Robotic-arm-assisted versus conventional total knee replacement (RACER-Knee): a pragmatic, multicentre, participant-masked and assessor-masked, superiority, randomised controlled trial

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Summary

Background Robotic systems are being increasingly used to assist with total knee replacement (TKR). Whether robotic systems improve outcomes after TKR is uncertain. We aimed to ascertain the clinical efficacy and cost-effectiveness of the Mako robotic-arm system compared with conventional instruments for TKR.

Methods We conducted a participant-masked and assessor-masked pragmatic, superiority, randomised controlled trial at ten hospitals in Great Britain involving 33 surgeons. Patients with advanced knee osteoarthritis underwent TKR with conventional instruments (cTKR) or with the Mako robotic-arm-assisted system (rTKR). Key exclusion criteria were inflammatory arthropathy, previous fracture, or the need for complex implants. Participants were randomly assigned (1:1) through a remote computer system using minimisation by age, BMI, centre, surgeon, and primary knee compartment involved. Participants and assessors were masked through methods including using sham incisions, additional draping, and masked operation notes. The primary outcome was the Forgotten Joint Score (FJS) at 12 months after randomisation according to the intention-to-treat principle using a linear mixed-effects model. The prespecified target difference was 12 points. The trial is registered with ISRCTN (ISRCTN27624068), and long-term follow-up is ongoing.

Findings Between Dec 21, 2021, and Dec 13, 2023, 807 patients were screened and 339 were randomly assigned: 168 to rTKR and 171 to cTKR. The median age was 68·8 years (IQR 61·3–75·2), 167 (49%) were female, and 172 (51%) were male. At 12 months, the mean FJS was 49·2 (SD 28·4; n=154) in the rTKR group and 50·2 (29·9; n=158) in the cTKR group. The adjusted mean difference was –1·5 (95% CI –7·5 to 4·5; p=0·62,) favouring cTKR. 16 participants in each group had one serious adverse event.

Interpretation In this pragmatic trial, rTKR as delivered in routine practice was more costly than cTKR and did not provide a clinically meaningful patient benefit at 12 months after randomisation. The two groups had similar safety (ie, harms) profiles.

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Introduction

Knee osteoarthritis is a major and increasing cause of disability worldwide.[1] More than 3 million knee replacement operations were done in 2023.[2,3] Most patients have substantial improvements in pain and function; however, 12–20% have persistent severe pain or are dissatisfied, and many others continue to have some pain or awareness of their replaced joint.[4–6] Various approaches, including robotic assistance, have been introduced to improve outcomes for patients undergoing knee replacement surgery.

The use of robotic assistance in total knee replacement (TKR) varies internationally: in 2024, robotic assistance was used in 6% of procedures in the UK, 16% in the USA, and 41% in Australia.[7–10] Compared with conventional TKR, robotic-assisted TKR could improve surgical precision, reduce iatrogenic bone and soft-tissue injury, and reduce early postoperative pain.[11–13]

With the most commonly used system (Mako; Stryker, Fort Lauderdale, FL, USA), a CT scan is done before surgery.[9] A three-dimensional plan defines the intended bone cuts and implant position, and the robotic system constrains the saw within prespecified boundaries. The surgeon controls a saw attached to the robotic arm.

Conventional instruments are generally used to achieve a straight leg, with the implants positioned perpendicular to the mechanical axes of the femur and tibia. However, limb alignment varies in the healthy population.[14] Many surgeons therefore favour alignment strategies tailored to the individual patient. Robotic-arm assistance allows surgeons to alter the angles and depths of bone cuts, enabling implant positioning to be customised to the

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Research in context

Evidence before this study

Total knee replacement (TKR) is one of the most common elective operations worldwide. Robotic systems that assist the surgeon to do TKRs have been introduced into care, but whether they improve patient outcomes remains uncertain. Before this study, a systematic review and meta-analysis of 22 studies, involving 2346 participants, evaluating robotic systems for TKR identified no randomised controlled trials of robotic systems in current use. Non-randomised studies suggested improved early outcomes with robotic surgery, including less pain, shorter length of stay, and greater satisfaction at 6 months compared with TKR. In 2025, we performed an updated systematic review and meta-analysis, for which the available evidence remained predominantly observational studies and which suggested better medium-term (3–12 months) outcomes with the Mako (Stryker, Fort Lauderdale, FL, USA) robotic system, the most widely used system worldwide, than with conventional instruments. During the conduct of our trial, RACER-Knee, the unmasked ROAM randomised controlled trial, which included 50 participants assigned to robot-assisted TKR and 50 assigned to conventional TKR, reported no significant between-group differences in its primary outcome, the Western Ontario and McMaster Universities Osteoarthritis Index, at 6 or 12 months.

Added value of this study

To our knowledge, RACER-Knee is the largest participant-masked and assessor-masked randomised controlled trial of robotic-arm-assisted TKR (rTKR). In a pragmatic comparison of rTKR versus conventional TKR (cTKR) as delivered in routine practice, we found no clinically meaningful difference in patient-reported outcomes, measured using the Forgotten Joint Score, at 12 months. rTKR was more costly and unlikely to be cost-effective. We updated our 2025 systematic review and meta-analysis of functional outcomes after Mako-assisted TKR by incorporating these results. We searched five databases up to March 1, 2026, and identified one other randomised trial, ROAM. Meta-analysis of the two available randomised trials (RACER-Knee and ROAM, involving 439 participants), showed no difference in patient-reported outcomes at 3 or 12 months. Serious adverse events were similar between groups in RACER-Knee. Both trials found that robotic TKR was unlikely to be cost-effective.

