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# Cost-effectiveness analysis of robotic-arm assisted versus manual total knee arthroplasty in the UK

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#### **Aims**

The aim of this study was to estimate the additional cost per quality-adjusted life-year (QALY) of robotic-assisted total knee arthroplasty (rTKA) compared to manually performed total knee arthroplasty (mTKA).

#### **Methods**

An economic evaluation was undertaken from the UK NHS and personal social services perspective, alongside a randomized controlled trial comparing rTKA and mTKA. Costs were estimated individually using a top-down approach and included all healthcare resources incurred during the trial. Costs were presented in 2021 GBP sterling (£). Responses to the EuroQol five-dimension three-level questionnaire were used to estimate QALYs for each participant. The incremental cost-effectiveness ratio (ICER) was evaluated against the current willingness-to-pay threshold recommended by the National Institute for Health and Care Excellence. Stochastic sensitivity analysis was performed using bootstrapping techniques, and results were shown through the cost-effectiveness acceptability curve and cost-effectiveness plane. Cost-effectiveness over one- and ten-year time horizons were explored using a decision model.

## **Results**

There were 100 participants randomized: 50 rTKA and 50 mTKA. Overall, 37 participants (39.4%) had some missing data on either costs or utilities, or on both. Multiple imputation was used for the base case results. The intervention was associated with incremental mean per-patient costs of £1,829 (95% CI 421 to 3,238) and an incremental QALY gain of 0.015 (95% CI -0.05 to 0.0796) at one year. The ICER at one year was £123,770. However, rTKA was likely to be cost-effective over a ten-year time horizon, with an ICER of £11,109. All except one of the scenarios (QALY gain reduction to 0.005) explored supported the cost-effectiveness of rTKA over a ten-year time horizon with an ICER below a £20,000 threshold.

## **Conclusion**

Over a short one-year time horizon, rTKA was not a cost-effective procedure compared to mTKA. However, when results were extrapolated out to a ten-year time horizon, which would need to be confirmed in future research, rTKA was likely to be cost-effective.

## Take home message

· Robotic arm-assisted total knee arthroplasty was cost-effective over a ten-year time horizon, with an incremental costeffectiveness ratio below the £20,000 threshold suggested by the National

Institute for Health and Care Excellence relative to manually performed surgery.

## Introduction

Total knee arthroplasty (TKA) is the standard procedure for patients with advanced or end-stage knee osteoarthritis



(OA), where more than one compartment of the knee is affected and conservative treatment methods have failed.<sup>1-4</sup> After surgery, patients report less pain and an improvement in quality of life.<sup>5</sup> Conventional manually performed TKA employs preoperative imaging, anatomical landmarks, and manual jigs to guide bone resection and implant positioning.<sup>6</sup> This method lacks reproducibility and precise implant placement, relying on surgeon skill.<sup>7,8</sup> Incorrect placement or imbalance is associated with chronic pain, slower patient recovery, longer rehabilitation, instability or loosening, and a shorter implant life.<sup>5,6,8-10</sup> About 3% of patients require revision surgery within five years following the procedure,<sup>11</sup> and approximately 10% to 20% of patients are not satisfied with the postoperative outcome.<sup>2,9,10</sup>

Computer- and robotic-assisted systems increase the accuracy of bone cuts and the precision of prosthesis implantation, with improved radiological outcomes.<sup>5,6,12-14</sup> In comparison with conventional TKA, robotic surgery potentially reduces complications, readmission rates, and care costs, in addition to improved patient-reported outcomes. 12,14,15 Prior cost analyses, mainly in the USA, indicate that the index costs associated with robot-assisted TKA (rTKA) are higher compared to manual TKA (mTKA) and constitute 64% to 94% of total costs. 16-22 This is primarily due to the robot (maintenance, depreciation, disposables), additional diagnostic imaging (CT scan), prolonged surgical time, operating theatre supplies, and postoperative recovery. 16,18,23-27 However, multiple studies suggest that reduced readmissions, medication/analgesia prescriptions, and rehabilitation costs associated with rTKA can offset this increase. 17-2225,28,,29 Published cost-effectiveness studies show that the intervention could become cost-effective in moderate to high volume settings mainly due to the lower risk of readmissions.<sup>30-32</sup> A price threshold model-based analysis developed in the UK emphasized the importance of lowering the risk of revision and improving patient-reported outcomes for rTKA to become a cost-effective option.<sup>33</sup>

