Total versus robotic-assisted unicompartmental knee replacement (TRAKER) for medial compartment osteorthritis: a randomized controlled trial

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Aims

Unicompartmental knee arthroplasty (UKA) is associated with an accelerated recovery, improved functional outcomes, and retention of anatomical knee kinematics when compared to manual total knee arthroplasty (mTKA). UKA is not universally employed by all surgeons as there is a higher revision risk when compared to mTKA. Robotic arm-assisted (ra) UKA enables the surgeon to position the prosthesis more accurately when compared to manual UKA, and is associated with improved functional outcomes and a lower early revision risk. Non-randomized data suggests that, when compared to mTKA, raUKA has a clinically meaningful greater functional benefit. This protocol describes a randomized controlled trial that aims to evaluate the clinical and cost-effectiveness of raUKA compared to mTKA for individuals with isolated medial compartment osteoarthritis (OA).

Methods

The total versus robotic-assisted unicompartmental knee arthroplasty (TRAKER) trial is a patient- and assessor-blinded, pragmatic parallel two-arm randomized superiority trial of adults undergoing elective primary knee arthroplasty for primary medial compartment OA at a single NHS hospital (ClinicalTrials.gov NCT05290818). Participants will be randomly allocated on a 1:2 basis to either raUKA or mTKA, respectively. The primary analysis will compare the Oxford Knee Score (OKS) six months after surgery. Secondary outcomes measured at three, six, and 12 months include the OKS, Forgotten Joint Score, patient expectations, EuroQol five-dimension questionnaire (EQ-5D), and EQ-visual analogue scale (EQ-VAS), patient satisfaction, range of motion, postoperative complications, need for further surgery, resource use, and financial costs. Cost-effectiveness will be measured over a ten-year time span. A total of 159 patients will be randomized (n = 53 raUKA vs n = 106 mTKA) to obtain 80% power to detect a five-point difference in OKS between the groups six months after surgery.

Conclusion

The trial findings will provide evidence about the clinical and cost-effectiveness of raUKA compared to mTKA in patients with isolated medial compartment OA. This will inform future National Institute for Health and Care Excellence guidelines on primary knee arthroplasty in the UK.

Take home message

- The research question of whether robotic-assisted unicompartmental knee arthroplasty results in a better patient-reported outcome, when compared to manually performed total knee arthroplasty for isolated medial compartment knee arthritis, addresses a key area of contention among surgeons.

Bone & Joint Open

Introduction

Osteoarthritis (OA) of the knee is a degenerative disease and the prevalence increases with age.[1] Unicompartmental knee arthroplasty (UKA) is an accepted management option for patients with end-stage isolated medial compartmental joint disease.[2] The potential advantages of UKA are accelerated recovery, improved functional outcomes, and retention of anatomical knee kinematics when compared to total knee arthroplasty (TKA).[3,4] However, UKA is not universally employed by all surgeons as there is an associated higher revision rate when compared to TKA.[5] The 20th National Joint Registry report demonstrated a probability of revision for the most common cemented unicompartmental knee arthroplasty was 11.4% at ten years, which was three to four times greater than the average revision rate for an unconstrained TKA (approximately 3%) in the same registry.[6] The higher revision rates associated with UKA are thought to be primarily due to component and postoperative limb malalignment, lower threshold to revise (revision bias), and surgeon volume.[7-10]

Approximately half the components inserted during manually performed UKA differ by more than 2° from the preoperative plan.[11] Robotic-assisted (ra) UKA enables the surgeon to position the prosthesis up to four times more accurately when compared to manual UKA, and is associated with improved early functional outcome.[12,13] It would also seem that implant positioning during raUKA is not influenced by surgeon volume.[14] A multicentre review of 432 raUKA demonstrated the six-year survival to be 97%.[15] There is also a lower risk of reintervention associated with raUKA compared to manually performed (m)UKA.[16] This improved survival rate, when compared to mUKA, is thought to be due to improved accuracy and reliability of implant placement.[15] Therefore, the potential functional benefits and lower complication rates of UKA could be enjoyed by the patient without the increased risk of early revision when compared mTKA for those with medial unicompartment disease.