Implications of all the available evidence

Uptake of rTKR is increasing rapidly worldwide, accounting for 6% of cases in the UK, 15% in the USA, and 41% in Australia. The available evidence from randomised controlled trials shows no clinical or cost-effective benefit of rTKR over cTKR during the first year after surgery. Under the willingness-to-pay thresholds evaluated, rTKR was more costly and was unlikely to be cost-effective.

patient's anatomy according to the surgeon's judgement. However, robotic-arm-assisted systems are more expensive than conventional instruments, which can be quicker to use.[15]

Few high-quality trials have compared robotic-arm assistance with conventional surgery, with the available evidence mostly comprising small, single-centre trials that showed marginal or no difference in patient-reported outcomes.[13,16,17] Observational data suggest potential benefits of robotic-assisted TKR at both early and late timepoints, although such benefits have not been observed in large registries.[8,10,17] To address this uncertainty, we conducted a pragmatic, multicentre, participant-masked and assessor-masked, randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of Mako robotic-arm-assisted TKR (rTKR) versus TKR with conventional instruments (cTKR) in patients with advanced knee osteoarthritis.

For the **trial registration** see https://www.isrctn.com/ISRCTN27624068

See **Online** for appendix

Methods

Study design and participants

This pragmatic, multicentre, parallel-group, participant-masked and assessor-masked, superiority, randomised controlled trial was conducted in ten hospitals in England, Scotland, and Wales. The trial was classified as stage 3 of the Idea, Development, Exploration, Assessment, and Long-term study framework (IDEAL). The study compared rTKR with cTKR but, to reflect routine practice, the specific surgical techniques or alignment strategies were not standardised.

The trial received ethics approval on July 29, 2020 (East Midlands–Nottingham 2 Research Ethics Committee, 20/EM/0159) and was registered with ISRCTN (ISRCTN27624068 on July 8, 2020). The final trial protocol has been published[18] and is available in the appendix together with the statistical analysis plan (appendix pp 31, 115). Patient and public involvement took place throughout the study, including during study design, choice of primary outcome, trial management meetings, and study oversight and dissemination. One patient partner is a coauthor (NG). The study was overseen by independent trial steering and data monitoring committees. Long-term follow-up is ongoing and is planned to continue until 10 years after randomisation.

Local clinical teams identified potential participants from surgical waiting lists, clinics, or preoperative education classes. Patients were deemed suitable for inclusion if they had knee osteoarthritis warranting TKR and persistent symptoms despite conservative treatment,

as assessed by the treating clinician. Exclusion criteria were osteoarthritis secondary to inflammatory arthropathy or intra-articular fracture; revision surgery or the need for complex implants; age younger than 18 years; being considered unfit for surgery by the treating clinician or having another contraindication to surgery; previous randomisation in the trial for the other knee; or inability to participate in trial procedures, including inability to provide informed consent or complete questionnaires in English. Eligible patients provided written informed consent before any study data collection, with potential participants given the option to consent remotely (with a process for telephone or video conference consent). Sex and ethnicity data were collected from hospital records.

Randomisation and masking

On the day of surgery, consent and eligibility were confirmed by the clinical team. Randomisation was done no more than 3 h before surgery. A bespoke web application, developed by Warwick Clinical Trials Unit but independent of the study team, was used to allocate treatment. An online platform and a telephone interactive voice response system were available. Participants were randomly allocated 1:1 to the two treatment groups using a minimisation algorithm. We did not use a burn-in period, but included a 70% random element for all allocations, with minimisation by patient age (<60 years *vs* ≥60 years) and BMI (<35 kg/m² *vs* ≥35 kg/m²), recruitment centre, operating surgeon, and primary knee compartment involved (medial, lateral, or patellofemoral).

Randomisation took place after all baseline data were collected, with medical history and demographic data collected from hospital records. To achieve blinding, additional draping was used in theatre to block participants' view of surgical equipment and some robotic system equipment was kept in theatre regardless of allocation. Participants who were conscious during the procedure listened to music through headphones. In the cTKR group, small sham skin incisions (typically 1–2 cm over the tibia) were made to match the additional skin incisions that participating surgeons would normally make during rTKR. In rTKR, these incisions accommodate bone pins that are used to guide the robotic arm. In the conventional TKR group, the incisions were made and closed in the same way, but no pins were inserted.

A masked operation note based on a standardised template was used for all cases. Unmasked surgical notes were entered directly into a secure database, with procedures in place for unmasking when required. All members of the clinical team, apart from the operating surgeon and theatre staff, were masked to treatment allocation. At the primary outcome timepoint, participants were asked whether they thought they knew which surgical treatment they had received to assess the success of participant masking; they reported either robotic-arm-assisted surgery, conventional surgery, or that they did not know which treatment they had received (appendix p 15).

Procedures

All treating surgeons delivered both intervention and control procedures, which were described in a surgical manual (appendix p 6). We focused on the Mako system, which was the most widely used robotic system worldwide when the study began (and is still, currently). All surgeons using the Mako system are required to undergo a surgical training course before using the system. Study surgeons were also required to have done at least ten rTKR procedures with the Mako system before joining the trial.

Participants in both groups underwent CT, typically within 12 weeks before surgery, to preserve masking and ensure identical preoperative procedures across groups. CT scans were transferred to Stryker in accordance with usual clinical practice for the Mako system, and a surgical plan was generated and made available to surgeons regardless of treatment allocation. A protocol was used to minimise radiation exposure from the study CT scans. The additional radiation exposure was discussed with and approved by patient partners during study development. Full details of both procedures are documented in the RACER-Knee surgical manual (appendix p 6), but briefly the interventions were as follows.

For rTKR, TKR was done using the Mako robotic system and Triathlon implants (Stryker, Fort Lauderdale, FL, USA). All implants were cemented. For all Mako procedures, a Stryker product specialist was present to operate the software and provide technical support. The preoperative plan initially used mechanical alignment, but surgeons could modify the plan during surgery according to their usual clinical practice, including to achieve balanced gaps on the Mako system. The alignment strategy was therefore not standardised or dictated by the study. To represent current use in practice, the decision about which alignment method to use during the operation was left to the surgeon and was not dictated by the study. Data on alignment changes made during surgery are in the appendix (p 27). All other care for patients undergoing rTKR, including anaesthesia and postoperative analgesia, followed standard care at the site.

