetric loss from the taper of 1mm^3 – which in our experience is of unquestionable clinical significance[5] – to diagnose taper failure, the resulting diagnostic accuracy of blood Co:Cr ratio was investigated using receiver operating curves (figure 4). This confirmed our suspicion that while high Co:Cr ratios are indeed indicative of a failing taper, this parameter has extremely poor sensitivity. This is clearly due to the fact that the bearing surfaces, aside from providing the bulk of the metal, also tend to generate variable ratios of Co:Cr (as well as agglomerated particle sizes) in both the joint fluid and the blood stream.

The results reported in this paper are of clinical importance not just in the assessment of patients with MoM prostheses, but particularly for those with CoCr femoral heads used as part of MoP systems. With MoP prostheses the relative contribution of CoCr from the bearing interface is far lower, meaning that interpretation of blood and joint Co and Cr concentrations will be of much greater significance in locating the source of debris.

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Table 1. Details of the full regression models used to examine variable interaction in the three parts of the study. "*" denotes linear regression and "ł" ordinal logistic regression.

Part 1: Particle size in retrieved tissues – all patients	
Predictors	**Dependent variables**
Total volumetric wear rate Proportion of wear contributed by taper Fluid grade Age Sex Device type	Agglomerated particle size gradeł
Part 2: Joint Co and Cr concentrations – all patients	
Total volumetric wear rate Proportion of wear contributed by taper Fluid grade Age Sex Agglomerated particle size grade Device type	Joint fluid Cr and Co concentrations*
Part 3: Blood Co and Cr concentrations – only unilateral patients included	
Total volumetric wear rate Proportion of wear contributed by taper Fluid grade Age Sex Agglomerated particle size grade Device type	Blood Cr and Co concentrations*

Table 2: Manufacturing and composition of the components in the study. ASTM F-75 and ASTM F1537 are similar alloys, with compositions by weight F-1537: Cr 26 – 30%; Mo 5 – 7%; Co balance and for F-75: Cr 27 – 30%; Mo – 5-7%; Co balance.

Component	CoCrMo alloy	As-cast versus wrought
ASR bearing surfaces	ASTM F75	As-cast
ASR taper sleeve	ASTM F799	Wrought
BHR bearing surfaces	ASTM F75	As-cast
BHR taper	ASTM F1357	Wrought
Pinnacle bearing surfaces	ASTM F1537	Wrought
Pinnacle taper	ASTM F1537	Wrought

Table 3: Aggregated metal particle size assessment.

Metal particle load grade within the macrophages	Ease of observation and magnification (eyepiece x objective lens)	Approximate size range (microns)
0	Granules absent or barely discernable x 400	< 0.5
1	Barely discernable x250, easily confirmed x400	0.5 – 1
2	Discrete granules resolved x100	1 – 2
3	Discrete granules resolved x25	10 – 20
4	Masses visible x10, naked eye	> 100

Table 4: Patient and implant details and distributions of measured parameters.

Patients and implants	
Mated explanted components (n)	199
Mean age (yrs) (range)	58 (21 - 84)
Male:female (n)	67:132
Mean (range) time to revision (mths)	58 (8 - 109)
Unilateral vs Bilateral	155:44
Device*	**(n, %)**
ASR	68 (34%)
Pinnacle THR 36mm	75 (38%)
ASR THR	37 (19%)
BHR	15 (7%)
BHR THR	4 (2%)
Reason for revision	**(n, %)**
ARMD	187 (94)
Loose components	6 (3)
Infection	2 (1.0)
Unexplained pain	4 (2.0)
Median (range) bearing surface volumetric wear rate (mm^3/year) : Hip resurfacings	7.35 (0.62 - 95.5)
Median (range) bearing surface volumetric wear rate (mm^3/year) : THRs	2.02 (0.27 – 68.9)
Median taper wear rate (mm^3/year) (range)	0.20 (0.01 - 8.34)
Median blood Co levels (µg/l) (range)	9.60 (0.70 - 271.0)
Median blood Cr levels (µg/l) (range)	9.90 (1.50 - 123.2)
Median joint fluid Co to Cr ratio (µg/l) (range)	0.69 (0.04 - 38.5)
Median joint fluid Co levels (µg/l) (range)	926 (13.0 - 46433)
Median joint fluid Cr levels (µg/l) (range)	894.4 (12.5 - 133120)
Fluid grades	0=3(1.5%); 1=41(20.6%);2=53(26.6%); 3=106(51.3%)
Particle sizes	0 = 9 (4.5%); 1 = 60(30.5%); 2=87 (43.7%); 3 = 28(14.1%); 4 = 15 (7.5%)

Table 5. Unilateral Pinnacle patient group used in final analysis.

Patients and implants	
Mated explanted components (n)	107
Bearing diameter	All 36mm
Mean age (yrs) (range)	65 (29 - 84)
Male:female (n)	36 : 71
Mean (range) time to revision (mths)	60 (12 - 130)
Reason for revision	
ARMD (n)	101
Loose components (n)	5
Infection	1
Wear rates and metal ion concentrations	
Median (range) total CoCr volumetric wear rate (mm^3/year)	2.17 (0.35 – 69.1)
Median (range) bearing surface volumetric wear rate (mm^3/year)	1.72 (0.19 – 68.9)
Median taper wear rate (mm^3/year) (range)	0.11 (0 – 2.16)
Median blood Co levels (µg/l) (range)	5.85 (0.68 - 215.4)
Median blood Cr levels (µg/l) (range)	6.81 (1.08 – 64.4)