The Knee Arthroplasty Trial (KAT) Design Features, Baseline Characteristics, and Two-Year Functional Outcomes After Alternative Approaches to Knee Replacement

The Kat Trial Group

ABSTRACT

Background

Continued development in total knee replacement aims at further improving quality of life and lengthening prosthetic survival. This study aimed to evaluate the effects of the following design features on the function and survival of the implant: metal backing of the tibial component; patella resurfacing; and a mobile bearing between tibia and femur.

Methods

A pragmatic multicenter randomized controlled trial involving 116 surgeons in 34 United Kingdom centers, allowed randomization to more than one comparison; 2352 participants were randomly allocated to metal backing of the tibial component or not (409); patella resurfacing or not (1715); and, or, mobile bearing or not (539). The primary outcome measures were the Oxford Knee Score (OKS), Short Form-12, EuroQual-5D and need for further surgery. The results are reported up to two-year follow-up.

Results

Functional status and quality of life scores were low at baseline but improved markedly across all trial groups following knee replacement (mean overall Oxford Knee Score: 17.98 at baseline, 34.82 at 2 year). Most of the change was observed three-months after surgery. Six percent of patients had further knee surgery within two years. There was no evidence of differences in clinical, functional status or quality of life measures between randomized groups at two years.

Conclusions

Patients undergoing total knee replacement have substantial improvement. This is the first adequately powered randomized controlled trial we are aware of investigating metal backed, patella resurfacing, and mobile bearing prostheses. We found no evidence of effect of these variants on early complications or functional recovery up to two years after total knee replacement.

INTRODUCTION

Total knee arthroplasty is now a common and established surgical procedure. Long-term observational studies indicate that more than 90% of modern primary knee replacements survive from 13 to 15 years[1]. Continued developments in design are aimed at further improving quality of life and lengthening prosthetic survival.

One common variation is the design of the tibial component. There are theoretical advantages of a metal backing plate 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 plastic which in turn risks internal loading exceeding the capacity of the plastic. This may cause sub-surface shearing effects and hence breakdown of the bearing surface. Also, metal backing is more expensive and good long-term results have been reported for 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 determinable[3].

Another variation is that the patella may or may not be resurfaced. Previous small scale randomized controlled trials, non-randomized cohort studies and a systematic review have not resolved this uncertainty[4, 5, 6].

More recent designs of knee replacement have focussed on whether performance and longevity can be improved by altering the design of the bearing between the tibia and femur, to address complications of wear and loosening. Some authors[7, 8] claim

that polyethylene wear and shearing effects at the prosthesis bone interface could be reduced if there was a moving component between the tibia and the femur. At the moment, only the mobile bearing New Jersey Knee (DePuy Orthopaedics) has any 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]; in particular, so-called to spin out of the mobile component[12, 13].

The Knee Arthroplasty Trial (KAT) is a pragmatic multicenter, randomized, controlled trial 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 or not it is more effective and cost-effective to resurface the patella; and whether a mobile bearing between the tibia and femur has a better outcome than standard designs without a moving bearing. In this report we describe complications and patient-assessed functional and quality of life outcomes up to two years.

MATERIALS AND METHODS

Surgeons

The trial was approved by relevant national and local research ethics committees. Orthopaedic surgeons were eligible to take part provided they performed knee replacements routinely. Surgeons elected which comparisons to contribute to, ahead of trial participation. We recognized that surgeons would vary in the comparisons for which they would accept random allocation. One hundred and sixteen surgeons in 34 United Kingdom (UK) centers participated.

Patients

All patients under the care of a collaborating surgeon were potentially eligible for inclusion if a decision had been made to have primary total knee replacement surgery. A patient was not eligible for a trial comparison if the surgeon considered that a particular type of operation was clearly indicated for example, a patient requiring a highly constrained knee replacement to replace function of the collateral ligaments. A patient remained eligible only if the surgeon remained comfortable that there was no indication for one choice either way within the trial; for example, the surgeon would not have chosen to replace a thin or osteopenic patella.

Where possible, patients schedulled 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 into a single comparison, individuals could be recruited to more than one comparison, if clinically appropriate. The minority of participants that were included in more than one comparison were randomized within each relevant comparison using a partial factorial design ensuring balance of allocation within and across comparisons.

Surgical procedures

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

Principal outcome measures

The principal outcome measures were: functional status (Oxford Knee Score, OKS), quality of life (Short Form (SF)12 and EuroQual (EQ)5D) and intra- and postoperative complications including the need for further surgery. Secondary outcomes, including costs and cost-effectiveness, are also being assessed but are not reported here. The questionnaire included: the Oxford Knee Score[14]; the SF-12[15]; the EQ-5D[16]; [17]; and questions about any further hospital admissions and surgery. The Oxford Knee Score was selected as a primary outcome measure because it had been developed specifically to measure outcomes of knee replacement surgery and had been shown by a range of independent studies to perform very well compared to alternative possible instruments[18, 19, 20].

