Assessing clinical and cost effectiveness of total versus partial knee replacement (TOPKAT): 10-year follow-up of a multicentre, randomised controlled trial

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Summary

Background The Total or Partial Knee Arthroplasty Trial (TOPKAT) aimed to evaluate the difference between total knee replacement (TKR) and partial (unicompartmental) replacement (PKR) for treatment of late-stage medial compartment knee osteoarthritis. As longevity is a key issue for joint replacement, extended follow-up periods are required to fully evaluate the long-term efficacy. In this analysis, we report the 10-year follow-up of the TOPKAT trial.

Methods TOPKAT was a multicentre, randomised, pragmatic comparative effectiveness trial including an expertise component. Patients with medial compartment knee osteoarthritis were enrolled from 27 UK National Health Service (NHS) hospitals and randomly assigned (1:1) to receive PKR or TKR by surgeons who were either expert in and willing to perform both surgeries or by a surgeon with particular expertise in the allocated procedure. Neither surgeons, patients, nor follow-up assessors were masked to allocation, but the implant type was not highlighted at any stage. The primary long-term endpoint was the Oxford Knee Score (OKS) in the intention-to-treat population at 10 years. Cost effectiveness was also assessed. Individuals with relevant lived experience were involved in the study design. This trial is registered with ISRCTN03013488 and ClinicalTrials.gov, NCT01352247, and is complete.

Findings Between Jan 18, 2010, and Sept 30, 2013, of 962 patients assessed for eligibility, 528 patients (306 [58%] male, 222 [42%] female, mean age 65 years [SD 8·7]) were randomly assigned (PKR n=264; TKR n=264). Follow-up primary outcome response rate for eligible patients (excluding those who had died or withdrew) at 10 years was 326 (73%) of 444. Both operations provided good outcome. The between-group estimates ruled out any individually clinically meaningful differences in mean OKS scores (mean difference 0·27, 95% CI −1·59 to 2·13) or cumulatively over 10 years in the area under the curve analysis (mean difference 0·45, 95% CI −0·98 to 1·88). At 10 years, by treatment received, complications were 53 (22%) of 245 for PKR and 74 (27%) of 270 for TKR, reoperations (including revision) were 21 (9%) for PKR and 23 (9%) for TKR, and revision rates were 15 (6%) for PKR and 11 (4%) for TKR. By treatment allocated, for PKR and TKR respectively, complication occurred in 55 (21%) of 263 and 72 (29%) of 252, reoperations in 20 (8%) and 24 (10%), with revisions in 13 (5%) and 13 (5%) patients. PKR was more cost-effective compared with TKR, being associated with increased health benefits (mean difference in quality-adjusted life years of 0·322, 95% CI −0·069 to 0·712) and lower health-care costs (mean difference in cost −£731, 95% CI −1352 to −110).

Interpretation 10-year results comparing TKR and PKR show similar clinical outcomes, reoperation rates, and revision rates, but cost effectiveness is in favour of PKR.

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Introduction

Osteoarthritis and degenerative joint disease is an increasing burden in an ageing population, particularly in the knee joint. Patients have pain and considerable dysfunction which can substantially decrease quality of life and well-being.[1,2] Knee replacement (arthroplasty) is an effective and routine surgery for the treatment of knee osteoarthritis for patients who have not responded to non-operative management.[3] Between 2021 and 2023, 300 906 knee replacements were done in England, Wales, the Isle of Man, and the Channel Islands[4] with the number expected to rise.[5] It is estimated that about 50% of knees needing replacement could potentially be treated by partial (unicompartmental) replacement (PKR), where only the damaged compartment of the knee is replaced.[6,7] Historically, there has been controversy whether PKR or TKR is the best approach for patients with unicompartmental disease. This controversy has been constrained by an evidence base limited by study design (observational) with its inherent selection bias and surgeon preference. There is also an absence of long-term follow-up data to guide treatment choice.

The primary results of the UK Total or Partial Knee Arthroplasty Trial (TOPKAT), which compared TKR and

Research in context

Evidence before this study

The TOPKAT study began in 2010 when evidence to guide choice in the type of arthroplasty used for late-stage isolated medial compartment knee arthritis was extremely scarce. At that time, we searched MEDLINE, Embase, and PubMed for related studies between Jan 1, 1990, and Dec 31, 2008, with the search terms "total", "partial", "unicompartmental", "knee replacement", "knee arthroplasty", "trial", and "outcome" with no language restrictions. Before 2009, only cohort studies, indirect comparisons, and retrospective studies had been done, which aimed to address specific aspects of each operation. Three small, randomised trials had been done, all in the UK. One of these trials had long-term follow-up (after 15 years), which showed the benefits of PKR; however, the study was underpowered for both knee score and revision frequency. The Knee Arthroplasty Trial had a component comparing partial knee replacement (PKR) with total knee replacement (TKR) but this comparison had to be terminated early because of inadequate recruitment. Since 2009, five randomised controlled trials have been published, three of these trials were small single-centre studies (comprising 56–72 participants per trial), one multicentre trial in Finland (n=143) with a 2-year follow-up, and the UK multicentre TOPKAT 5-year follow-up results. To our knowledge, there are three ongoing trials. At this time, the National Institute for Health and Care Excellence guidelines confirmed that there was minimal randomised trial data on which to guide treatment, and there are no robust randomised trials reporting outcomes in the longer term (ie, beyond 5 years).

Added value of this study

This study is the first large multicentre randomised study that reports 10-year data comparing TKR and PKR for treatment of late-stage medial compartment knee osteoarthritis. As longevity is a key issue for joint replacement, the longer follow-up period in this study provides important evidence to help fully evaluate the long-term efficacy. At 10 years no differences were seen between the procedures in clinical outcomes, and there were similar incidences of reoperations and revisions. PKR was seen to be more cost-effective compared with TKR. This longer-term data adds an additional dimension and further weight to the long-term performance of both these approaches to knee replacement, strengthening the overall interpretation and guidance for practice.