To address the gap in the literature, a clinical trial was developed in the UK NHS setting. The ROAM (RObotic Arm-assisted versus Manual) study aimed to compare clinical outcomes between rTKA versus mTKA using a jig-based system.<sup>34</sup> The primary endpoint was to compare the change in knee-specific function subscale from baseline to six months after procedure, which has been reported elsewhere.<sup>15,35</sup> The present study sought to evaluate the economic and quality-of-life outcomes from the ROAM trial. Given the impact of cost-effectiveness on rTKA adoption in orthopaedic practice, this analysis is crucial for informing patients and healthcare decision-makers paying for these procedures.

## Methods

In this economic evaluation alongside a single-centre randomized clinical trial, the costs and quality-adjusted life-years (QALYs) of patients undergoing rTKA or mTKA were compared. The study was registered (ISRCTN 47889316). The methods and surgical techniques have been described in a previous publication and the surgeons were beyond their learning curve. The primary economic analysis was from the UK NHS and personal social services perspective, with a time horizon of 12 months. A secondary analysis was undertaken using a model-based approach over a time horizon of ten years.

#### Measurement and valuation of resource use

Healthcare resource use was collected using trial case report forms (CRFs). The CRFs were completed at baseline and at two, six, and 12 months. Costs were reported in 2021 GBP sterling (£). When necessary, costs were adjusted by means of the NHS Cost Inflation Index (NHSCII).<sup>36</sup>

The index costs covered surgery, inpatient stay, staff, overhead/administration, medications, and procedure-related complications. The surgery costs included imaging, implant surgical equipment and instruments, operating theatre as well as respiratory services, anaesthesia, thromboprophylaxis, laboratories, and other medical supplies. The capital cost of the Mako robot (Stryker, USA) was included in the theatre costs; it included the cost of purchasing the equipment and the Orthosensor (Verasense; Zimmer Biomet, USA) with any necessary add-ons, as well as the annual maintenance service fees. The length of stay in hospital immediately following initial surgery was calculated for each patient as the difference between the date of surgery and the discharge date. The main source of perioperative costs was the patient level information and costing system (PLICS).<sup>37</sup>

Healthcare resource use was collected through the study-specific CRFs. Patients reported outpatient visits, GP visits, nurse appointments, rehabilitation sessions (outpatient, home), hospital readmissions, emergency department visits, and other therapeutic services. The unit cost of the healthcare resources was obtained from NHS reference costs 2020/2021.<sup>38</sup> The cost per minute and average consultation length in minutes can be obtained from the Unit Costs of Health and Social Care.<sup>37</sup> For readmissions, only costs related to hospital stay were considered. The costs of complications were obtained from literature (references listed in the the Supplementary Material). The unit costs related to follow-up are reported in Supplementary Tables i to iii.

## Measurement of effectiveness

Patient outcome data were collected using the Euro-Qol five-dimension three-level questionnaire (EQ-5D-3L) at baseline and at two, six, and 12 months.<sup>39</sup> These were converted into utilities using the time trade-off preference elicitation technique, in a representative sample of the UK population.<sup>40</sup> QALYs were calculated using the 'area under the curve' method,<sup>41</sup> and adjusted for baseline EQ-5D-3L scores.

## Sensitivity analysis

We conducted a number of sensitivity analyses for areas of uncertainty in the cost-effectiveness analyses: 1) we considered the effect of missing data, estimated by multiple imputation, when compared to the complete case analysis; and 2) we analyzed a scenario where the surgery costs with implausible values were estimated by means of multiple imputation.

