Early metallosis-related failure after total knee replacement

A REPORT OF 15 CASES

Metallosis describes the accumulation of metal particles within tissues and was first seen in the setting of the fixation of fractures with metal implants.1 It has been extensively reported after metal-on-metal (MoM) bearing total hip replacement and is associated with osteolysis and early failure.2-5

It is normally much less common after total knee replacement (TKR) because direct MoM contact is avoided, but can occur when the polyethylene surfaces of an implant have worn away. This can allow unintended MoM contact at the tibiofemoral6,7 or patellofemoral components,8 or with constrained implants using MoM bushes.9 Metallosis typically occurs as a late event in the life of a failing implant which has already experienced considerable polyethylene wear. It has not previously been described in the early phase of an otherwise well-functioning implant with no MoM contact.

We describe a series of 14 patients (15 knees) who had problems within two years of TKR. All have required revision. Each case was associated with metallosis. In all there had been no direct MoM contact, and the metallosis appeared to have arisen because of two-body abrasive wear involving ceramic material used in the manufacturing process of the femoral component which had subsequently become embedded in the polyethylene-bearing surface of the tibial component.

The same cementless rotating-platform TKR prosthesis (LCS; DePuy, Warsaw Indiana) was used in each case without patellar resurfacing. This prosthesis had previously been shown to have an excellent long-term survival.10-15 All the patients had their primary surgery between October 2006 and November 2007. At this time a modified femoral component was available and this was used in each of the 15 knees. The original component had a beaded porous coating (Porocoat; DePuy), whereas the new component used the same beaded porous coating but with an additional 35 μm thick layer of plasma-sprayed hydroxyapatite (Duofix; DePuy), which had already been used on tibial and acetabular components with good results,16,17 and had been shown to be effective in animal studies.18 The Duofix femoral component had been used in a total of 362 knees at our hospital. It appears to have been the common factor in all 15 failed knees. There was a worldwide voluntary recall by the manufacturer in July 2009, and the original successful porous titanium-coated implant is now used as an alternative.

We describe the presentation, diagnosis, management and possible aetiology of early failure because of metallosis in TKR. Information regarding the reasons for failure has been sought from the manufacturer.

Patients and Methods

A review of the medical records of all patients undergoing revision TKR at our hospital

©2011 British Editorial Society of Bone and Joint Surgery
doi:10.1302/0301-620X.93B2.25150 $2.00
between 2005 and 2010 revealed 14 patients (15 knees) in whom a dual-coated uncemented femoral component had been implanted, which subsequently required revision. In each case considerable metallosis was seen. Table I gives the clinical details of the patients and their presenting symptoms. Most did well initially but developed increasing pain, stiffness and/or swelling. One (case 11) presented with discoloration of the skin over the proximal shin which extended into the calf. This was subsequently found to be due to a large cystic cavity filled with metal debris. Initially, very little was known about the cause of the early failure. As the series progressed, our understanding of the underlying problem increased. Consequently, a variety of working diagnoses were formulated and investigated. For this reason there was some inconsistency in the pre-operative investigations and surgical management of these patients.

**Results**

Table II details the working diagnosis at the time of initial presentation and the results of the investigations carried out. Measurement of serum inflammatory markers (white cell count (WCC), ESR and CRP) was unhelpful. Plain radiography did not show any obvious sign of loosening or infection. The arthroscopic appearance of the knees was striking, and showed extensive grey metal staining of the synovium with marked linear scratching of the femoral component in line with the axis of movement (Fig. 1).
These appearances were unmistakable. Synovial biopsies were taken at arthroscopy and these consistently showed the same histological features as the biopsies taken at revision surgery described below. Radioisotope three-phase bone scanning was used in some patients and showed a modest increase in scintigraphic activity for both the tibial and femoral components which was interpreted as being non-specific for this problem.

