The Unispacer knee implant
EARLY CLINICAL RESULTS

The Unispacer knee system is a cobalt-chrome self-centring tibial hemiarthroplasty device for use in the treatment of isolated medial compartment osteoarthritis of the knee. The indications for use are similar to those for high tibial osteotomy, but insertion does not require bone cuts or component fixation, and does not compromise future knee replacement surgery. A prospective study of a consecutive series of 18 patients treated with the Unispacer between June 2003 and August 2004 was carried out to determine the early clinical results of this device. The mean age of the patients was 49 years (40 to 57). A total of eight patients (44%) required revision within two years. In two patients revision to a larger spacer was required, and in six conversion to either a unicompartmental or total knee replacement was needed. At the most recent review 12 patients (66.7%) had a Unispacer remaining in situ. The mean modified visual analogue score for these patients at a mean follow-up of 19 months (12 to 26) was 3.0 (0 to 11.5). The mean pain level was 30% that of the mean pre-operative level of 10. The early clinical results using this device have been disappointing.

This study demonstrates that use of the Unispacer in isolated medial compartment osteoarthritis is associated with a high rate of revision surgery and provides unpredictable relief of pain.

The surgical management of established osteoarthritis (OA) of the knee in younger patients is difficult and remains controversial. The options include high tibial osteotomy, unicompartmental knee replacement (UKR), or total knee replacement (TKR). The clinical results of high tibial osteotomy vary considerably, with the procedure requiring a high degree of technical precision to achieve a satisfactory outcome. Furthermore, TKR following proximal tibial osteotomy has been shown to have a high rate of radiological loosening and an 8% revision rate at a mean of 5.9 years. The overall benefits of TKR are well established, with both fixed- and mobile-bearing designs appearing to perform well according to national joint registries. Good results have also been reported in patients under 55 years of age. In the younger age range however, a higher rate of polyethylene wear related to activity has also been documented, as well as a higher revision rate. An alternative approach might be the use of a metallic interposition arthroplasty.

Metallic interposition hemiarthroplasty was introduced by Macintosh and McKeever in the 1950s as a treatment for isolated medial or lateral compartment OA of the knee. Two series published in 1985 reported 70% and 72% excellent results.

A recent paper concluded that the McKeever hemiarthroplasty was a good option in carefully-selected patients who were too young or too active for a UKR or TKR. The concept has been re-introduced with the Unispacer Knee System (Zimmer Inc., Warsaw, Indiana) which is a highly polished cobalt-chrome interposition arthroplasty. It is inserted without the need for bone cuts and does not require fixation to bone. It is intended as a self-centring mobile-bearing spacer in the medial compartment of the knee for patients for whom routine conservative treatment has failed (Fig. 1). In a report on the early results in 2003, a 50% higher revision rate at one year was noted compared with the McKeever device at eight years. Another report has suggested there are insufficient data to support the widespread use of this device. With the discrepancy in outcome between the older series of interposition arthroplasties and the poor contemporary results, we investigated the early clinical results of the Unispacer innovation.

A prospective study was carried out between two centres (Wakefield Orthopaedic Clinic and Sportsmed SA, Adelaide, Australia) to deter-

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mine the early survival of this new device in a cohort of patients considered to fit the clinical indications as recommended by the manufacturer.

**Patients and Methods**

Between June 2003 and August 2004, 18 consecutive patients underwent insertion of a Unispacer knee implant for isolated medial compartment OA, at one of the participating hospitals. Patients with significant functional limitation that persisted despite conservative therapy, which had included pharmacological treatment, physiotherapy, injection of the knee, and arthroscopic procedures were offered this procedure. The patients had to be between the ages of 40 and 60 years and be considered more active than average, assessed by participation in moderate manual labour and/or low-stress sports. Patients were required to have an intact and functional anterior cruciate ligament, as determined by clinical examination using the Lachmann and the pivot-shift tests, supported by arthroscopy and/or MR imaging.

Potential candidates entered a detailed education programme and were provided with a full explanation of all available treatments and the expected results. A requirement for implantation of the Unispacer device was the acceptance by the patient that this was an experimental procedure, and that symptom improvement may continue for between three and 12 months, and the aim was to provide a 70% to 80% improvement in pain.