We used the non-parametric bootstrap approach,<sup>42</sup> with 500 replications for each of the 60 imputed datasets, to estimate 95% CIs around estimated cost differences, and for QALY differences, in order to address uncertainty. To present the level of uncertainty on cost-effectiveness estimates, we used the cost-effectiveness plane to present combinations of incremental cost and incremental QALY data from bootstrap replicates, and used the cost-effectiveness acceptability curve

(CEAC) to present the probability that the intervention is cost-effective over a range of willingness-to-pay (thresholds).<sup>41</sup>

#### **Decision model**

We also developed a decision model (Supplementary File iv) to extrapolate the results of this study beyond the time horizon of the trial to ten years. This analysis was conducted from the perspective of the NHS, using costs and outcomes from the trial supplemented with data from the published literature with a discount rate of 3.5% per annum. The following assumptions were made for the decision model:

- There were no differences in overall mortality and revision rate between the two arms due to the type of TKA undertaken; the revision mortality and post-revision mortality were assumed to be same;
- The difference in health-related quality of life (HRQoL) between the two arms at 12 months in the ROAM trial was maintained in each of the years modelled; and
- Revisions will be mTKA irrespective of initial procedure.

Results were reported as incremental cost-effectiveness ratios (ICERs) with CEACs to present deterministic and probabilistic sensitivity analyses alongside some scenario analyses to explore the impact of certain assumptions. The following scenarios were explored:

- Time horizon was varied to five and 20 years post-surgery;
- Starting age of patients was varied between 70 and 80 years;
- The QALY gain from rTKA was increased to 0.020 and reduced to 0.005 and 0.010 from that observed in the trial (0.015); and
- · Revision rate difference between the two arms.

## Statistical analysis

Data were reported as missing if the CRFs and participant questionnaires were incomplete. The graphs for the identification of missing data patterns were developed in R, using the functions matrix.plot() and aggr() of the VIM package described by Zhang.43 Multiple imputation was used for missing data, under the assumption that the data was missing at random (MAR). Costs and EQ-5D-3L indexes at each timepoint were imputed using chained equations with predicted mean matching based on the five nearest neighbours. Costs were imputed at the level of the major aggregate costs (e.g. surgery, follow-up, complications, readmissions). Considering the sample size, the imputation of the indices was preferred to the domains.44 The imputation model was stratified by trial arm and included BMI, age, patient-reported outcome measures (PROMs) (Western Ontario and McMaster Universities osteoarthritis index (WOMAC), 45 Oxford Knee Score (OKS), 46,47 and Forgotten Joint Score (FJS)), 48 and EuroQol five-dimension guestionnaire (EQ-5D)<sup>39</sup> at baseline. These variables were selected based on a review of the economic literature. The multiple imputation was performed using the MI command in Stata (StataCorp, USA). Passive imputation was used for those variables that were functions of other included variables.

The number of imputations (n = 60) was selected to be greater than the proportion of missing data following White et al.<sup>49</sup> The cost-effectiveness analysis was conducted on the imputed dataset following the methodology outlined in Faria et al<sup>50</sup> to apply 'Rubin's rules', so that variation within and

between the set of 60 imputed datasets was reflected in the analysis.

Both unadjusted and adjusted analyses were performed to estimate the cost-effectiveness of rTKA compared to mTKA. A generalized linear model (GLM) was applied to compare costs and QALYs, adjusting for imbalance in baseline characteristics. The GLM extends the linear modelling approach to data that is not normally distributed. We used a  $\gamma$  distribution as the family suitable when fitting skewed healthcare cost data. The link function used in GLM specifies how the mean of the dependent variable depends on the predictors. In the analysis, we used identity link function, implying a linear relation between the cost and predictors. The QALY data were analyzed using a Gauss family and an identity link.

An adjusted analysis was carried out using seemingly unrelated regression (SUR). SUR enables the simultaneous estimation of costs and effects for each individual by accounting for unobservable individual characteristics that could affect both costs and effects, and lead to a potential correlation between two variables.<sup>52</sup> We conducted this analysis in Stata v. 18 (StataCorp) using the SURcommand suest.

