

A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT)

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Scientific summary

The effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT)

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Scientific summary

Background

In the late 1990s, new developments in knee replacement were identified as a priority for research within the NHS. The newer forms of arthroplasty were more expensive and information was needed on their safety and cost-effectiveness. The Knee Arthroplasty Trial (KAT) was commissioned by the Health Technology Assessment (HTA) programme to address this need.

Objectives

The trial examined four key questions relating to knee replacement:

1. *Should the patella be resurfaced or not?* There is considerable variability in the use of resurfacing in the UK, with many surgeons routinely resurfacing the patella and many not. There is no clear evidence as to which approach is best.
2. *Should mobile or fixed bearings be routinely used?* Mobile bearings have the theoretical advantages of decreased wear and improved kinematics, which should result in an improvement in functional outcome and a decrease in the long-term failure rate. The main theoretical disadvantage is instability and dislocation of the bearing. It is not clear whether mobile bearings have clinical advantages or disadvantages.
3. *Should the tibial component be all polyethylene or have a polyethylene bearing supported by a metal backing?* Previous randomised controlled trials (RCTs) and meta-analyses of these trials found no difference in clinical outcome between the two types of tibial component. As all-polyethylene components are substantially cheaper than metal-backed components, the general recommendation is that all-polyethylene devices should be used in the elderly to reduce costs.
4. *Should unicompartmental or total knee replacement generally be used?* There is some evidence to suggest that unicompartmental replacement is associated with improved functional results, fewer complications, a faster recovery and lower costs than total replacements, but also a higher failure rate. It is not clear whether the advantages outweigh the disadvantages.

Methods

The trial was a partial factorial, pragmatic, multicentre RCT designed to assess clinical outcomes, complications and cost-effectiveness. The primary outcome measure was functional status as measured by the Oxford Knee Score (OKS). Other outcome measures were as follows: quality of life as measured by the Short Form 12 (SF-12) and EuroQoL 5D (EQ-5D); intraoperative and postoperative complications including the need for additional surgery; cost; and cost-effectiveness. Participants were followed up for a median of 10 years. A trial-based cost-utility analysis was conducted to evaluate whether patellar resurfacing, mobile bearings and all-polyethylene tibial components are cost-effective from the costing perspective of the NHS and the health perspective of the patients undergoing knee replacement. The economic evaluation took a 10-year time horizon, with future costs and quality-adjusted life-years (QALYs) discounted at 3.5% per annum.

Results

In total, 116 surgeons in 34 UK centres participated in the trial. From July 1999 to January 2003, 4070 potentially eligible participants were identified and 2374 (58%) gave their consent and were randomised. Of these, 22 participants were subsequently found to have been randomised in error, which left 2352 participants formally in the trial: 1715 in the comparison assessing the patellar resurfacing; 539 in the comparison assessing the mobile bearing; 409 in the comparison assessing the metal backing; and 34 in the comparison assessing total versus unicompartmental knee replacement. There were 345 participants randomised to more than one comparison.

We found no significant difference in clinical outcome, in terms of pain and function, complications, readmission or reoperations, between participants with and without patellar resurfacing. However, there was a non-significant trend towards improved quality of life [mean QALY difference 0.187; 95% confidence interval (CI) -0.025 to 0.399 ; $p = 0.08$] and decreased costs (mean cost difference $-\pounds 104$; 95% CI $-\pounds 630$ to $\pounds 423$; $p = 0.70$) associated with resurfacing, suggesting that we can be more than 95% confident that patellar resurfacing is cost-effective compared with no resurfacing at a threshold of $\pounds 7250$ per QALY gained. Of the non-resurfaced cases, 2.8% had late resurfacing, which was of little benefit. This late resurfacing was done in the first 5 years. Of the resurfaced group, 1% had reoperations for complications of the resurfacing during the second 5 years. Our findings were independent of whether or not the trochlear design was anatomical.

We found no conclusive evidence of any risks or benefits associated with mobile bearings in terms of postoperative functional status, quality of life, reoperation and revision rates or cost-effectiveness. There was a 2% incidence of instability or bearing dislocation in the mobile bearing group and none in the fixed bearing group. Although mobile bearings were more expensive for the hospital than fixed bearings, these initial costs were partly offset by decreases in the cost of subsequent follow-up. Overall, mobile bearings increased costs by $\pounds 85$ (95% CI $-\pounds 911$ to $\pounds 1081$; $p = 0.87$) and QALYs by 0.051 (95% CI -0.333 to 0.435 ; $p = 0.79$) and had a 59% chance of being cost-effective.

