KNEE
Examination of ten fractured Oxford unicompartmental knee bearings


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Since the Oxford knee was first used unicompartmentally in 1982, a small number of bearings have fractured. Of 14 retrieved bearings, we examined ten samples with known durations in situ (four Phase 1, four Phase 2 and two Phase 3). Evidence of impingement and associated abnormally high wear (> 0.05 mm per year) as well as oxidation was observed in all bearings. In four samples the fracture was associated with the posterior radio-opaque wire. Fracture surfaces indicated fatigue failure, and scanning electron microscopy suggested that the crack initiated in the thinnest region. The estimated incidence of fracture was 3.20% for Phase 1, 0.74% for Phase 2, 0.35% for Phase 3, and 0% for Phase 3 without the posterior marker wire. The important aetiological factors for bearing fracture are impingement leading to high wear, oxidation, and the posterior marker wire. With improved surgical technique, impingement and high wear should be prevented and modern polyethylene may reduce the oxidation risk. A posterior marker wire is no longer used in the polyethylene meniscus. Therefore, the rate of fracture, which is now very low, should be reduced to a negligible level.

Fracture of ultra-high-molecular-weight polyethylene (UHMWPE) tibial bearings is a rare complication of knee replacement. There are only a few reports concerning fractures of unicompartmental knee replacement (UKR) bearings, with most indicating irradiation and shelf ageing as the primary cause.

Fracture of UHMWPE components has been associated with oxidation and/or abnormal loading, leading to excessive wear and fatigue. Oxidation can occur during storage or in vivo, and can be exacerbated by fusion defects in UHMWPE, which can be caused by incomplete consolidation or by the addition of calcium stearate during manufacture. Fusion defects have also been associated with poor clinical performance. In the mid-1990s, sterilisation by irradiation in air was also shown to increase oxidation and to be detrimental to clinical performance. Subsequently, irradiation in inert gas or a vacuum was introduced.

Since 1982 the Oxford Knee (Biomet, Swindon, United Kingdom) has been used for UKR. This design uses a spherical femoral component, a flat tibial component and an interposed unconstrained UHMWPE mobile bearing. The aim of the design was to minimise constraint while maximising the contact area and minimising wear. This design of the articulation has remained the same for all phases of the Oxford UKR. The Phase 3 device was introduced in 1998, with a range of femoral component radii having matching meniscal bearings.

At the time of the Phase 1 prosthesis the significance of impingement of the bearing against bone or cement was not appreciated. In two reports, ten of 16 (63%) and 31 of 47 (66%) retrieved bearings showed evidence of impingement, which was associated with higher wear rates. In 1986 the anterior lip of the bearing was lowered to minimise impingement, and in 1987 the Phase 2 surgical technique was introduced. A 20-year in vivo study using radiostereometric analysis (RSA) demonstrated decreased wear in Phase 2 bearings (mean: 0.022 mm/yr) compared with Phase 1 bearings (mean: 0.07 mm/yr), suggesting impingement was common with Phase 1 and rare with Phase 2 bearings.

Prior to 1986, all the bearings were machined from blocks of RCH 1000 polyethylene (Hoechst, Oberhausen, Germany) which contained calcium stearate, and were irradiated in air. The Phase 2 bearings were direct compression moulded using Hi-Fax 1900 resin (Montell Polyolefins, Wilmington, Delaware), which was stearate free. Until 1995, Phase 2 components were also irradiated in air. After this date, Biomet launched ArCom polyethylene, which is sterilised in argon, and thereafter this was used for the
Phase 2 bearings. Until 2005 the Phase 3 bearings were manufactured in the same manner as the Phase 2 components, after which the resin was changed to GUR 1050 (Ticona, Oberhausen, Germany).

This study of retrieved fractured Oxford UKR bearings aimed to determine the mode of fracture, the cause of fracture and the clinical implications thereof.

