

■ CASE REPORT

Damage of an Oxinium femoral head and polyethylene liner following 'routine' total hip replacement

R. W. McCalden,
K. D. Charron,
R. D. Davidson,
M. G. Teeter,
D. W. Holdsworth

From London Health
Sciences Centre,
University of Western
Ontario, London,
Ontario, Canada

■ R. W. McCalden, MD,
MPhil(Edin), FRCSC, Consultant
Orthopaedic Surgeon,
Associate Professor

■ K. D. Charron, Mechanical
Engineering Technologist
(MET)
University of Western Ontario,
London Health Sciences
Centre, 339 Windermere Road,
London, Ontario, Canada N6A
5A5.

■ R. D. Davidson, Metallurgical
Technologist, Manager
Scientific Operations
Surface Science Western
The University of Western
Ontario, Research and
Development Park
Convergence Centre, 999 Collip
Circle, London, Ontario,
Canada N6G 0J3.

■ M. G. Teeter, BSc, PhD
Candidate
Medical Biophysics

■ D. W. Holdsworth, PhD,
Professor
Department of Surgery,
Schulich School of Medicine
and Dentistry
University of Western Ontario,
Robarts Research Institute, 100
Perth Drive, London, Ontario,
Canada N6A 5K8.

Correspondence should be sent
to Professor R. W. McCalden;
e-mail:
Richard.McCalden@lhsc.on.ca

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We present a case of early retrieval of an Oxinium femoral head and corresponding polyethylene liner where there was significant surface damage to the head and polyethylene. The implants were retrieved at the time of revision surgery to correct leg-length discrepancy just 48 hours after the primary hip replacement. Appropriate analysis of the retrieved femoral head demonstrated loss of the Oxinium layer with exposure of the underlying substrate and transfer of titanium from the acetabular shell at the time of a reduction of the index total hip replacement. In addition, the level of damage to the polyethylene was extensive despite only 48 hours *in situ*.

The purpose of this report is to highlight the care that is required at the time of reduction, especially with these hard femoral counter-faces such as Oxinium. To our knowledge, the damage occurring at the time of reduction has not been previously reported following the retrieval of an otherwise well-functioning hip replacement.

Survivorship after total hip replacement (THR) in the long term has been limited by aseptic loosening and osteolysis secondary to wear and particulate polyethylene debris.¹⁻³ In response, many bearing options and materials are now available in the hope that implants will last longer. Recently, a material known as oxidised zirconium, or Oxinium (Smith & Nephew, Memphis, Tennessee), has been used to manufacture femoral head components for THR, as it demonstrates excellent wear characteristics against polyethylene *in vitro*.^{4,5}

We report the case of the early retrieval of an Oxinium femoral head and corresponding polyethylene liner which demonstrated significant surface damage to the head and adjacent polyethylene. The implants were retrieved at the time of revision surgery for leg-length discrepancy after only 48 hours *in situ*. The patient whose specimen was retrieved gave informed consent to her case being written-up.

Case report

A 62-year-old semi-retired physiotherapist presented with osteoarthritis of the left hip and underwent THR through a direct lateral approach. The surgery was performed by an orthopaedic resident under the direct supervision of an experienced arthroplasty surgeon in a university teaching hospital. The surgery was uneventful. Approximately 5 mm of leg

lengthening and restoration of femoral offset was achieved, based on intra-operative assessment using a leg-length/offset guide. The components consisted of an R3 no-hole shell (with a diameter of 52 mm) (Smith & Nephew), an R3 zero degree cross-linked polyethylene liner with a 32 mm inner diameter (Smith & Nephew) a Synergy high-offset femoral component (size 11) (Smith & Nephew) and a 32 +0 Oxinium femoral head (Smith & Nephew). The immediate post-operative radiographs were satisfactory.

On the first post-operative morning, she complained of excessive lengthening of the left leg when mobilised for the first time. Clinical examination and repeat radiographs suggested a 'true' leg-length discrepancy of approximately 1.0 cm to 1.3 cm. She was unhappy with this situation and was offered an immediate revision which was undertaken on the second morning. After removing the staples and the fascial sutures the hip was dislocated. The femoral head was carefully disassociated from the trunnion. On inspection, there was clear evidence of metal transfer, consisting of a metallic line on the inferior aspect of the black femoral articulating surface. There were also corresponding deep scratches in the adjacent polyethylene. It was clear that there had been contact between the Oxinium head and the exposed metal rim of the acetabular component at the time of the initial reduction.