For cTKR, participants allocated to the control group received TKR done with conventional instruments and the same Triathlon implants for rTKR. Although the initial strategy was to achieve mechanical alignment (conventional instruments are designed to achieve neutral alignment and are not designed for intra-operative adjustments), surgeons could follow their routine clinical practice. Patient-specific instruments or computer navigation were not used. All implants were cemented. All other care for patients undergoing cTKR, including anaesthesia and postoperative analgesia, followed standard care at the site.

For rehabilitation, a standardised programme of inpatient and outpatient physiotherapy was developed for all participants following TKR. In accordance with UK National Institute for Health and Care Excellence (NICE) guidance, this included standardised postoperative information, home exercise plans, and the potential for supervised physiotherapy as required.[19] A physiotherapy manual was given to all sites and a rehabilitation booklet was provided to all participants (appendix p 6). Physiotherapy components are reported in line with Template for Intervention Description and Replication criteria (appendix p 29).

Outcomes

The primary clinical efficacy outcome was the Forgotten Joint Score (FJS) at 12 months after randomisation.[20] The FJS is a 12-item patient-reported outcome measure, scored from 0 to 100, in which 0 represents the worst outcome (constant awareness of the replaced knee joint) and 100 represents the best outcome (no awareness of the replaced knee joint). FJS was centrally assessed, and we chose 12 months as the primary timepoint because recovery in FJS, pain, and function after TKR generally plateaus by this time and is maintained in the medium term.[21–24] The primary health economic outcome was cost per quality-adjusted life year (QALY) gained at 12 months after randomisation.

Secondary outcomes were split into two time periods: in hospital and out of hospital. The latter were collected 3, 6, and 12 months after randomisation. A full schedule of assessments is in the protocol (appendix p 66).[18]

In-hospital outcomes (collected by sites) were mean pain intensity, measured using an 11-point Numerical Rating Scale for immediate pain on the mornings of days 1, 2, and 3 after surgery; pain over the past 24 h; pain when the operated knee was at rest and when it was moved over the first 3 days after surgery; estimated blood loss (calculated using Brecher's formula[25]); opioid use to the end of day 3 as total morphine equivalent dose (appendix p 17); and hours from end of surgery to hospital discharge.

Out-of-hospital outcomes (patient-reported and centrally assessed) were overall knee function using the FJS; FJS scored using a novel item response theory method; EuroQol 5-Dimension 5-Level (EQ-5D-5L) utility scores calculated with the Hernández crosswalk values,[26] with EQ-5D-5L also recorded at 6 weeks; Oxford Knee Score; Oxford Participation and Activities Questionnaire; pain during the previous week measured with the Patient-Reported Outcomes Measurement Information System Pain Intensity scale, version 2; satisfaction with the knee replacement measured with a 5-point Likert scale; Participant Global Impression of Change, measured with a single 7-point Likert-scale item; reoperations and complications, including implant survival; and health resource use using participant questionnaires capturing hospital admissions, outpatient care, community health and social care services, and medication use.

For process outcomes, participants were asked to report the number of physiotherapy sessions they attended, and had long-leg radiographs, short leg lateral x-rays, and a CT scan of the knee 3 months after surgery. The alignment of the implants in all three planes was measured using a standardised imaging protocol (imaging manual, appendix p 6) by three senior resident orthopaedic surgeons under the supervision of a senior radiologist. The main definition of alignment for the purposes of precision were the hip–knee–ankle (HKA) angles from the long leg radiograph. Precision was defined as the difference between the observed HKA angle and the target alignment in surgery, taken as the predicted final HKA from the Mako system and zero for conventional instruments (as these are designed to achieve mechanical alignment).

Safety outcomes were adverse events and serious adverse events (SAEs), which were recorded within 12 months after randomisation and centrally assessed, either when reported directly to the central team by the recruitment site, after the site became aware of the event, or after investigation of events self-reported by the patients in follow-up questionnaires. The collection of patient-reported outcomes was coordinated centrally. SAEs related to potential infections were further assessed and classified according to standard criteria[27] by an independent panel consisting of a microbiologist and an orthopaedic surgeon masked to group allocation.

Statistical analysis

The sample size was based on a target between-group difference of 12 points in the FJS and an assumed SD of 30 points.[18,28] We selected this difference because it corresponds approximately to a 1-point improvement in each of the 12 FJS items. This difference corresponded to a moderate standardised effect size of 0·4 and was consistent with values subsequently reported in the literature.[29] With 90% power and a two-sided type I error rate of 5%, 266 participants were needed (133 per group). Allowing for up to 20% loss to follow-up, the target sample size was 332 participants. No a-priori sample size or power calculations were done for secondary outcomes. The primary outcome sample size calculation was done using R, version 3.5.1.

All analyses were planned and performed according to the intention-to-treat principle, unless otherwise specified. Because missing data were few, no imputation or other adjustment for missing data was used. The detailed statistical analysis plan was finalised on Dec 14, 2023, before the final analysis—trial statisticians were unmasked. For per-protocol and as-treated analyses, participants were classified as having received rTKR if their TKR was completed according to the Mako plan and done entirely with the robotic-arm device. Participants were classified as having received cTKR if their TKR was

done without or with only partial use of the robotic-arm device. Analyses were conducted in Stata (version 18.0) and R (version 4.5.0).

The primary analysis was done using a linear mixed-effects model. Treatment allocation, age (<60 years *vs* ≥60 years), BMI (<35 kg/m² *vs* ≥35 kg/m²), sex (male *vs* female), primary compartment involved (medial, lateral, or patellofemoral), and baseline FJS were added as fixed effects. Site of recruitment and operating surgeon were added as random (intercept) effects, with surgeons nested within sites. Continuous secondary outcomes were analysed in a similar manner, although only patient-reported outcomes had baseline scores added. Model diagnostics were assessed to establish fit for all statistical models where appropriate. Categorical outcomes were summarised using descriptive statistics and between-group differences estimated using a χ^2 test, counts were modelled using a negative binomial model in the same manner as the primary outcome at each timepoint without any adjustment for differential follow-up (ie, an exposure–time offset was not used). Prespecified subgroup effects of BMI (<35 kg/m² *vs* ≥35 kg/m²) and primary compartment involved (medial, lateral, or patellofemoral) were assessed by adding treatment-by-subgroup interaction terms to the mixed-effects model (appendix, p 12). Post-hoc exploratory analyses examined the effects of surgeon caseload and experience, implant type, and whether patella resurfacing occurred.