Informed consent for the procedure and participation in the study was then obtained from each patient. All operations were performed by experienced knee replacement surgeons (DGC, PLL, SAB, RSP) who had undergone formal training on cadavers in the use of the Unispacer knee. The surgical technique involves an initial arthroscopy through standard anteromedial and anterolateral portals, and debridement of the medial compartment and meniscus. A total medial meniscectomy is performed, with particular attention to complete removal of the posterior horn, which could otherwise restrict posterior translation of the Unispacer implant. A longitudinal medial arthrotomy is then performed to allow the removal of osteophytes and any remaining medial meniscus. The residual articular cartilage of the medial compartment is then ‘trimmed’ to prevent areas of potential implant impingement, especially close to the tibial insertion of the anterior cruciate ligament and the anterior part of the medial femoral condyle. Articular cartilage is removed from the anterior aspect of the intercondylar notch, where the implant would otherwise impinge during anterior translation and rotation in full extension. The anterior/posterior length of the compartment is then measured and matched with a trial implant. These are available in a range of sizes. A dynamic assessment of the inserted trial is then made based on visual and fluoroscopic evaluation with knee flexion and extension, specifically looking for restoration of alignment and the trial to remain centered under the femoral condyle through the range of motion without subluxation. When the correct trial size has been determined it is exchanged for the definitive component of the selected size and thickness. Without any bone cuts required, the implant is inserted and is not secured to the tibia or femur. The medial arthrotomy is closed in the usual way. Postoperatively, patients were allowed to mobilise bearing full weight, protected in a knee brace left unlocked to allow knee flexion, for two to four weeks and encouraged to mobilise as fully as pain and swelling would permit.

There were ten women and eight men with a mean age at operation of 49 years (40 to 57). Patients were followed up for a minimum of 12 months. Patients were assessed clinically for wound healing, pain relief using a modified visual analogue scale and range of motion using a goniometer, by the operating surgeon at two weeks, six weeks, six months and 12 months. Radiological assessment included weight-bearing anteroposterior and lateral radiographs of the affected knee taken post-operatively (Fig. 2) and at 12 months.

The outcome was evaluated clinically by a modified visual analogue scale where 0 represented no pain, and 10 represented pain equivalent to the pre-operative level. A score > 10 was used to represent pain worse than pre-operative pain.

**Results**

The patients were followed up for a mean of 17.1 months (3 to 26) The early clinical results were disappointing, with 17 patients reporting persistent symptoms within the first three to six months after surgery. A total of 12 also required further interventions, which included the use of non-steroidal anti-inflammatory drugs, intra-articular injection of steroid, manipulation under anaesthetic, and revision surgery.

Of the original cohort of 18 patients, 12 (66.7%) have the Unispacer Knee in situ and are not seeking revision surgery at a mean of 19 months (12 to 26). This includes two
patients who underwent exchange of the prosthesis. The mean post-operative pain score at final review was 3.0 (0 to 11.5) or 30% of the pre-operative pain level where the Unispacer had been retained (Table I). A total of 11 patients with a Unispacer still in situ have reported fair or good results, with scores of 4 points or less. The range of movement was satisfactory after operation, with 17 patients achieving full extension, while one had a fixed-flexion deformity of 5° (pain score 3). The mean flexion angle was 118° (105° to 135°).

**Revisions.** There were eight implant failures (44%). In two patients the Unispacer required exchange due to component subluxation (Fig. 3). These were successfully revised to a larger sized unispacer prosthesis.

The remaining six failures required full revision. In three patients the Unispacer was removed and a UKR was undertaken. In the remaining three patients conversion to a TKR was required. The mean time to revision was 10 months (3 to 16) after the initial operation. The main reasons for revision included pain, swelling, instability, component subluxation and medial erosion. In one patient the conversion to TKR was conducted for osteonecrosis of both the medial and lateral femoral condyles. All patients who have undergone revision have been satisfied with their outcome (Table II).

Apart from the failures, there were two other patients who required further surgical intervention. One required a manipulation under anaesthetic for stiffness three weeks after operation; the final pain score at 25 months was 4.

