KNEE

A randomised controlled clinical trial and gait analysis of fixed- and mobile-bearing total knee replacements with a five-year follow-up

This study compared the outcome of total knee replacement (TKR) in adult patients with fixed- and mobile-bearing prostheses during the first post-operative year and at five years’ follow-up, using gait parameters as a new objective measure. This double-blind randomised controlled clinical trial included 55 patients with mobile-bearing (n = 26) and fixed-bearing (n = 29) prostheses of the same design, evaluated pre-operatively and post-operatively at six weeks, three months, six months, one year and five years. Each participant undertook two walking trials of 30 m and completed the EuroQol questionnaire, Western Ontario and McMaster Universities osteoarthritis index, Knee Society score, and visual analogue scales for pain and stiffness. Gait analysis was performed using five miniature angular rate sensors mounted on the trunk (sacrum), each thigh and calf. The study population was divided into two groups according to age (≤ 70 years versus > 70 years).

Improvements in most gait parameters at five years’ follow-up were greater for fixed-bearing TKRs in older patients (> 70 years), and greater for mobile-bearing TKRs in younger patients (≤ 70 years). These findings should be confirmed by an extended age controlled study, as the ideal choice of prosthesis might depend on the age of the patient at the time of surgery.

A variety of scoring and evaluation systems with different implant designs have been used to assess outcome after joint replacement, making it difficult to compare studies. A need for patient-based evaluation systems has been identified. Instruments that have increased sensitivity and specificity in evaluating quality of life compared with traditional scoring systems enhance the surgeon’s ability to assess outcome, and may be helpful when comparing forms of treatments such as two types of prosthesis. Sophisticated laboratory techniques for measurement of angles and gait analysis assume the functional handicap of patients, but their use has been hindered by the extensive time and associated cost required for measurement and analysis. This limits their use in clinical practice. A portable ambulatory gait analysis system has been validated for the evaluation of patients after joint replacement and allows for long-term monitoring. Compared with standard laboratory techniques such as movement capture stereophotogrammetry, ambulatory techniques offer the possibility of performing gait analysis in a clinical setting such as a hospital corridor or clinic, or the patient’s environment, without the need for complex marker and camera set-up.

Since their introduction in 1977, mobile-bearing (MB) knee prostheses have been designed to provide less constrained kinematics, with the aim of minimising polyethylene wear and reducing the stress at the bone-cement-prosthesis interface. Four reviews of studies comparing fixed-bearing (FB) and MB total knee replacements (TKR) found no evidence of superiority for either type of implant with respect to range of movement (ROM), pain, stiffness or function. Although several randomised controlled trials of FB and MB TKRs with a follow-up of more than four years have been published, further information is still needed.

The purpose of this double-blind randomised controlled clinical trial was to assess the outcome of primary TKR in adult patients undergoing fixed- or mobile-bearing TKR using the same manufacturer and design for all other parts of the implant, during the first post-operative year and at five years after surgery, using gait parameters as a new objective outcome measure. Our hypothesis was that the outcome measured by the portable system in real-life conditions would identify differences between the designs.

Patients and Methods

Between February 2004 and November 2005, consecutive patients with unilateral osteoarthritis of the knee and awaiting TKR at
a university hospital were eligible to participate in the study, which had ethical approval. Exclusion criteria included patients with osteoarthritis of the hip and/or neurological symptoms. A total of 56 patients (56 knees) consented to participate and were randomly assigned to receive either a NexGen LPS (Zimmer Inc., Warsaw, Indiana) mobile-bearing prosthesis (n = 26) or a NexGen LPS fixed-bearing prosthesis (Zimmer Inc.) (n = 26). Patients were blinded to the type of prosthesis they received. Randomisation was achieved by a computer-generated list with blocks of five patients. No patients were lost to follow-up. One patient was excluded during follow-up because of post-operative knee laxity in varus (lateral ligament), unrelated to the type of bearing (fixed in this case), which required revision at seven months. The CONSORT\textsuperscript{20} flow diagram of patient recruitment, allocation and follow-up is shown in Figure 1.