#### **Results**

#### **Baseline characteristics**

Of the 100 patients, 50 (50%) were assigned to the rTKA group, of whom 48 (96%) received the allocated intervention, and 50 (50%) were assigned to the mTKA group, of whom 46 patients (92%) received allocated intervention. The groups were well balanced on most of the baseline characteristics (Supplementary Table v).

## Completeness of data

Responses to questionnaires, particularly those related to resource use and quality of life, were the main sources of any remaining missing data. Overall, 19 participants (20.2%) were missing data on their quality of life, 36 (8.3%) were missing data on their costs, and 37 (39.4%) were missing either cost data or utility data, or both.

The proportion of people with complete quality-oflife data decreased with follow-up and was higher in the intervention arm (Supplementary Table vi). Supplementary Figure a presents the pattern of missing data. Some individuals exhibit intermittent missing data, indicating that the missing data does not adhere to a monotonic pattern.

Complete case analysis requires both cost and EQ-5D-3L data for the cost-effectiveness analysis. Approximately 57 (60.6%) met these criteria (27 (56.3%) intervention, 30 (65.2%) control). An exploration of the missing data in surgery, follow-up, and readmission costs showed no significant differences between groups. EQ-5D-3L score missing responses were higher in mTKA (11; 23.9%) than in rTKA (8; 16.7%), i.e. there was a greater proportion of patients in the manual revision group with missing quality-of life data.

Lower EQ-5D at baseline was linked to missing cost data (Supplementary Table vii). This suggests that the data are unlikely to be MAR. Other covariates (age, sex, and BMI) were associated with missingness but were not statistically significant at the 5% level.

Logistic regressions examined whether missingness affects previously observed outcomes by regressing missing costs or QALYs at each timepoint on their previous values. For missing costs, regression analyses yielded results that were not statistically significant (p > 0.05). Missing sixmonth QALYs were significantly associated with two-month QALYs. Missing 12-month QALYs were not statistically related to previous months. These analyses supported the assumption of MAR.

#### Costs

The box plots (Figure 1) show that the distribution of surgery and readmission costs for individual patients was higher in the rTKA group. Follow-up costs are similar in both groups, while complications were slightly lower in the rTKA group compared to the standard procedure.

The estimated costs after imputation are summarized in Supplementary Table viii. The initial procedure and hospitalization mean costs were significantly higher for rTKA patients compared to mTKA patients (£5,675 vs £4,018; p < 0.001). The rTKA had higher theatre and surgeon costs than mTKA, and the differences were statistically significant. The £1,656 initial cost difference was driven primarily by the cost of the theatre, which included the costs of the robot as well as additional consumables required to perform the procedure. rTKA took a mean of 27 minutes longer, leading to higher surgeon and theatre costs.

The length of the hospital stay for the surgery did not differ significantly between groups: rTKA had a mean of 4.3 days (SD 3.3) and mTKA a mean of 4.0 days (SD 3.0). These results are reflected in the ward cost analysis, with no significant differences between groups.

The rTKA group had higher mean follow-up costs than the control group (£563 vs £543; p = 0.857), but the differences were not statistically significant (Supplementary Table ix).

The number of readmissions was similar between groups (Supplementary Table x). However, the mean cost per patient in the rTKA group was significantly higher due to a higher number of patients (eight vs five; p=0.501) and a longer hospital stay (4.2 days vs 2.6 days; p=0.297). It should be noted that readmission reasons were self-reported, and cost calculations assumed uniform daily costs, potentially differing from actual costs due to lacking detailed hospitalization data.

rTKA patients had slightly fewer complications (defined as all types of complications) than mTKA patients, but the differences in incidence (27.9% vs 31.9%; p = 0.679) and in the mean costs per patient (£533 vs £690; p = 0.645) were not statistically significant. The most frequent complications were severe pain (four patients in the rTKA group vs two patients in the mTKA group) and knee stiffness (two in rTKA vs six in mTKA).

