The painful metal-on-metal hip resurfacing


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We carried out metal artefact-reduction MRI, three-dimensional CT measurement of the position of the component and inductively-coupled plasma mass spectrometry analysis of cobalt and chromium levels in whole blood on 26 patients with unexplained pain following metal-on-metal resurfacing arthroplasty.

MRI showed periprosthetic lesions around 16 hips, with 14 collections of fluid and two soft-tissue masses. The lesions were seen in both men and women and in symptomatic and asymptomatic hips. Using three-dimensional CT, the median inclination of the acetabular component was found to be 55° and its positioning was outside the Lewinnek safe zone in 13 of 16 cases. Using inductively-coupled plasma mass spectrometry, the levels of blood metal ions tended to be higher in painful compared with well-functioning metal-on-metal hips.

These three clinically useful investigations can help to determine the cause of failure of the implant, predict the need for future revision and aid the choice of revision prostheses.

Metal-on-metal (MOM) hip resurfacing prostheses were predicted to provide the high performance required for young active patients and good medium-term results have been reported. However, the United Kingdom National Joint Registry Report of 2007 suggested that early failure may be greater than with total hip replacement (THR), with fracture of the femoral neck (37%) being the most common cause. Improved patient selection and surgical technique may lessen the incidence of this complication, but it is difficult to predict how the incidence of unexplained pain (28%) or unclassified causes (18%) of failure could be reduced. As a comparison the incidence of failure for all hips replacements was 14% for periprosthetic fracture, 12% for pain and 7% for unclassified causes. A possible cause of unexplained pain in the MOM hip is an aseptic lymphocyte-dominated vasculitis-associated lesion. This is the histopathological description of an unusual reaction which has been found in the periprosthetic tissues of some patients undergoing revision of a MOM hip. Hitherto the diagnosis could only be made from periprosthetic tissue samples which were usually collected during revision surgery, or through biopsy. The significance of this finding is unclear since we do not know whether well-functioning MOM hips also show a similar tissue response. Diagnosis may be aided by MRI and metal artefact reduction sequences are available which allow good visualisation of periprosthetic tissues despite the presence of metal. Several authors have described the appearance of inflammatory masses in this region, but their clinical significance and relationship to aseptic lymphocyte-dominated vasculitis are unknown.

It has been suggested that unexplained hip pain is also associated with high levels of metal ions in the blood so that the levels of cobalt (Co) and chromium (Cr) may be biomarkers of likely failure. The association of high level of metal ions and an angle of inclination of the acetabular component greater than approximately 50° has also been widely reported and may lead to pain and failure. However, valid measurement of this angle requires customised CT protocols and measurement software which are not in widespread use.

We have therefore prospectively studied the clinical predictive value of three investigations for the diagnosis of unexplained pain in MOM hips, namely the levels of Co and Cr in whole blood, low-dose CT using three-dimensional (3D) software measurement of the position of the component and metal artefact reduction sequences of MRI.

Patients and Methods

We included the first 26 consecutive, consenting patients (9 men with a mean age of
52.3 years (33 to 63), 17 women with a mean age of 52 years (38 to 70) at primary operation; 18 unilateral, 8 bilateral) who presented with unexplained, painful MOM resurfacings from February 2008. Ethical approval had been granted by the appropriate committee. All patients had previously undergone a traditional hip assessment, comprising a clinical history and examination, blood infection screen and examination of serial pelvic radiographs.

The patients underwent 3D CT (n = 16) to measure the position of the component, inductively-coupled plasma mass spectrometry to determine the levels of Co and Cr in whole blood (n = 25) and metal artefact reduction sequences MRI (n = 26) to view the periprosthetic soft tissues.

**Three-dimensional CT.** A low-dose CT scan was taken according to the Imperial College Hip CT Protocol, DICOM images (Digital Images and Communications in Medicine) were obtained and analysed using previously validated 3D CT reconstruction software.

The measurement involved definition of an anatomical frame of reference to neutralise pelvic rotation. We used the anterior pelvic plane and set points on the most anterior prominences of the anterior superior iliac spines bilaterally.
and the most anterior point of one of the pubic tubercles. From the anterior pelvic plane, transverse and parasagittal planes were established. A cup-face plane was then formed by setting points on the rim of the acetabular component. The anatomical inclination was determined as the angle to the transverse plane and anatomical version as the angle to the parasagittal plane.