Sample size estimation

The size of effect on the OKS sought for each comparison (and hence the sample size chosen) was based on: the size of differences in OKS that seemed likely judged on current experience, and the size of effect that was likely to offset any adverse effects and cost differences. For the tibial metal backed and mobile bearing comparisons, this was 3 points: 350 participants provided 80% statistical power and 470 participants 90% power to identify this difference (P<0.05). For the patellar resurfacing comparison, the difference sought was 1.5 points: 1400 participants provided 80% power (P<0.05).

Randomization

If the surgeon thought a patient was eligible to participate in a comparison for which the surgeon had registered, fuller details of the trial were provided and signed informed consent to participate was sought. For patients who joined the trial, the relevant aspect(s) of the replacement were chosen prior to surgery by random allocation. An automated centralized telephone randomization service was called. After basic identifying and had been given over the phone, an allocation to the relevant comparison as described above or combination of comparisons was given, stratifying by surgeon, with minimization (randomization balanced with respect to specified variables) according to the patient's age (<59, 60-79>, 80+), gender (male, female), and site of disease (single knee, both, 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 participants through postal questionnaires. Follow-up questionnaires were completed at approximately three-months, 1-year, and two-years after the operation; one reminder was sent if necessary, followed by a phone call reminder if still unreturned, with the option then offered to complete the questionnaire over the telephone. The questionnaire included: the Oxford Knee Score[14]; the SF-12[15]; the EQ-5D[16]; [17]; and questions about any further hospital admissions and surgery. The Oxford Knee Score was selected as a primary outcome measure because it had been developed specifically to measure outcomes of knee replacement surgery and had been shown by a range of independent studies to perform very well compared to alternative possible instruments[18, 19, 20].

Statistical analysis

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

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 non-randomization were: refusal to take part (546; 32%); surgeon did not want to randomize (462; 27%); scheduled patients where we missed the opportunity to recruit them (351; 21%); surgery cancelled or deferred or non attendance (146; 9%); patient not eligible (84; 5%); surgeon undertaking the procedure not registered to participate in the trial (38; 2%); necessary equipment not available (24; 1%); and reasons unknown (45; 3%). Twenty-two patients were subsequently found to have been randomized in error: 14 were randomized twice; five were not eligible; and three, were surgeons not registered to participate in the comparison. This left 2352 patients formally in the trial: 409 in the comparison metal backing, 1715 in patellar resurfacing, and 539 in mobile bearing. Background information for the CONSORT statement can be found in Figure 1.

Baseline data

Table 1 provides a description of the groups at trial entry. The overall mean age was 70 years (SD 8 years, range 22 to 93), 43.7% (1014 of 318) were men, and the mean Body Mass Index was 29.7. Within randomized comparisons, demographic and clinical data were well balanced at baseline although there were small differences across the three comparisons; participants recruited to patella resurfacing tended to be healthier as judged by the ASA (p = 0.004)[21].

Management and operation details (Table 2)

The majority (83.1%; 1927 of 2318) of subjects underwent the procedure as planned. Only a small number of intraoperative complications were observed (2.7%; 59 of 2201 participants overall) and few problems were caused by the operative procedure (1.2%; 27 of 2201). Overall, there were no differences between randomized groups in these respects. Median operation times were significantly lower in the metal versus non-metal comparison compared to the other two comparisons (p<0.001), but there was no evidence of a difference within the group comparisons. There was evidence that the operating surgeon was more likely to be a fully trained specialist orthopaedic surgeon (holds certificate of completion of specialist surgical training in orthopaedics or equivalent in the UK,) in the metal versus non-metal comparison compared to the other two comparisons (p<0.001). Whether the surgeon was fully trained or still in supervised training did not differ within each trial comparison. Lateral patella retinacular release was performed most commonly in the patella resurfacing group (17.1%) (136) and least commonly in the non-metal backed group (10.2%) (20) (Table 3).