Fig. 1

Micro-CT scanned image showing the polyethylene liner at retrieval. Damage to the articular surface is broad in the medial/anterior area of articulation.

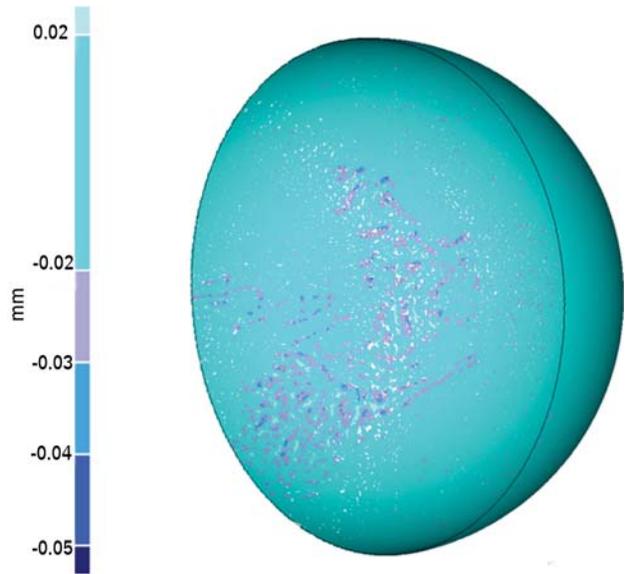


Fig. 2

Surface deviation map showing the polyethylene liner (constructed from micro-CT image with Geomagic software). Gradient scale depicts depth of damage to articular surface.

Accordingly, the liner was replaced. Although it was found to be stable, the femoral component was removed and the femur was re-prepared such that the final broach was advanced approximately 8 mm or 9 mm further than the primary component. The final component, a size 12 high-offset Synergy stem (Smith & Nephew) was then inserted and was deemed to be axially and rotationally stable. A -3 32 mm Oxinium femoral head component (Smith & Nephew) was used. The hip was reduced with care, ensuring that there was no contact between the head and the exposed metal rim of the acetabular component. Post-operatively there were no complications and she made an uneventful recovery. At one year she has a Harris hip score⁶ of 93 with a satisfactory radiological appearance.

Implant analysis

Materials and methods. A thorough investigation of the retrieved head and liner was undertaken. After removal, the liner and head were submerged in a 10% formalin solution for 48 hours. The implants were then removed and placed in an ultrasonic bath for 20 minutes. After drying, the Oxinium head was digitally photographed (Canon EOS (Canon Virginia Inc., Newport News, Virginia), Olympus C5050 digital camera with Olympus Z4045 stereomicroscope (Olympus Imaging America Inc., Center Valley, Pennsylvania)) while the polyethylene liner was imaged with the use of micro-CT, from which surface deviation maps were created. The Oxinium head was examined using a scanning electron microscope (SEM) (LEO 440 SEM (Carl Zeiss SMT Inc., Peabody, Massachusetts) equipped with Quartz Xone EDX system (Quartz Imaging Corporation,

Vancouver, British Columbia)). Both secondary electron and back-scattered electron imaging techniques were used. The former provides information on surface topography and the latter is sensitive to differences in atomic number. Elemental analysis was carried out using energy-dispersive X-ray spectrometry. This can detect all elements above the atomic number 5 (carbon through to uranium) and has a minimum detection limit of ~0.5wt% for most elements. An electron beam of 10 kV was used to obtain both SEM images and energy-dispersive X-ray intensity element maps. Lastly, Fourier transform infrared spectroscopy analysis was conducted to identify whether carbon-based deposits represented organic matter or polyethylene debris.

Results. Surface damage, in the form of deep scratches and gouges, was readily apparent to the naked eye on the polyethylene liner. Using a micro-CT imaging technique⁷ the liner was imaged (Fig. 1). A map of the surface deviation was created with specialised software (Geomagic Qualify (Geomagic Inc., Durham, North Carolina)) (Fig. 2). Analysis demonstrated surface deviations in the cross-linked polyethylene surface ranging from 14 μm to 38 μm in depth.

