Total knee replacement performed with either a mini-midvastus or a standard approach

A PROSPECTIVE RANDOMISED CLINICAL AND RADIOLOGICAL TRIAL

We report the clinical and radiological results of a two- to three-year prospective randomised study which was designed to compare a minimally-invasive technique with a standard technique in total knee replacement and was undertaken between January 2004 and May 2007. The mini-midvastus approach was used on 50 patients (group A) and a standard approach on 50 patients (group B). The mean follow-up in both groups was 23 months (24 to 35).

The functional outcome was better in group A up to nine months after operation, as shown by statistically significant differences in the mean function score, mean total score and the mean Oxford knee score (all, p = 0.05). Patients in group A had statistically significant greater early flexion (p = 0.04) and reached their greatest mean knee flexion of 126.5˚ (95˚ to 135˚) 21 days after operation. However, at final follow-up there was no significant difference in the mean maximum flexion between the groups (p = 0.08).

Technical errors were identified in six patients from group A (12%) on radiological evaluation.

Based on these results, the authors currently use minimally-invasive techniques in total knee replacement in selected cases only.

Much has recently been written about minimally-invasive total knee replacement (TKR).1-3 Miniature versions of both the subvastus and midvastus approaches and truly quadriceps-sparing medial or lateral approaches have been described.1 Although the application of minimally-invasive surgical approaches in unicompartmental knee replacement are now widely accepted,4,6 the use of similar approaches in TKR has aroused both interest and suspicion.1

The contemporary literature does not, however, support the widespread use of such techniques.1,2 Supporters suggest that patients undergoing minimally-invasive surgical TKR have a faster recovery, experience less pain and obtain increased flexion,7-15 but opponents suggest that there is no better functional outcome and that poor visualisation could compromise the proper placement of the components.1,16-18

The few cohort studies available publish early (up to two-year), objective clinical outcomes,7-15,18 and the two existing controlled trials present results only up to three months.17,19

We report the two- to three-year objective and subjective clinical and radiological results of a prospective randomised trial which was designed to compare the outcome of TKR, performed with either a mini-midvastus or a standard approach.

Patients and Methods

Beginning in January 2004, all patients aged between 50 and 80 years with osteoarthritis of the knee joint requiring TKR who had been admitted under the care of one surgeon (ThK) were considered eligible to participate in the study (Fig. 1). Written informed consent was obtained from all patients and the study was approved by the National and Hospital Ethical Committees. Additional inclusion criteria were good mental health, < 15˚ varus or valgus deformity, fixed-flexion deformity of < 20˚, flexion > 90˚ and a body mass index (BMI) < 35 kg/m².7,9 Exclusion criteria were rheumatoid arthritis, previous surgery on the same joint, and arthritis of the ipsilateral hip and contralateral hip and knee joints. A total of 50 patients were recruited to each group; there were 34 men and 66 women, with 46 right and 54 left knees. The groups were matched for gender, age, operated side and BMI (Table I).

The last patient was recruited in May 2005 and a final follow-up evaluation was per-
formed in May 2007. The mean follow-up in both groups was 23 months (24 to 35).

Computer-generated randomisation and closed envelopes were used to allocate patients to either the minimally-invasive group (group A) or the standard group (group B). The demographic and clinical details of the patients in both groups are shown in Table I. In patients from group A, a mini-midvastus surgical approach as described by Laskin,8 Laskin et al,9 and Haas et al7 and the special minimally-invasive surgical instrumentation for Genesis II (Smith & Nephew, Memphis, Tennessee) was used. This surgical approach consisted of a slightly medial longitudinal skin incision which begins 2 cm proximal to the patella, extends over the medial half of the patella, and ends distal to the level of the tibial tubercle. A mini-midvastus capsular incision was used extending 2 cm into the vastus medialis obliquus muscle from a point 2 cm proximal to the patella. The deep incision was then extended around the medial border of the patella and distally to the level of the tibial tubercle. The patella was displaced laterally and was not everted. During the procedure the knee was flexed and extended (between 20˚ and 70˚) as necessary to move the soft-tissue mobile window to allow proximal or distal exposure. The knee was hyperflexed only for the insertion of the tibial component. Special attention was paid to avoiding interruption of the suprapatellar pouch. In group B, a standard anterior midline approach was used. The skin incision was from 5 cm to 10 cm proximal to the superior pole of the patella to 2 cm to 4 cm distal to the medial extent of the tibial tubercle. The quadriceps tendon was split along its medial one-third, and the incision was con-