In hospital care and short term complications (Table 3)

Postoperative complications were reported in 14.9% (328 of 2207) of patients; however, specific problems such as wound infection, septicemia, deep vein thrombosis or pulmonary embolism, cerebral vascular accident, and myocardial infarction were all rare. Overall, 1.8% (40 of 2206) of participants had further knee surgery. Four had knee dislocations. One participant allocated to both patella resurfacing and fixed bearing, but who actually received a mobile bearing prosthesis, subsequently required closed reduction of the joint for dislocation of the rotating insert four days after the initial operation. The participant had a further dislocation

two weeks later and was re-admitted for revision of the spacer and femoral component. One participant allocated to patella resurfacing had a subluxation of the bearing and required reoperation for replacement of the platform insert and the remaining two participants who had dislocations required manipulation under anaesthetic (one allocated to both no patella resurfacing and mobile bearing and the other allocated to no patella resurfacing). Six participants died in the immediate postoperative period: two from a pulmonary embolism; one from a myocardial infarction; one from ischaemic heart disease; one from pneumonia; and one from a cerebrovascular accident. Overall, 95.2% (2101 of 2207) participants were discharged home directly. The length of hospital stay was a median of 9 days. There were no differences between the randomized groups in any of the above described areas.

Patient assessed outcome (Table 4)

Functional status and quality of life scores were low at baseline but improved markedly across all trial groups following knee replacement (mean overall OKS score: 18.0 at baseline, 30.5 at 3 months, 34.2 at 1 year, 34.82 at 2-years). Thus, most of the change was observed by three months after surgery (although further small improvements were observed at 1-year and 2-years) (Figures 2, 3 and 4). Within the individual trial comparisons, there was no evidence of differences in functional status or quality of life measures between randomized groups at 2-years (Table 4).

Complications after surgery (Table 5)

Overall, 9.9% (230 of 2318) were re-admitted for reasons related to the surgery on the knee and 5.8% (135 of 2318) went on to have further knee surgery. Three participants had above the knee amputations: two within two months of the initial operation and one three-months after surgery. In one participant (allocated to non-metal backed)

the knee became infected after an open repair of the quadriceps tendons following a fall, another was due to vascular insufficiency one month after the initial operation (allocated to no patella resurfacing), and a third was due to diabetic ischemia (allocated to metal backed). Fifteen participants have undergone staged revisions due to infection. Fifteen participants have had single stage revisions. Seven participants allocated to have no patella resurfacing have subsequently had their patellae resurfaced. The principal reasons for readmission related to 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 statistically significant differences in the number of patients requiring a readmission: for metal versus non metal backed odds ratio 1.50 (95% CI 0.84 to 2.70), for patella resurfacing versus no patella resurfacing odds ratio 1.08 (95% CI 0.87 to 1.35) and for mobile versus fixed bearing odds ratio 0.83 (95% CI 0.52 to 1.33).

DISCUSSION

This multicenter United Kingdom (UK) -based trial has shown that as a group, patients undergoing primary TKR had substantial improvements in pain and function, whether assessed by condition-specific measures designed to evaluate TKR or by more generic measures of health-related quality of life. Benefits were observed by three-months after surgery, but there were further small improvements in pain, physical function and health-related quality of life subsequently up to two-years after surgery. No statistically significant differences in outcome were observed within any of the three randomized comparisons. This is as might be expected for the metal backing and rotating platform studies at this stage as alterations in these designs are with a view to longer-term benefit. In contrast, patella resurfacing might be expected to reduce pain and improve early function, but this was not observed. The lack of difference in improvement in scores irrespective of whether the patella was replaced 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 this was most commonly for manipulation under anaesthesia.

The trial was pragmatic in design, which is unusual in orthopaedic surgery but widely used to evaluate other health care. Pragmatic trials aim 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 is recruited enhancing generalisability. The trial involved a large number of UK orthopaedic surgeons, and hence reflects a wide range of practice in the UK, geographically and in terms of types of center and details of technique and strategy. Surgeons elected which of the comparisons to recruit to. For each comparison, randomization was stratified by surgeon to ensure balance between the trial groups in this respect.

Outcomes focused on matters of concern to patients, using validated measures, independent of surgeon opinion. Each comparison included several hundred participants, such that the estimates of differences were relatively precise. With respect to the OKS, the upper confidence interval for any of the one-year comparisons was 2.95 points, The upper bound of the confidence interval around the estimate effect of the interventions excludes the pre specified effect that was deemed clinically important in all comparisons, so we can conclude that at one year there is no evidence of superiority of metal-backed over non-, nor mobile bearing over fixed as defined by three points on the OKS, and in the resurfacing comparison no evidence of superiority of resurfacing over not resurfacing as defined by 1.5 points on the OKS. These are short term results though, and this does not rule out superiority over longer term.

It should also be recognized that not every participant received the prosthesis allocated, and the prosthetic types in each of the groups may have subtle design variations; secondary sub-group analyses are planned to explore this possibility.

The KAT study has 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 trials. At this stage it is not possible to suggest to healthcare providers that one particular design or variation in design has clinical advantages that warrant limiting surgeon choice. It is generally accepted that variations in 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.

Annual follow-up is in place and will continue for at least ten years. While the main comparisons at 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 be investigated. Data from the KAT study will also be used to estimate the costs of each intervention and hence relative cost-effectiveness within each randomized comparison.