The Oxinium femoral head was inspected and demonstrated an intersection of two material transfers/scratches on the articulating surface (Fig. 3a). Attention was focused at the intersection and was photographed with a stereomicroscope at 20 \times magnification (Fig. 3b). The area of interest underwent SEM imaging at various magnifications (Fig. 4). This revealed damage to the surface consisting of a raised area (possible titanium transfer from the acetabular shell), deep scratches in the oxidised zirconium surface with possible exposure of the underlying zirconium substrate,



Fig. 3a

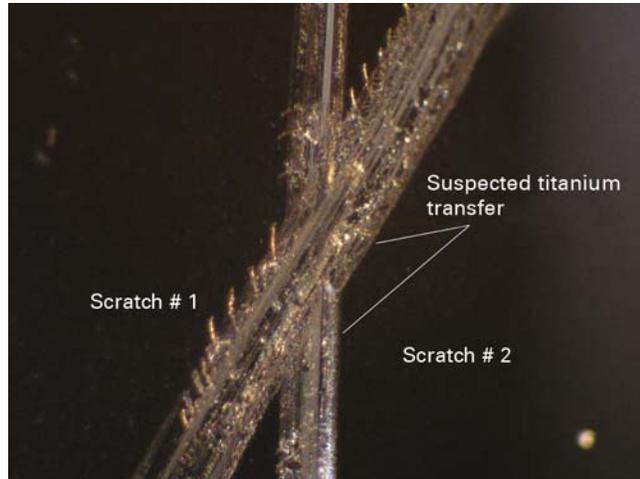


Fig. 3b

Digital photographs of the retrieved Oxinium femoral head, showing a) two obvious damage features, potentially material transfer from the acetabular shell or scratches through the Oxinium surface, and b) a stereo-microscope image (20 × magnification) of the intersection of the two damage features, which appear to be scratches with suspected titanium transfer from the acetabular shell.

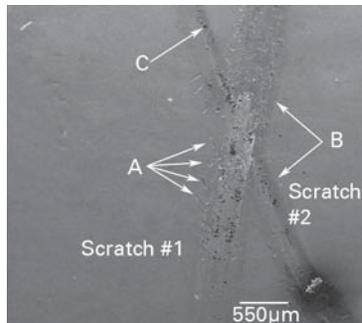


Fig. 4a

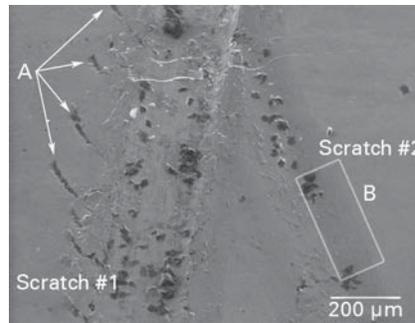


Fig. 4b

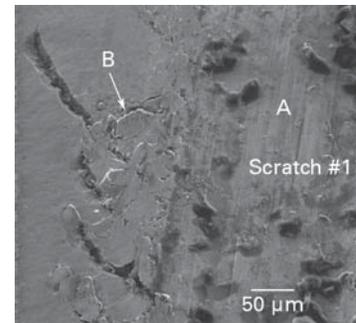


Fig. 4c

Secondary electron images showing macro and micro damage to the Oxinium coating at different levels of magnification. Figure 4a (magnification × 30) – there appears to be a tangential pattern of surface fatigue bordering scratch 1 (A). Darker borders of the scratches (B) may represent the transfer of titanium from the acetabular shell. The darker debris (C) is carbon rich, possibly polyethylene debris or organic material. Figure 4b (magnification × 100) – the tangential pattern of fatigue (A) suggests that Oxinium has flaked off the surface of the femoral head along the outer edges of scratch 1 and in part on scratch 2. Hairline cracking is visible (B) along scratch 2. Figure 4c (magnification × 250) – surface fatigue has resulted in the loss of the Oxinium surface, exposing the zirconium substrate (A). Granules of oxidised zirconium that are about to flake off are identifiable (B). Extensive surface cracking has occurred.

and tangential cracking along the edges of the scratch damage. Examination at higher magnification (Fig. 4c) clearly showed the presence of smaller cracks in the Oxinium coating. These cracks indicated that the coating had been damaged and could delaminate or flake off at any time. Back-scattered electron imaging revealed the difference in composition of the materials based on atomic number differences (Fig. 5). Elements with higher atomic numbers back-scatter electrons more strongly than those with a lower atomic number, thus appearing brighter in the image. Energy-dispersive x-ray intensity element maps were obtained for the area shown in Figure 6. These maps clearly showed the spatial distribution of the major elements of interest (oxygen, titanium, aluminium, zirconium and

carbon). The oxygen map confirmed the presence of oxidised zirconium on either side of the damage and scratched regions. The lack of oxygen detected in the scratched region clearly indicated that exposure of the underlying femoral head substrate had occurred. The titanium and aluminium element maps confirmed that metal transfer from the acetabular shell had also occurred. The carbon-rich deposits were further analysed with Fourier transform infrared spectroscopy which identified them as organic in nature, most likely fibrinous deposits, rather than polyethylene.