Cobalt and chromium analysis. Before revision blood samples were taken from the antecubital vein in 25 patients using a 21-gauge needle connected to a Vacutainer (BD, Oxford, United Kingdom) system and collected in trace-element tubes containing sodium EDTA. Standard operating procedures were established for the measurement of Co and Cr in biological fluids using dynamic reaction-cell...
inductively coupled plasma mass spectrometry (Perkin Elmer Elan DRCII, Waltham, Massachusetts). A PC3 (Elemental Scientific Inc., Omaha, Nebraska) chilled cyclonic spray chamber with 400 μl/min of PFA nebuliser and a SC4-FAST autosampler (Elemental Scientific Inc.,) was used for the introduction of the sample solutions to the inductively-coupled plasma. This combination of nebuliser and spray chamber minimised the deposition of blood components in the introduction system which would have compromised sensitivity. All samples were run blind and validated against certified reference materials (Seronorm trace elements whole blood; SERO AS,Billingstad, Norway), showing varying concentrations of Co and Cr within the range typically observed in this type of sample. The method was validated with studies previously published following a blinded, interlaboratory study. Renal function was evaluated through the surrogate blood creatinine level which provided an estimated glomerular filtration rate (eGFR).

Patients with unilateral (n = 18) and bilateral (n = 8) prostheses were analysed separately to avoid confounding. The levels of Co and Cr were compared with data from previously published control groups of well-functioning unilateral and bilateral resurfacing prostheses.14-17 The significance, set at 95%, of any differences between the groups was tested using the Wilcoxon rank-sum test on SPSS version 15.0 for Windows (SPSS Inc., Chicago, Illinois).

Results

Three-dimensional CT. All the angles of the acetabular component were expressed as the anatomical angle. There was a median inclination of 55° (39° to 78°) and version of 31° (48° to 47°). These values were within the safe zone of Lewinnek et al18 in only three of 16 patients (Fig. 1a). All the acetabular components were anteverted except one...
who was retroverted 47°. He described pain on hip flexion which was restricted to 60°. At operation the hip was found to be subluxing during flexion due to anterior impingement (Fig. 1b). Ten patients had inclination of the component greater than 50°, the threshold for a clinically detectable increase in whole-blood metal ion levels.19

Inductively-coupled plasma mass spectrometry. Patients with unilateral resurfacing had median whole-blood levels of Co of 4.5 (0.5 to 386.3) parts per billion (ppb) and of Cr of 3.0 ppb (0.8 to 179.0). The Wilcoxon signed-rank test showed that whereas the Co value was significantly different from that of a reference series with well-functioning unilateral prostheses (p = 0.001), the Cr value was not (p = 0.065) (Fig. 2a). Patients with bilateral prostheses had median whole-blood levels of Co of 10.6 ppb (2.6 to 72.1) and of Cr of 7.9 ppb (2.3 to 42.1). The Wilcoxon signed-rank test showed that both values were significantly different from those of a reference series with well-functioning bilateral prostheses (p-values of 0.012 and 0.003 respectively (Fig. 2b).

Discussion
We found three clinically relevant results. First, 13 of the 16 painful MOM hip resurfacings that had undergone CT scanning were associated with positions of the component outside the safe zone of Lewinnek as measured by 3D CT.18 Secondly, the patients had higher blood metal levels than those with well-functioning prostheses.14-17 Thirdly, metal artefact reduction sequences MRI demonstrated the presence of periprosthetic masses in 14 of the 26 painful MOM hips.

Currently, most patients with a painful MOM hip are assessed by the same diagnostic algorithms as used for the painful non-MOM hip. These include the taking of a clinical history and examination followed by a review of serial plain radiographs, blood inflammatory markers and hip aspirates. Isotope bone scanning to determine loosening and infection10 and CT to determine the position of the component, particularly in a case of dislocation, are occasionally used. However, hip resurfacing appears to have specific modes of failure which are not detectable using these protocols. These may be attributable to two main causes, namely high rates of wear with high local levels of Co and Cr and an adverse response to the metal wear debris.

Metal artefact reduction sequences MRI. A total of 15 patients (7 men, 8 women) had periprosthetic lesions demonstrated by metal artefact reduction sequences MRI. There were 16 lesions, 14 around symptomatic prostheses and two around the contralateral asymptomatic hip. They were of two types, fluid collections in 14 (Figs 3 and 4) and soft-tissue masses in two (Fig. 5).

The fluid collections were well circumscribed and best seen on T2-weighted sequences. Their cores had signal intensities similar to that of bladder fluid, while their pseudocapsules appeared hypointense (dark) to skeletal muscle and often featured areas of no signal (Fig. 4). They varied in size, ranging from 11 × 15 × 21 mm to 110 × 65 × 140 mm (median 40 × 30 × 42 mm). They were situated within the compartment of the iliopsoas tendon in five cases, behind the joint in six and lateral to it in three.