## Cost-effectiveness

Cost-effectiveness results from an NHS perspective are presented in Table I. In the complete-case study, rTKA was more effective (0.014 additional QALYs, 95% CI -0.0504 to 0.0785) and more expensive than mTKA (£2,236, 95% CI £425 to £4,046) after 12 months. Differences in QALYs was not statistically significant. The ICER for rTKA compared to mTKA was £158,785.

The results of the multiple imputation showed that the rTKA arm was on average more costly (£1,829; 95% CI £421 to £3,238) and more effective (0.015 additional QALYs, 95% CI -0.05 to 0.0796) than mTKA. Using the multiple imputed dataset, the incremental cost per QALY at 12 months is £123,770.

## Sensitivity analysis

Uncertainty of the difference between alternatives was estimated in the bootstrap analysis. The cost-effectiveness plane (Figure 2) shows that the difference in costs and QALYs between the alternatives are mainly in the north-east quadrant (66.5% of simulations), which represents greater effect at greater cost for rTKA compared with mTKA. One-third of rTKA patients (32.8%) had higher healthcare costs and fewer QALYs than mTKA patients, 0.1% had lower costs and fewer QALYs, and 0.5% had lower costs and more QALYs.

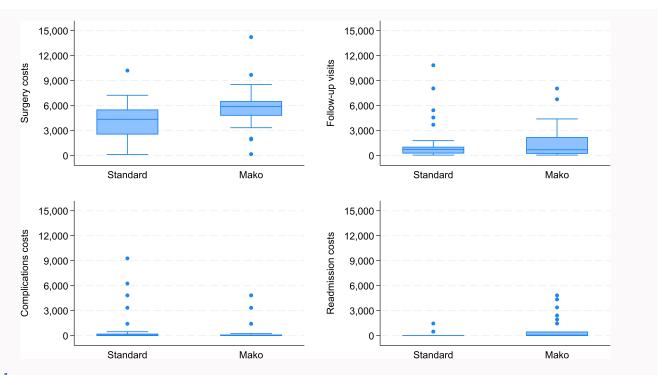
Figure 3 indicates the probability that the intervention is cost-effective at different values of the cost-effectiveness threshold. The cost-effectiveness of rTKA at £20,000 and £30,000 is 8.2% and 16.0%, respectively (Figure 3).

Sensitivity analysis included a regression scenario with missing data imputed and adjustment made for age, BMI, and the difference in baseline HRQoL (Table II). This scenario estimated that on average the rTKA arm cost £1,886 more than the mTKA. rTKA also implied 0.0152 more QALYs, resulting in a mean ICER of £123,485/QALY. As in the base case, HRQoL was marginally better with rTKA, but unlike cost, it did not reach statistical significance. An additional scenario was considered in which the surgery costs of the outliers were imputed. This scenario showed that rTKA cost £462 and added 0.0158 QALYs to mTKA. The incremental cost per QALY at 12 months was £29,277, making it cost-effective at £30,000/QALY gained.

The decision model extrapolated beyond the 12-month time horizon of the trial follow-up. The difference in cost between the two arms over ten years was £1,833 (rTKA was more expensive than mTKA) and rTKA gained 0.17 QALYs than mTKA, resulting in an ICER of £11,109. The probabilistic results were similar, with an ICER of £11,429. One-way sensitivity analyses showed that post-index procedure costs for rTKA and mTKA appear to drive the ICER, with higher costs for rTKA resulting in a higher ICER, whereas higher costs for mTKA reduce the ICER. All the scenario analyses conducted suggest that rTKA would likely be cost-effective over mTKA except for a reduced 12-month QALY gain for rTKA (0.005 rather than the observed 0.015 from the trial data) where the ICER was £33,328. Details are presented in the Supplementary file iv.