Revision surgery was carried out between seven and 32 months after the initial operation. The retrieved implants showed deep scratching which was clearly visible to the naked eye. On the femoral component the scratches were linear and aligned with the axis of movement (Fig. 2). On the tibial component, under the rotating platform, the scratches were circular and aligned with the rotational movement at this interface. In several cases, cystic cavities extended from the joint capsule into the calf or popliteal fossa. The components were typically well-fixed with good bone quality where it had not been invaded by cysts.

The implants were removed using a combination of microsaws, flexible osteotomes and punches. In each case exuberant grey metal staining of the synovium was seen macroscopically (Fig. 3). Complete synovectomy was carried out with a chondrotome using a previously-described technique, until all macroscopic evidence of metallosis had been removed and the cysts had been debrided.

The synovium was sent for histological examination by haematoxylin and eosin staining and polarised light microscopy, which consistently showed black refractile particulate matter, some of which had been engulfed by macrophages, with sparse neutrophils and no or few particles of polyethylene wear (Fig. 4). Table III details the timing of revision surgery, the histological findings, the requirements of the revision prostheses and the outcome of revision surgery to date.

Discussion
We report a new and previously undescribed mechanism of early failure of a modified metal-on-polyethylene TKR. Patients typically did well initially but then lost mobility
and developed pain with or without a joint effusion. Arthroscopy and synovial biopsy reliably confirmed the diagnosis, but required histological examination to confirm the presence of metallosis. The role of outpatient knee aspiration for metallosis in the diagnosis of this problem is the subject of an ongoing investigation. Scintigraphy has previously been shown to be sensitive for identifying a problem, but unhelpful in distinguishing between metallosis and infection.20

Table III. Details of the histological findings and outcomes in the 14 patients (15 knees)

<table>
<thead>
<tr>
<th>Case</th>
<th>Months to revision</th>
<th>Histological findings</th>
<th>Number of stems</th>
<th>Number of augments</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>Femur only revised - ongoing symptoms, 2nd revision 20/12 later</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>4</td>
<td>28</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>5</td>
<td>11</td>
<td>Metallosis</td>
<td>2</td>
<td>4</td>
<td>Satisfactory; depressed</td>
</tr>
<tr>
<td>6</td>
<td>21</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>7</td>
<td>26</td>
<td>Metallosis</td>
<td>1</td>
<td>3</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>8</td>
<td>23</td>
<td>Metallosis</td>
<td>1</td>
<td>2</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>9</td>
<td>29</td>
<td>Metallosis</td>
<td>1</td>
<td>3</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>10</td>
<td>19</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Infected prosthesis - awaiting 2-stage 2nd revision</td>
</tr>
<tr>
<td>11</td>
<td>29</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>12</td>
<td>11</td>
<td>Metallosis</td>
<td>1</td>
<td>0</td>
<td>Ongoing pain, awaiting 2nd revision</td>
</tr>
<tr>
<td>13</td>
<td>19</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>2nd revision, malalignment</td>
</tr>
<tr>
<td>14</td>
<td>29</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>15</td>
<td>32</td>
<td>Metallosis</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
</tbody>
</table>

Fig. 4
Photomicrograph showing giant cells laden with metal particles (black fragments) (haematoxylin and eosin × 1000).