Implications of all the available evidence

Knee replacement is increasing in frequency, and it has an associated substantial cost implication to any health-care provider. It is also essential that patients receive the most efficacious operation for this condition. Before this study, and despite several cohort-based reports, knowledge of whether one operation type is superior, remained uncertain. This 10-year study has indicated that both TKR and PKR are beneficial interventions but, on the basis of combined clinical and cost-effectiveness data and providing that the operation is done by those with adequate experience, we recommend that PKR be offered as the treatment of choice for late-stage, isolated medial compartment osteoarthritis of the knee.

PKR for the treatment of late-stage medial compartment knee osteoarthritis, showed that both procedures were effective, offered similar clinical outcomes, and resulted in a similar incidence of reoperations and complications at 5 years. PKR was seen to be more cost-effective, with lower surgery and follow-up health-care costs alongside the modest greater clinical effectiveness, compared with TKR.[8] However, it is widely acknowledged that the relative value of knee replacement surgery cannot be assessed purely on the basis of only short-term and mid-term outcomes[9] as it is well known from registry data[10] that implants might take some years to fail (or be revised). It is also well known that the long-term revision rates are higher for PKR than for TKR. However, revisions of PKR tend to be relatively straightforward conversions to primary TKR, whereas revision TKR tends to be more complex, often with worse outcomes. As a result, the threshold for revising can be lower for a PKR than a TKR, which might contribute to the higher revision rate for PKR.[11] Additionally, it is only over this longer timeframe that the true health economic impact and patients long-term functional and quality of life improvements can be confidently assessed.[12] As such, there is a need for longer term follow-up data and a minimum of 10-year data is considered a requirement for arthroplasty evaluation.[13]

Before TOPKAT, evidence to guide choice in the type of arthroplasty used for late stage isolated medial compartment knee arthritis was limited to large cohort–registry studies and small randomised controlled trials.[14,15] Since publication of the TOPKAT 5-year follow-up results, a multicentre trial done in Finland has also been completed,[9] however, this was a small randomised controlled trial (n=143) limited to a 2-year follow-up period. Although 5-year results of TOPKAT provided good mid-term evidence, there are no robust randomised trials reporting outcomes in the longer term (ie, beyond 5 years). A systematic review and meta-analysis comparing PKR and TKR only identified one study examining any outcome greater than 5 years and concluded that longer term data from a randomised controlled trial were needed.[16] As longevity is a key issue for joint replacement, longer follow-up periods and long-term outcomes, such as reoperation and revision, are required to fully evaluate the long-term efficacy. The aim of this study was to assess the clinical and cost-effectiveness of PKR compared with TKR in patients with medial compartment knee osteoarthritis at long-term follow-up (10 years).

Methods

Study design and participants

TOPKAT was a multicentre, randomised, pragmatic comparative effectiveness trial. The study design, eligibility criteria, randomisation, details of the interventions and delivery have previously been reported.[8,17] Patients with isolated osteoarthritis of the medial compartment of the knee were enrolled from 27 UK National Health Service (NHS) secondary care hospitals (68 surgeons). The trial compared the overall management strategy of PKR treatment with TKR treatment. No specified brand or sub-type of implant was investigated. Individuals with relevant lived experience evaluated the study concept, recruitment procedures, and progress, and feedback was incorporated into the final trial design. The study obtained approval from the UK National Research Ethics Service (Research Ethics Committee South Central Oxford C) in September 2009 (09/H0606/88). Written informed consent was obtained for all patients. An independent Trial Steering Committee and Data Monitoring Committee provided oversight of the trial. The trial is registered with ISRCTN, ISRCTN03013488, and ClinicalTrials.gov, NCT01352247.

Randomisation and masking

The trial used a combined expertise-based and equipoise-based approach, in which patients with isolated osteoarthritis of the medial compartment of the knee and who satisfied general requirements for a medial PKR were randomly assigned (1:1) to receive PKR or TKR by surgeons who were either expert in, and willing to do, both surgeries or by a surgeon with particular expertise in the allocated procedure. This latter expertise based design allowed surgeons not in equipoise (a preference for one implant or the other) to partake in the trial. We used a web-based randomisation service at the Centre for Healthcare Randomised Trials (Aberdeen Centre for Evaluation, University of Aberdeen, UK). For randomisation we used a minimisation algorithm that incorporated sex, age band (<50 years, 50–70 years, or >70 years), baseline Oxford Knee Score (OKS) band (14 or less, 15–21, or 22 or more), and delivery unit. A delivery unit was either an equipoise surgeon or a pair of expertise surgeons with complementary expertise.[17] Surgeons, patients, and follow-up assessors were not masked to allocation, but the implant type was not highlighted at any stage.

See Online for appendix

Procedures

The trial compared the TKR procedure versus the PKR procedure and surgeons were free to use the implant of their own choice. Details of the interventions and delivery have previously been reported.[8,17] Patients were followed up every year from 1 year to 5 years post-randomisation, and then at 7 and 10 years. All assessments after 5 years were patient self-reported measures (sent directly to the patient) with no clinic-based evaluation.

Outcomes

The original primary endpoint for TOPKAT was the OKS 5 years after randomisation in all patients assigned to groups in the intention-to-treat population. Secondary outcomes included the University of California, Los Angeles Activity Score,[18] the High Activity Arthroplasty Score,[19] the EuroQol five dimensions, three levels (EQ-5D-3L),[20] the Lund Satisfaction Score,[21] the frequency of complications (determining the number of patients who required re-admission and reoperation), and three patient-reported anchor type questions regarding satisfaction, a comparison of problems with their knee before versus after the surgery, and if they would have the operation again. We also assessed a composite outcome for failure (a combination of reoperation and poor outcomes, as determined by an improvement in OKS of less than four points). This composite outcome assessment has not been validated, and it is therefore considered an exploratory outcome. Data on use of health-care services were collected for a health economics analysis. For this long-term evaluation, these same outcomes were assessed at 10 years post-randomisation.