Discussion

Oxidised zirconium (Oxinium) has been developed by Smith & Nephew as a new material for the counter-face of

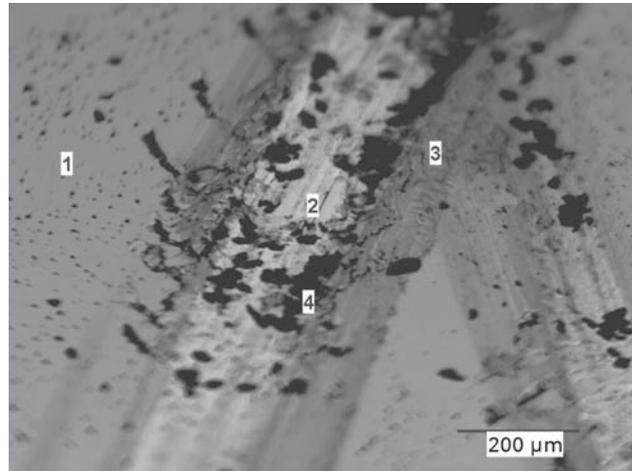


Fig. 5

Back-scattered electron image showing the damaged region of interest. Region 1 is the undamaged oxidised zirconium surface. The brighter scratched region (2) is the underlying metal substrate (the Oxinium coating has been removed). Region 3 is titanium transfer from the acetabular shell. Dark regions (4) are carbon-rich material.

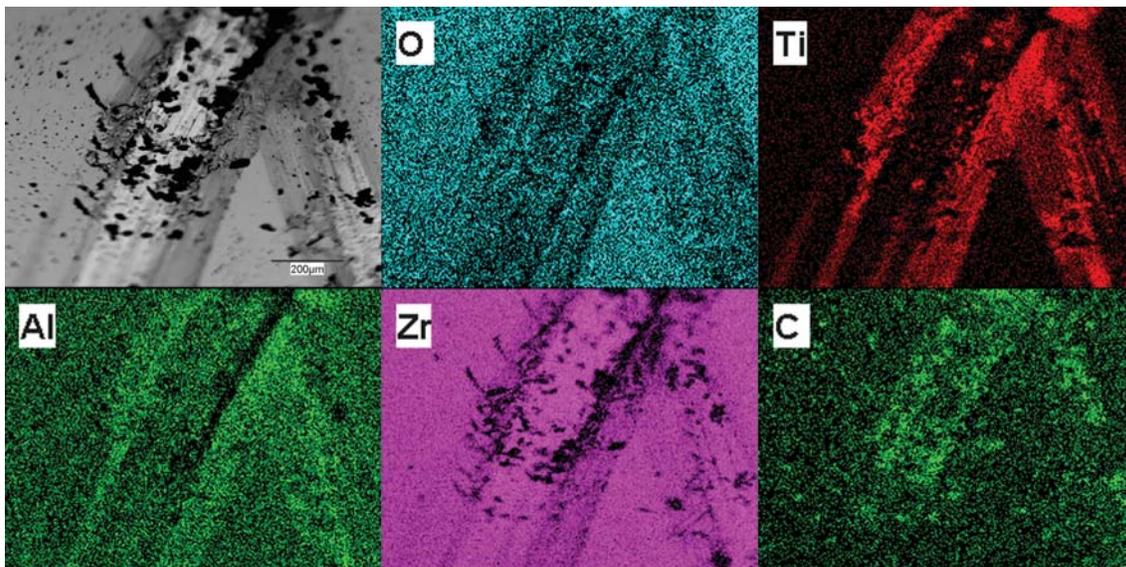


Fig. 6

Back-scattered electron image and energy dispersive x-ray intensity element maps showing the concentration of major elements at the damaged region of interest. Image intensity is directly proportional to the element concentration. O, oxygen; Ti, titanium; Al, aluminium; Zr, zirconium; C, carbon. The O intensity is much weaker, while the Zr intensity is much higher, confirming the complete loss of the oxidised zirconium coating in this area. The concentration and distribution of material transfer from the acetabular shell is well-represented with the mapping of Ti and Al.