**Patients and Methods**

We were able to collect 14 fractured Oxford UKR bearings. Four bearings were excluded from the study, as the duration of implantation was not known, leaving a total of ten fractured bearings from ten patients for investigation. Four were Phase 1, four Phase 2 and two Phase 3. At implantation, five bearings had a minimum thickness of 3.5 mm, three were 4.5 mm thick and two were 5.5 mm thick.

The mean age of the patients at the time of surgery was 60.3 years (50 to 69) and the mean duration of the prostheses in situ was 16.8 years (6.6 to 23.9) (Table I). There were six women and four men, with a mean weight of 80.1 kg (70 to 100; data available for only eight patients). Loosening of the femoral component was observed in one patient; in all other cases no component loosening was observed at the time of revision surgery to retrieve the fractured bearing. Rupture of the anterior cruciate ligament (ACL) was not reported in any of the patients.

The fracture of the bearings could have been caused by a variety of different mechanical factors. Qualitative observation of oxidation, wear and fracture was performed through macroscopic examination and scanning electron microscopy. Wear and oxidation were assessed through dimensional measurements and infrared spectroscopy, respectively.

All bearings were examined visually by one author (EP) under a bright light and the following details were recorded: 1) damage to the articulating surface (graded from 0 to 3: 0 = undamaged, 1 = roughened, 2 = occasional pits > 1 mm across, and 3 = severely pitted); 2) evidence of incongruent articulation; 3) if the polyethylene appeared whitened and opaque in areas; 4) evidence of delamination; 5) evidence of impingement, and if so whether it was anterior or posterior; 6) type of fracture (type 1, transverse fracture through or near the bottom of the spherical concavity; type 2, angled fracture; type 3, fragmentation); and 7) the relationship of the position of the fracture to the posterior radio-opaque marker.

Delamination was defined as loss of sheets of polyethylene from the bearing surface, and impingement was defined as polyethylene damage at the margins of the bearings.

The fracture surface morphology of one of the bearings (B5) was qualitatively assessed using a scanning electron microscope (SEM, JSM840A; Jeol, Tokyo, Japan). Prior to examination the specimen was sputter-coated with gold to ensure conductivity.

Wear was quantitatively assessed by measuring the bearing dimensions using a calibrated digital calliper (series 500 Digimatic ABSolute; Mitutuyo, Kawasaki, Japan). The minimum thickness at the bottom of the spherical concavity, the mean anterior height, the mean posterior height and the length and width of each bearing were measured. The original nominal thickness values were taken from the marked size of the bearing. Original thickness values were corrected using the method described by Psychoyios et al., in which 0.06 mm was subtracted from the thickness of non-autoclaved bearings and 0.32 mm was subtracted from autoclaved bearings. Where the method of sterilisation at retrieval was unknown, it was assumed as a worst-case scenario that the bearing had been autoclaved. From the measurements, the linear wear could be calculated by subtracting the measured minimum thickness from the corrected original nominal thickness. The penetration rate was calculated by dividing the linear wear by the time in situ.

It was only possible to quantify the degree of oxidation for one bearing in this study because all other components had been stored in air after retrieval. For the bearing that was investigated (B9), 300 μm-thick microtome slices were