Statistical analysis

Sample size was calculated for the OKS and the incidence of reoperations at 5 years. Target sample size was 500 patients to provide 80% power to detect a 2·0-point difference in OKS with SD of 8·0 points (or, equivalently, 90% power to detect a 3·0-point change at a 5% [two-sided] significance level with an SD of 10·0 points). This was adequate to detect a change in incidence of reoperations of 7% between groups (from 5% to 12%) at 80% power.[22,23] Of note, a study[24] done and published after the TOPKAT trial was planned suggested that the minimal clinically important difference for the OKS was 5 points. This minimal clinically important difference was assessed at preoperative score level (about 20 points). TOPKAT was exploring minimal clinically important difference at postoperative scores (around 40 points), where owing to the marked ceiling effect in OKS (in some populations), the minimal clinically important difference might well be much less.

Full details of the statistical analyses for this 10 year follow-up are contained in the statistical analysis plan (appendix pp 72–88). In brief, the statistical analysis was primarily done on an intention-to-treat basis and used all available participant data. The OKS scores at 10 years, which were compared with a repeated measures mixed effects linear regression analysis, were adjusted for minimisation factors and baseline OKS, and a random effect for surgery delivery unit and participant. We used all available data without imputation of missing data; in the mixed modelling framework, this assumes that data are missing at random, meaning that missingness depends only on observed covariates and outcome. An independent residual correlation structure was used, as

	PKR (n=264)	TKR (n=264)
Age, years	65·2 (8·8)	64·7 (8·5)
Sex		
Male	153 (58%)	153 (58%)
Female	111 (42%)	111 (42%)
Study knee		
Left	140 (53%)	141 (53%)
Right	124 (47%)	123 (47%)
Duration of osteoarthritis		
<3 years	75 (28%)	73 (28%)
3–5 years	82 (31%)	72 (27%)
6–10 years	59 (22%)	73 (28%)
>10 years	36 (14%)	30 (11%)
Missing data	12 (5%)	16 (6%)
Medical history of conditions		
Other joint problems	106 (40%)	96 (36%)
Cardiovascular	80 (30%)	86 (33%)
Diabetes	27 (10%)	26 (10%)
Gastrointestinal	17 (6%)	18 (7%)
Respiratory	19 (7%)	12 (5%)
Cancer	6 (2%)	8 (3%)
Renal or urological	8 (3%)	8 (3%)
Neurological	7 (3%)	6 (2%)
Mental health	7 (3%)	6 (2%)
Thyroid problems	3 (1%)	2 (1%)
Other*	5 (2%)	4 (2%)
Employment status		
Retired	159 (60%)	162 (61%)
Unemployed	15 (6%)	21 (8%)
Employed	82 (31%)	73 (28%)
Missing data	8 (3%)	8 (3%)
Body-mass index (n=210 *vs* 221)	31·0 (4·6)	31·1 (4·8)
Extent of knee arthritis affecting mobility (Charnley ABC)		
Single	99 (38%)	119 (45%)
Both	142 (54%)	121 (46%)
Multiple arthritis or medical infirmity	6 (2%)	11 (4%)
Missing	17 (6%)	13 (5%)
General health (n=259 *vs* n=260)	2·6 (0·9)	2·8 (0·9)
General health relative to 1 year ago (n=259 *vs* n=260)	3·3 (0·8)	3·3 (0·8)
(Table 1 continues in next column)		
(Continued from previous column)		
Previous treatment on study knee		
Analgesia	207 (78%)	184 (70%)
Arthroscopy	44 (17%)	47 (18%)
Arthroscopic Investigative washout–debridement	44 (17%)	36 (14%)
Open or arthroscopic meniscus	33 (13%)	30 (11%)
Knee injection with steroids	19 (7%)	21 (8%)
Knee injection with viscosupplementation	2 (1%)	3 (1%)
Knee injection (type not stated)	4 (2%)	6 (2%)
Acupuncture	4 (2%)	5 (2%)
Chiropractor or osteopath	1 (<1%)	3 (1%)
Cartilage implantation	1 (<1%)	2 (1%)
Anterior cruciate ligament repair	1 (<1%)	0
Other†	0	3 (1%)
None	13 (5%)	26 (10%)
Problems with the other knee		
None	86 (33%)	99 (38%)
Mild	93 (35%)	74 (28%)
Moderate	63 (24%)	52 (20%)
Severe	18 (7%)	30 (11%)
Missing	4 (2%)	9 (3%)
Contralateral knee		
TKR	24 (9%)	14 (5%)
PKR	16 (6%)	16 (6%)
Unsure	1 (<1%)	1 (<1%)
None	208 (79%)	217 (82%)
Missing	15 (6%)	16 (6%)
Oxford Knee Score	18·8 (7·0)	19·0 (7·2)
High Activity Arthroplasty Score (n=258 *vs* n=256)	4·8 (2·3)	4·6 (2·3)
University of California Los Angeles Activity score (n=260 *vs* n=260)	3·6 (1·5)	3·7 (1·5)
American Knee Society score (objective; n=260 *vs* n=259)	41·0 (16·1)	42·3 (16·0)
American Knee Society score (functional; n=262 *vs* 259)	59·3 (15·6)	58·7 (15·5)
EQ-5D-3L (n=257 *vs* n=252)	0·428 (0·301)	0·381 (0·324)
EQ-5D-3L visual analogue score (n=249 *vs* n=257)	62·8 (27·0)	60·7 (28·7)

Data are mean (SD) or n (%), unless otherwise indicated. PKR=partial knee replacement. TKR=total knee replacement. EQ-5D-3L=EuroQol (five dimensions, three levels). *Includes high body-mass index (PKR n=1; TKR n=1), antiphospholipid syndrome (TKR n=1), glaucoma (PKR n=1), cataracts (TKR n=1), anaemia (PKR n=2), appendicectomy (TKR n=1), and lipoma of intra-abdominal organs (PKR n=1). †Includes laser treatment (n=1), offloader knee brace (n=1), and aspiration (n=1).