A detailed health economic analysis will be published elsewhere, and full details are provided in the Health Economic Analysis Plan (appendix p 6). In this Article, we present only the base-case analysis. A prospective within-trial economic evaluation was conducted from the perspective of the UK National Health Service (NHS) and Personal Social Services over a 12-month time horizon. Unit costs were obtained from national sources, and all costs were converted to 2024 prices and reported in pounds sterling (£).

The cost of rTKR included the standard conventional TKR cost plus per-patient costs or savings associated with robotic-arm-assisted technology, on the basis of costs provided by Stryker. The total robotic technology cost incorporated rental, maintenance, and consumable costs, assuming a 5-year technology lifespan and an annual throughput of 300 TKR procedures. Future robotic technology costs were discounted at 3·5% in accordance with NICE guidance. For both cTKR and rTKR, participants reported resource use during follow-up, to which unit costs were subsequently applied. QALYs were derived from EQ-5D-5L data using the van Hout crosswalk values[30] and estimated with the area-under-the curve method.

Following the intention-to-treat principle, costs—including costs of the initial hospital admission and subsequent NHS and Personal Social Services resource use—and QALYs over 12 months were estimated jointly using bivariate seemingly unrelated regression, to derive incremental costs and QALYs. The models were adjusted for age group, BMI, sex, and primary compartment involved; the QALY model was additionally adjusted for baseline EQ-5D-5L utility. Non-parametric bootstrap sampling with 3000 replicates was used to quantify uncertainty. Results were summarised as incremental cost per QALY gained, with cost-effectiveness planes and net monetary benefit at willingness-to-pay thresholds of £15 000, £20 000, and £30 000 per QALY gained. Multiple imputation was used for missing costs and EQ-5D-5L utility data.

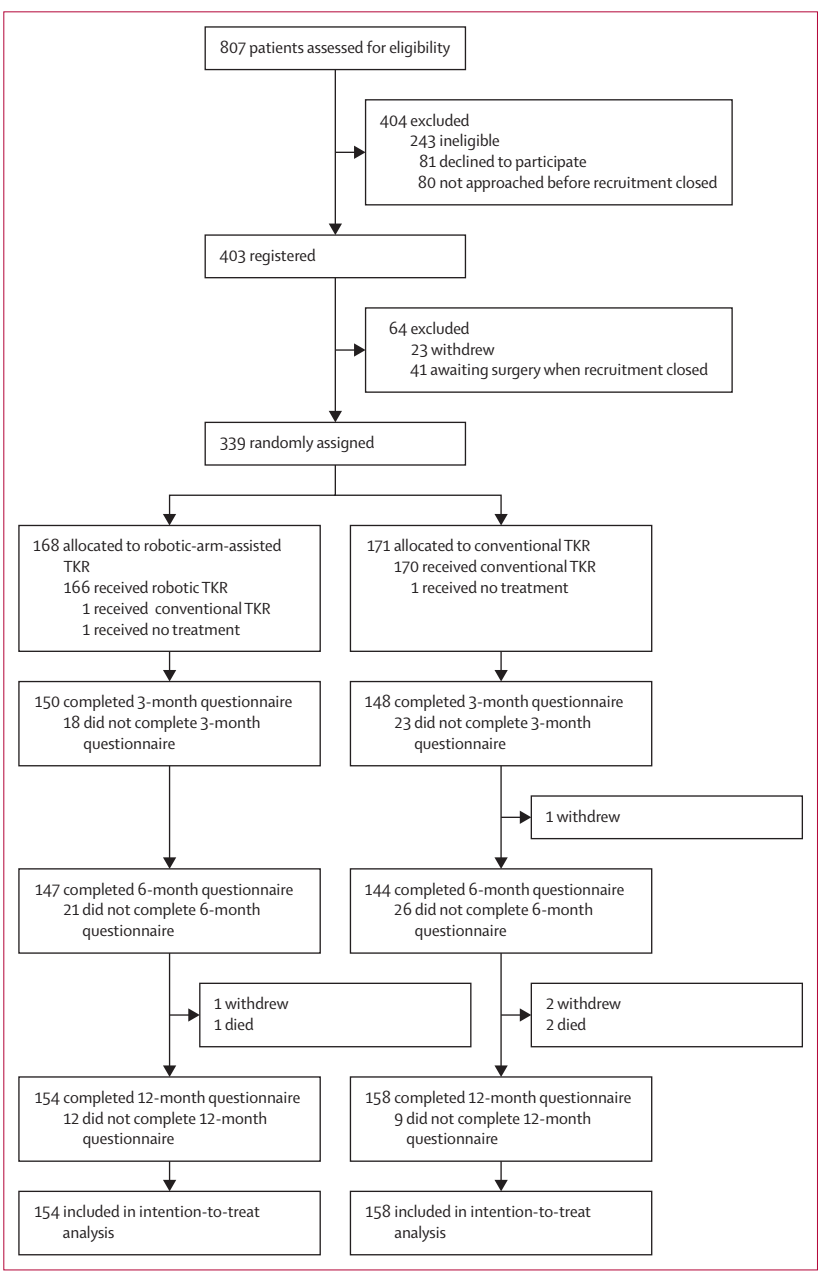

Figure 1: **Trial profile**
TKR=total knee replacement.

Role of the funding source

RACER-Knee was funded by the National Institute of Health and Care Research Health Technology Assessment programme (NIHR128768). The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the paper. Stryker provided funding for consumables, surgical instruments, preoperative CT costs, 15 min of theatre time, the provision of robotic systems at two of the recruitment sites, and provided surgeon training. The independence of the trial team was protected by contracts agreed by Stryker, the sponsor, and the UK National Institute for Health and Care Research. Stryker has reviewed the paper for intellectual property infringements or accuracy about describing the company but has had no other role in interpreting the data or preparing the manuscript.