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**Table I. Manufacturing and clinical details regarding each bearing**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Phase</th>
<th>Centre†</th>
<th>Nominal thickness (mm)</th>
<th>Implantation Date</th>
<th>Revision Date</th>
<th>Gender</th>
<th>Age at primary operation (yrs)</th>
<th>Weight (kg)</th>
<th>Loosening</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>1</td>
<td>Skövde</td>
<td>4.5</td>
<td>Nov 1986</td>
<td>Sept 2005</td>
<td>F</td>
<td>62.8</td>
<td></td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B2</td>
<td>1</td>
<td>Skövde</td>
<td>4.5</td>
<td>June 1986</td>
<td>Jan 2005</td>
<td>F</td>
<td>69.0</td>
<td></td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B3</td>
<td>1</td>
<td>Skövde</td>
<td>5.5</td>
<td>April 1985</td>
<td>Oct 2007</td>
<td>F</td>
<td>62.5</td>
<td>73</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B4</td>
<td>1</td>
<td>Skövde</td>
<td>5.5</td>
<td>April 1988</td>
<td>June 2010</td>
<td>F</td>
<td>51.9</td>
<td>75</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B5</td>
<td>2</td>
<td>Wilhelm</td>
<td>4.5</td>
<td>Nov 1994</td>
<td>May 2006</td>
<td>M</td>
<td>67.0</td>
<td>77</td>
<td>No</td>
<td>-</td>
</tr>
<tr>
<td>B6</td>
<td>2</td>
<td>Skövde</td>
<td>3.5</td>
<td>June 1993</td>
<td>Sept 2006</td>
<td>M</td>
<td>60.3</td>
<td>80</td>
<td>F</td>
<td>Femoral Total knee replacement</td>
</tr>
<tr>
<td>B7</td>
<td>2</td>
<td>NOC</td>
<td>3.5</td>
<td>June 1991</td>
<td>Sept 2010</td>
<td>M</td>
<td>65.0</td>
<td>70</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B8</td>
<td>2</td>
<td>Skövde</td>
<td>3.5</td>
<td>March 1996</td>
<td>March 2010</td>
<td>M</td>
<td>61.1</td>
<td>88</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B9</td>
<td>3</td>
<td>Mac</td>
<td>3.5</td>
<td>Jan 2003†</td>
<td>Aug 2009</td>
<td>F</td>
<td>50.0</td>
<td>100</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
<tr>
<td>B10</td>
<td>3</td>
<td>Skövde</td>
<td>3.5</td>
<td>May 2000†</td>
<td>Feb 2011</td>
<td>F</td>
<td>53.4</td>
<td>78</td>
<td>No</td>
<td>Bearing exchange</td>
</tr>
</tbody>
</table>

* all components were medium-sized, with the exception of B9 and B10, which were small
† Skövde: Skaraborgs Sjukhus Kärsjukhuset, Skövde, Sweden; Wilhelm: Clinic Wilhelm Schulthess, Zurich, Switzerland; NOC: Nuffield Orthopaedic Centre, Oxford, United Kingdom; Mac: Spire Regency Hospital, Macclesfield, United Kingdom
‡ bearings manufactured in or before 1999
taken and analysed in accordance with ASTM F2102.19

The oxidation index was examined as a function of depth through the thinnest part of the component. A Fourier transform infrared (FTIR) spectrometer (IFS-28; Brüker Optics, Ettlingen, Germany) fitted with a microscope (IR Scope II; Brüker Optics) was used for the analysis. The spectra were obtained in transmission mode; 64 scans at 4 cm⁻¹ resolution were averaged to obtain each spectrum. The aperture size of the spectral window was set at 100 μm² and ten positions were analysed at 350 μm intervals through the cross-section of the sample. The oxidation index was then calculated according to ASTM F2102.19

The incidence of fracture for each phase was calculated using data from the centre that had provided the majority of the retrieved bearings, namely Skaraborgs Sjukhus Kärnsjukhuset, Skövde, Sweden. All of the fractured bearings from this centre were within a published series of UKRs performed between 1983 and January 2005.2 Most of the bearing fractures occurred after the final review date of this series and so have not previously been reported. There were 543 patients in the series (300 women (55%) and 243 men (45%)) in whom a total of 682 UKRs had been performed (125 Phase 1, 271 Phase 2 and 286 Phase 3). The mean age of those patients at operation was 67.9 years (48 to 94). The mean patient weight was 81 kg (49 to 150; data not available for all patients). The nominal thickness of the bearings ranged from 3.5 mm to 11.5 mm, with 316 bearings (46.3%) between 3.5 mm and 5.5 mm. None of the patients was lost to follow-up. The incidence of fracture was calculated as a maximum of 27 years’ follow-up for Phase 1 components, 22 years for Phase 2 components and 12 years for Phase 3 components.

