The Knee Arthroplasty Trial (KAT)

Design Features, Baseline Characteristics, and Two-Year Functional Outcomes After Alternative Approaches to Knee Replacement

By the KAT Trial Group*

Background: The aim of continued development of total knee replacement systems has been the further improvement of the quality of life and increasing the duration of prosthetic survival. Our goal was to evaluate the effects of several design features, including metal backing of the tibial component, patellar resurfacing, and a mobile bearing between the tibial and femoral components, on the function and survival of the implant.

Methods: A pragmatic, multicenter, randomized, controlled trial involving 116 surgeons in thirty-four centers in the United Kingdom was performed; 2352 participants were randomly allocated to be treated with or without a metal backing of the tibial component (409), with or without patellar resurfacing (1715), and/or with or without a mobile bearing (539). Randomization to more than one comparison was allowed. The primary outcome measures were the Oxford Knee Score (OKS), Short Form-12, EuroQol-5D, and the need for additional surgery. The results up to two years postoperatively are reported.

Results: Functional status and quality-of-life scores were low at baseline but improved markedly across all trial groups following knee replacement (mean overall OKS, 17.98 points at baseline and 34.82 points at two years). Most of the change was observed at three months after the surgery. Six percent of the patients had additional knee surgery within two years. There was no evidence of differences in clinical, functional, or quality-of-life measures between the randomized groups at two years.

Conclusions: Patients have substantial improvement following total knee replacement. This is the first adequately powered randomized controlled trial, of which we are aware, in which the effects of metal backing, patellar resurfacing, and a mobile bearing were investigated. We found no evidence of an effect of these variants on the rate of early complications or on functional recovery up to two years after total knee replacement.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Total knee arthroplasty is now a common and established surgical procedure. Long-term observational studies have indicated that >90% of modern primary knee replacements survive for thirteen to fifteen years[1]. Continued developments in design have been aimed at further improving quality of life and increasing the duration of prosthetic survival.

One common variation is the design of the tibial component. Use of a metal-backed base-plate has theoretical advantages in that it distributes load more evenly across the interface and reduces stresses, which may contribute to loosening and to failure of the polyethylene articular surface. However, metal backing reduces the thickness of the polyethylene that can be implanted in the available space, thus increasing the internal stress distribution in the polyethylene, which in turn increases the risk that internal loading will exceed its capacity. This may cause subsurface shearing effects

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and hence breakdown of the bearing surface. Also, metal backing is more expensive, and good long-term results have been reported after the use of non-metal-backed components[2]. Limited comparisons between metal-backed and non-metal-backed components have been performed, and to our knowledge no definitive difference has been determined[3].

Another variation is that the patella may or may not be resurfaced. Previous small-scale randomized controlled trials, nonrandomized cohort studies, and a systematic review have not resolved the uncertainty regarding the benefits of patellar resurfacing[4-6].

More recent studies of knee replacement have focused on whether performance and longevity can be improved by altering the design of the bearing between the tibial and femoral components, to address complications of wear and loosening. Some authors[7,8] have claimed that polyethylene wear and shearing effects at the prosthesis-bone interface could be reduced if there was a moving component between the tibia and femur. To our knowledge, only the mobile-bearing New Jersey Knee (DePuy Orthopaedics, Warsaw, Indiana) has been the subject of long-term follow-up[9]. A relatively recent Cochrane review has shed little light on the potential advantages of the more complex rotating-platform designs[10]. Dislocation of the mobile component has been a not infrequently reported problem[9,11], with so-called spin-out of the mobile component being mentioned in particular[12,13].

The Knee Arthroplasty Trial (KAT), a pragmatic, multicenter, randomized, controlled trial, was designed to determine whether a metal-backed plate for the tibial component is more effective and cost-effective than a single high-density-polyethylene component, whether it is more effective and cost-effective to resurface the patella, and whether a mobile bearing between the tibial and femoral components is associated with better outcomes than standard designs without a mobile bearing. In this report, we describe complications and patient-assessed functional and quality-of-life outcomes up to two years after the surgery.