The rate of TKA has doubled over the last 20 years in the UK to over 100,000 being performed annually, which is estimated to grow by more the 30% over the next two decades.[17,18] The Total or Partial Knee Arthroplasty Trial (TOPKAT) concluded that mUKA was a cost-effective intervention during the first five years.[19] A systematic review assessing the longer-term economic benefits found that the cost savings of mUKA persisted over the lifetime of the patient despite the associated increased revision risk.[3] More specifically raUKA has been shown to have a clinically meaningful greater functional benefit at six months postoperatively when compared to mTKA, but this was from a non-randomized study.[20] The risk of revision after mUKA is strongly associated with surgeon volume, with those performing UKA for 40% or more of their primary KA practice having the lowest risk, however in the UK over 80% of surgeons perform fewer than 10 mUKAs per year.[2] It is estimated that one-third of patients could undergo a UKA rather than a TKA, but fewer than 10% nationally do so due to the increased risk of revision.[5] This potentially results in a proportion of patients undergoing a mTKA having a worse functional outcome, with a greater risk of postoperative complications, than if they underwent a raUKA.

Aims and objectives

The purpose of this research is to compare the functional outcomes of patients with end-stage medial compartment OA of the knee who undergo a conventional mTKA with those undergoing raUKA, and to assess the associated cost economics (cost-utility analysis) of such technology. The null hypothesis is that an optimally aligned raUKA does not improve the knee-specific patient-reported functional outcome when compared to a mTKA for patients with isolated medial compartment OA of the knee.

Primary objective

To compare the change in knee-specific patient-reported function, as measured by the Oxford Knee Score (OKS)[21,22] from baseline to six months following knee arthroplasty between the two groups.

Secondary objectives

1. To compare changes in knee-specific activities of daily living (measured using the OKS and activity and participation questionnaire (APQ))[23] from baseline to three, six, and 12 months.
2. To compare changes in joint awareness (measured by the Forgotten Joint Score (FJS)[24,25] from baseline to three, six, and 12 months.
3. Preoperative patient expectation and fulfilment at six and 12 months will be assessed using the Hospital of Special Surgery (HSS) Knee Replacement Expectations Questionnaire.[26,27]
4. To compare satisfaction using a validated outcome measure at three, six, and 12 months.[28]
5. To compare the health-related quality of life (HRQoL) using the EQ-5D and EQ-VAS at baseline, three, six, and 12 months.[29,30]
6. To compare range of motion (ROM) of the knee at baseline, at discharge, three, six, and 12 months
7. To compare the cost-effectiveness of the two interventions from a UK NHS perspective.
8. To compare any differences in knee stability and power between the two groups.

Plan of investigation

Trial design

A single-site, prospective, parallel randomized controlled superiority trial will be conducted to compare the functional benefit and cost-effectiveness of raUKA compared to standard mTKA. Patients listed for a standard mTKA who meet the criteria for a raUKA will be identified from the waiting list through screening by the research team. Patients who have a date for surgery at the study centre and a planned preassessment clinic will be sent a patient information leaflet (PIL) (see PIL V2.0: Supplementary Material). A member of the research team will then contact the patient via telephone, obtaining consent to discuss the study with them. If they would like to enrol or discuss this further, this will take place at their planned preassessment clinic (two to six weeks prior to planned surgical date). For those wishing to enrol, participants will be randomly allocated using a ratio of 2:1 to either standard care (mTKA) or the intervention group (raUKA), respectively. Participants randomized to standard care will undergo a conventional mTKA. Participants randomized to the

Table I. Participant assessment timepoints.

Assessment	Baseline screening	Telephone call	Routine pre-assessment clinic	Routine admission for surgery	Routine 3-mth clinic appointment	Additional 6-mth postal questionnaire	12-mth routine clinic appointment
Timepoint			-4 weeks ± 2 weeks	Week 0	Week 12 ± 2 weeks	Week 26 ± 2 weeks	Week 52 ± 4 weeks
Screening and first approach	x						
Information provision	x						
Confirm if patient would like to participate		x					
Written informed consent			x				
Baseline data collection			x				
Randomization			x				
Routine knee radiograph not for research			x				x
CT scan for those in randomized to robotic group			x				
Surgical intervention and data collection				x			
Follow-up PROMs, ROM, knee stability, and power					x	x*	x
Complications/ AEs				x	x	x	x
Health service resource use data collection					x	x	x

*Only PROMs will be assessed.
AEs, adverse events; PROMs, patient-reported outcome measures; ROM, range of motion.

intervention group will undergo a raUKA with the assistance of the Mako robot (Stryker Orthopaedics, USA) to optimize the balance and alignment of the implant. Participants will be followed up at routine clinic appointments at three and 12 months postoperatively, with a postal questionnaire at six months postoperatively and a telephone reminder two weeks later for those which have not been returned (Table I). After the 12 months' follow-up, the participants will continue with the institution's standard postoperative care.