## Discussion

During the 12-month study period, rTKA was more costly and more effective than mTKA. The complete case analysis showed that rTKA had a cost-effectiveness ratio above the National Institute for Health and Care Excellence (NICE) threshold at 12 months' follow-up. This is possibly related to the high proportion of missing data, as questionnaires were completed electronically, but also the study was developed during the COVID-19 pandemic, affecting follow-up and data collection. Complete case analysis in a small sample size would discard data from many participants, making it inefficient. Imputation mitigates the effects of missing data, but it is not possible to infer the responses of those who did not complete the



Distribution of per patient costs in the form of box plots. The box representing the IQR and the blue line in the bow being the median.

Table I. Cost-effectiveness of the intervention from an NHS perspective.

Model	Intervention	Unadjusted costs (£)	Adjusted incremental costs (£)*	Unadjusted QALYs	Adjusted incremental QALYs*	ICER
Complete case data (n = 76) Adjusting by HRQoL in baseline	rTKA	6,936.8 (2,541.5 to 11,332.1)	2,235.6 (425 to 4,046.3)	0.5149 (0.3719 to 0.6579)	0.0141 (-0.0504 to 0.0785)	158,785
	mTKA	4,701.2 (2,346.6 to 7,055.7)		0.5008 (0.422 to 0.5796)		
Multiple imputation (n = 93) Adjusting by HRQoL in baseline	rTKA	7,202.9 (6,820.3 to 7,585.6)	1,829.4 (420.7 to 3,238)	0.5067 (0.4892 to 0.5241)	0.0148 (-0.05 to 0.0796)	123,770
	mTKA	5,369.2 (5,168.7 to 5,569.7)		0.4919 (0.4825 to 0.5013)		

<sup>\*</sup>Adjusted results are based on the results of the SUREG analysis in Stata v. 18 (StataCorp, USA).

HRQoL, health-related quality of life; ICER, incremental cost-effectiveness ratio; mTKA, manual total knee arthroplasty; QALY, quality-adjusted life year; rTKA, robotic-assisted total knee arthroplasty.

questionnaire from those who did. Imputation for missing data lowered the ICER. The Cls surrounding the cost estimates were wide but significant. The Cls surrounding the QALY estimates spanned zero. The cost difference changed drastically between imputed cases and complete cases, largely because of the proportion of missing data during follow-up. Imputed data showed a 0.0148 QALY difference (vs 0.0141 in complete cases). However, the ICER for rTKA versus mTKA was still above £30,000 at 12 months' follow-up. The principal driver of this result was the higher surgical costs in the rTKA arm.

In most of the sensitivity analyses considered in the within-trial analysis, the intervention was not cost-effective, possibly due to the short time horizon employed within the trial. However, when the imputation of the surgical costs of the outliers was performed, the difference in costs between the alternatives was significantly reduced, so that the intervention was considered cost-effective at 12 months. Furthermore, there is the potential for rTKA to be cost-effective

over a longer, more appropriate time horizon, as explored through the decision model, which suggested a significantly reduced ICER over a ten-year time horizon. Most TKAs will last beyond 20 years following surgery,<sup>53</sup> and our scenario analyses suggested a further reduction in ICER over a 20-year time horizon.

It is reasonable to conclude that the expected high cost of the surgical procedure associated with rTKA is intended to facilitate better patient health. However, interpreting the small between-arm QALY difference requires some considerations. First, these differences are consistent with the modest mean effect size in analysis of the intervention on the primary WOMAC clinical outcome.<sup>35</sup> Second, EQ-5D-3L lacks sensitivity to factors influencing HRQoL. This limitation has led to an updated version, the EQ-5D five-level (5L) questionnaire, being developed to address some of these issues.<sup>54</sup> The third consideration relates to the missing data. In most of the quality-of-life and surgery costs, the amount of missing data was moderate, typically less than 20%, but in some of the

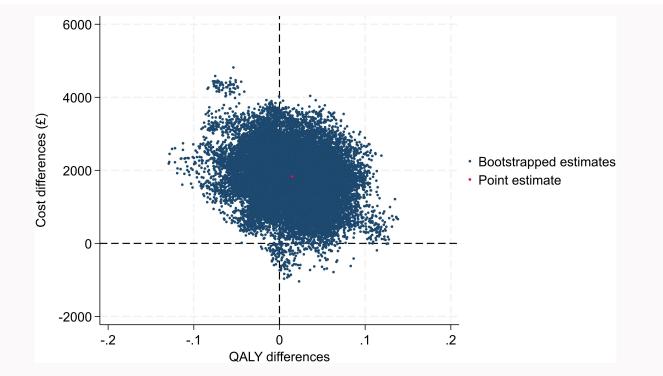


Fig. 2
Cost-effectiveness plane for robotic-assisted total knee arthroplasty (TKA) versus manual TKA. QALY, quality-adjusted life-year.