Materials and Methods

Surgeons

The trial was approved by relevant national and local research ethics committees and was registered in a public trials registry (registry number, 1SRCTN45837371). Orthopaedic surgeons were eligible to take part if they performed knee replacements routinely. Before participating in the trial, the surgeons chose the comparisons to which they would contribute. We recognized that surgeons would differ in terms of the comparisons to which they would allow their patients to be randomly allocated. One hundred and sixteen surgeons in thirty-four centers in the United Kingdom participated.

Patients

All patients under the care of a collaborating surgeon were potentially eligible for inclusion if a decision had been made for them to have primary total knee replacement. A patient was not eligible for a trial comparison if the surgeon considered a particular type of operation to be clearly indicated (for example, if a patient required a highly constrained knee replacement to replace function of the collateral ligaments). A patient remained eligible only if the surgeon remained convinced that there was no indication for one particular choice within the trial; for example, a patient with a thin or osteopenic patella would not be eligible for the patellar resurfacing comparison because the surgeon would not have chosen patellar resurfacing for such a patient.

When possible, patients scheduled for a total knee replacement were sent information about relevant aspects of the study in advance of their hospital admission.

While it was anticipated that most participants would be enrolled in a single comparison, individuals could be recruited for more than one comparison if that was clinically appropriate. Only a minority of participants were included in more than one comparison, and they were randomized within each relevant comparison with use of a partial factorial design to ensure balance of allocation within and across comparisons.

Surgical Procedures

Within the randomized comparisons, all prostheses had suitable alternative designs. Surgeons followed their standard practice—i.e., the technique that they utilized did not require any modification for the purposes of the trial, and the outcomes were thus not influenced by a so-called learning-curve effect. We did not influence surgeons regarding whether they should utilize cruciate-retaining or substituting implants. All other aspects of care, such as prophylaxis against deep vein thrombosis, were left to the discretion of the responsible surgeon.

Principal Outcome Measures

The principal outcome measures were functional status as measured with the Oxford Knee Score[14] (OKS), quality of life as measured with the Short Form-12[15] (SF-12) and the EuroQol-5D[16,17] (EQ-5D), and intraoperative and postoperative complications including the need for additional surgery. Secondary outcomes, including costs and cost-effectiveness, are also being assessed but are not reported here. The OKS was selected as a primary outcome measure because it had been developed specifically to measure outcomes of knee replacement and had been shown by a range of independent studies to perform very well compared with alternative instruments[18-20].

Sample Size Estimation

The size of the effect on the OKS sought in each comparison (and hence the sample size chosen) was based on the size of the difference in the OKS that seemed likely, as judged on the basis of current experience, and the size of the effect that was likely to offset any adverse effects and cost differences of the prosthetic design variable. The difference in OKS sought was 3 points for the comparisons involving the tibial metal backing and the mobile bearing, with 350 participants providing 80% statistical power and 470 participants providing 90% power to identify this difference ($p < 0.05$). The difference sought was

1.5 points for the patellar resurfacing comparison, with 1400 participants providing 80% power to detect this difference ($p < 0.05$).

Randomization

If the surgeon thought that a patient was eligible to participate in a comparison for which the surgeon had registered, fuller details of the trial were provided and the patient was asked to sign an informed consent form to participate. For the patients who joined the trial, the relevant aspect(s) of the replacement were chosen prior to the surgery by means of random allocation. An automated centralized telephone randomization service was called and, after basic identification had been given over the telephone, the patient was allocated to the relevant comparison or combination of comparisons. The randomization was stratified by surgeon, with minimization (randomization balanced with respect to specified variables) according to the patient's age (less than sixty years, sixty to seventy-nine years, or eighty years or more), sex (male or female), and site of disease (one knee, both knees, or general arthritis).

Data Collection

Data were collected prospectively on standard forms to record preoperative, operative, and postoperative information. Data describing functional status and quality of life were collected directly from questionnaires sent by mail to the participants. Follow-up questionnaires were completed at approximately three months, one year, and two years after the operation. One reminder was sent if necessary, and, if the questionnaire was still not returned, this was followed by a telephone-call reminder, with the patient then offered the option of completing the questionnaire over the telephone. The questionnaire included the OKS[14], the SF-12[15], the EQ-5D[16,17], and questions about any additional hospital admissions and surgery.