**Table I. Modified visual analogue scores for all patients with the Unispacer in situ**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yrs)</th>
<th>Gender</th>
<th>Follow-up (mths)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>46</td>
<td>F</td>
<td>26</td>
<td>3.5</td>
</tr>
<tr>
<td>2*</td>
<td>54</td>
<td>M</td>
<td>25</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>F</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>F</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>5*</td>
<td>40</td>
<td>F</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>57</td>
<td>M</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>42</td>
<td>M</td>
<td>15</td>
<td>3.5</td>
</tr>
<tr>
<td>8</td>
<td>46</td>
<td>F</td>
<td>21</td>
<td>11.5</td>
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<tr>
<td>9</td>
<td>43</td>
<td>F</td>
<td>14</td>
<td>2</td>
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<tr>
<td>10</td>
<td>57</td>
<td>M</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>52</td>
<td>F</td>
<td>12</td>
<td>3.5</td>
</tr>
<tr>
<td>12</td>
<td>48</td>
<td>M</td>
<td>12</td>
<td>2</td>
</tr>
</tbody>
</table>

* patients 2 and 5 were revised to a larger component. The follow-up given is the time since the revision.
points. The remaining patient also required a manipulation under anaesthetic at 11 weeks and a subsequent arthroscopic washout and debridement for continuing pain at ten months; this had minimal benefit and the pain score at 21 months was 11.5 (worse pain than pre-operatively).

**Discussion**

The main benefits claimed for the Unispacer device are preservation of the knee joint and pain relief, so that it can be considered as a ‘holding’ procedure for younger patients who are likely to require TKR at some stage in the future.

In this series the early clinical results for patients who still had the device *in situ* showed that most reported significant symptoms which persisted for six months after surgery, but at a mean of 19 months’ follow-up pain scores had improved to a maximum 4 of 10 or better in 11 of the 12 patients. This mean overall pain relief was a 70% improvement on pre-operative pain for those who still had the device *in situ*. This extent of pain relief is less than had been predicted, and compares unfavourably with the 80% improvement reported elsewhere.\(^\text{16}\)

Revision surgery at a mean of 19 months’ follow-up with this device was required in eight patients (44%), with six requiring conversion to UKR or TKR. This is much higher than anticipated, compared with other reports in the literature.\(^\text{16,20}\) Although patient selection may have been a factor in the number of revisions, our patients were carefully chosen according to the manufacturer’s guidelines at the time of the study. The two patients requiring exchange to a larger spacer are attributable to operative technique and the method of intra-operative implant sizing despite the use of fluoroscopy. This reflects a learning curve that concurs with the experience of others.\(^\text{16,20}\)

There is some evidence to question the hypothesis that increased activity leads to increased risk of revision after TKR for OA.\(^\text{21}\) Unicompartmental knee replacement has been shown to provide pain relief and excellent functional results in patients who are active and under the age of 60 at the time of surgery,\(^\text{22,23}\) although recent data from the Australian Joint Registry show a significantly higher early revision rate for UKR compared with TKR.\(^\text{5}\) Nevertheless, it calls into question the usefulness of the Unispacer device.

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**Table II. Patients requiring revision surgery**

<table>
<thead>
<tr>
<th>Failure number</th>
<th>Reason for revision</th>
<th>Time from initial Unispacer implantation (mths)</th>
<th>Operation performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Impingement</td>
<td>3</td>
<td>Large Unispacer inserted</td>
</tr>
<tr>
<td>2</td>
<td>Impingement, spacer dislocation</td>
<td>6.5</td>
<td>Large Unispacer inserted</td>
</tr>
<tr>
<td>3</td>
<td>Pain and swelling</td>
<td>9</td>
<td>Unicompartmental knee replacement</td>
</tr>
<tr>
<td>4</td>
<td>Pain and swelling</td>
<td>10</td>
<td>Unicompartmental knee replacement</td>
</tr>
<tr>
<td>5</td>
<td>Anterior dislocation of the Unispacer in unloaded flexion</td>
<td>15</td>
<td>Unicompartmental knee replacement</td>
</tr>
<tr>
<td>6</td>
<td>Osteonecrosis (medial and lateral femoral condyles)</td>
<td>9</td>
<td>Total knee replacement</td>
</tr>
<tr>
<td>7</td>
<td>Pain and tibial erosion</td>
<td>12</td>
<td>Total knee replacement</td>
</tr>
<tr>
<td>8</td>
<td>Pain and tibial erosion</td>
<td>16</td>
<td>Total knee replacement</td>
</tr>
</tbody>
</table>

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**Fig. 3a**

Lateral radiographs of the Unispacer *in situ* with failure caused by an undersized component showing a) significant impingement occurring in flexion, and b) the component subluxes in extension.
The early results of the Unispacer knee system in this series have been disappointing. Despite achieving the objectives of bone stock preservation and ease of revision, the findings of this study do not support the widespread introduction of this implant. The limited clinical improvement seen in some patients who were able to tolerate the slow recovery may indicate that this device could have a role in narrower clinical indications than those used for this study. However, on the basis of the findings in this study, the use of the Unispacer knee system is not recommended.

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