Table 1: **Baseline characteristics**

more complex alternatives (exchangeable and unstructured) did not converge. OKS data were collected at baseline, and annually at 1, 2, 3, 4, and 5 years, with additional follow-up at 7 years and 10 years post-randomisation. Participants who died during follow-up were included in the analysis up to the time of death, with post-death data treated as missing. This approach corresponds to a hypothetical estimand, estimating treatment effects as if all participants had remained alive and continued follow-up. As both interventions are surgical treatments for the same indication and not expected to influence mortality differentially, this assumption is considered reasonable. We also did an analysis of OKS that used the area under the curve (AUC), generated for each participant with the trapezoidal rule, to describe the effects of TKR and PKR on OKS across all available timepoints. This analysis provides a comparative distribution of how many patients get the

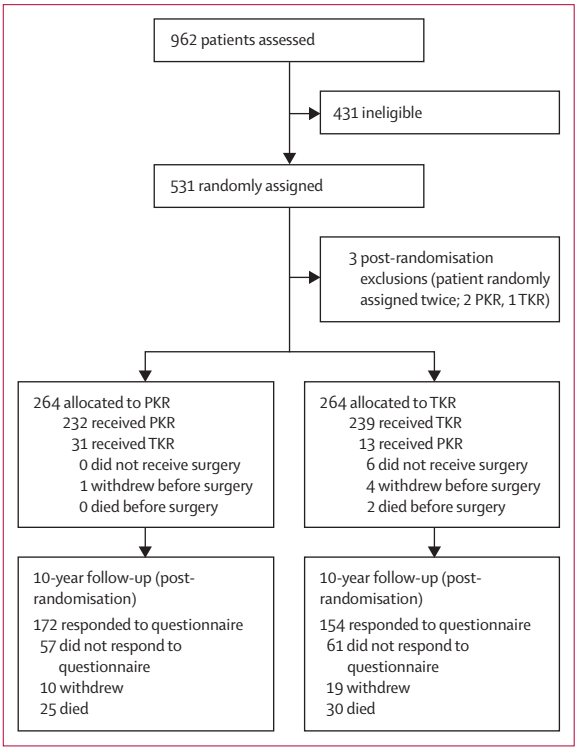

Figure 1: **Trial profile**
The 10-year intention-to-treat analysis includes only patients who provided results for the Oxford Knee Score assessment. PKR=partial knee replacement. TKR=total knee replacement.

best functional or pain scores for each implant after surgery over the entire duration of follow-up. Impact of surgeon experience (defined by the number of procedures of each operation type done by the surgeons before the study) on OKS, adding an additional factor and a treatment-by-experience interaction to the model, was also explored. We did prespecified subgroup analyses (OKS band, age band, expertise *vs* equipoise and sex [post-hoc]) evaluated with treatment-by-subgroup interactions. To assess the effect of compliance (the operation being delivered as intended), an instrumental variable method was used to estimate the complier-average causal effect at 10 years after randomisation.

The incidence of complications and reoperations, including revisions (post-hoc) and other binary variables were compared with Poisson regression, to estimate risk ratios, and they were adjusted for minimisation covariates with Huber–White cluster-robust standard errors, clustered by surgical delivery unit, to account for within-cluster correlation. Low frequency event data relating to complications, including reoperations and revisions were analysed both per protocol, on an intention-to-treat basis (as allocated), and on an as-treated basis. This is because some complications might or might not be directly attributable to the intervention received.[12] If a complication or revision is directly attributable to the intervention received it is best analysed as-treated) conversely, if the complication is attributable to patient factors outside the implant inserted, it is best analysed by treatment allocated.

We also did a within-trial cost-effectiveness analysis done from an NHS perspective, using the same methods and unit costs (GBP; 2016–17 prices) as reported in the 5-year within trial analysis.[8] In brief, total costs and quality-adjusted life-years (QALYs) for all 528 participants were estimated from the date of recruitment until the earliest of death, withdrawal from study, or the end of follow-up at 10 years. Patients were sent a postal questionnaire asking about health-care use related to the study knee (valued by use of national costs), which also included the EQ-5D-3L questionnaire (valued by use of standard UK tariff), at 2 months, 12 months, and annually up to 5 years and then at years 7 and 10. Hospital admissions related to the study knee were identified from postal questionnaires, clinic visits, and assessment of hospital records for all participants. Multiple imputation was used to impute missing data on EQ-5D-3L utility scores, total health-care costs (except inpatient care, which was complete), and OKS scores, at each follow-up timepoint (appendix p 8). Both costs and QALYs were discounted at 3·5% per year. Joint uncertainty around incremental total costs and QALYs (ie, the difference between PKR and TKR), and in the cost-effectiveness was captured (appendix p 8). Significance was judged at the two-sided 5% level and treatment effect estimates are presented with corresponding 95% CIs; all analysis was done with Stata version 18.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Jan 18, 2010, and Sept 30, 2013, of 962 patients assessed for eligibility, 528 patients with medial compartment knee osteoarthritis were randomly assigned (PKR n=264; TKR n=264) into TOPKAT (306 [58%] male, 222 [42%] female, mean age 65 years [SD 8·7 years]). The groups were well balanced on all baseline characteristics (table 1).[8] The types of implants used in the study reflected current practice.[8] Of the 264 patients who were originally assigned to the PKR group, 25 (9%) participants had died, ten (4%) had withdrawn, leaving 229 patients in follow-up. 172 (75%) of 229 remained eligible for follow-up and provided results for assessment of the primary outcome (complete OKS) at 10 years. Of the 264 patients assigned to the TKR group, 30 (11%) had died, 19 (7%) had withdrawn, leaving 215 patients in follow-up. 154 (72%) of 215 of those remaining eligible for follow-up and provided results for assessment of the primary outcome (complete OKS) at 10 years (figure 1).