Statistical Analysis

The three comparisons were analyzed as separate trials. Data were analyzed on the basis of the procedure allocation irrespective of the method of replacement that was actually used (intention-to-treat principle). The functional status and quality-of-life outcomes within each trial comparison were compared by using analysis of covariance that adjusted for baseline scores and the minimization factors. Readmission rates within each trial were analyzed with use of logistic regression analysis. The Mann-Whitney U test was used to compare operative times between the trials, and the chi-square test was used to compare binary outcomes (grade of surgeon) between the trials. Descriptive statistics are presented when appropriate, and effect sizes are presented with the associated 95% confidence intervals estimated with robust standard errors to account for potential surgeon effects.

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Results

Participant Flow and Recruitment

From July 1999 to January 2003, 4070 potentially eligible patients were identified and 2374 (58%) gave their consent and were randomized. The main reasons for nonrandomization were the patient's refusal to take part in the study (546; 32%), the surgeon not wanting the patient to be randomized (462; 27%), a missed opportunity to recruit a scheduled patient (351; 21%), cancellation or deferral of the surgery or nonattendance on the part of the patient (146; 9%), ineligibility of the patient (eighty-four; 5%), the surgeon undertaking the procedure not being registered to participate in the trial (thirty-eight; 2%), unavailability of necessary equipment (twenty-four; 1%), and unknown reasons (forty-five; 3%). Twenty-two patients were subsequently found to have been randomized in error: fourteen were randomized twice, three were not eligible, three were treated by surgeons who were not registered to participate in the comparison, and two were excluded for other reasons. This left 2352 patients formally in the trial: 409 were included in the comparison assessing the metal backing; 1715, in the comparison assessing the patellar resurfacing; and 539, in the comparison assessing the mobile bearing. Background information for the CONSORT statement can be found in Figure 1.

Baseline Data

A table in the Appendix provides a description of the groups at the time of entry into the trial. The overall mean patient age (and standard deviation) at the time of the index arthroplasty was 70 ± 8 years (range, twenty-two to ninety-three years), 43.7% (1014 of 2318) were men, and the mean body mass index was 29.7 kg/m^2. Within the randomized comparisons, demographic and clinical data were well balanced at baseline although there were small differences across the three comparisons; participants recruited into the patellar resurfacing group tended to be healthier as judged by their American Society of Anesthesiologists (ASA) grade[21] ($p = 0.004$).

Management and Operation Details (see Appendix)

The majority of the subjects (83.1%; 1927 of 2318) underwent the procedure as planned. Intraoperative complications were observed in only a small percentage of the patients (2.7%; fifty-nine of 2201), and the operative procedure caused problems in few patients (1.2%; twenty-seven of 2201). Overall, there were no differences between the randomized groups in these respects. The median operative time in the group allocated to the comparison of the metal and non-metal-backed com-