**Results**

In eight of the ten bearings the fractures were categorised as type 1 or type 2, which represent a single fracture, either transverse or at an angle to the mediolateral direction. Sample B6 had fractured into four parts in the posterior region of the bearing (Fig. 1) and sample B4 had fractured into at least three parts, although only two large parts had been retrieved; therefore, both B4 and B6 were categorised as type 3. In samples B6, B8, B9 and B10 the fracture was in the region of the posterior radio-opaque marker wire. In samples B9 and B10 the marker wire had become detached from the bearing. The fracture surface of sample B5, examined using SEM, appeared to have two distinct regions (Fig. 2). The central region was relatively smooth, with curved lines radiating outwards from the thinnest part of the bearing. The outer region appeared less ordered, was rougher, and appeared fibrous in areas with this feature found around the perimeter of the bearing to a depth of approximately 1 mm.

Articular surface damage was evident on all bearings and ranged from grade 1 to grade 3 (two grade 1, five grade 2, three grade 3). Anterior extra-articular impingement was observed on all of the bearings, and in two instances impingement occurred on both anterior and posterior sides of the bearing (Table II). Some samples (B3, B4, B5, B6, B7, B8 and B10) demonstrated particularly high wear, and these tended to have evidence of incongruent articulation, with the articulating area being away from the centre of the bearing, or intra-articular impingement (Fig. 3). The mean penetration rate for Phase 1 components was 0.088 mm/yr (0.046 to 0.126), for Phase 2 components it was 0.142 mm/yr (0.088 to 0.196), and for Phase 3 components it was 0.165 mm/yr (0.062 to 0.267) (Table III).

All the bearings showed some whitening, and delamination was observed in seven (Fig. 1, Table III). The oxidation index of sample B9, measured superior to inferior along the fracture surface using FTIR, was largest at the articular surfaces and decreased towards the centre (Fig. 4). The maximum oxidation index measured was 6.2.

In Skövde, of the 682 Oxford UKRs implanted between 1983 and 2005, none were lost to follow-up. Four (3.2%) of the 125 Phase 1 Oxford bearings, two (0.74%) of the 271 Phase 2 components and one (0.35%) of the 286 Phase 3 components had fractured. The age, gender and weight of
the patients with fractured bearings in Skövde were comparable with those of the series as a whole, with the possible exception of age, which was slightly lower.

Discussion
The majority of components fractured in the mediolateral direction. The similarity in fracture position suggests that the mechanism is systematic and not due to random variations in material quality. The central zone of the fracture surface revealed curved ridges, also called striations, which are evidence of propagation of a fatigue crack. The striations appeared to radiate outwards from the thinnest central point of the bearing, indicating that this was the site of initiation of the fracture. Similar fracture surface morphology has been observed on UHMWPE specimens that have been irradiated in air, artificially aged using heat, and loaded dynamically to failure. In summary, the results indicate a fatigue fracture, initiated in the thinnest region of the bearing.

In every case there was abnormally high wear (≥ 0.05 mm/yr) for a fully congruent mobile bearing. Such a wear rate would be considered low for a fixed bearing component. In all retrieved bearings there was evidence of impingement, which probably released bone or cement debris which acted as a third body resulting in the high wear. In five, rapid wear had resulted in the bearing becoming very thin (< 3 mm), and there was evidence of incongruous eccentric wear or impingement. Previous retrieval studies have shown that if the knee is working normally with no impingement the mean wear rate is 0.01 mm/yr and the maximum is 0.03 mm/yr, and where there is evidence of impingement the wear rate is increased. An RSA study showed that over 20 years in Phase 2 bearings, where the risk of impingement was low, the mean wear rate was 0.02 mm/yr and maximum 0.03 mm/yr, whereas in Phase 1 bearings, which had a higher risk of impingement, the mean wear rate was 0.07 mm/yr.
In four bearings the fracture had occurred in the region of the posterior radio-opaque marker wire. The hole for the wire makes the polyethylene thinner in this region and may act as a stress raiser. It may therefore be a site at which the fracture initiates. In the small Phase 3 bearings the marker wire was nearer the centre of the articulation than in the other bearings, and so probably contributed to the fractures in these bearings. Since 1999 the posterior marker wire has been replaced by two marker balls, so this mechanism of fracture can no longer occur with new bearings. None of the fractured bearings had the two posterior marker balls so the incidence of fracture in the Phase 3 bearings without a posterior marker wire was 0%.