At the 10-year follow-up, we found no difference in primary outcome of OKS between groups (mean difference 0·27, 95% CI −1·59 to 2·13; p=0·78; table 2; figure 2). There were also no differences in secondary outcome scores between those allocated to PKR than those allocated to TKR at 10 years (table 2). A kernel density plot of the OKS scores at final follow-up showed similar profiles for TKR and PKR (appendix p 5).

Patient satisfaction after 10 years did not differ between the groups (143 [85%] of 168 patients allocated to PKR were satisfied versus 124 [82%] of 151 patients allocated to TKR who were satisfied; risk ratio [RR] 1·04, 95% CI 0·96 to 1·13; p=0·32; appendix p 2). At 10 years, there were no between-group differences in whether the patient's knee was better or if they would choose to have the operation again (appendix p 2).

The OKS did not differ between the surgeon groupings at 10 years (ie, expertise paired *vs* single surgeons in equipoise; interaction effect 0·83, 95% CI −2·48 to 4·14; p=0·61), nor between the age band, sex, or OKS band subgroups (appendix p 5). At 10 years, there was also no effect of surgeon experience, as defined by the number of procedures of each operation type done by the surgeons before the study (appendix p 2).

At 10 years, 53 (22%) of 245 patients receiving PKR had complications compared with 74 (27%) of 270 patients receiving TKR (RR 0·78, 95% CI 0·58 to 1·04; p=0·10 by treatment received). With intention-to-treat analysis, 55 (21%) of 263 patients allocated to PKR and 72 (29%) of 252 patients allocated to TKR had complications (RR 0·73, 0·56 to 0.94; p=0·016). A breakdown of the complications is outlined in table 3.

The frequency of reoperation (including revision) by treatment received was similar for both groups at 10 years. 21 (9%) of 245 patients receiving PKR had a reoperation and 23 (9%) of 270 patients receiving TKR had a reoperation (RR 0·95, 95% CI 0·53 to 1·72; p=0·88). With intention-to-treat analysis, 20 (8%) of 263 with PKR and 24 (10%) of 252 with TKR had reoperations (RR 0·79, 0·47 to 1·33; p=0·37; table 3; appendix p 2).

At 10 years after surgery, the overall number of patients who had undergone revision was 26: by treatment received 15 (6%) of 245 patients who had received PKR and 11 (4%) of 270 patients who had received TKR had a revision (RR 1·42, 95% CI 0·72 to 2·79); p=0·31. With the intention-to-treat analysis 13 (5%) of 263 PKR and 13 (5%) of 252 TKR patients had revisions (RR 0·95, 95% CI 0·44 to 2·02; p=0·89). Reported reasons for revision were mainly unexplained pain (four patients receiving PKR *vs* five patients receiving TKR) or bearing dislocation (six patients PKR *vs* 0 patients TKR). Note that bearing dislocation is a somewhat unique problem to mobile bearing PKR, fixed bearings cannot dislocate.

There were 89 (34%) of 264 failures of PKR and 104 (39%) of 264 failures of TKR, as defined by the composite outcome for failure (a combination of reoperation and poor outcomes, as determined by an improvement in OKS of less than four points), which was not significantly different between groups (RR 0·86, 95% CI 0·66 to 1·11; p=0·24). During the period up to the 10-year follow-up, 55 deaths were reported: 25 (10%) deaths in the PKR group and 30 (11%) deaths in the TKR group (appendix p 3). The planned secondary analysis of the unadjusted OKS showed similar results to the primary outcome analysis at 10 years.

The complier-average causal effect analysis at 10 years showed no difference (0·54, 95% CI −1·08 to 2·17; p=0·51). At 10 years, the mean AUC was 37·6 (SD 8·1) for 167 participants in the PKR group and 37·2 (SD 8·4) for 147 participants in the TKR group (mean difference 0·45, 95% CI −0·98 to 1·88; p=0·53; appendix p 3). A kernel density plot for OKS over the 10-year follow-up period is shown in the appendix (p 5).

In the within-trial cost-effectiveness analysis at 10 years, cost effectiveness was in favour of PKR (figure 3). PKR

	Partial knee replacement		Total knee replacement		Effect size (95% CI)	p value
	Mean (SD)	n	Mean (SD)	n		
Oxford Knee Score (primary outcome)						
Baseline	18·8 (7·0)	264	19 (7·2)	264	..	..
10 years	37·3 (10·1)	167	37·5 (9·7)	147	0·27 (−1·59 to 2·13)	0·78
EQ-5D-3L score						
Baseline	0·428 (0·30)	257	0·381 (0·32)	252	..	..
10 years	0·699 (0·30)	162	0·745 (0·26)	148	−0·021 (−0·074 to 0·033)	0·45
EQ-5D visual analogue scale						
Baseline	62·8 (27·0)	249	60·7 (28·7)	257	..	..
10 years	71·8 (18·9)	169	71·2 (18·6)	147	1·75 (−1·55 to 5·05)	0·30
High Activity Arthroplasty Score						
Baseline	4·8 (2·3)	258	4·6 (2·3)	256	..	..
10 years	7·3 (3·5)	160	7·4 (3·2)	143	−0·06 (−0·64 to 0·52)	0·84
University of California, Los Angeles Activity score						
Baseline	3·6 (1·5)	260	3·7 (1·5)	260	..	..
10 years	4·6 (1·8)	165	4·6 (1·8)	150	0·11 (−0·23 to 0·44)	0·54

EQ-5D-3L=EuroQol five dimensions, three levels.