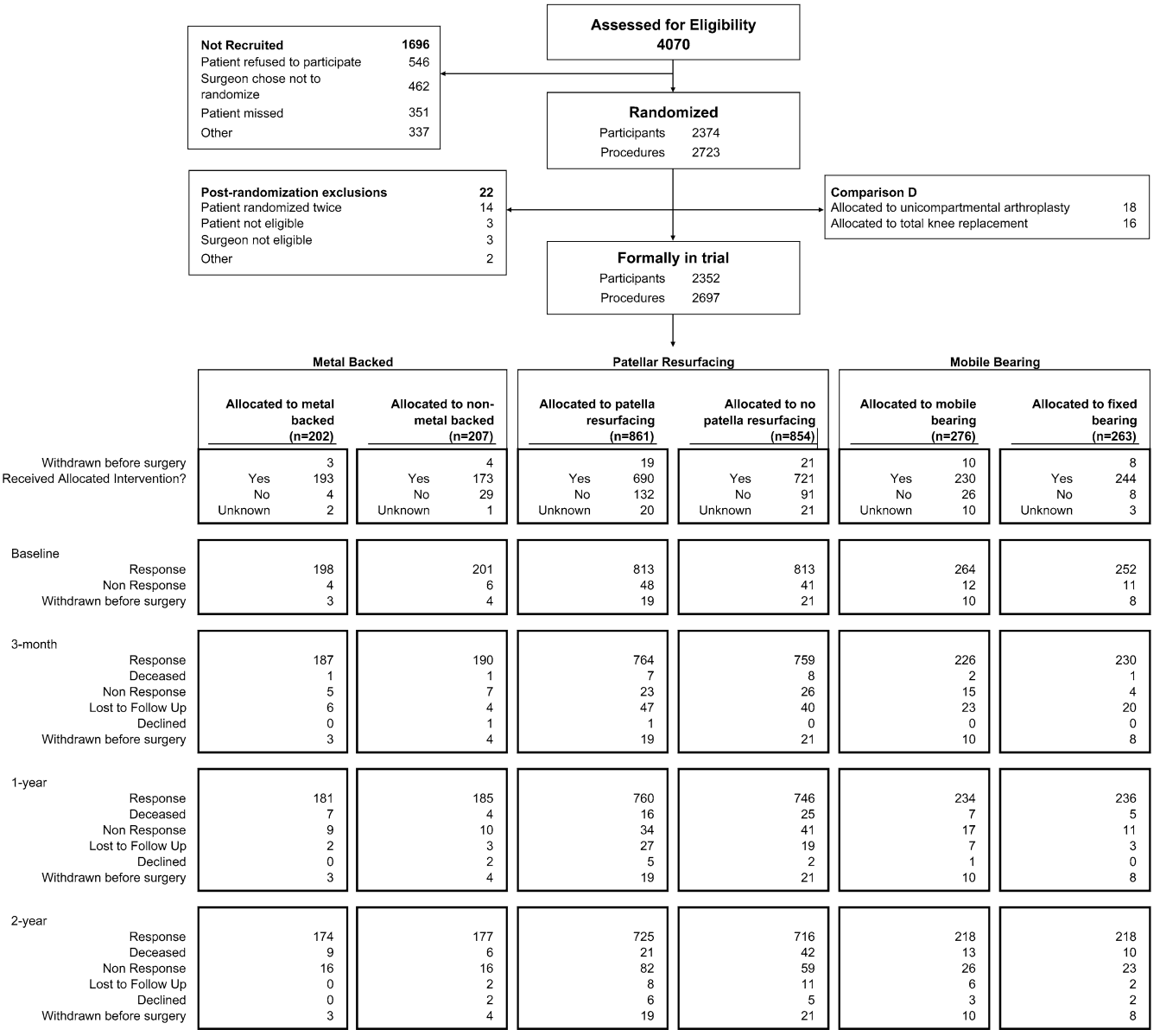

Fig. 1
CONSORT flowchart.

ponents was significantly lower than that in the other two comparison groups ($p < 0.001$), but there was no evidence of within-group differences. There was evidence that the group in which the metal and non-metal-backed components were compared was more likely than the other two comparison groups to have been operated on by a fully trained specialist orthopaedic surgeon (holding a certificate of completion of specialist surgical training in orthopaedics or the equivalent in the United Kingdom) ($p < 0.001$). Whether the surgeon was fully trained or still in supervised training did not differ within each trial comparison. Lateral patellar retinacular release was performed most commonly in the patellar resurfacing group (17.1%; 136) and least commonly in the group treated with a non-metal-backed component (10.2%; twenty).