Surgical procedure. The surgeon was informed of the type of bearing the night before the operation. All operations were performed by three surgeons (BMJ, PFL, KB) using the same operative technique and post-operative care following a standard protocol. Exposure was through a midline incision and medial parapatellar arthrotomy under tourniquet control. Pulsatile lavage of the bony surface was undertaken before cementing the components. The patella was resurfaced in all patients. Appropriate soft-tissue procedures were performed to realign the knee. Antibiotic prophylaxis with intravenous cefuroxime (1.5 g) was administered half an hour before inflation of the tourniquet and six hours after surgery. Thromboprophylaxis involved subcutaneous low-molecular-weight heparin, adjusted according to body weight, beginning on the night before surgery and continuing daily until acenocoumarol was
prescribed on the fourth post-operative day and continued for six weeks. Physiotherapy with continuous passive and controlled active movement was started on the first post-operative day, and mobilisation fully weight-bearing on the second post-operative day.

**Data collection.** Patients were evaluated by an independent, blinded observer (CV) pre-operatively and post-operatively at six weeks, three months, six months, one year and five years. Each patient performed two walking trials of 30 m at his/her preferred speed, and the EuroQol five-dimensions questionnaire (EQ-5D), a visual analogue scale (VAS) pain and stiffness scores (range 0 to 10 points, where 0 is no pain/stiffness and 10 is maximum pain/stiffness), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Society score (KSS) were recorded. Assessment of gait included lower limb and trunk rotations measured by five miniature inertial sensors (a single gyroscope and two axial accelerometers) mounted on the trunk (sacrum) and each thigh and calf, respectively, and linked to a portable data logger Physilog (BioAGM, La-Tour-de-Peilz, Switzerland) as described by Dejnabadi et al. Temporal parameters such as gait cycle time and limb (expressed as a proportion of the gait cycle, as the absolute difference between initial and terminal double stance) and spatial parameters such as gait speed, stride length, the maximum angular velocity of the knee, and sagittal range of rotation of the operated thigh (thigh ROM), calf (calf ROM) and knee (knee ROM) were computed. Anteroposterior and lateral (with 30° of flexion) radiographs of the knee and a skyline patellar radiographs were collected pre-operatively and at each follow-up. Full weight-bearing radiographs of the lower limbs were collected pre-operatively and at six months’ follow-up. Limb alignment, the position of each component, and the development of radiolucent lines (RLLs), defined as gaps > 2 mm at the bone–cement interface, were analysed according to Knee Society recommendations.

**Statistical analysis.** Because the FB prosthesis has been used in our institution for more than ten years, the FB group was designated the control group. We determined a sample size for this study of TKR in patients with osteoarthritis based on a minimum significant change (or difference) of 10° in ROM during gait with a standard error of 8, and a minimum significant change (or difference) of 12 points in WOMAC score (three answers) with a margin of measurement error of 13. Using these values, an α of 0.05 and β of 0.8, the required sample size was calculated to be 24 patients in each group to achieve a power of 80%. Descriptive analysis was completed on demographic information and clinical and radiological outcomes. Non-parametric tests (Wilcoxon’s signed ranks or rank sum tests) were used for comparison of scores, with p ≤ 0.05

Clinical outcomes included VAS pain, VAS stiffness, KSS function, WOMAC and EQ-5D. Data were analysed with Stata v11 software (Stata Corp., College Station, Texas).

A difference in ages was observed between groups at baseline, therefore the effect of age was tested on the parameters of outcome. Statistical comparisons between groups were performed on a limited age-matched set of 25 patients in each group (MB/FB), by removing data for the four oldest patients from the FB group and those for the youngest patient from the MB group. This produced two groups homogeneous for baseline variables, adding strength to the statistical analysis at follow-up. Secondary analyses were stratified by age (less than the population median of 71, versus equal to or greater than the median), and robust multivariate regressions explaining outcomes by bearing type were controlled for age.

**Results**

Demographics and pre-operative data for the age-matched patient groups are shown in Table I, for which there were no statistically significant differences.

The post-operative EQ-5D, VAS pain and stiffness, WOMAC and KSS results are summarised in Table II. The mean VAS stiffness score was clinically and statistically lower in the FB group than the MB group at one year (1.0 (SD 1.9) versus 2.4 (SD 2.1); p < 0.01). The mean VAS pain score was also significantly lower in the FB group at three months (2.4 (SD 2.0) versus 3.8 (SD 2.4); p = 0.02), and at one year, but not at six months (Table II). However, the difference at one year was < 1.3 points, which is considered the minimum clinically significant difference for this scale.

The mean WOMAC score showed a statistically and clinically significant difference at one year follow-up in favour of the FB group (FB, 13.4 (SD 16.6); MB, 22.8 (SD 15.9); p = 0.02), which had disappeared by five years. There were no clinically meaningful differences between the two groups for the EQ-5D and KSS. Significant differences, both statistically and clinically, were observed for all clinical scores in both groups, between baseline and follow-up at three months, six months, one year and five years, except for the EQ-5D score at five years in the MB group, which showed a decrease to the level of the general population reference for the country (74 (SD 18)).