Table 2: **Primary and secondary outcomes, at baseline and 10 years**

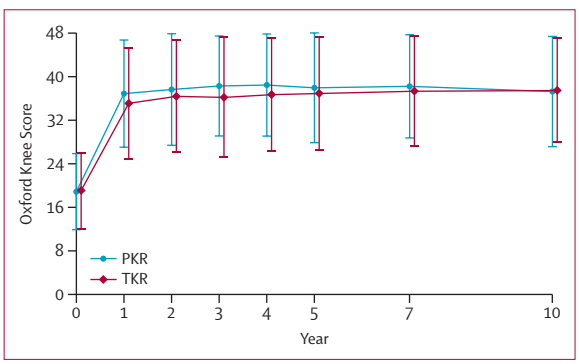

Figure 2: **Oxford Knee Score over time**
PKR=partial knee replacement. TKR=total knee replacement.

	Treatment as allocated		Treatment received	
	PKR n=263	TKR n=252	PKR n=245	TKR n=270
Number of participants with a complication	55 (21%)	72 (29%)	53 (22%)	74 (27%)
Total number of complications	89	120	87	122
Details of complications, related to primary operation				
Intra-operative				
Number of participants	..	3 (1%)	1 (<1%)	2 (1%)
Number of complications		3	1	2
Blood transfusion	..	2	..	2
Medical reasons	..	1	1	..
Postoperative				
Number of participants	10 (4%)	19 (8%)	10 (4%)	19 (7%)
Number of complications	10	19	10	19
Blood transfusion	..	6	..	6
Respiratory problems	2	4	3	3
Renal and urological problems	3	2	2	3
Miscellaneous	2	3	2	3
Treated deep vein thrombosis or pulmonary embolism	2	1	2	1
Cardiac problems	..	2	..	2
Treated deep vein thrombosis or pulmonary embolism–cardiac problems	..	1	..	1
Anaesthetic problems	1	..	1	..
Required re-admission				
Required medical treatment only				
Number of participants	6 (2%)	10 (4%)	5 (2%)	11 (4%)
Number of complications	6	13	5	14
Unexplained pain	2	4	2	4
Knee dislocation	1	..	1	..
Bearing dislocation	1	..	1	..
Wound breakdown	..	2	..	2
Bronchopneumonia	..	1	..	1
Cardiac problems	..	1	..	1
Cellulitis	1	4	..	5
Treated deep vein thrombosis or pulmonary embolism	..	1	..	1
Superficial infection	1	..	1	..
Required surgery				
Number of participants	20 (8%)	24 (10%)	21 (9%)	23 (9%)
Number of complications	28	36	33	31
Unexplained pain	10	11	13	8
Knee stiffness	1	10	..	11
Bearing dislocation	5	..	5	..
Knee dislocation	1	..	1	..
Device loosening (tibia)	1	3	3	1
Infection	2	1	2	1
Ligamentous instability	1	1	1	1

(Table 3 continues in next column)

	Treatment as allocated		Treatment received	
	PKR n=263	TKR n=252	PKR n=245	TKR n=270
(Continued from previous column)				
Pain from trauma	..	1	1	..
Periprosthetic fracture	1	..	1	..
Unexplained pain and knee stiffness	1	7	1	7
Mechanical failure and infection	..	1	..	1
Unexplained pain and swelling	1	..	1	..
Unexplained pain and skin complication	1	..	1	..
Unexplained pain and bearing dislocation	1	..	1	..
Device loosening (tibia) and renal–urological problems	1	..	1	..
Bearing dislocation and renal–urological problems	1	..	1	..
Unknown	..	1	..	1
Re-admission further surgery intra-operative				
Number of participants (and complications)	1 (<1%)	1 (<1%)	1 (<1%)	1 (<1%)
Other reasons	1	..	1	..
Medical reasons	..	1	..	1
Re-admission further surgery postoperative				
Number of participants	3 (1%)	..	3 (1%)	..
Number of events	4	..	4	..
Blood transfusion	1	..	1	..
Renal and urological problems	1	..	1	..
Skin complications	1	..	1	..
Bearing dislocation, renal–urological problems and blood transfusion	1	..	1	..
Did not require re-admission				
2-month follow-up				
Number of participants	7 (3%)	13 (5%)	5 (2%)	15 (6%)
Number of events	9	14	5	18
Wound infection	3	6	3	6
Unexplained pain	2	1	1	2
Wound breakdown	1	2	..	3
Swelling	1	2	..	3
Miscellaneous	..	2	..	2
Knee stiffness	1	1	..	2
Skin complication	1	..	1	..
1-year follow-up				
Number of participants	14 (5%)	17 (7%)	13 (5%)	18 (7%)
Number of events	16	20	15	21
Unexplained pain	9	11	8	12
Knee stiffness	1	5	1	5
Swelling	3	1	3	1
Instability	1	1	1	1
Wound infection	1	..	1	..

(Table 3 continues in next column)

was more cost-effective (mean difference in QALYs 0·322, 95% CI −0·069 to 0·712) and less expensive than TKR (mean difference in cost −£731, 95% CI −1352 to −110. This reflects better outcomes, as measured by QALYs derived from EQ-5D-3L scores, survival and lower index surgery costs and health-care follow-up costs (appendix p 3). PKR therefore dominated TKR with lower costs, higher QALYs, and with a 97% probability of being cost-effective at £20 000 per QALY. Even assuming equal costs of the implant device, PKR was less costly and more effective than TKR (appendix p 6).

Rates of missing data on resource use increased with follow-up time but were similar between treatment groups. The proportion of missing data imputed to inform the cost-effectiveness analysis ranged between 2% at baseline to 35% at 10 years).

Discussion

TOPKAT is the largest and longest trial follow-up comparing PKR and TKR in the world. It shows that both TKR and PKR are effective, offer similar clinical outcomes, and have similar reoperation and revision rates out to 10 years. Outside of health economic considerations, there is no strong clinical evidence to select one type of implant over another.