In-Hospital Care and Short-Term Complications (see Appendix)

Postoperative complications were reported in 14.9% (328) of 2207 patients; however, specific problems such as wound infection, septicemia, deep vein thrombosis or pulmonary embolism, cerebrovascular accident, and myocardial infarction were all rare. Overall, 1.8% (forty) of 2206 participants had additional knee surgery. Four had knee dislocation. One participant allocated to be treated with both patellar resurfacing and a fixed-bearing prosthesis, but who actually received a mobile-bearing prosthesis, required closed reduction of the joint because of dislocation of the rotating insert four days after the initial operation. The participant had another dislocation two weeks later and was readmitted for revision of the

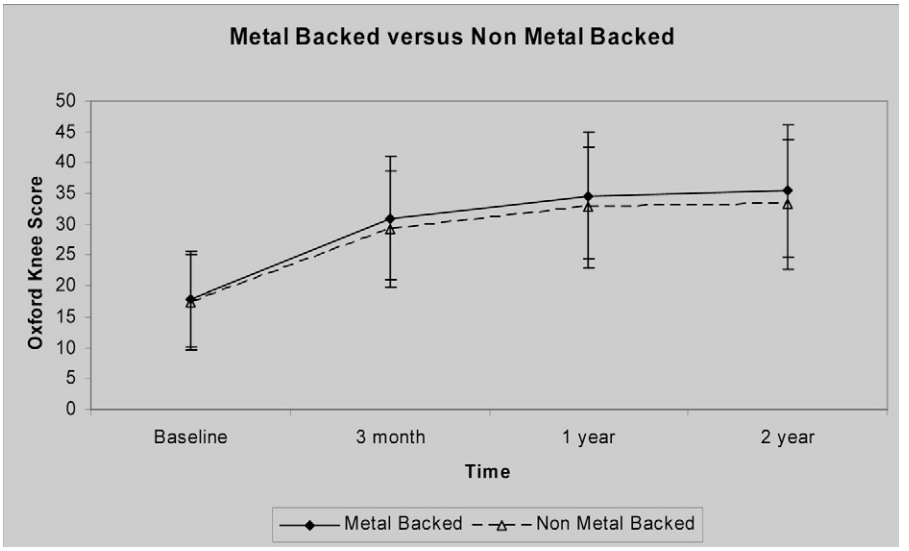

Fig. 2

Oxford Knee Scores (OKS) for the group allocated to receive a metal-backed component compared with those for the group allocated to receive a non-metal-backed component. The bars represent one standard deviation.

spacer and femoral component. One participant allocated to the patellar resurfacing group had a subluxation of the bearing and required a reoperation for replacement of the platform insert. The remaining two participants who had dislocation (one allocated to both the no-patellar-resurfacing group and the mobile-bearing group and the other allocated to the no-patellar-resurfacing group) required manipulation under anesthesia. Six participants died in the immediate postoperative period: two died from a pulmonary embolism; one, from a myocardial infarction; one, from ischemic heart disease; one, from pneumonia; and one, from a cerebrovascular accident. Overall, 95.2% (2101) of 2207 participants were discharged directly to their home. The median length of the hospital stay was nine days. There were no differences between the randomized groups with regard to any of the above factors.

