Cementless Oxford unicompartmental knee replacement shows reduced radiolucency at one year


We randomised 62 knees to receive either cemented or cementless versions of the Oxford unicompartmental knee replacement. The implants used in both arms of the study were similar, except that the cementless components were coated with porous titanium and hydroxyapatite. The tibial interfaces were studied with fluoroscopically-aligned radiographs.

At one year there was no difference in clinical outcome between the two groups. Narrow radiolucent lines were seen at the bone-implant interfaces in 75% of cemented tibial components. These were partial in 43%, and complete in 32%. In the cementless implants, partial radiolucencies were seen in 7% and complete radiolucencies in none. These differences are statistically significant (p < 0.0001) and imply satisfactory bone ingrowth into the cementless implants.

Most designs of unicompartmental knee replacement (UKR) use cement to fix the components to the bone. Aseptic loosening, however, is a cause of failure and cementless fixation, by inducing bone growth into the porous-coated surfaces of the prosthesis, is an alternative. Several encouraging reports of cementless UKR have been published,

The Oxford UKR (Biomet UK Ltd, Bridgend, United Kingdom), which has been used as a cemented implant for many years, needed relatively little modification of its components to satisfy the perceived requirements for cementless fixation. We report the early clinical and radiological outcomes of a randomised, controlled trial of this implant, used with and without cement.

Patients and Methods

After obtaining ethical approval, we recruited 61 patients (62 knees). As one patient died from an unrelated cause during the first year, an additional patient was recruited. All patients had primary anteromedial osteoarthritis and all fulfilled the pre-operative criteria for UKR as described for the Oxford design.

There were 32 cemented and 30 cementless UKRs. The two groups were well matched for mean age (cemented 63.8 yrs, 46 to 78; cementless 64.7 yrs, 45 to 82), gender (cemented 20 men, 12 women; cementless 16 men, 14 women) and body mass index (cemented 28.9, 20.1 to 37.7; cementless 27.9, 21.3 to 39.9). The mean pre-operative Oxford Knee score (OKS), American Knee Society score (AKSS) and Tegner scores of the two groups were not significantly different (Table I).

At the beginning of the operation, the surgeon confirmed that the joint was suitable for UKR by inspection of the articular surfaces and the anterior cruciate ligament. At that stage, one of a series of envelopes was opened to decide which version of the implant to use. The instructions in the envelopes had been randomly generated by computer.

The cementless tibial component of the Oxford UKR (Fig. 1) is identical to the cemented version, except that its undersurface carries a layer of porous titanium with a calcium hydroxyapatite (HA) coating. At operation, the tibia was prepared in the same way for both types of implant, but the slot for the keel was made slightly narrower for the uncemented version, allowing a tight press-fit to be achieved.

The inner surfaces of the cementless femoral component (Fig. 1) are also covered with HA-coated porous titanium. The femur was prepared in the same way for both procedures, but primary fixation was enhanced in the cementless version by the cylindrical, rather than conical, shape of its main peg, and by the addition of a small anterior peg.

All operations were performed through a short medial parapatellar arthrotomy without dislocation of the patella. The technique was...
the same for cementless and cemented implants, except that at the end of the operation the uncemented components were firmly impacted until secure. All operations were performed by three consultants (DWM, CAFD, AJP) or under their supervision. The post-operative management was the same in both groups, allowing early weight-bearing as soon as tolerated.

Clinical and radiological evaluation. Clinical assessment was performed pre-operatively, at six months and at one year after operation by an independent observer (CJ) using the OKS (0 to 48, 48 being the best outcome), the Tegner activity score and the AKSS both objective and functional (AKSS-obj, AKSS-Fn). Complications were recorded.

Tibial bone-implant interfaces were assessed post-operatively on radiographs taken with the X-ray beam precisely aligned with the tibial component as previously described. This requires the use of an image intensifier mounted on a C-arm and exploits the regular geometry of the tibial implant, which has flat surfaces in both vertical and horizontal planes. The X-ray beam is adjusted until the anteroposterior projection of the tibial component appears on the screen as an ‘end-on’ silhouette (Fig. 2), with its horizontal plateau and vertical wall both appearing as thin as possible. A high-resolution radiograph is then made. All follow-up radiographs were made in the same way, ensuring their precise repeatability. For descriptive purposes, the interface under the tibial implant was divided into three areas: zone A medial to the keel, zone B surrounding the keel and zone C lateral to the keel.

Table I. Clinical scores for the two designs of Oxford unicompartmental knee replacement

<table>
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<tr>
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<th>Cemented component</th>
<th>Cementless component</th>
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<tr>
<td></td>
<td>Pre-operative (n = 32)</td>
<td>Six months (n = 32)</td>
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<tr>
<td>OKS</td>
<td>21.7 (6.4)</td>
<td>36 (10.8)</td>
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<tr>
<td>AKSS (obj)</td>
<td>44.2 (12.7)</td>
<td>79.9 (19.7)</td>
</tr>
<tr>
<td>AKSS (Fn)</td>
<td>60.6 (12.6)</td>
<td>85.2 (17.8)</td>
</tr>
<tr>
<td>Tegner</td>
<td>1.9 (0.8)</td>
<td>3 (1.0)</td>
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* Oxford knee score
† American Knee Society score (obj, objective; Fn, functional)
and zone C lateral to the keel. The interface lateral to the vertical wall was not studied, as it is non-weight-bearing.

