The early radiological results of the uncemented Oxford medial compartment knee replacement

We carried out a prospective investigation into the radiological outcomes of uncemented Oxford medial compartment unicompartmental replacement in 220 consecutive patients (231 knees) performed in a single centre with a minimum two-year follow-up. The functional outcomes using the mean Oxford knee score and the mean high-activity arthroplasty score were significantly improved over the pre-operative scores ($p < 0.001$). There were 196 patients with a two-year radiological examination performed under fluoroscopic guidance, aiming to provide images acceptable for analysis of the bone–implant interface. Of the six tibial zones examined on each knee on the anteroposterior radiograph, only three had a partial radiolucent line. All were in the medial aspect of the tibial base plate (zone 1) and all measured < 1 mm. All of these patients were asymptomatic. There were no radiolucent lines seen around the femoral component or on the lateral view. There was one revision for loosening at one year due to initial inadequate seating of the tibial component. These results confirm that the early uncemented Oxford medial unicompartmental compartmental knee replacements were reliable and the incidence of radiolucent lines was significantly decreased compared with the reported results of cemented versions of this implant. These independent results confirm those of the designing centre.

Unicompartmental knee replacement (UKR) has undergone a resurgence over the last 15 years, with advocates claiming that patients recover faster and with better function than with total knee replacement (TKR).\(^1\,^2\) This procedure has been recommended for younger patients with unicompartmental arthritis who are expected to require a higher level of function. However, data from joint registries have shown a reduced survival rate of UKR, with early revision and poorer long-term outcomes than with TKR.\(^3\,^4\) Subsequent revision of a UKR has also been shown to produce poorer results than primary TKR, especially in the younger age group.\(^5\,^6\)

One of the most common causes of failure of UKR requiring revision has been loosening of the components,\(^5\) in particular the tibial component, with some studies showing up to 90% of the implants having partial or complete radiolucent lines.\(^7\,^9\) The cemented Oxford UKR (Biomet UK Ltd, Bridgend, United Kingdom), with its mobile polyethylene bearing, has been popularised as an implant that will uncouple the forces across the implant–bone interface and, as such, should show improved survival with respect to aseptic loosening, in particular loosening of the tibial component.\(^10\) However, aseptic loosening of both the tibial and the femoral component has continued to be reported as a frequent cause for revision surgery with this implant.\(^5\)

The uncemented Oxford III UKR (Biomet UK Ltd) has been developed to allow ingrowth of bone into the porous titanium and calcium hydroxyapatite coating on the components in an attempt to limit the failure seen with cemented components. Apart from an extra fixation peg on the anterior aspect of the femoral component, the design was essentially the same as the cemented version with the same congruent articulating geometry. Early good results have been reported from the designing centre, but there has been little confirmation from other independent centres.\(^11\) We have used the uncemented Oxford III as the implant of choice in all appropriately selected patients for the last five years. This study prospectively reviews the early radiological results of this implant at two years, with particular emphasis on the development of radiolucent lines (RLLs). Our hypothesis was that the incidence of component loosening and the production of RLLs would be reduced with this design of UKR compared with the reported incidence in cemented medial compartment UKRs.
Patients and Methods
Selection criteria. All patients who had isolated medial compartment osteoarthritis and were clinically appropriate from May 2005 until September 2008 were offered an Oxford III un cemented unicondylar replacement. Patients were selected if they had a correctable varus deformity, a fixed flexion of < 10°, an asymptomatic lateral compartment, an intact anterior cruciate ligament and no previous high tibial osteotomy. Stress radiographs were only performed if there was clinical concern about the lateral compartment, and long leg radiographs were not performed routinely. No patient was excluded because of age, gender, diagnosis or reduced bone density. Intra-operative confirmation of solitary medial compartment arthritis was obtained.
Study design. This prospective observational study included all patients who fulfilled the selection criteria with a minimal follow-up of two years. All were operated on by four experienced surgeons (GJH, ARM, IDP, PJB) who used the Oxford III as the only UKR during the course of the study. As this study was an audit of the radiological and functional outcome in patients who had undergone a standard treatment and follow-up protocol, which did not require any additional patient input, ethical committee approval was not required.

Although the main emphasis was the radiological outcome, all patients were functionally assessed pre-operatively, at six months and at two years by an independent research nurse using the Oxford knee score (OKS), where 0 is the worst score and 48 the best, and the high-activity arthroplasty score (HAAS). Radiological assessment was performed immediately post-operatively, and at six months, one year and two years by an experienced musculoskeletal radiologist (BW) who was independent and blinded to the clinical outcome. All patients underwent fluoroscopic screening of their knee to achieve a true anteroposterior radiograph so that the tibial base plate was positioned at 90° to the radiograph and the bone-implant junction could be reliably assessed, as previously described. The tibial base plate was divided into six weight-bearing areas of interest (Fig. 1) looking for evidence of RLLs or failure of bone-implant integration. The vertical aspect of the implant adjacent to the tibial spine was non-weight-bearing and, as in other studies, was not considered important with respect to the stability of the implant and so was not included in the results. The lateral radiograph was difficult to assess accurately because of the concave shape of the femoral component. The only flat areas were the posterior femoral flange and the femoral pegs, which could be aligned at 90° to the beam to assess the bone-implant junction accurately, presenting one area of interest around the component and six areas around the two pegs (Fig. 1). The keel of the tibial component could also be assessed to give one area of interest on the tibial side.