The soft-tissue masses were more solid and again best seen on a T2-weighted sequence. They were less well circumscribed than the fluid collections and had no obvious capsule. They were more hyperintense than skeletal muscle but hypointense to bladder fluid. They were characterised by loss of muscle definition and tissue planes. Gross muscle oedema was present around these masses, most apparent on STIR sequences. Two masses were detected. The first measured 110 × 60 × 90 mm and extended medially from the joint. The second extended from the compartment of the iliopsoas tendon through the joint and spread posteriorly and laterally. It measured 65 × 42 × 132 mm and on MRI, the patient’s thigh was grossly swollen (Fig. 5).
The position of the component may influence the risk of failure of a MOM hip because suboptimal acetabular version may cause impingement, and inclination angles greater than 50° may cause high rates of wear. The risk of impingement is greater for a hip resurfacing than a THR because the head-neck ratio is reduced. High inclination angles in MOM hips can increase the blood levels of metal wear debris up to 150 times greater than the median blood levels in patients with well-functioning MOM hips. Unfortunately, assessment of the position of the component of large-diameter MOM hips is difficult in practice because the large metal head obscures edges of the acetabular component on plain radiography and axial CT. Appropriate CT protocols and validated 3D measurement software are needed to overcome these difficulties and to minimise the radiation dose. We have demonstrated these in our protocol.

We found that placement of the acetabular component was variable. They were positioned within the putative safe zone (inclination 30° to 50°, version 5° to 25°) of Lewinnek et al\textsuperscript{18} in only one-fifth of cases and there was a large range of inclination and version. The former was greater than 50° in more than half the cases. This has been linked to raised levels of metal ions in blood\textsuperscript{14} and may predispose to a high wear rate. The findings in our study suggest that 3D CT is useful in two ways. First, it can be used to confirm a working diagnosis of impingement as in our case of extreme retroversion, and secondly, it can identify components at risk of high wear. Although the Lewinnek safe zone was originally used to determine the risk of dislocation, we have used it to predict impingement and subluxation, and therefore high rates of wear, particularly since hip resurfacings have a low head-to-neck ratio. Also, steep inclination and perhaps extreme version increase the risk of wear and the production of metal ions. We believe that when mechanical symptoms are diagnosed clinically, 3D CT may be useful to highlight major malposition of the components and is more accurate than pelvic radiographs. Our study numbers were too small to validate adequately the Lewinnek safe zone for the painful resurfaced hip, but our experience suggests that this range provides a useful guide to the optimal positioning of the component.

The use of blood metal levels as biomarkers of wear rate is an exciting possibility for monitoring a MOM hip. There is debate on the relationship between the wear rate and blood metal levels.\textsuperscript{20} Recent reports have shown that patients with bilateral MOM hips have 1.5 times the level of Co and Cr in blood than those with unilateral MOM hips\textsuperscript{21} and that removal of a MOM hip results in a rapid...
fall in blood metal levels.\textsuperscript{22} In our patients the levels of Co were significantly greater than in those with well-functioning MOM hips and this suggests that painful hip resurfacings have greater wear rates. However, the levels of Cr were barely raised in patients with unilateral MOM hips and therefore analysis of blood metal ions as a screening test for painful MOM hips is likely to be sensitive but not specific. As seen from our ranges, for 100% sensitivity the threshold for blood metal levels would need to be set at around 0.5 ppb for unilateral and 2.0 ppb for bilateral resurfacings. However, within our control population we noted that some patients had extremely high blood metal levels and therefore, even at 50 ppb, the test was not 100% specific for painful MOM hips. Our control data suggest that, with a threshold of 15 ppb, the test would have a specificity of around 98%. We have begun prospective metal ion and clinical monitoring of all patients with high levels to verify the value of this test.

Whereas plain radiographs can show a fracture, osteolysis and loosening of the component, they cannot diagnose soft-tissue inflammatory masses or fluid collections which may indicate an adverse reaction to metal or infection. This distinction is important because it will determine the likelihood of single-stage revision for sterile inflammatory masses or two-stage revision for infective masses. However, we are currently unable to distinguish between infective and sterile inflammatory masses on MRI.

We found a higher incidence of lesions in men which contrasts with the findings of two recent studies\textsuperscript{23,24} in which lesions were present only in women. A further difference in our group concerned bilateral lesions which were present in only one case and therefore not an indicator that a lesion around one hip is likely to be associated with another on the contralateral side. Also, we found lesions in asymptomatic hips. Their clinical significance is unclear and they may be a potential cause of hip pain. Our study provides an estimate for the incidence of these lesions in patients with unexplained hip pain. Further work is needed to determine the incidence in hips which fail from other known causes and in well-functioning hips. The aetiology and pathogenesis of these lesions also remains to be determined.

Our protocol for the painful MOM hip demonstrated a high probability of a periprosthetic mass on metal artefact reduction sequences MRI, a higher blood metal level than in the well-functioning MOM hip and a position of the component outside the Lewinnek safe zone. These observations may help to determine causes of failure, indicate the most appropriate treatment to predict the likelihood of future revision and to aid the choice of prosthesis if replacing the contralateral hip.

The authors wish to thank G. Lloyd and T. Panetta for their vital assistance with this work.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


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