environmental scanning electron microscopy of the retrieved polyethylene components by the manufacturer identified particles embedded in the polyethylene. Mass spectrometry was used to ascertain the composition of these particles and identified them as alumina ceramic. This is used to roughen the beaded porous coating of the component before the application of the hydroxyapatite coating as part of the manufacturing process. A complete explanation of the cause of this problem has not been made available by the manufacturer at the time of writing. It has been suggested that in some cases alumina particles may have broken up during the process and the resulting debris retained on the femoral component after washing but before coating with hydroxyapatite. Once the component was implanted these particles could have been shed into the joint and become embedded in the polyethylene bearing, creating a highly abrasive surface capable of causing wear of both the tibial and femoral surfaces causing metallosis, but very few polyethylene particles. Such a phenomenon has been observed to cause considerable metallosis after revision hip arthroplasty following fracture of a ceramic head.21
This problem of small modifications leading to unanticipated failure has been seen in orthopaedics on numerous occasions. The transition from the polished first-phase Exeter total hip replacement stem (Stryker, Kalamazoo, Michigan) to the matt-finished second phase (Stryker) caused a surprising increase in the rate of aseptic loosening.22,23 After this discovery the concept of the taper slip phenomenon arose. Similarly, alteration in the manufacturing of polyethylene components led to a dramatic change in the rate of failure of well-performing TKRs.24-26 Gamma irradiation in air led to oxidative damage and subsequent clinical failure in a manner that was not anticipated.27,28 Changes in the coolant and cleaning process used during the manufacture of Sulzer acetabular components (Zimmer, Warsaw, Indiana) led to the failure of bone ingrowth on the cementless surface, leading to early aseptic loosening.29

There is a considerable danger in extrapolating data from one design to a modified design even when the modifications are small and logical. It is prudent to regard any modified design as a new implant and to consider its clinical introduction with similar scrutiny, even when modifications are minor. Changes to implantation equipment and jigs without a change to the implant may also have adverse effects. Changes in manufacturing processes or materials may be less apparent to the surgeon, since the implant may appear to be identical, but can have similar serious consequences. Information must be sought from the manufacturer as to whether the implant and system being used are identical to those which registry data or published articles have used. Careful attention to implant failures in a personal series is required and any concerns about implant-related failures should be raised promptly.26

National joint registries typically group implants into families, and publish a combined figure (for example, reporting the cruciate-retaining and cruciate-substituting versions of an implant together). This level of data may be insufficient in situations where certain subgroups, or even sizes, of component may have specific problems.30 In this instance the performance of the LCS implant is likely to show deteriorating survivorship in joint registries as a proportion of this series as problematic femoral components are revised. This will reflect badly on the current system in use, which is not subject to metallisation. The LCS Porocoat implant and LCS Duofix implant should ideally be reported as separate entities by joint registries.

Part of this problem is caused by using the same name for implants with several evolutions of design, and designs based on different philosophies. This is surely a part of marketing strategy, but we should be careful to appreciate differences since these can have profound effects on the success of implants. As registries grow in size the value of the data may be enhanced by breaking it further down into classes and sizes of component, so that specific enquiries may be made about the subtype of an implant being used.

References
9. Buechel FF Sr, Buechel FF Jr, Pappas MJ, D’Alessio J. Modified design as a new implant and to consider its clinical introduction with similar scrutiny, even when modifications are small and logical. It is prudent to regard any modified design as a new implant and to consider its clinical introduction with similar scrutiny, even when modifications are minor. Changes to implantation equipment and jigs without a change to the implant may also have adverse effects. Changes in manufacturing processes or materials may be less apparent to the surgeon, since the implant may appear to be identical, but can have similar serious consequences. Information must be sought from the manufacturer as to whether the implant and system being used are identical to those which registry data or published articles have used. Careful attention to implant failures in a personal series is required and any concerns about implant-related failures should be raised promptly.26

National joint registries typically group implants into families, and publish a combined figure (for example, reporting the cruciate-retaining and cruciate-substituting versions of an implant together). This level of data may be insufficient in situations where certain subgroups, or even sizes, of component may have specific problems.30 In this instance the performance of the LCS implant is likely to show deteriorating survivorship in joint registries as a proportion of this series as problematic femoral components are revised. This will reflect badly on the current system in use, which is not subject to metallisation. The LCS Porocoat implant and LCS Duofix implant should ideally be reported as separate entities by joint registries.

Part of this problem is caused by using the same name for implants with several evolutions of design, and designs based on different philosophies. This is surely a part of marketing strategy, but we should be careful to appreciate differences since these can have profound effects on the success of implants. As registries grow in size the value of the data may be enhanced by breaking it further down into classes and sizes of component, so that specific queries may be made about the subtype of an implant being used.