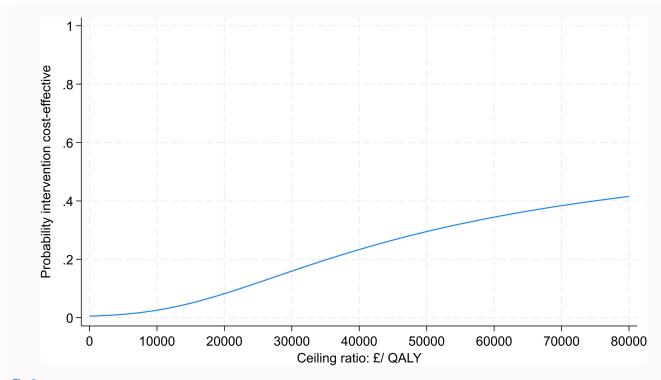


Fig. 3

Cost-effectiveness acceptability curve from NHS perspective for imputed model. QALY, quality-adjusted life-year.

resource use follow-up periods, a little more than 23% was missing. Cost components that contributed most to total costs (surgery) were derived from hospital registry data (PLICS) and thus should not be influenced by imputed missing questionnaires. However, some errors in the procedure costs reported in PLICS for some cases tend to underestimate the costs in the mTKA group and would therefore favour that arm.

In the rTKA group, the higher intraoperative costs were due to marginally longer operating theatre time and higher theatre costs (supplies and robotic-specific costs). TKA extended operating time by about 30 minutes, aligning with prior findings. Theatre costs accounted for approximately 57% of the rTKA total cost. It is possible that these increased times will reduce, and therefore will also bring

Table II. Cost-effectiveness of the intervention in different scenarios.

Model	Intervention	Unadjusted costs (£)	Adjusted incremental costs (£)*	Unadjusted QALYs	Adjusted Incremental QALYs*	ICER
Multiple imputation (n = 93) Without adjusting by covariates	rTKA	7,349.3 (7,055.3 to 7,643.3)	1,823.1 (411.8 to 3,234.4)	0.6899 (0.6736 to 0.7063)	0.0186 (-0.0579 to 0.095)	98,126
	mTKA	5,521.5 (5,409.8 to 5,633.2)		0.6714 (0.6646 to 0.6783)		
Multiple imputation (n = 93)	rTKA	5,279.6 (4,202.8 to 6,356.3)	1,886.5 (1,709.3 to 2,063.6)	0.6084 (0.5586 to 0.6582)	0.0152 (0.0073 to 0.0231)	123,485
Adjusting by age, BMI, and HRQoL in baseline	mTKA	3,393.1 (2,493.5 to 4,292.7)		0.5932 (0.5513 to 0.6351)		
Multiple imputation (n = 93) Base case: imputation of outliers	rTKA	7,538.9 (6,798.6 to 8,279.3)	461.8 (-2,128.7 to 3,052.4)	0.5065 (0.4891 to 0.5239)	0.0158 (-0.0489 to 0.0805)	29,277
	mTKA	7,085.9 (6,686.4 to 7,485.3)		0.4908 (0.4814 to 0.5001)		

<sup>\*</sup>Adjusted results are based on the results of the SUREG analysis in Stata v. 18 (StataCorp, USA).