Table III summarises the radiological results. There was no significant difference between the two groups with respect to implant positioning. No peri-prosthetic femoral RLLs were observed. There were two non-progressive tibial peri-prosthetic RLLs (one in zone 1 in the FB prosthesis group, and one in zone 2 in the MB group).

Gait analysis showed no significant difference between the groups at any interval. However, there was an effect of time, with the mean of all gait parameters being worse at five years than at the one-year follow-up (Fig. 2). This decrease was statistically significant for all parameters (gait cycle time, p = 0.04; stride length, p = 0.03; knee ROM, p < 0.001; knee maximum angular velocity, p = 0.02; calf
ROM, p < 0.001; limp, p < 0.001) except stride velocity (p = 0.94) and thigh ROM (p = 0.89; all Wilcoxon’s rank sum test), and could be considered the normal decline caused by the ageing of the patients.25
Secondary analysis stratifying the population by age (≤70 years versus > 70 years, where 71 years was the median of the entire cohort) demonstrated that the effect of bearing type differed depending on the age of the patient. For example, the mean VAS pain (Fig. 3) at six weeks and three months was similar in the two groups for younger patients, but was significantly greater in older MB patients compared with older FB patients (at six weeks: 5.1 (SD 2.3) versus 3.1 (SD 2.0), p = 0.04; at three months: 3.9 (SD 2.4) versus 2.0 (SD 1.8), p = 0.03). With respect to gait, from three months onwards, stride length (Fig. 4) in younger patients was longer in those patients with MB implants. In contrast, in older patients stride length was shorter in those with MB implants. However, this effect did not reach the threshold for statistical significance.

The results of robust multivariate regression explaining outcomes by bearing type, controlling for age, in three populations (all patients, younger patients, older patients) are shown in Table IV. The coefficients corresponding to the bearing type indicate that, even when controlling for age, the effect of bearing type was significantly inverted in older people compared with younger people (i.e. a positive effect for young patients and a negative for older). The EQ-5D, VAS pain and KSS function scores, gait cycle time, gait speed, stride length, knee ROM, knee maximum angular velocity, thigh ROM, calf ROM and limp demonstrated a
relationship to the bearing type that changed across time or across age groups. Sensitivity analyses to determine an age threshold for the use of MB implants were inconclusive owing to the insufficient sample size for this kind of statistical analysis.

Complications. There was one post-operative complication in a patient with a FB TKR who presented with post-operative varus knee laxity due to a deficiency in the fibular collateral ligament at six weeks after surgery and underwent revision surgery at seven months postoperatively. This patient was excluded from the results.

Discussion
This double-blind, randomised controlled trial demonstrated significant differences in objective parameters between MB and FB TKRs. We included traditional
Table IV. Robust multivariate regression explaining outcomes by bearing type, in the full cohort (All), younger patients (≤ 70 years; Y), and older patients (> 70 years, O) when assessing the mean values of the parameters tested. Values: effect of mobile bearing on the outcome (β coefficient of robust multivariate regression)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>6 Weeks</th>
<th>3 Months</th>
<th>6 Months</th>
<th>1 Year</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>Y</td>
<td>O</td>
<td>All</td>
<td>Y</td>
</tr>
<tr>
<td>EQ-5D†</td>
<td>1.4</td>
<td>3.69</td>
<td>-0.3</td>
<td>-1.6</td>
<td>3.8</td>
</tr>
<tr>
<td>VAS Pain†</td>
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<td>-0.9</td>
<td>2.2</td>
<td>1.4</td>
<td>0.7</td>
</tr>
<tr>
<td>VAS Stiffness</td>
<td>0.9</td>
<td>-0.1</td>
<td>1.5</td>
<td>1.3</td>
<td>0.0</td>
</tr>
<tr>
<td>WOMAC</td>
<td>8.0</td>
<td>4.1</td>
<td>13.2</td>
<td>4.7</td>
<td>-0.5</td>
</tr>
<tr>
<td>KSS</td>
<td>-6.9</td>
<td>-6.0</td>
<td>-7.7</td>
<td>-4.5</td>
<td>-9.5</td>
</tr>
<tr>
<td>KSS function†</td>
<td>-11.5</td>
<td>-8.0</td>
<td>-15.5</td>
<td>-5.7</td>
<td>-10.7</td>
</tr>
<tr>
<td>Gait Cycle Time (s)†</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>-0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Stride velocity (ms)†</td>
<td>-0.1</td>
<td>-0.1</td>
<td>-0.1</td>
<td>-0.0</td>
<td>-0.0</td>
</tr>
<tr>
<td>Stride length (m)†</td>
<td>-0.0</td>
<td>-0.0</td>
<td>-0.10</td>
<td>-0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Knee ROM (°)†</td>
<td>-2.2</td>
<td>-0.3</td>
<td>-3.3</td>
<td>0.8</td>
<td>3.1</td>
</tr>
<tr>
<td>Knee maximum angular velocity (°/s)†</td>
<td>-22.6</td>
<td>0.3</td>
<td>-68.2</td>
<td>-12.5</td>
<td>-10.6</td>
</tr>
<tr>
<td>Shank ROM (°)†</td>
<td>-1.8</td>
<td>-0.2</td>
<td>-3.9</td>
<td>-0.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Thigh ROM (°)†</td>
<td>-1.1</td>
<td>-1.1</td>
<td>-3.3</td>
<td>-1.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Limp (%GCT)†</td>
<td>-0.2</td>
<td>-0.6</td>
<td>0.1</td>
<td>0.2</td>
<td>-0.2</td>
</tr>
</tbody>
</table>