We found that the functional results with a metal-backed tibia were better than with an all-polyethylene tibia. This difference was statistically significant with the EQ-5D and SF-12 but not with the OKS. The complication, reoperation and revision rates were not significantly different, although the major reoperation rate for the all-polyethylene tibia (3%) was more than twice that for the metal-backed tibia (1%). The group randomised to all-polyethylene tibial components accrued lower costs (mean difference $-\pounds 10$; 95% CI $-\pounds 872$ to $\pounds 851$; $p = 0.98$) and fewer QALYs (mean difference -0.293 ; 95% CI -0.706 to 0.119 ; $p = 0.16$) than those randomised to metal backing. The economic analysis showed that the metal-backed tibia was cost-effective compared with the all-polyethylene tibia, costing $\pounds 35$ per QALY gained for the population as a whole and being particularly cost-effective in those aged ≥ 70 years (95% probability).

Between designing and recruiting for KAT, the technique for unicompartmental replacement changed, as surgeons started using a minimally invasive approach. As a result, surgeons were keen to learn the new technique rather than randomise participants. Owing to the poor recruitment rate, recruitment to this comparison in KAT was stopped.

Conclusions

This trial is the largest RCT of knee replacement ever conducted and provides a wealth of data on the management and outcomes following knee surgery. It has achieved very high levels of follow-up, with a median of 10 years, and has important implications for clinical practice. The success of KAT has demonstrated that large pragmatic trials with economic evaluations are possible in orthopaedics and provides an exemplar for the conduct of such studies.

Evidence from KAT is supportive of routine resurfacing of the patella, whatever the design of the trochlea. If a patient has not undergone primary patellar resurfacing, the findings do not support late resurfacing, as this is of little, if any, benefit.

We found no evidence of a difference between mobile and fixed bearings in function and quality of life. Moreover, there was no significant difference in complication, reoperation or revision rates, and there was substantial uncertainty around estimated cost-effectiveness. We did, however, identify two disadvantages of mobile bearings that could encourage surgeons to use fixed-bearing devices. First, there was a 2% incidence of instability or bearing dislocation in the mobile bearing group. Second, although there was no significant difference in overall costs in the long term, there was a short-term saving for the hospital for fixed bearings, as they are appreciably cheaper.

The findings from KAT strongly suggest that the metal-backed tibias are beneficial and cost-effective. We believe that the previous recommendation that all-polyethylene tibias should be used to save money in the elderly is a false economy, as they are not only more costly in the elderly but also less effective.

Although recruitment to the comparison of unicompartmental knee replacement versus total knee replacement was stopped in KAT, the experience gained from KAT informed a new study, known as TOPKAT (Total Or Partial Knee Arthroplasty Trial). The TOPKAT study, funded by the National Institute for Health Research HTA board, finished its recruitment in September 2013 (HTA project reference number 08/14/08).

With the increasing longevity of knee replacement patients, longer follow-up is required to assess the long-term sustainability of these findings. Longer follow-up will also help to answer some important outstanding questions. In the patellar resurfacing trial there was, with increasing follow-up, an increasing number of reoperations for complications of resurfacing and a decreasing number of late resurfacings. If this trend continues, the data may no longer support routinely resurfacing the patella. In the mobile bearing trial, there was a trend towards increased cost-effectiveness of mobile bearings in patients aged < 70 years and fixed bearings in patients aged \geq 70 years. Further follow-up is required to obtain clearer evidence to inform the use of mobile or fixed bearings. In the metal-backing trial, we found a trend towards an increased revision rate with all-polyethylene tibias. If this continues, the evidence will provide a strong clinical reason to avoid all-polyethylene tibias. We found some evidence of potential interactions between the various different randomisations. Further follow-up is required to determine if these are important.

We believe the 10-year KAT data set is the best knee replacement data set available, as it includes information about complications, revisions, patient-reported outcomes and health economics. Further work is needed to analyse the data set in detail to answer many of the current key issues in knee replacement surgery not related to the randomisations.

Trial registration

This trial is registered as ISRCTN45837371.

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