<table>
<thead>
<tr>
<th>Table I. Demographic data of the patients in each group</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Mean age at surgery in yrs (range)</td>
<td>71.1 (52 to 78)</td>
<td>70.8 (54 to 77)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female:Male</td>
<td>Female:Male</td>
</tr>
<tr>
<td></td>
<td>31:19</td>
<td>35:15</td>
</tr>
<tr>
<td>Knee</td>
<td>Left:right</td>
<td>Left:right</td>
</tr>
<tr>
<td></td>
<td>28:22</td>
<td>26:24</td>
</tr>
<tr>
<td>Mean body mass index (range)</td>
<td>32 (27 to 35)</td>
<td>31.5 (28 to 35)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Osteoarthritis</td>
<td>Seronegative arthritis</td>
</tr>
<tr>
<td></td>
<td>44</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Seronegative arthritis</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Post-traumatic arthritis</td>
<td>1</td>
</tr>
</tbody>
</table>
continued distally through the medial parapatellar retinaculum, medial to the patellar ligament and 5 mm medial to the tibial tubercle. In this group the standard instrumentation for Genesis II (Smith & Nephew) was used. One surgeon (ThK) performed all the operations in a vertical laminar air-flow theatre, and the Genesis II Oxinium prosthesis (Smith & Nephew) was used for all patients. Modern cementing technique, such as that used in hip surgery, was used for the fixation of both components. The patella was not replaced; instead the patellar aponeurosis at a distance of 5 mm all around the patella was released with electrocautery; osteophytes were removed and the patella was reshaped in all patients. Computer-assisted surgical systems were not used. All patients had patient-controlled epidural analgesia for 48 hours post-operatively. Prophylactic antibiotics were used pre- and post-operatively for two days, until the removal of the drain, and low molecular weight heparin anticoagulation was continued for 30 days post-operatively. Intensive physiotherapy was started from the first post-operative day.

Clinical outcome data (both objective and subjective) were prospectively collected for all patients at regular intervals commencing pre-operatively, and continuing post-operatively on the first, third and sixth days, at three and six weeks, three, six and nine months, at one year, and annually thereafter. The following validated rating systems for TKR\(^20\) were used: the Knee Society clinical rating system (knee score, function score and total score),\(^21\) and the Oxford knee score.\(^22,23\) Pain in the form of a visual analogue scale (VAS) ranging from 0 to 100 points (0, no pain; 100, worst pain) and the ability to actively elevate the leg with the knee extended were also recorded on the first, third and sixth days and at three and six weeks post-operatively. For radiological evaluation, standard antero-posterior, lateral and Merchant view radiographs and the Knee Society radiological rating system were used.\(^24\) Radiographs were taken and analysed at three weeks, six months, one year and every year thereafter. At each interval patients were examined twice by two groups of independent observers, comprising one specialist and one resident in each group. The average clinical rating of the groups was recorded and analysed. The same two groups of observers, blinded to the surgical approach used, evaluated all the radiographs after the final clinical follow-up evaluation.

For statistical analysis Student’s \(t\)-test and the paired \(t\)-test were used to evaluate possible statistical differences of values within and between groups. Statistical significance was set at \(p < 0.05\).

A post hoc power analysis for detecting a final mean difference in the knee scores of 3.2 between the two groups, based on the estimated common SD of 1.68, with a standardised effect of 1.91, at a 5% level of significance, with 50 patients allocated in each group, was 99%.\(^25\) The power for detecting a final mean difference of 13 in the function score between the two groups, based on the estimated common SD of 2.47, with a standardised effect of 5.26, at a 5% level of significance with 50 patients allocated to each group, was 99%. The power for detecting a final mean difference in total score between the two groups of 8.0 based on the estimated common SD of 5.0 with a standardised effect of 1.60, at a 5% level of significance with 50 patients allocated to each group, was 99%. Lastly, the power for detecting a final mean difference in the Oxford knee scores between the two groups of -3.3, based on the estimated common SD of 1.63 with a standardised effect of -2.03, at a 5% level of significance with 50 patients allocated to each group, was also 99%.

This confirmed that there were enough patients in the study to test the hypothesis that minimally-invasive surgery gave better results than standard TKR.

Results

At final follow-up all patients were available for evaluation and 96 (96%) were compliant in their attendance for the interval evaluations. During the operation six patients undergoing the minimally-invasive approach required conversion to a standard approach, in two patients due to partial avulsion of the insertion of the patellar ligament into the tibial tubercle, in two because it was not possible to displace the patella laterally and in two because tightness of the soft tissues prevented adequate exposure. These six patients (group A1) were replaced by other patients recruited to group A so that 50 patients remained under investigation (Fig. 1). The patients allocated to group A1 were also followed using the same assessment scales.