HRQoL, health-related quality of life; ICER, incremental cost-effectiveness ratio; mTKA, manual total knee arthroplasty; QALY, quality-adjusted life year; rTKA, robotic-assisted total knee arthroplasty.

down the costs associated with rTKA. No significant differences in prosthesis costs were identified due to the use of the same type of implant; however, variations could arise with manual technique in clinical practice, as surgeons can select preferred implants while the rTKA evaluated (Mako; Stryker, USA) is a closed system that accepts only one type of implant.

The literature shows that rTKA is associated with shorter hospital stays, reducing lengths by 0.1 to 0.9 days.<sup>16-1820-2224,27-29</sup> Our study found comparable median stays but more long-stay outliers in the robotic group, resulting in similar mean ward costs between the two groups. The increase in costs of the index procedure (1.41 times) is in line with studies reported in other regions, particularly the USA. In non-randomized studies that included the upfront costs of the robot, the costs of rTKA are between 1.00 and 1.34 times higher than those of mTKA. 16,24-27 Unfortunately, due to the lack of randomization, these studies are likely subject to selection bias. Information regarding follow-up costs is contradictory. Some studies report lower costs with rTKA, particularly in post-acute care facilities and readmissions. 17,19,20,22,29 However, the mechanisms associated with such a cost reduction are not fully understood.<sup>30</sup> In the present study, differences in follow-up costs were not significant, though the data on readmission costs were limited.

The majority of cost-utility studies identified were developed in the USA and are model-based.<sup>30-32</sup> A study that only considers procedure duration found better results in moderately large settings involving patients with a high revision risk.<sup>30</sup> Those considering a long-term time horizon show consistent results, influenced by institution procedure volume and lower revision rates.<sup>31,32</sup> Another analysis with reduced revision rates suggests an ICER of USD \$376,145/QALY, potentially cost-effective only through increased procedures.<sup>55</sup>

This study had limitations. It relied on a 12-month trial follow-up, possibly missing the longer-term benefits of surgery. It may be necessary to model or collect data from patients with longer-term follow-ups to extrapolate these results in a more robust model-based analysis. The trial also has limited generalizability, since it involved two surgeons in a single centre in the UK and included a relatively small number of patients. The study database lacked the granularity

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to access a more detailed costing of surgery- and robot-related costs. The analysis does not provide any evidence regarding the impact of efficiency enhancements on costs. Follow-up service use data was self-reported, potentially leading to recall accuracy issues. Thus, absolute costs after 12 months of follow-up for rTKA and mTKA patients may be underestimated. However, this would not be likely to affect one group more than another. The study collected data on post-procedure readmissions, but did not objectively determine whether they were procedure-related, reoperation, or revision.

The study included surgeons experienced in the manual technique, but future research should consider the learning curve with the Mako system, which impacts performance, precision, and operating time, and procedure costs in the short term.<sup>2</sup> Longer-term data are needed to assess whether improved alignment in rTKA leads to lasting gains in function, implant survival, and patient satisfaction. 13,22,32 Information should be collected about which subgroups could receive the greatest benefit in order to define a risk-prioritized treatment policy. A prior study pointed to patients who are at the highest revision risk due to their demographic characteristics (younger age, higher BMI, and male sex).<sup>30</sup> Economies of scale may reduce intervention costs. Future cost-effectiveness analyses should consider procedure volume to estimate technology cost effects more accurately. Evaluating various contracting or agreement types for technology use is also relevant.56

In conclusion, rTKA was not a cost-effective alternative to mTKA in the short term at the commonly applied NICE threshold. It is plausible that rTKA would be cost-effective over a longer ten-year time horizon, if further data were to be collected, as supported by the decision model developed within this study.

## **Supplementary material**

Tables showing unit costs of health and social service resource use, complication costs, unit costs of mobility aids, baseline characteristics, number and proportion of individuals with complete data by treatment allocation, logistic regression for missingness of costs and quality-adjusted life-years on baseline variables, and comparisons of procedure costs, readmissions and complication

costs, and readmissions and complication costs for robotic-assisted total knee arthroplasty (TKA) versus manual TKA; details of the decision model; and figure showing the pattern of missing data.

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## **Data sharing**

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