Whitening, which is associated with polyethylene oxidation,\textsuperscript{23} was observed in all samples, and delamination, also associated with oxidation,\textsuperscript{24} was seen in seven samples, indicating that oxidation had occurred. This was more than the 32\% of bearings (15 out of 47) with delamination observed by Kendrick et al\textsuperscript{3} in a series of unfractured retrieved bearings. The oxidation index of sample B9 was found to be 6.2 at the surface of the bearing, which is above the critical oxidation level defined by Kurtz.\textsuperscript{7} For accurate oxidation measurements, retrievals should be stored for as little time as possible prior to analysis, ideally in an inert environment. For this reason, the oxidation index of only one sample could be calculated.

The sequence of events that caused the fractures can be hypothesised based on the trends observed. All components demonstrated oxidation, impingement and high wear. The high wear was probably the result of impingement. The initiation and propagation of cracks caused by fatigue requires the presence of tensile stresses. These could arise from the outward force component of spherical articular pressure causing opposing tensile forces in the anterior and posterior directions on the minimum transverse cross-section (Fig. 5). Reduction in thickness due to wear, resulting from impingement and oxidation, would increase the levels of tensile stress in this region. The tensile stress would also increase in the region of the radio-opaque wire. Embrittlement due to oxidation,\textsuperscript{25} particularly in Phase 1 and Phase 2 components which were irradiated in air\textsuperscript{6,7} and/or manufactured with stearate-containing resin,\textsuperscript{6-10} would exacerbate the risk of the formation of cracks.

The incidence of revision due to a fractured bearing for Phase 1 components was 3.20\% at a maximum of 27 years’ follow-up, which exceeded that of the Phase 2 of 0.74\% at 22 years’ maximum follow-up, and was larger still than that of the Phase 3 components of 0.35\% at 12 years’ maximum follow-up. This demonstrates that fatigue fractures caused a minority of the revisions of the Oxford UKR. The results also suggest that the performance has improved with each design phase and each improvement in surgical technique to avoid impingement. However, it must be acknowledged that the overall length of time that Phase 1 bearings have been in clinical use is longer than that of Phase 2, which in turn is longer than that of Phase 3. Because fatigue cracks take time to initiate and to propagate, this might be the cause of the differences in the incidence of fractures.

In the majority of cases no component loosening or ligament injury was observed. Provided the ACL is intact and the components are secure, it is reasonable to replace the fractured bearing with a new one. It is however important to identify the bone or cement that is causing the impingement and remove this, and also to ensure that the bearing is tracking normally. Damage to the articular surfaces caused by metal articulating on metal can usually be ignored. This is because it usually results a small shallow dimple, which does not affect the articulation.

We recognise the limitations of this study, in particular the small number of samples on which the conclusions are based. In samples where the method of sterilisation was unknown at retrieval, it was assumed as a worst-case scenario that components were autoclaved. This assumption, if invalid, would lead to an over-estimation of wear. It was only possible to examine one sample for FTIR analysis and SEM, therefore the results might not be representative of the entire group. Impingement, articular surface damage and oxidation were assessed qualitatively, which could introduce some subjectivity into the analysis.
In conclusion, the rate of revision for bearing fracture has been shown to be very low. Impingement, high wear and oxidation were seen in all fractured bearings, suggesting that these are important aetiological factors. In addition, the posterior radio-opaque marker wire appears to be important. This marker wire was removed from the design over ten years ago. With modern polyethylene and inert packaging, the risk of oxidation and hence fatigue fracture is substantially reduced. With good surgical technique, impingement can be avoided and the bearing should be unconstrained, so wear will be very low; as a result, fracture of the polyethylene bearing should not occur.

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References