The radiographs were further assessed looking for the appropriate implant size by measuring the distance of the tibial component from the posterior aspect of the tibia and from the medial edge of the tibia in millimetres. This was measured on standard digitised radiographs using the measuring tool supplied with the software. A positive number indicated a distance short of these landmarks, whereas a negative number indicated overhang of the component. Evidence of gross subsidence and change in tibial slope was...
also assessed. Of necessity the views looking for RLLs were non-weight-bearing, and no long leg alignment views were obtained, therefore the mechanical alignment of the tibial implant could not be accurately assessed, although all were measured looking for gross anatomical malalignment on the routine knee radiograph.

Statistical analysis. Paired $t$-tests were performed to compare the pre-operative and 24-month post-operative intervals for both the Oxford and HAAS scores. These comparisons were made for the group as a whole and for gender and age ($\leq 65$ years or $> 65$ years) subgroups. Statistical significance was set at $p < 0.05$.

Results
A total of 220 patients (231 knees) with a minimum follow-up of two years were available, 135 (58%) of whom were male. Their mean age was 67 years (38 to 90); 108 (47%) were $\leq 65$ years of age at the time of their procedure. At review five patients had died, but were reported at their last follow-up as having a well-functioning implant. There were 30 patients who lived out of the area and could not be examined appropriately, or who had radiographs that were not acceptable and who were reluctant to return for further studies. All but four of these patients completed two-year functional assessments and all confirmed that their implant was functioning satisfactorily. This left 185 patients (196 knees) with fully completed clinical and radiological results.

There was a significant improvement in the mean OKS (from 22.4 pre-operatively to 42.2 post-operatively, $p < 0.001$) and mean HAAS (from 4.1 to 10.4, $p < 0.001$) at two years (Table I) which were independent of gender ($p < 0.001$) and age ($> 65$ years versus $\leq 65$ years; $p < 0.001$).

Of the 1176 tibial zones (six in each of the 196 knees) examined on the coronal radiographs, there were only three with RLLs. All were in zone 1 and were < 1 mm in width (Fig. 2), and all were unchanged from the six-month examination. There were no RLLs seen in any of the lateral tibial radiographs or in relation to any of the femoral components.

The tibial component was well sized, with a mean distance from implant to posterior tibial cortex of 1.48 mm (-1 to 6.6) and from the medial tibial cortex of 0.37 mm (-2.5 to 5.2). All tibial components were inserted with posterior slope ranging from 1° to 10° (mean 6.7°) (measured on the non-weight-bearing lateral radiograph). There were no grossly malaligned tibial components; in particular, there were no knees in valgus > 5° measured on the non-weight-bearing coronal radiograph.

One patient required a revision procedure owing to a problem with the tibial component. This implant was inadequately impacted at operation and failed to settle with weight-bearing. The component was revised at 12 months because of pain and progressive radiolucency (Fig. 3). There were no other reoperations for any cause during the follow-up period.

Discussion
UKR for isolated medial compartment arthritis of the knee is a controversial procedure according to recent data from National Joint Registries, showing a significantly higher revision rate than TKR. Advocates of this procedure argue that patients recover faster and regain better function with UKR. However, concern remains about the long-term survival of these cemented implants, with significant tibial and femoral loosening at an early stage compared with TKR.5