Most of the bone-implant interface on the femur is non-planar and hidden within the concavity of the component, so it cannot be imaged. However, the flat interface of the posterior facet can be seen on a lateral projection. For the lateral radiograph, using the image intensifier, the direction of the X-ray beam was adjusted until it was parallel to the posterior facet of the implant.

Statistical analysis. Student’s t-test was used to compare clinical scores and the chi-squared test to compare the incidence of radiolucencies. A value of p < 0.05 was considered significant.

From prior knowledge gained using the method of screened radiography described above, we expected that radiolucencies would be seen in about 70% of cemented tibial components by the end of the first post-operative year. With this expectation, the number of patients recruited was determined from a power calculation based on the presumption that cementless components would halve the incidence of radiolucencies.

Results

At six months and one year after operation the clinical scores of the two groups were not significantly different (Table I). At one year, the mean OKS score for the cemented group was 39 (SD 9.2) and 42 (SD 5.3) for the cementless group.

Radiological evaluation. The immediate post-operative radiographs showed that 13 (43%) of the cementless tibial components had a zone of radiolucency at the bone-implant interface (Fig. 3), demonstrating that initially these components were imperfectly seated (Fig. 3a). These radiolucencies gradually diminished (Fig. 3b). At six months they were still seen in nine knees, but at one year they were present in only two.

Immediately post-operatively, no femoral cemented or tibial component had a radiolucency at any interface.

At one year, no problems were identified radiologically in either group. There was no evidence of osteoarthritis of the lateral compartment and no tibial or femoral subsidence. No radiolucencies were seen around any of the femoral components. All radiolucencies beneath the tibial component had a sclerotic margin, and none was more than 1 mm thick.

A detailed analysis of the interfaces beneath the tibial components demonstrated significant differences between the groups (Tables II and III). A thin radiolucent line appeared around the cemented components in 24 knees (75%). These lines were complete (i.e. in all three zones) in 11 knees (32%) and partial in 13 (43%). Radiolucencies were visible at the interfaces of only two (7%) of the cementless tibial implants, and in neither case were they complete. This difference is highly statistically significant (p < 0.0001).
Complications. One patient in the cemented group developed chronic regional pain syndrome and remains on oral medication for this. The knee continues to function satisfactorily, with a range of movement from full extension to 120° of flexion. One patient in the cementless group developed a haematoma. Because of concerns about infection this knee was treated ten days after surgery with an open wash-out, and exchange of the polyethylene insert. This patient has continued to do well since the wash-out.

Discussion
The method of fluoroscopically-controlled radiography that we have routinely used to image the Oxford implant has, over many years, provided abundant evidence of the usual radiological appearances of the interfaces of the tibial component when implanted with cement. A thin radiolucent line, defined by a radiodense line in the adjacent bone, commonly develops during the first year after implantation. The incidence was first reported in 1984 as being 96% in a series of bicompartmental implantations.\textsuperscript{13} The incidence was 81% in a series of 26 phase 1 and 2 medial Oxford UKRs, all followed for a minimum of ten years.\textsuperscript{14} Only one radioluency was more than 1 mm thick and, during the ten-year follow-up the appearance of the radiolucencies remained substantially unaltered.\textsuperscript{14} In a series of 688 Oxford phase 3 implants, complete or partial radioluencies were seen in 70% of 101 knees at five years.\textsuperscript{15} Neither the pathological basis for these radiographic appearances nor their clinical significance need be discussed in the context of this paper. However, the literature
does show that the high incidence of radiolucencies reported in the cemented arm of our study is not unexpected and also that the radiographic technique can detect a layer of radiolucent material, no more than 1 mm thick, between the bone and the radio-opaque metal and cement. This requires alignment of the X-ray beam, focusing on the implant and the film with much greater accuracy than is achieved for most other purposes. In Figure 4, the two radiographs of the same knee were taken on the same occasion; this patient was not part of this trial. This demonstrates how minor changes in the alignment of the X-ray beam can make major changes to the radiograph produced. If detection of radiolucency is so sensitive to small errors in technique, it may be that there is always a thin layer of radiolucent material surrounding cemented Oxford knees, and that it is the quality of the radiographs that determines how frequently it is observed.

At the time of insertion of the implant we aimed to achieve precise apposition of the porous prosthetic surfaces against the cut bone, however, the presence of radiolucencies on the immediate post-operative radiographs suggests that in nearly half of the cases this was only incompletely achieved. Nevertheless, by one year, whether due to subsidence of the implants or to filling of the gaps with new bone, radiolucencies were seen in only two UKRs, and were incomplete in both.

Because the radiographic method demonstrated the presence of radiolucencies up to 1 mm thick in 75% of the cemented implants, the fact that the same method failed to detect any radiolucency in 93% of the cementless implants, and showed only partial radiolucency in the remainder, is probably reliable evidence of their satisfactory incorporation in the tibial bone.

Functional recovery after Oxford knee replacement is almost complete after a year and does not improve much thereafter, so the absence of any significant differences between the clinical scores in the two arms of the study suggests that fixation of the components was similarly effective in both groups.