the femoral head for articulation against polyethylene in THR.^{4,5} Thermally driven oxygen diffusion transforms the surface of the metallic alloy into a low friction oxidised layer approximately 4 µm to 5 µm thick. Hunter and Long⁸ demonstrated Oxinium to have 4900 times less abrasive volumetric wear and 640 times less deep scratches than

CoCr when articulating against bone cement. Similarly, Good et al,⁵ using a roughened-head protocol, demonstrated 61% less polyethylene wear and 45% fewer polyethylene particles with 'rough' Oxinium heads compared to 'rough' CoCr heads. Furthermore, Bourne et al,⁴ in reviewing large numbers of retrieved CoCr heads, created an

experimental dislocation model which demonstrated considerable advantage to the damaged Oxinium heads articulating against both conventional and highly cross-linked polyethylene compared with CoCr heads. In addition, Oxinium heads retrieved from patients with recurrent dislocation demonstrated less deep scratches and less build-up of adjacent material around the scratches compared with those of CoCr.

With respect to the clinical results of Oxinium femoral heads for THR, only studies with short follow-up exist. Lewis et al⁹ showed no difference in clinical outcome at two years in a randomised controlled trial comparing Oxinium with CoCr heads. Garvin et al¹⁰ reported a low rate of wear ($4 \mu\text{m} \pm 59 \mu\text{m}$ per year) at short-term follow-up with Oxinium heads articulating with highly cross-linked polyethylene.

To date, there have been three reports concerning the surface damage observed on retrieved Oxinium heads, all retrieved after many or unsuccessful closed reductions for dislocation.¹¹⁻¹³ Evangelista et al¹¹ and Kop et al¹³ both reported significant surface damage to the Oxinium heads, characterised by gouging and cracking of the oxide layer and metal transfer which was not fully characterised. The latter study further demonstrated greater indentation damage and deeper scratches in the Oxinium heads compared with retrieved CoCr heads, which they associated with the decreased bulk hardness of the underlying Oxinium substrate.

More recently, Jaffe et al,¹² through more extensive analysis, demonstrated similar findings on four retrieved Oxinium heads retrieved from patients with recurrent dislocation and confirmed the presence of titanium metal transfer through energy-dispersive x-ray analysis. In addition, they performed *in vitro* wear analysis on a hip simulator using the retrieved Oxinium heads, artificially damaged Oxinium heads and pristine Oxinium heads, clearly demonstrating an increase in polyethylene wear of up to 50 times associated with increasing surface damage. All authors recommended either replacement of the Oxinium head in the setting of a failed or recurrent closed reduction or, at the very least, close monitoring for excessive wear.

The analysis of the retrieved specimens from our case demonstrated clear evidence of surface damage, with loss of the Oxinium layer and exposed underlying substrate, and transfer of titanium material from the acetabular shell at the time of reduction of the THR. The implant was retrieved at the time of early revision for leg-length discrepancy. The amount of polyethylene damage was surprising after only 48 hours *in situ*, in which the patient had only been mobilised for a period of 24 hours after operation. There is little question that the damage of the articulating surface occurred at the time of the initial reduction as contact was made between the Oxinium head and the exposed titanium shell. It is plausible that lengthening of the leg, by

making the reduction of the hip more difficult, contributed to the level of contact between the head and the acetabular shell. To our knowledge, damage occurring at the time of reduction has not been reported previously following a retrieval of an otherwise well-functioning hip replacement. The probability of this head/shell contact has been increased by the design of the R3 shell in which the polyethylene insert is flush with the face of the shell, leaving an exposed rim of metal.

The purpose of this report was not to condemn the technology used or the design of this implant system, but rather to highlight the care that needs to be taken when reducing the hip at operation, especially with the hard femoral counter-faces (such as Oxinium or ceramic heads) and in particular where the metal edge of the acetabular shell is prominent. We can only speculate as to the true incidence of this phenomenon or what the long-term effects might be. However, based on the level and speed of polyethylene damage that was observed, it might negate the potential benefits of using a hard counter-face against a highly cross-linked polyethylene liner.

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