REFERENCES

1. Ranawat CS, Flynn WF Jr, Saddler S, Hansraj KK, Maynard MJ (1993). Long-tern results of total condylar knee arthroplasty. A 15-year survivorship study. Clinical Orthopaedics 1993; 290: 94-102.

2. Vince KG, Insall JN, Kelly MA (1989). The total condylar prosthesis. 10- to 1two-year results of a cemented knee replacement. J Bone Joint Surg (Br) 1989; 71(5): 793-7.

3. Najibi S, Lorio R, Surdum JW, Whang W, Appleby D, Healy WL (2003). All-polyethylene and metal-backed tibial components in total arthroplasty: a matched pair analysis of functional outcome. J Arthroplasty 2003; 18(7 Suppl 1):9-15.

4. Wood DJ, Smith AJ, Collopy D, White B, Brankov B, Bulsara MK (2002). Patellar resurfacing in total knee arthroplasty : a prospective trial, J Bone Joint Surg Arm 2002 ; 84-A(2) :187-93.

5. Ozturk A, Bilgen S, Atici T, Ozer O, Bilgen OF (2006). The evaluation of patients undergoing total knee arthroplasty without patellar resurfacing, Acta Orthop Traumatol Turc, 2006; 40(1):29-37.

6. Pakos EE, Nitzana EE, Trikalinos TA (2005). Patellar resurfacing in total knee arthroplasty, A meta-analysis, J Bone Joint Surg Am 2005: 87(7): 1438-45.

7. Buechel MD, Pappas MJ (1990). Long-term survivorship analysis of cruciate-sparing versus cruciate-sacrificing knee prostheses using meniscal bearings. Clinical Orthopaedics 1990; 260: 162-9.

8. O'Connor JJ, Goodfellow JW (1996). Theory and practice of meniscal knee replacement: designing against wear. Proc Inst Mech Eng H 1996; 210(3): 217-22.

9. Buechel MD, Pappas MJ (1989). New Jersey low contact stress knee replacement system. Ten year evaluation of meniscal bearings. Orthop Clin North Am 1989; 20(2): 147-77.

10. Jacobs W, Anderson P, Limbeek J, Wymenga A (2004). Mobile bearing vs fixed bearing prostheses for total knee arthroplasty postoperative functional status in patients with osteoarthritis and rheumatoid arthritis (2004). Cochrane Database Syst Rev 2004 :(2):CD003130.

11. Weaver JK, Derkash RS, Greenwald AS (1993). Difficulties with bearing dislocation and breakage using movable bearing total knee replacement system. Clinical Orthopaedics 1993; 290: 244-52.

12. Stiehl JB, Hamelynck KJ, Voorhorst PE. Int Orthop. 2006 Jun;30(3):190-9. Epub 2006 Mar 18

13. Huang CH, Ma HM, Lee YM, Ho FY. : Clin Orthop Relat Res. 2003 Nov;(416):265-70.

14. Dawson J, Fitzpatrick R, Murray D, Carr A. Development and validation of a questionnaire to assess patients' perceptions in relation to total knee replacement surgery. J Bone Joint Surg 1998: 80-B: 63-9.

15. Ware J, Kosinski M, Keller S. A 12-item short-form health survey. Med Care 1996; 34: 20-33.

16. The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. Health Policy 1990; 16(3): 199-208

17. Dolan P, Gudex C, Kind P, Williams A. The time trade-off method: results from a general population study. Health Economics 1996; 5(2): 141-54.

18. Dunbar MJ, Robertsson O, Ryd L, and Lidgren L. Appropriate questionnaires for knee arthroplasty. Results of survey of 3600 patients from the Swedish Knee Arthroplasty Registry. J Bone Joint Surg (Br) 2001; 83: 339–344.

19. Liow RY, Walker K, Wajid MA, Bedi G, and Lennox CM, Functional rating for knee arthroplasty: comparison of three scoring systems. Orthopedics 2003; 26: 143–149.

20. Garratt AM, Brealey S, and Gillespie WJ, DAMASK Trial Team. Patient-assessed health instruments for the knee: a structured review. Rheumatology 2004; 43: 1414–1423.

21. Cullen, D.J. et al. (1994) ASA Physical Status and age predict morbidity after three surgical procedures. Ann. Surg. 220, 3-9.

Formatted: English (U.K.)

Figure Legend

Figure 1 CONSORT Flowchart

Figure 2 Oxford Knee Score Metal Backed versus Non Metal Backed

Figure 3 Oxford Knee Score Patellar Resurfacing versus No Patellar Resurfacing

Figure 4 Oxford Knee Score Mobile versus Fixed Bearing