The mean length of incision in extension measured at three months post-operatively was 11 cm (10 to 12) in group A and 18 cm (16 to 20) in group B. At the end of the operation a mean elongation of 1.2 cm (0.8 to 1.4) of the incision was observed in group A, which decreased during the three post-operative months. Temporary discoloration of the margins of the incision, due to subcutaneous haematoma and bruising from excess wound tension, was also observed in group A. The mean blood loss of 613 ml (80 to 1400) collected in the drain was statistically significantly less in group A than in group B (1016 ml (550 to 1550); \(t\)-test, \(p = 0.01\)). The mean operative duration from incision to closure was significantly longer in group A, at 75 minutes (65 to 95), than in group B, at 55 minutes (45 to 70) \(t\)-test, \(p = 0.04\). All patients were discharged on the sixth post-operative day and all followed the same intensive rehabilitation programme.

Pre-operative and final follow-up results, and differences between and within groups for the objective knee score, function score, total score and the subjective Oxford knee score are shown in Table II. No statistically significant differences were observed when the knee score was compared between the groups at each time interval (Fig. 2), and at final follow-up (Table II). Statistically significant differences were observed when the function score was compared between the groups at all time intervals (Fig. 3), and at final
follow-up (Table II). Statistically significant differences were observed when the total score was compared between groups at different intervals up to the ninth post-operative month (Fig. 4). Statistically significant differences were observed when the Oxford knee score was compared between the groups at different time intervals up to the ninth post-operative month only (Fig. 5 and Table II). At final follow-up there was no statistically significant difference between the groups in total score (Table II).

Pain, as estimated by the VAS, was statistically significantly higher in group A than in group B on the first and third post-operative days (paired t-test, \( p = 0.01 \)) (Fig. 6). At final follow-up there was no difference in the parameter of pain of the knee score between the groups, with 29 patients in group A (58%) and 28 patients (56%) in group B having no pain, 18 patients in group A (36%) and 19 patients (38%) in group B experiencing mild occasional pain, and three patients in group A (6%) and three in group B (6%) with had moderate occasional pain. The parameter flexion of the knee score increased from a pre-operative mean of 111˚ (80˚ to 125˚) to a final mean of 126.5˚ (95˚ to 135˚) in group A, and from a pre-operative mean of 108˚ (85˚ to 125˚) to a final mean of 116˚ (90˚ to 130˚) in group B. At final follow-up no statistically significant difference (paired t-test, \( p = 0.08 \)) was detected between groups. However, patients from group A had a statistically significantly

### Table II. Pre-operative and final follow-up results (mean, range) and statistical differences between groups for the knee score, function score, total score, and Oxford knee score

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Difference *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective knee score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>35.7 (14 to 65)</td>
<td>31.6 (12 to 70)</td>
<td>NS</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>97 (92 to 100)</td>
<td>93.8 (65 to 100)</td>
<td>NS</td>
</tr>
<tr>
<td>Difference (t-test)</td>
<td>( p = 0.01 )</td>
<td>( p = 0.01 )</td>
<td></td>
</tr>
<tr>
<td><strong>Objective function score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>46.4 (10 to 60)</td>
<td>46.5 (20 to 50)</td>
<td>NS</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>97 (90 to 100)</td>
<td>84 (71 to 100)</td>
<td>( p = 0.01 )</td>
</tr>
<tr>
<td>Difference (t-test)</td>
<td>( p = 0.01 )</td>
<td>( p = 0.01 )</td>
<td></td>
</tr>
<tr>
<td><strong>Objective total score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>82.1 (35 to 115)</td>
<td>78.9 (57 to 110)</td>
<td>NS</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>192 (180 to 200)</td>
<td>184 (115 to 200)</td>
<td>NS</td>
</tr>
<tr>
<td>Difference (t-test)</td>
<td>( p = 0.01 )</td>
<td>( p = 0.01 )</td>
<td></td>
</tr>
<tr>
<td><strong>Subjective Oxford knee score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>44.3 (38 to 50)</td>
<td>43.8 (39 to 51)</td>
<td>NS</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>20 (14 to 28)</td>
<td>23.3 (20 to 32)</td>
<td>NS</td>
</tr>
<tr>
<td>Difference (t-test)</td>
<td>( p = 0.01 )</td>
<td>( p = 0.01 )</td>
<td></td>
</tr>
</tbody>
</table>

* paired t-test; NS, not statistically significant
greater range of movement on the first, third, sixth and 21st post-operative days than those from group B (Fig. 7) (paired t-test, p = 0.04). It was noticeable that patients in group A reached the highest mean knee flexion much more rapidly than those in group B (Fig. 7). In group A 30 patients (60%) were able to raise their operated leg against gravity with the knee in extension after the first post-operative day and all of this group could do so by the third post-operative day. In group B all patients were able to perform this same exercise also by the third post-operative day. Patients in group A1 who had required their surgical exposure to be corrected to a standard incision had outcomes similar to group B scores, and experienced no ill-effect. Owing to the small number of patients in group A1, no attempt at further analysis was made.