The small clinical differences in favour of PKR that were seen at 5 years[8] are ameliorated at 10 years, although cost effectiveness remains in favour for PKR. The cost effectiveness results are worthy of further comment.

Over the 10 years' duration of the TOPKAT trial, we found that PKR improved health-related quality of life and reduced health-care costs compared with TKR in individuals with osteoarthritis of the medial compartment of the knee. This is the case whether true device costs (PKR implants cost less than TKR) or equal device costs were used. The cost-effectiveness results are consistent with a previous modelling study based on data from the UK National Joint Registry (NJR), which found that PKR is expected to generate better health outcomes at lower costs over a patient's lifetime compared with TKR.[25]

Following the index surgery, participants in both treatment groups saw considerable improvements in their EQ-5D utility, reflecting the known clinical benefits of knee replacement surgery in patients with osteoarthritis and poor functional outcomes.[26] Differences in EQ-5D-3L utility scores favoured PKR but were not typically significantly different by treatment allocation up to 5 years of follow-up. After 5 years, the difference favoured TKR but again was not significantly different. However, QALYs, which reflect the patients' health related quality of life including the morbidity and mortality associated with the surgery and complications, were found to be consistently and significantly higher in those allocated PKR versus TKR beyond 1 year. Costs of the index surgery were significantly lower in those allocated PKR versus TKR. Follow-up health-care costs were significantly lower in those allocated PKR versus TKR over the first 2 years of follow-up, driven predominantly by fewer outpatient visits. Cumulative health-care costs were significantly lower in the PKR group through to the trial follow-up, even when assuming equal device costs.

The revision rate for PKR in the study warrants comment. Although the revision rate for TKR largely

	Treatment as allocated		Treatment received	
	PKR n=263	TKR n=252	PKR n=245	TKR n=270
(Continued from previous column)				
Periprosthetic fracture	..	1	..	1
Miscellaneous	1	..	1	..
Skin complication	..	1	..	1
5-year follow-up				
Number of participants	14 (5%)	14 (6)	12 (5%)	16 (6%)
Number of events	15	14	13	16
Unexplained pain	12	8	10	10
Knee stiffness	1	1	1	1
Medical reasons	..	2	..	2
Miscellaneous	1	1	1	1
Wound infection	..	1	..	1
Infection	..	1	..	1
Ligamentous instability	1	..	1	..

Data are n (%) of participants or n of complications. PKR=partial knee replacement. TKR=total knee replacement.

Table 3: **Complications for those who received surgery by both treatment allocated and received**

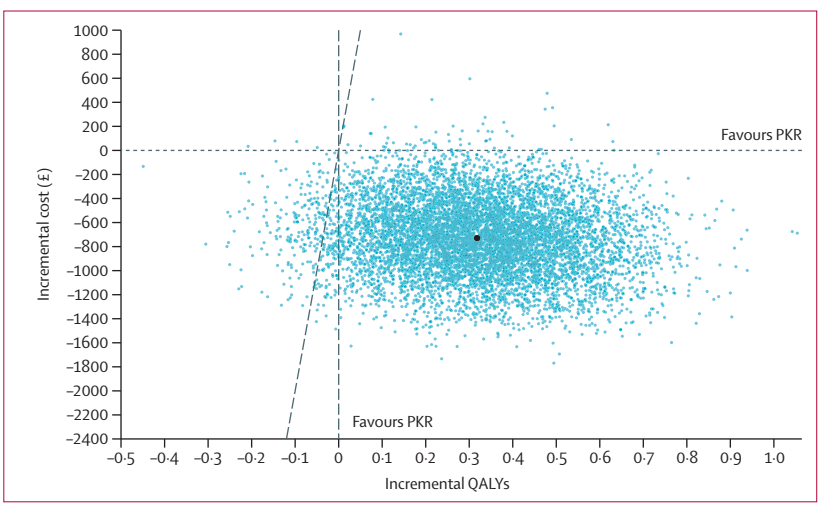

Figure 3: **Cost-effectiveness plane at the 10-year follow-up**

Plots are a series of simulations showing the likelihood that PKR yields more or fewer QALYs than TKR (x-axis), and costs more or less than TKR (y-axis). Each point represents the joint uncertainty in the statistics: incremental costs and QALYs. Coordinates to the left and above the dashed line (ie, in the top left quadrant of the graph) have a cost-effectiveness ratio above £20 000 per QALY gained; those to the right and below the line (ie, in the bottom right quadrant of the graph) are less than £20 000 per QALY gained. The diagonal dashed line is the willingness to pay threshold. PKR=partial knee replacement. QALYs=quality-adjusted life-years. TKR=total knee replacement.

mimicked the NJR data, the rate of revision for PKR was lower in the TOPKAT trial than for any partial knee implant in the NJR (appendix p 7). This initially appears surprising given that the NJR revision rate of PKR is much higher than TKR and a similar revision pattern might have been expected in TOPKAT.

There are several potential explanations for the disparity in revision rates for PKR between the TOPKAT trial and the NJR. The low revision rate of PKR in TOPKAT might reflect the characteristics of the surgeon population in the study. NJR data shows that the number of PKRs implanted per surgeon per year can have a substantial influence on the surgeon's revision rate and there is evidence that most surgeons (outside TOPKAT) implant less than five PKRs per year.[27] Note that all surgeons implanting PKR in TOPKAT implanted at least 10 PKRs in the year preceding the study and were self-identified users of PKR. This would lend itself to an expected lower revision rate than the general PKR performing surgeon population.

It is also important to note that the revisions in TOPKAT following PKR tended to be relatively minor procedures, such as replacing a bearing for dislocation. In contrast, the revisions of TKR tended to be more complex, requiring revision TKR components.[27] The bearing dislocation rate in the PKR was higher (6 [3%] of 263) than would be expected and all dislocations occurred in mobile bearing PKR. This might in part be because most mobile bearing PKRs were implanted with instrumentation that is no longer used—more contemporary instrumentation has been associated with a lower dislocation rate.