<table>
<thead>
<tr>
<th>OKS</th>
<th>Pre-operative</th>
<th>24-month</th>
<th>HAAS</th>
<th>Pre-operative</th>
<th>24-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>22.4 (0.54)</td>
<td>42.2 (0.50)</td>
<td>4.1 (0.16)</td>
<td>10.4 (0.14)</td>
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<tr>
<td>Males</td>
<td>23.7 (0.70)</td>
<td>42.7 (0.68)</td>
<td>4.6 (0.21)</td>
<td>10.4 (0.18)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>20.6 (0.84)</td>
<td>41.7 (0.72)</td>
<td>3.4 (0.24)</td>
<td>10.4 (0.21)</td>
<td></td>
</tr>
<tr>
<td>$\leq 65$ years</td>
<td>22.7 (0.74)</td>
<td>42.2 (0.67)</td>
<td>4.3 (0.22)</td>
<td>10.7 (0.15)</td>
<td></td>
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<tr>
<td>$&gt; 65$ years</td>
<td>22.0 (0.80)</td>
<td>42.3 (0.74)</td>
<td>3.9 (0.24)</td>
<td>10.0 (0.23)</td>
<td></td>
</tr>
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* significant difference from pre-operative score ($p < 0.0001$)
RLLs have been observed in both mobile and fixed bearing implants, with some reporting up to 90% complete RLLs in cemented UKRs, whereas others have observed increased RLLs associated with uncemented prostheses. There has been no direct correlation with the presence or absence of RLLs and either an increased rate of loosening or functional outcome. However, a complete and progressive RLL beneath the whole component is suggestive of failure of ‘bonding’ of the component to bone, creating a risk of loosening and failure. Progressive RLLs have been compared to ‘physiological’ lines, but their significance remains uncertain, and a recent study has advocated caution when considering the prognosis. The Oxford UKR, which has a mobile bearing, unloads the shear stresses on the implant–bone interface and thus converts most of the forces across this interface to compressive forces. This potentially limits any movement of the implant and may be the reason for the reduced pain and low incidence of aseptic loosening reported with an Oxford UKR in patients with complete RLLs that may otherwise be seen in a fixed bearing device. This might also explain the low rate of progression of RLLs and subsequent revision reported with the cemented Oxford UKR in the designing centre. Regardless of this, aseptic loosening of both the femoral and tibial components remains a significant reason for early revision surgery with the Oxford UKR, and the presence of RLLs, particularly complete and progressive lines, is of concern.

This study has confirmed our hypothesis and has shown that the uncemented Oxford UKR resulted in an almost complete elimination of RLLs compared with previously published results with the cemented component, and confirms the initial early results from the designing centre.

Pegs and stems on uncemented tibial trays in TKR have been shown to increase bone ingrowth and bonding. A common general observation in this study was the marked early reaction of the bone under the keel of the implant with apparent increased bone density directly beneath the keel (Fig. 3a). The single revision procedure reported in this study might have been due to the rapid ingrowth of bone around the keel, which prohibited the implant from settling onto the tibial plateau as a result of not being fully impacted. Early radiolucencies under incompletely impacted implants have been reported by others, but with time and weight-bearing all of these have disappeared. We believe that this failure was related to a technical error and was not directly related to the uncemented component. Femoral loosening with UKRs has been a less common cause for revision, but there have been some concerns regarding the cemented Oxford femoral component in patients with excessive flexion who may have levered the implant forward, resulting in early femoral loosening. The uncemented Oxford III UKR has an extra femoral peg for fixation and has been designed to be inserted with the component in a few degrees of flexion, thereby limiting the ability to apply a distally directed force. This study has shown that there were no RLLs underneath the femoral component or around the pegs, and that all components were unchanged in position after two years, suggesting that all were fully ingrown and stable.

Correct sizing of the tibial implant is important to avoid subsidence or soft-tissue impingement. We confirmed that when this component is well sized with respect to the underlying tibial plateau, subsidence or change of position did not occur.

Others have reported excellent early functional results with the cemented Oxford UKR, and our study mirrors those findings when using the uncemented version. The results of the 2009 annual report of the New Zealand Joint Registry show that at six months the mean national OKS for all UKRs was 38.99, compared to 37.05 for TKR. The mean six-month OKS in our study was higher, at 41.8, which may be due to the implant or related to the specialist nature of the four surgeons performing the procedures. However, without knowing the pre-operative OKS from the joint registry we cannot confirm that the two groups were initially comparable. Others have shown that the outcome for UKR is related to surgical experience, and the individual case loads of all four surgeons exceeded 100 knee replacements per year. Of note, the New Zealand national revision rate for all cemented Oxford UKRs was 1.44 per 100 component years, compared to 0.61 per 100 component years for the national results of the uncemented Oxford UKR. We were able to show that good functional results can be achieved within six months, with no statistical improvement from this date to two years. We used a validated high-activity questionnaire to try and show...
any differences related to gender and age but were unable to show any statistical difference.

One weakness of this study is that it is an observational study with no control group in a highly selected group of patients with unicompartmental osteoarthritis. However, we believe that this is offset by the relatively high follow-up rate at two years and the high-quality radiographs aligned accurately to report on changes at the implant–bone interface. In addition, this study was completed in an independent centre having no affiliation with the designing group.

Another weakness of was the lack of post-operative long leg views to measure the mechanical axis. Nevertheless, clinical examination showed that all knees were in neutral alignment, and this was confirmed by measurement of the anatomical axis on non-weight-bearing radiographs. No knee was in gross valgus, suggesting that there was no overstuffing of the medial compartment.

Unfortunately, 30 patients had to be excluded from the radiological analysis because they either had poor images or were outside the area and could not attend for screened radiographs. This could potentially have biased the results, but all of those patients had been screened at six months and one year with no evidence of radiolucent lines. All of these patients confirmed that their implants were intact and functioning well.

In conclusion, we have shown excellent functional results with the uncemented Oxford III UKR with a significant improvement in the incidence of RLLs, and confirmed the early results from the designing centre.

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