At final follow-up, radiological evaluation revealed tibial component malalignment on the frontal plane judged by a deviation from the neutral axis of > 3˚ (varus placement) in three of the knees (6%) in group A and in nine (18%) in group B. Anterior placement of the femoral component was also found in three knees (6%) from patients in group A. Non-progressive lucent lines in zones 1 and 2 of the tibial component were found on anteroposterior radiographs in four knees (8%) from group A and in five (10%) from group B. On lateral radiographs non-progressive lucent lines in zone 2 were found in two knees (4%) from group A and three knees (6%) from group B. There was no radiological evidence of osteolysis due to polyethylene wear debris in either group.

Superficial wound healing problems due to marginal skin necrosis occurred in four knees from group A (8%) and in two knees (4%) from group B. No infection developed in any patient. Deep-vein thrombosis, which was confirmed by triplex ultrasound, occurred in one knee from group A (2%) and in two knees (4%) from group B; no patient had
suffered a pulmonary embolus. One patient in each group (2%) complained of anterior knee pain. In one knee in group A with a post-operative range of flexion of 0° to 80°, and in one patient in group B with a post-operative range of flexion of 0° to 70°, manipulation under anaesthesia was performed to improve flexion after the fourth post-operative week. These patients obtained 95° and 90° of flexion, respectively at final review.

Discussion

The conventional operative technique for TKR has involved an extensile approach with wide exposure to facilitate optimal placement of the instruments and components. Historically, dissection was accomplished through a 20 cm to 25 cm midline skin incision. Most commonly a long medial parapatellar arthrotomy was made, although some surgeons preferred a subvastus or midvastus approach. This was followed by extensive soft-tissue dissection and eversion and lateral dislocation of the patella. Using such surgical approaches and condylar designs, either cemented or hydroxyapatite-coated, has led to consistently reproducible and enduring results in TKR. 26-32 For most studies ten-year survival of greater than 90% has been achieved. 26,28-31

Two concerns for patients prior to TKR are pain, and length of recovery. 33,34 Obtaining satisfactory results with standard TKR may require a long recovery period. Patients are often advised that it can take six months to two years for full functional recovery. 35,36 The surgical approach and the implantation technique may produce much soft-tissue disruption, leading to extended recovery periods. 3,7,12,35,36 Although these issues may not preclude the result from ultimately being successful, these aspects of patient outcome should be addressed. The ultimate functional result may be good but still fall short of the patient’s expectations for early recovery and a return to full activity. 33,34

Minimally-invasive techniques have been used in numerous types of surgical procedures, both arthroscopic and open. The introduction and success of minimally-invasive surgery for unicompartmental knee replacement has sparked interest in applying similar methods in TKR. 4,6 Many different techniques have been described, including subvastus, midvastus, and limited medial or lateral parapatellar, truly quadriceps-sparing approaches. 37,38 In general, these approaches are distinguished from conventional exposure by their shorter incision, avoidance of patellar eversion, and smaller instruments. The extensor mechanism is handled somewhat differently with each approach. In theory, patients who have surgery performed through small incisions with less muscle and soft-tissue damage have less blood loss, a reduction in post-operative pain, and a faster recovery with an improved range of movement and reduced hospital stay. Proponents of minimal access surgery have shown that patients undergoing TKR have an accelerated rehabilitation and easier recovery. 7,15 On the other hand, the limited surgical exposure may increase the complexity of the procedure, the duration of surgery, and the possibility of prosthetic malalignment. 1,3,16,18