	Robotic-arm-assisted total knee replacement (n=168)	Conventional total knee replacement (n=171)
Age (years), median (IQR)	68·9 (61·4–75·3)	68·5 (61·3–75·2)
Age group		
<60 years	34 (20%)	35 (20%)
≥60 years	134 (80%)	136 (80%)
Sex		
Female	80 (48%)	87 (51%)
Male	88 (52%)	84 (49%)
BMI (kg/m²), median (IQR)	32·0 (28·0–35·2)	31·6 (27·9–35·3)
BMI group		
<35 kg/m²	121 (72%)	121 (71%)
≥35 kg/m²	47 (28%)	50 (29%)
Affected knee		
Left	75 (45%)	85 (50%)
Right	93 (55%)	86 (50%)
Most-affected knee compartment		
Medial	129 (77%)	127 (74%)
Lateral	31 (18%)	31 (18%)
Patellofemoral	8 (5%)	13 (8%)
Duration of symptoms		
<1 year	2 (1%)	2 (1%)
1–5 years	76 (45%)	70 (41%)
6–10 years	41 (24%)	42 (25%)
>10 years	49 (29%)	56 (33%)
Not reported	0	1 (<1%)
Ethnicity		
White	151 (90%)	160 (94%)
Asian or Asian British	9 (5%)	7 (4%)
Black, African, Caribbean, or Black British	5 (3%)	3 (2%)
Mixed or other ethnic group	3 (<1%)	0
Missing	0	1 (<1%)
Forgotten Joint Score	9·0 (10·3)	9·2 (10·8)
EuroQol 5-Dimension 5-Level	0·392 (0·270)	0·376 (0·280)
Oxford Knee Score	19·3 (7·7)	18·7 (7·9)
Oxford Participation and Activities Questionnaire	10·5 (15·2)	9·7 (15·2)
PROMIS Pain Intensity	66·1 (7·2)	66·1 (7·3)

Data are n (%) or mean (SD) unless otherwise specified. PROMIS=Patient-Reported Outcomes Measurement Information System.

Table 1: **Baseline characteristics in the intention-to-treat population**

Results

From Dec 21, 2021, to Dec 13, 2023, we screened 807 potential participants from ten sites in England, Scotland, and Wales; 564 (70%) of 807 were eligible to participate, 403 (50%) registered to take part in the study and 339 (42%) were randomly assigned: 168 to rTKR and 171 to cTKR (figure 1; appendix p 7). 33 surgeons took part, who had a median of 69 knee replacement cases annually (range 17–256; appendix p 25). Three participants did not receive their allocated treatment: one participant allocated to rTKR received cTKR because a robotic arm failed to register, and two—who became ineligible between randomisation and start of surgery—received no treatment. All 339 participants were included in the intention-to-treat population.

Baseline characteristics are shown in table 1. The median age of participants was 68·8 years (IQR 61·3–75·2), 167 (49%) were female, and 172 (51%) were male. 311 (92%) participants were White, which aligns with age-stratified census data.[31] Primary outcome data were available from 312 participants (92%) at 12 months after randomisation. Of the 27 participants without 12-month data, three (1%; one in the rTKR group and two in the cTKR group) had withdrawn from follow up, three had died (1%; one in the rTKR group and two in the cTKR group; no deaths were related to the study procedures), and 21 (6% of total randomly assigned; 12 in the rTKR group and nine in the cTKR group) did not complete the 12-month questionnaire.

FJS improved from baseline in both groups (figure 2). At 1 year, the mean FJS was 49·2 (SD 28·4) in the rTKR group and 50·2 (29·9) in the cTKR group. In the primary adjusted analysis, the adjusted mean between-group

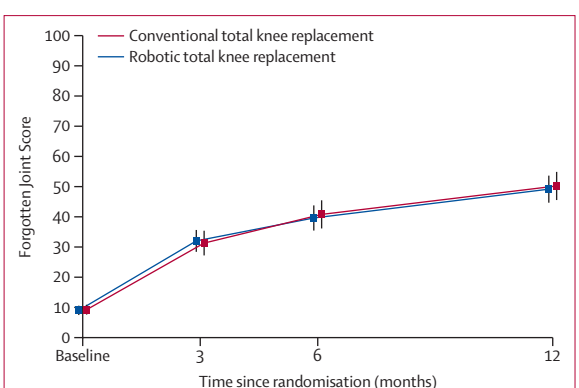

Figure 2: **Forgotten Joint Score over 12 months after randomisation**
Data are means; error bars show 95% CIs. Group-specific points are displaced slightly horizontally for visibility.

difference in FJS was –1·5 (95% CI –7·5 to 4·5; p=0·62), which excluded our predetermined target difference of 12 points and was not statistically significant. The planned per-protocol and as-treated analyses were similar (per-protocol adjusted mean difference –1·4 [95% CI –7·4 to 4·6], n=309 of a possible 336; as-treated adjusted mean difference –1·3 [–7·3 to 4·6], n=310 of a possible 337). Secondary out-of-hospital outcomes at each timepoint were similar, showing small differences between groups that were not significant (table 2). Secondary in-hospital outcomes, including early pain scores, opiate use, and time to discharge showed no clear between-group differences.

16 participants in each group had one SAE each. Six of the SAEs were related to infection: one deep incisional infection in the rTKR group; one pin-site sham incision infection in the conventional TKR group; two deep joint-space infections, one in each group; and two superficial incisional infections in the cTKR group (appendix p 9). Overall, 21 participants in the rTKR group and 16 participants in the cTKR group had at least one adverse event (table 3; appendix pp 9–10).