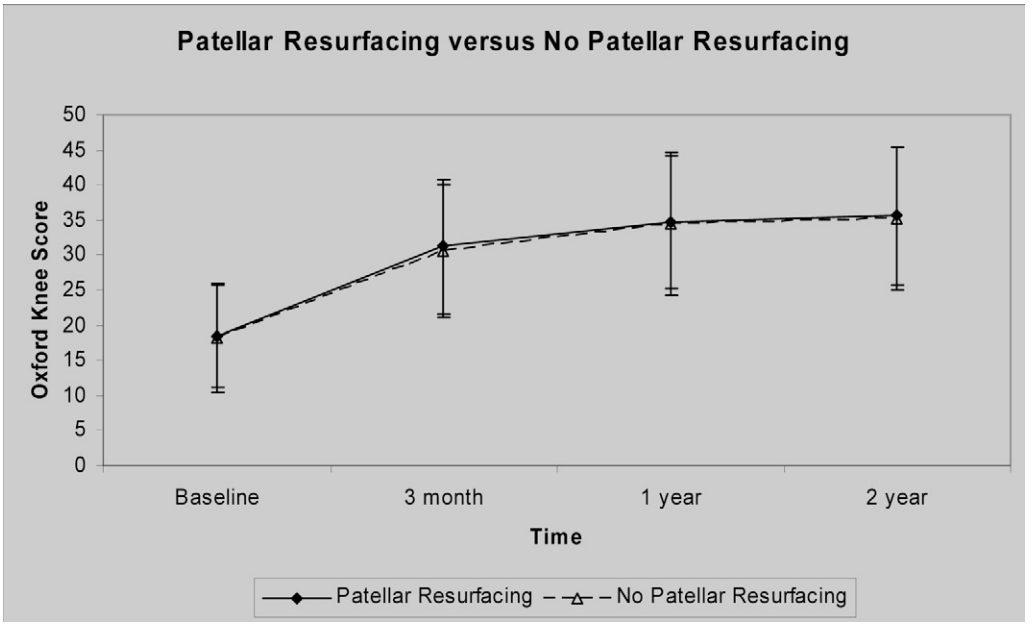

Fig. 3

Oxford Knee Scores (OKS) for the group allocated to receive patellar resurfacing compared with those for the group allocated to receive no patellar resurfacing. The bars represent one standard deviation.

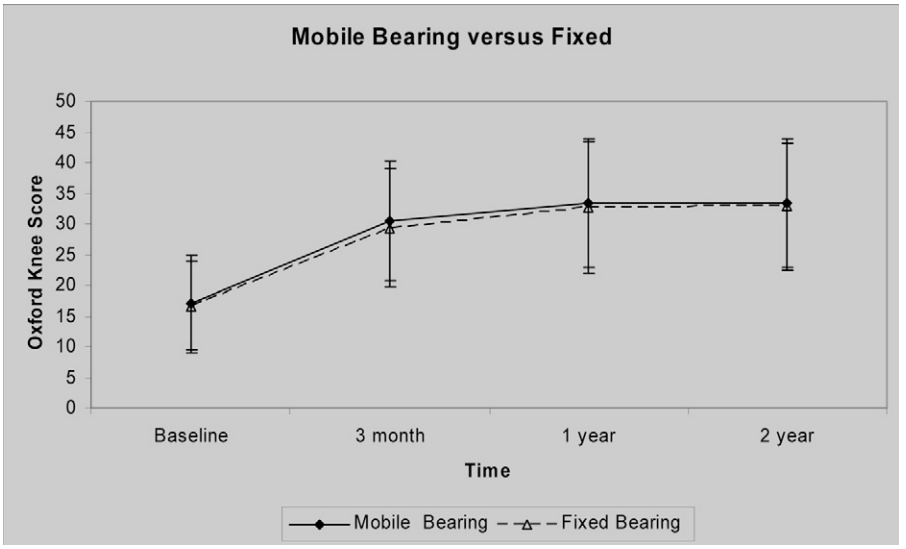

Fig. 4

Oxford Knee Scores (OKS) for the group allocated to receive a mobile bearing compared with those for the group allocated to receive a fixed bearing. The bars represent one standard deviation.

Patient-Assessed Outcomes (see Appendix)

Functional status and quality-of-life scores were low at baseline and improved markedly across all trial groups following the knee replacement. The mean overall OKS was 18.0 points at baseline, 30.5 points at three months, 34.2 points at one year, and 34.8 points at two years. Thus, most of the change was observed by three months after the surgery, although additional small improvements were observed at one and two years (Figs. 2, 3, and 4). Within the individual trial comparisons, there was no evidence of differences in functional status or quality-of-life measures between the randomized groups at two years.

Complications After Surgery (see Appendix)

Overall, 9.9% (230) of 2318 patients were readmitted to the hospital for reasons related to the surgery on the knee and 5.8% (135) of 2318 had additional knee surgery. Three participants had an above-the-knee amputation: two within two months after the initial operation and one, three months after the surgery. One of the amputations (in a participant allocated to receive a non-metal-backed component) was due to a knee infection that developed after an open repair of the quadriceps tendon following a fall, another (in a participant allocated to no patellar resurfacing) was due to vascular insufficiency one month after the initial operation, and the third (in a participant allocated to receive a metal-backed component) was due to diabetic ischemia. Fifteen participants underwent staged revisions due to infection. Fifteen participants had single-stage revision. Seven participants who had been allocated to have no patellar resurfacing subsequently had the patella resurfaced. The principal reasons for readmission related to the surgery were suspected deep vein thrombosis or pulmonary embolism and infection such as pneumonia or urinary tract infection. Within each trial comparison, there were no significant differences in the number of patients requiring readmission: the odds ratio was 1.50 (95% confidence interval, 0.84 to 2.70) for the comparison of metal and non-metal-backed components, 1.08 (95% confidence interval, 0.87 to 1.35) for the comparison of patellar resurfacing and no patellar resurfacing, and 0.83 (95% confidence interval, 0.52 to 1.33) for the comparison of mobile and fixed bearings.