Other factors that might have influenced revision rate in TOPKAT compared with the NJR include the effect of simply being in a well monitored clinical trial. This awareness (Hawthorne effect) could lead to greater caution about performing revision. Another reason might be the relative ease of revising PKR compared with revising TKR (outside the trial—ie, reflected in NJR data)—there is potential for a lower threshold for revision of PKR than for TKR. Equally, TOPKAT surgeons might have been much more careful in ensuring that the patients have isolated medial osteoarthritis before enrolling them compared with the national use of PKR. Progression of osteoarthritis and multicompartment disease is a common reason for revision of PKR.

Overall, the results provide support for the proponents of both implant types. Those in favour of PKR are reassured that, although post-operation function might not be substantially better than for TKR, the revision rate (which has been a source of concern from some datasets and publications) is not substantially worse. Moreover, the complication rate might be better for PKR when implanted by use of standard inclusion criteria and appropriate expertise. On the other hand, TKR proponents can be reassured that the functional outcomes and reoperation rates are not inferior to those of PKR for isolated anteromedial arthritis of the knee. However, these are generalised findings from a clinical trial, which might or might not apply to individual patients. Therefore, as National Institute for Health and Care Excellence guidelines suggest, the pros and cons of each procedure should be explained to the patient and shared decision making should dictate what type of knee replacement is used.

There are some further aspects of the TOPKAT trial that warrant comment including some strengths and limitations. In terms of strengths, the duration of follow-up (10 years) is a major achievement for a randomised controlled trial of joint replacement. The comprehensiveness of follow-up data at 10 years is also satisfactory and provides robust evidence. The inclusion of an expertise design component has also been a success showing that such a design can be useful for surgical evaluation where strong surgeon preferences on procedure type exist. The trial has also provided a robust answer to a reccurring question in knee arthroplasty and can be used to guide orthopaedic practice—an area of practice that, in the main, was informed previously by non-randomised cohort data. Low frequency event data were analysed both per protocol, on an intention-to-treat basis, and on an as-treated basis to maximise understanding. The findings for reoperations and revisions were similar with both analyses, whereas for complications there was a difference (favouring PKR) with intention-to-treat, but not with as-treated analysis.

For limitations, although a randomised controlled trial remains the best method of controlling confounders, the somewhat selective nature of a trial can also produce less generalisable results. For example, owing to learning curve effects, surgeons doing small numbers of PKRs in their practice might be expected to get worse results with PKR than found in this study. All surgeons doing PKR in TOPKAT had to have done the operation for at least 1 year and to have done it at least 10 times in the previous year (and many surgeons had substantially greater experience). Although this reflects a relatively high level of experience, surgeons with even longer experience and doing a larger number of PKRs might be expected to get better results than in the study. The same argument exists for TKR. Furthermore, younger high demand patients, who tend to do particularly well following PKR, might not have been recruited to the study. It should also be remembered that the trial might have included more carefully selected patients than in the wider population.

There was also some minor lack of compliance with the allocated implant, which can affect trial interpretation—although the complier-average causal effects analysis showed consistent findings. Also, because of the longevity of the study (well over 10 years), the issue of obsolescence (of both the devices and technique) cannot be ruled out when considering policy and practice change. Since patients were recruited to the study there have been other improvements in PKR, such as the

widespread use of cementless fixation, which decreases the incidence of loosening. There have also been improvements in TKR. In terms of the economic evaluation alongside the trial, the amount of missing data on use of health-care resources and EQ-5D-3L was a challenge (16% across the time periods), particularly in later years of follow-up. However, we accounted for this using multiple imputation[28] and linear interpolation. This assumes data is missing at random conditional on modelled covariates and we found no strong evidence to contradict this assumption.

Knee replacement is a good operation with both total and partial approaches providing good clinical outcomes at 10 years. This 10-year randomised controlled trial data provides the strongest, most robust evidence yet about the relative merits of TKR and PKR. There were no significant differences between implants in clinical outcomes, reoperations, or revisions. However, the lower complication rate and the dominant health economic findings support continued recommendation for PKR.

Contributors

JH, JAC, and GM did the statistical analysis and ML and JL the health economics analysis. DJB wrote the first draft of the report with input from LJD, JAC, GM, JH, JL, and MKC. Subsequent drafts were reviewed and revised by DWM, AJP, and AJC. JH, JAC, GM, ML, and JL directly accessed and verified the underlying data reported in the manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

DJB reports institutional research grant funding from the National Institute for Health and Care Research (NIHR) outside the submitted work and holds an NIHR Senior Investigator award. JAC reports grants from the NIHR Health Technology Assessment (HTA) programme and was a member of the NIHR HTA efficient trial designs board for 2 years, during the conduct of the study. GM reports grants from NIHR HTA, during the conduct of the study. AJP reports consultancy fees from Zimmer Biomet, outside the submitted work. AJC serves as a board member of the Royal College of Surgeons and the University of Bristol and is a patent holder for BioPatch. DWM reports grants and personal fees from Zimmer Biomet, outside the submitted work, and receives royalties related to partial knee replacement (from Zimmer Biomet). MKC reports grants from NIHR during the course of the study and serves as chair of the NIHR–MRC Better Methods Better Research Funding Committee. All other authors declare no competing interests.

Data sharing

The data collected for the study, including individual participant data and a data dictionary defining each field in the set, will be made available to researchers on request to the study team and with appropriate reason when accompanied by a peer-reviewed protocol. The shared data will be deidentified participant data. Data will be shared with investigator support, after approval of a proposal, with a signed data access agreement. The study protocol, statistical analysis plan, and informed consent forms are available online. https://fundingawards.nihr.ac.uk/award/08/14/08.

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