In our prespecified subgroup analyses, there was no evidence that the effect of treatment on 12-month FJS differed by BMI group or primary knee compartment involved (appendix p 13). Post-hoc exploratory analyses

	Robotic-arm-assisted total knee replacement (n=168)	Conventional total knee replacement (n=171)	Adjusted effect estimate (95% CI)
Primary outcome			
Forgotten Joint Score at 12 months	49·2 (28·4); 154	50·2 (29·9); 158	–1·5 (–7·5 to 4·5), p=0·62
Secondary outcomes			
Forgotten Joint Score			
At 3 months	32·0 (22·6); 150	31·3 (25·4); 148	0·6 (–4·6 to 5·8)
At 6 months	39·6 (25·8); 147	40·8 (28·6); 144	–1·1 (–7·0 to 4·8)
Post-surgery pain averaged across days 1–3 in operated knee			
At the moment	5·3 (2·1); 161	5·5 (2·1); 162	–0·1 (–0·6 to 0·3)*
At rest over past 24 h	5·3 (1·9); 161	5·4 (1·9); 162	–0·1 (–0·5 to 0·3)*
When moving over past 24 h	7·0 (1·7); 161	6·8 (1·7); 162	0·2 (–0·2 to 0·5)*
Total opioid usage (morphine equivalent dose) days 1–3	79·8 (74·8); 165	83·0 (62·7); 170	–1·5 (–14·9 to 11·9)*
Hours from surgery completion to discharge	76·1 (113·4); 159	73·4 (54·1); 165	3·8 (–15·0 to 22·5)*
EuroQol 5-Dimension 5-Level (utility score)			
6 weeks	0·642 (0·185); 154	0·638 (0·199); 155	–0·002 (–0·043 to 0·038)
3 months	0·667 (0·208); 151	0·691 (0·192); 150	–0·025 (–0·067 to 0·018)
6 months	0·722 (0·207); 147	0·724 (0·247); 149	–0·006 (–0·051 to 0·040)
12 months	0·759 (0·198); 154	0·737 (0·270); 158	0·012 (–0·035 to 0·060)
Oxford Knee Score			
3 months	32·3 (8·5); 151	32·5 (9·0); 149	–0·2 (–2·0 to 1·7)
6 months	35·1 (8·7); 147	35·1 (9·5); 149	–0·1 (–1·9 to 1·7)
12 months	37·3 (9·1); 155	36·9 (9·9); 157	0·3 (–1·8, 1·9)
Oxford Participation and Activities Questionnaire score			
3 months	43·6 (27·8); 151	46·2 (32·9); 150	–2·4 (–9·2 to 4·3)
6 months	52·6 (29·3); 147	53·8 (33·4); 149	–1·8 (–8·7 to 5·0)
12 months	60·2 (30·6); 155	59·0 (32·1); 157	1·2 (–5·5 to 7·8)
PROMIS Pain Intensity (T-score)			
3 months	52·1 (8·9); 149	51·7 (9·6); 147	0·1 (–1·9 to 2·1)*
6 months	50·1 (10·8); 144	49·2 (10·3); 148	0·6 (–1·7 to 2·9)*
12 months	45·9 (9·6); 153	46·3 (10·6); 153	–0·6 (–2·7 to 1·5)*
Physiotherapy sessions within 12 months			
Total number of sessions	5·4 (5·3); 164	6·5 (6·4); 164	0·8 (0·6 to 1·0)†
Health economic costs			
Initial admission (including robotic system costs) per allocation group	£7814·03 (1257·97); 159	£6819·49 (261·21); 167	994·55 (795·04 to 1194·06)
Total NHS and PSS cost 0–3 months	£759·38 (1268·48); 141	£671·23 (713·06); 140	88·15 (–152·24 to 328·55)
Total NHS and PSS cost 3–6 months	£236·70 (290·62); 139	£327·72 (391·81); 140	–91·03 (–171·94 to –10·12)
Total NHS and PSS cost 6–12 months	£195·71 (354·36); 154	£297·52 (603·52); 155	–101·81 (–212·08 to 8·47)
Total NHS and PSS cost 0–12 months , mean (bootstrap SD); n‡	£8979·69 (210·38); 116	£8140·66 (109·45); 116	839·03 (370·95 to 1307·11)

(Table 2 continues on next page)

	Robotic-arm-assisted total knee replacement (n=168)	Conventional total knee replacement (n=171)	Adjusted effect estimate (95% CI)
(Continued from previous page)			
Process outcomes			
Time from skin incision to final dressing, min	92 (24·5); 165	83 (22·3); 170	10·5 (6·8 to 14.3)
Radiology: 3 months after operation			
Hip–knee–ankle angle§	−0·8° (2·8); 111	−0·7° (3·7); 133	−0·1 (−0·9 to 0·7)
Absolute difference between achieved and planned hip–knee–ankle angle	2·0° (1·8); 102	2·8° (2·4); 133	−0·8 (−1·4 to −0·3)
Lateral distal femoral angle	89·9° (2·0); 111	89·1° (2·3); 133	0·8 (0·2 to 1·3)
Medial proximal tibial angle	89·5° (2·0); 111	89·6° (2·1); 133	0·0 (−0·6 to 0·5)
Tibial slope	3·1° (2·2); 143	4·4° (2·7); 149	−1·3 (−1·9 to −0·8)
Femoral rotation	3·0° (2·5); 98	3·1° (2·6); 119	0·0 (−0·7 to 0·6)
Tibial rotation	18·4° (10·0); 122	17·9° (9·2); 134	0·6 (−1·8 to 3·0)

Data are mean (SD); n, unless otherwise stated. Negative values favour conventional total knee replacement, unless otherwise indicated. NHS=UK National Health Service. PROMIS=Patient-Reported Outcomes Measurement Information System. PSS=Personal Social Services. *Positive values favour conventional total knee replacement. †Adjusted rate ratio (negative binomial model). ‡Complete-case estimates; uncertainty estimated by non-parametric bootstrapping; no imputation applied. §Negative values represent varus alignment.

Table 2: **Key trial outcomes at each follow-up point**

	Robotic-arm-assisted total knee replacement (n=168)	Conventional total knee replacement (n=171)	All participants (n=339)
Adverse events per participant			
Yes (any number)	21 (13%)	16 (9%)	37 (11%)
1 adverse event	19 (11%)	13 (8%)	32 (9%)
≥2 adverse events	2 (1%)	3 (2%)	5 (1%)
Participants with any serious adverse event			
1 serious adverse event	16 (10%)	16 (9%)	32 (9%)

Data are n (%).