Discussion

This multicenter trial of patients treated in the United Kingdom showed that, as a group, patients who had undergone primary total knee replacement had substantial pain relief and improvement in function, as assessed with condition-specific measures designed to evaluate the results of total knee replacement and with more generic measures of health-related quality of life. Benefits were observed by three months after the surgery, but there were additional, small improvements in pain, physical function, and health-related quality-of-life scores up to two years after the surgery. No significant differences in outcome were observed within any of the three randomized comparisons. This is what might be expected, at this stage, in the comparison assessing metal backing and that assessing the rotating platform, as those design features were developed in an effort to obtain a longer-term benefit. In contrast, patellar resurfacing might have been expected to reduce pain and improve early function, but that was not observed. The lack of a difference in improvement in scores irrespective of whether the patella was resurfaced or not is consistent with the findings of Pakos et al.[6]. The rate of knee-related readmissions in their study was perhaps higher than might have been expected, although the most common reason for readmission was manipulation with the patient under anesthesia.

The current trial was pragmatic in design; such trials are unusual in orthopaedic surgery but widely used to evaluate other health-care issues. The aim of pragmatic trials is to evaluate interventions in a usual-care context in terms of outcomes that are most important to patients. Entry criteria are relatively flexible so that a range of patients are recruited, enhancing generalizability. The trial involved a large number of orthopaedic surgeons in the United Kingdom and hence reflects a wide range of practice in the United Kingdom, geographically and in terms of types of centers and details of technique and strategy. Surgeons chose the comparisons into which their patients could be recruited. For each comparison, randomization was stratified by surgeon to ensure a balance between the trial groups in this respect. We focused on outcomes that are of concern to patients and used validated measures, independent of surgeon opinion. Each comparison included several hundred participants, so the estimates of differences were relatively precise. With respect to the OKS, in comparisons (B) and (C), the upper bound of the estimated confidence intervals provided evidence against the prespecified minimum clinical differences. In the smallest comparison (A), the confidence interval is slightly wider but also indicated the prespecified minimum difference unlikely. From this, we can conclude that there was no evidence of superiority of metal-backed tibial components over non-metal-backed tibial components, patellar resurfacing over not resurfacing, or mobile-bearing over fixed-bearing designs at two years. These are short-term results, however, and superiority over the longer term cannot be ruled out. It should also be recognized that not every participant received the prosthesis that had been allocated to him or her and the prosthetic types used in each of the groups may have subtle design variations; secondary subgroup analyses are planned to explore this possibility.

The KAT study demonstrated that large simple-in-design trials across a range of practices in orthopaedics are feasible. However, the study also demonstrated the need for individual surgeons to be clinically uncertain about the appropriate treatment choice.

The short-term results in the three trials are broadly consistent with evidence from other studies[3,10]. At this stage, it is not possible to suggest to health-care providers that one particular design or variation in design has clinical advantages that warrant limiting surgeon choice. It is generally accepted that variations in the outcomes of different knee prostheses tend to emerge with longer-term follow-up, and hence recommendations based on generic aspects of design may well be possible in the future.

The patients in this study will continue to be followed annually for at least ten years. While the main comparisons at the time of follow-up will be between the generic variants of total knee replacement, possible effects of subtle difference in design between manufacturers and between surgeons will also be investigated. Data from the KAT study will also be used to estimate the costs of each intervention and hence the relative cost-effectiveness within each randomized comparison.

Appendix

(eA) Data tables are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD/DVD (call our subscription department, at 781-449-9780, to order the CD or DVD). ■

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