† EQ-5D, EuroQol score; VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; KSS, Knee Society score; ROM, range of movement.
‡ the parameter shows inversions in bearing effect across time or across age groups (positive effect for young people and negative for older)
§ the bearing type is independently significantly associated with the outcome
NS, no solution of the robust regression

outcomes measures as well as a comparison of the kinematic performance of fixed- and mobile-bearing implants of otherwise similarly designed posterior-stabilised knee replacements. These parameters were obtained during dynamic use of the knee when the patient walked for at least 30 m in a corridor, rather than during a static clinical examination or taking only two or three steps.

No evidence of superiori has been found for either MB or FB TKRs with regard to ROM, functional performance, VAS pain or WOMAC scores. This was confirmed in a further review by Huang, Liau and Cheng and in a Cochrane systematic review and meta-analysis. Our study demonstrated that both types of bearings have a similar impact on outcomes measures as well as a comparison of the kinematic performance of fixed- and mobile-bearing implants of otherwise similarly designed posterior-stabilised knee replacements. These parameters were obtained during dynamic use of the knee when the patient walked for at least 30 m in a corridor, rather than during a static clinical examination or taking only two or three steps.

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Our study could also be underpowered, as sample size was determined on a pilot study with differences that were not achieved here.

There was no significant difference in objective gait parameters between the two groups at any time when the population was considered as a whole. However, when the effect of age on these parameters was considered, we found that the effect of a mobile bearing was negative in older patients (> 70 years) compared with a positive effect in younger patients (≤ 70 years) in terms of outcome results.

Statistically significant effects and differences between mobile- and fixed-bearing groups were confirmed by multivariate analysis.

Multivariate regression explaining outcomes by bearing type and controlling for age showed that the bearing effect was hidden in the whole population, whereas a statistically significant difference between MB and FB groups appeared when stratified by age. Although the difference of bearing effect was not visible at one year's follow-up in the usual outcome measures, it was significant on almost all objective gait parameters. We believe this effect would be seen for all outcome measures with more statistical power, as trends were consistent. In the older population, we consistently observed results in favour of the FB implant at almost any time point during follow-up because of weaker muscles and ligaments, and thus they may benefit more from this prosthesis. In contrast, gait parameters including stride length, knee maximum rotation speed, thigh and calf ROM, and limp in the younger cohort showed better results for MB prostheses at five years. Overall, these results imply that older patients may benefit less from a MB TKR. Larger studies with sufficient power are needed to determine the precise age threshold above which FB TKR might be appropriate.

Mobile-bearing TKR was developed to reduce the rate of aseptic loosening by reducing the knee constraint. Our observations of the gait parameters in younger patients are promising and should be further examined in studies where ages are carefully matched before surgery. Several authors have reported dislocations of the MB prosthesis. We...
did not experience this problem, but if it arose it would require early revision and argue in favour of FB implants.

In conclusion, this randomised controlled trial comparing FB and MB posterior-stabilised TKR with gait analysis demonstrated a better outcome with respect to gait for FB TKR in patients over 70 years of age, and a better outcome with MB TKR in younger patients. These findings should be confirmed by an extended age controlled study.

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References