Table 3: **Participants with any adverse event within 12 months of randomisation**

of whether patellar resurfacing, implant bearing type, surgeon caseload, or surgeon experience were associated with 12-month FJS are presented in the appendix (p 13).

As a prespecified secondary assessment of participant masking, participants were asked whether they thought they knew which treatment they had received. 153 (45%) of 339 participants reported that they did not know, of whom 73 (48%) received rTKR and 80 (52%) received cTKR. 157 participants (46%) believed that they did know, and 29 (9%) did not respond. Of the 157 participants who thought they knew their allocation, 145 (92%) believed that they had received rTKR, and 12 (8%) believed they had received cTKR. Of those who thought they knew their allocation, 88 (56%) of 157 correctly identified their allocated group, and 69 (44%) were incorrect. An exploratory analysis showed that those participants who thought that they had received rTKR had higher FJS values than those who thought they had received cTKR (mean 53·1 *vs* 31·5; appendix p 15).

Secondary analyses showed that the use of robotic assistance increased the mean operating time by 10·5 min (95% CI 6·8–14·3; p<0·0001). In exploratory radiological analyses, rTKR resulted in greater precision of the HKA angle relative to the planned target than did cTKR (mean difference −0·8° [95% CI −1·4 to −0·3]; p=0·0027; table 2). The lateral distal femoral angle was slightly higher (0·8° [0·2 to 1·3]; p=0·0046), and the tibial slope was slightly shallower in the rTKR group than the cTKR group (−1·3° [−1·9 to −0·8]; p<0·0001). Other radiological measures showed no clear between-group differences. Further details of the surgery and physiotherapy delivered, including additional exploratory radiological and process measures, are provided in the appendix (pp 18–25). In a secondary analysis, participants in the cTKR group had more physiotherapy sessions within 12 months than participants in the rTKR group, although there was no clear evidence of a between-group difference (adjusted relative rate 0·8 [95% CI 0·7–1·0]; p=0·055; table 2).

The prespecified health economic analysis showed that the cost of the initial admission was substantially higher in the rTKR group than in the cTKR group (mean difference £994·55 [95% CI 795·04–1194·06]), primarily because of the robotic system costs. After multiple imputation of missing data, rTKR was associated with higher overall costs (mean imputed incremental cost £958 [542 to 1375]) and slightly fewer QALYs (mean imputed incremental QALYs −0·004 [−0·037 to 0·030]) and was therefore dominated by cTKR in the base-case analysis. The probability that rTKR was cost-effective at willingness-to-pay thresholds of £15 000, £20 000, and £30 000 per QALY gained was 0·27%, 0·87%, and 4·2%, respectively, and the net monetary benefit was negative at each threshold (−£1002 [−1732 to −293]; −£1019 [−1888 to −160]; and −£1052 [−2215 to 126], respectively).

Discussion

In this multicentre, pragmatic, participant-masked and assessor-masked trial, we found no difference in 12-month FJS between rTKR and cTKR. The mean difference was small (–1.5, favouring cTKR), and the limits of the 95% CI excluded our target difference of 12 points on the FJS. These findings provide no evidence of a clinically meaningful benefit of rTKR, as delivered in this trial, over cTKR.

We found no clear differences between the two groups across a range of secondary outcomes important to patients, either at early timepoints or up to 12 months. Separate mixed-methods work identified walking and functional activities, early pain (first 6 weeks), late pain (at 12 months), and reoperations (up to 10 years) as priorities for people undergoing TKR.[32] In our trial, outcomes were similar between groups across these domains. For acute pain,[33] Oxford Knee Score,[34] and EQ-5D-5L,[35] the 95% CIs excluded previously reported minimal important differences. These findings make clinically meaningful between-group differences in those outcomes unlikely, although the analyses were not adjusted for multiple comparisons and secondary outcomes should be interpreted carefully.

In the cost-effectiveness analysis, rTKR was dominated by cTKR and had only a 4% probability of being cost-effective at a willingness-to-pay threshold of £30 000 per QALY gained. Within the 12-month time horizon and under current NICE willingness-to-pay thresholds, rTKR as used in this trial is unlikely to be a cost-effective alternative to cTKR.

Safety outcomes were similar between groups, with no clear evidence of a difference in SAEs or adverse events. More deep infections (incisional and joint space) were observed in the rTKR group than in the cTKR group (three *vs* one, respectively). Given the small number of events, this numerical difference could have arisen by chance. The overall number of SAEs related to infection, including deep and superficial infections, was also similar between groups. Rare outcomes such as infection are better assessed through registry surveillance. At present, we are not aware of any evidence of differential revision rates or infection rates related to robotic assistance from the major national registries.[7,8,10]

To reflect how rTKR and cTKR are delivered in routine practice, the trial used a pragmatic design in which surgeons followed their usual surgical techniques for both procedures. Further details of the surgical approaches are provided in the appendix (p 27). The multicentre, pragmatic nature of this study design allowed a generalisable sample of patients and wide spread of surgeons from across Great Britain. Participating surgeons were generally high-volume knee replacement surgeons, performing a median of 69 procedures annually, compared with a UK median of 37 in 2024.[36] Further details are provided in the appendix (p 25).

The optimal alignment for a knee replacement, and whether it differs between individuals, remains uncertain. This trial cannot establish whether any specific alignment strategy is superior and should not be interpreted as doing so; it was a pragmatic evaluation of rTKR rather than a trial of a specific alignment approach. Two published trials are evaluating personalised approaches to knee alignment using the Mako system, and others are ongoing.[37–39] If personalised alignment is shown to improve outcomes, technologies that enable precise implant positioning, including robotic systems, might have a role.