There is little published literature to support the widespread use of these techniques, 7-15,18 and the benefits to patients have not been well documented in peer-reviewed studies. 1,3,12 In studies with a follow-up of two to three years, authors have noted some apparent benefits of the minimally-invasive approach during the initial post-operative period, including improved gains in early flexion, 7,9,11,18 reduced pain scores and analgesic use, 8,9 improved quadriceps function, 3,8,13 reduced blood loss, 3,8,11 and shortened length of post-operative stay. 3,8,13 The cosmetic benefit for patients has also been shown. 8,9,14,15 However, some authors have reported disadvantages, including increased operative time, 7,11,18 and increased blood loss. 9 Of these studies, only three were comparative. 7,9,11 Two studies evaluated dissimilar groups, comparing a mini-midvastus approach with a standard medial parapatellar arthrotomy. 7,9 The other compared the quadriceps-sparing procedure with the standard approach. 11 Only two randomised controlled trials have been reported. In the first, a North American multicentre study, with the follow-up limited to 12 weeks, mini-midvastus minimally-invasive TKR, surprisingly, reported no improvement over the standard approach for the Knee Society clinical and radiological scores. 17 In the second, there was also no difference in the 12-week recovery and early clinical results between the mini-subvastus and the quadriceps-sparing approaches. 19 Finally, in a study with a mean follow-up of 1.8 years in which both knees of the same patient were randomised to receive TKR with either a quadriceps-sparing or a standard approach, no differences were found in blood loss, knee score, function score, pain or range of movement. 39 In contrast, operative time and complications were greater in the quadriceps-sparing procedures. 39 Despite the limited published literature, some orthopaedic manufacturers have gone to direct marketing, promoting preliminary clinical results and encouraging patients to seek out surgeons who will perform minimally-invasive surgical techniques. 1,2

In 2003, after the worldwide attention gained by minimally-invasive TKR surgery, 7-9 a mini-midvastus approach was adopted in our department. Despite the confidence gained after 34 cases were initially performed, several questions were raised concerning the clinical efficacy, the limitations and possible complications of minimally-invasive techniques for TKR, which led to our establishing this randomised controlled trial. We chose to report two- to three-year objective and subjective clinical results because functional improvement following TKR has been shown to continue up to the second post-operative year. 35,36 There was a definite, albeit temporary, functional effect up to nine months post-operatively in those cases performed with a mini-midvastus approach. Function, total knee and Oxford knee scores were greater in the minimally-invasive group during this period. Patients in the minimally-invasive group reached the highest mean knee flexion early, in the third post-operative week. Haas et al, 7 Laskin 8
and Laskin et al. also found improved early flexion in their series. At final follow-up, however, despite the fact that the minimally-invasive group had a mean of 10° more flexion, this difference was not statistically significant.

The price of this temporary functional effect was an increased operation time of approximately 20 minutes, which increases the indirect financial cost of such operations, an intra-operative conversion of the mini-midvastus to a standard approach for six patients and, most importantly, technical errors of component positioning in six patients (12%), which may adversely affect the long-term performance of the TKR.

Computer-assisted surgery is a new technology with enormous potential but with recognised risks. Its accuracy has been shown, and its use has been shown to be associated with a reduced number of technical errors for component positioning in TKR in three prospective controlled trials, but without any demonstrable improvement in the functional results at two years. Although logical to couple computer navigation with minimally-invasive techniques in TKR, the current cost of the equipment and software and the lengthening of the operative time may present an obstacle.

Several terms are used to describe different variations of approaches in minimally-invasive TKR surgery (less invasive surgery, smaller incision surgery, minimally-invasive surgery). The absolute length of the incision is not important but the goal is to restrict the surgical trauma to only what is needed for a safe exposure. Reduced soft-tissue dissection, lack of eversion of the patella, and in situ bone resection to minimise the subluxation of the knee are more important in producing improved outcomes. However, it must be recognised that excessive tension is often applied to the wound margins, which may compromise healing, although the smaller instruments developed for minimally-invasive surgery should lessen this risk. It will require several years to determine the differences in outcome, complications and limitations of the mini-midvastus and quadriceps-sparing approaches. At present the only controlled comparative study shows no differences.

It has been suggested that minimally-invasive techniques result in less post-operative pain and a reduced requirement for analgesics. In our study, the same modern protocol of peri-operative pain control was used in both groups. During the first post-operative week, pain was apparently greater in the minimally-invasive group. In our opinion, pain management, in the cohort studies published, is a serious confounding factor and reduced pain levels should not be presented as a benefit of minimally-invasive TKR.

There is a definite psychological factor in patients choosing minimally-invasive technique. A small incision influences patients’ satisfaction post-operatively. This prospective randomised study confirmed that there is a definite but temporary functional effect of minimally-invasive techniques in TKR which has a definite cost: that of component malposition and prolongation of operative time.

The authors of this study currently perform minimally-invasive TKR in selected cases only, following appropriate counselling of patients.

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