Patients, clinical staff, and assessors outside the operating theatre were masked to treatment allocation via draping, and some robotic equipment was left visible for all participants. Responses to the masking assessment suggested that masking was broadly maintained overall, although participants were much more likely to believe that they had received rTKR than cTKR. In a post-hoc exploratory analysis, participants who believed that they had received rTKR had higher FJS values than those who believed that they had received cTKR. This association could reflect attribution of a good outcome to robotic-arm-assisted surgery rather than an effect of perceived allocation itself (appendix p 15).

The study has limitations. In this Article, we report outcomes up to the primary assessment at 12 months. Longer-term follow-up is planned to assess patient-reported outcomes, revision surgery, and cost-effectiveness. Registry analyses have not identified differences in outcomes between rTKR and cTKR.[8] However, because robotic systems are relatively new, follow-up in registries remains relatively short.[8] The Mako system is the most widely used robotic system in both Australian and American registries,[7,8] but these findings should not be generalised to all robotic systems. Because the technologies differ, each system requires evaluation in adequately designed trials.

CT-based planning was used but the effects were not evaluated in this trial, and the findings therefore do not establish whether CT-based planning itself provides benefit. A CT scan and a preoperative plan were generated for both groups to maintain participant masking and to minimise differences attributable to preoperative planning. CT-based planning has been used in patient-specific instrumentation and computer-assisted surgery for many years.[40] Previous evaluations of these approaches have shown no clear patient benefit or only small differences in selected outcomes.[40,41] Because CT imaging and planning were used in both groups, the trial was designed to evaluate the additional effect of robotic-arm assistance during surgery, while minimising differences attributable to other components of the care pathway.

In conclusion, 33 surgeons across ten centres participated in this pragmatic, participant-masked and assessor-masked, randomised controlled trial comparing

rTKR with cTKR. No specific alignment strategy was prescribed. As used in this trial, rTKR was more costly than cTKR and did not provide a clinically meaningful benefit to patients up to 12 months after randomisation.

Contributors

JG and HP verified the data and independently performed the statistical analyses. ED and AM conceived the study. MB, NCl, DD, ED, DE, CH, FH, AM, JM, HM, HP, BR, SR, JS, CS, JS, TS, AT, and MU were co-applicants or grant holders and contributed to study design. HM, SF, and SN accessed and verified the health economic data and performed the health economic analysis. NG was a patient representative and co-applicant and contributed patient perspectives throughout the trial. CK provided clinical expertise, contributed to study management, and collected data. HB and NCr administered the project. All authors had access to the data, read and approved the draft manuscript, and had final responsibility for the decision to submit for publication.

Declaration of interests

JM, SF, DD, and DE report funding from the UK National Institute for Health and Care Research (NIHR) for this study. AM reports a NIHR grant to institution and Stryker benefit in kind for this study; is chief or co-investigator on two other studies with NIHR grants to institution and Stryker benefit in kind; reports further NIHR grants; has received payment for expert testimony for the UK COVID Inquiry; is Director and Chief Medical Officer of VerIQ; is Secretary for the British Patellofemoral Society; was research lead of the British Association of Surgery for the Knee; is on a clinical advisory board for Sagence; and holds stock in VerIQ and Sagence. AT reports research grants from Stryker Masters Services Framework research agreement, NIHR, and Versus Arthritis; royalties from Corin; and consulting fees and payment for presentations from Stryker, Corin, Adler, and Quadsense. CS reports research grants from Stryker; consulting fees from Stryker, Smith & Nephew, and Osstec; payment for lectures from Zimmer Biomet; was a member of a Data Safety and Monitoring Board and an advisory board for Smith & Nephew; is Editor in Chief for *Bone & Joint Research*; and is on the editorial board of *The Bone & Joint Journal*. CK reports a salary from the RACER-Knee grant and Stryker benefit in kind for this study. ED reports an NIHR grant and Stryker excess treatment costs for this study; research funding from Smith & Nephew and Stryker to institution; royalties from Smith & Nephew and Microport; consulting fees from Smith & Nephew, Microport, and Garland Surgical; payment for lectures from Smith & Nephew, Stryker, and Microport; payment as an expert witness for Irwin Fritchie Urquhart Moore & Daniels and Hogan Lovells International; financial support for attending meetings from Smith & Nephew, Stryker, Zimmer Biomet, and Microport; holds shares in VerIQ and Garland Surgical; and is the Director of Precision Joint Replacement. FH reports an NIHR grant for this study; research grants from the NIHR, Stryker, Smith & Nephew, Corin, and the International Olympic Committee; royalties or licenses from Smith & Nephew, Stryker, Corin, MatOrtho, and Springer; consulting fees for Stryker; payments for lectures and presentations from Stryker, Zimmer Biomet, and AO Recon; financial support for travel from Stryker, Zimmer Biomet, AO Recon, and *The Bone & Joint Journal*; is a member of *The Bone & Joint Journal* editorial board; is President of the International Hip Society; is President of the European Hip Society; and is an International Society for Technology in Arthroplasty board member. HP reports an NIHR grant to institution and Stryker benefit in kind for this study; research grants from the NIHR; and participated in three independent oversight committees for NIHR-funded studies. MU reports an NIHR grant to institution and Stryker funding to the UK National Health Service for this study; grants from the NIHR, Norwegian Medical Research Council, and Australian National Health and Medical Research Council; royalties from the University of Warwick; accepted travel and accommodation costs as an invited speaker on back pain, at UK scientific meetings from the British Pain Society and the Society for Back Pain Research; participated in a Data Safety and Monitoring Board for the NIHR; is a director at and shareholder in Clinvivo; and declares that Stryker has supplied clinical materials for another ongoing and one completed randomised controlled trial, both funded by the NIHR. NCl reports funding from Stryker for other research grants not related to this manuscript; and is an editorial board member of *The Bone & Joint Journal* and *Bone & Joint Research*. All other authors declare no competing interests.

Data sharing

The trial protocol, statistical analysis plan, and participant documents are available online (appendix). A data sharing pack containing de-identified participant data and a data dictionary will be made available upon reasonable request. Requests are subject to agreement from the chief investigators and a signed data sharing agreement and should be made to the Warwick Clinical Trials Unit at wctudataaccess@warwick.ac.uk in the first instance.

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