Primary and secondary endpoints and outcome measures

Primary outcome measure

The primary goal of joint arthroplasty surgery is to restore function and reduce pain – the outcome measures have been chosen to reflect these factors. The primary outcome will be change in functional ability as measured by the OKS, which consists of 12 questions assessed on a Likert scale with values from 0 to 4, to give a summative score.[21,22] The change in the score will then be calculated from baseline to six months (primary endpoint) following surgery. A power calculation using the minimal clinically important difference (MCID) for the OKS has been performed to assess the required sample size for the study.

Secondary outcome measures

The following outcome measures will be used to assess changes in activity levels, joint awareness, and satisfaction and health status:

1. Change in activity participation from baseline to three, six (APQ only), and 12 months following knee arthroplasty surgery. The OKS (as described above) and the APQ will be used to assess activity participation. The APQ consists of eight additional questions assessing activity and participation that are graded from zero (worst) to foue (best).[23]
2. Change in joint awareness from baseline to three, six, and 12 months following knee arthroplasty surgery. The FJS is a patient-reported outcome scale designed to assess joint awareness during various activities of daily living.[24,25] It uses a five-point Likert response format, consisting of 12 equally weighted questions with the raw score transformed to range from zero (worst) to 100 (best) points. In previous studies the score has shown good reliability and convergent validity, performed well in known-group comparisons, and has been found to be sensitive to change over time.[31]
3. Patient expectation preoperative and fulfilment will be assessed at three, six, and 12 months following knee arthroplasty surgery. The HSS is a validated measure of patient preoperative expectations of surgery.[26,27] The level of patient expectation is indicated on a five-point Likert scale as 'very important', 'somewhat important', 'a little important', 'I do not expect this', or 'this does not apply to

me'. After surgery patients will complete a similar expectation questionnaire, but are asked whether the same expectations had been fulfilled, which again is assessed on a five-point Likert scale as: 'greatly', 'a lot', 'a little', 'I did not expect this', or 'this did not apply to me'.

4. Patient satisfaction at three, six, and 12 months following surgery. This will be assessed following surgery by asking four questions with a different focus:
   i. "Overall how satisfied are you with the results of your knee arthroplasty surgery?"
   ii. "How satisfied are you with the results of your knee arthroplasty surgery for improving your ability to do housework or yard work (such as cooking, cleaning, or gardening and raking leaves)?"
   iii. "How satisfied are you with the results of your knee arthroplasty surgery for improving your ability to do recreational activities (such as taking walks, swimming, bicycling, playing golf, dancing, going out with friends)?"
   iv. "How satisfied are you with the results of your knee arthroplasty surgery for relieving your pain?"

The response to each question will be recorded using a four-point Likert scale: very satisfied, somewhat satisfied, unsure, somewhat dissatisfied, and very dissatisfied. These questions and the five-point Likert assessment have been validated and demonstrated to be reliable for measuring satisfaction following primary knee arthroplasty surgery.[28]

5. Change in patient-reported quality of life from baseline to three, six, and 12 months following knee arthroplasty surgery. Quality of life will be assessed using the EuroQol five-dimension three-level questionnaire (EQ-5D-3L) and EQ-VAS general health questionnaire which evaluates five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[29,30] This is a two-page questionnaire that consists of five dimensions, with the responses recorded at three levels of severity (no problems, some problems, or extreme problems). The second page consists of a standard vertical 20 cm visual analogue scale (EQ-VAS) which is transformed to a scale of zero to 100 measuring current HRQoL. Each patient's health state, derived from the EQ-5D, will be measured before and after their surgery to determine the change in their health gain or loss after their knee arthroplasty surgery. The health state will then be multiplied by the time spent in that state to derive the quality-adjusted life year (QALY) gained or lost. The cost per QALY will then be calculated by dividing the cost of the procedure by the QALYs gained after surgery.
6. To compare ROM of the knee at baseline, at discharge three, six, and 12 months following knee arthroplasty surgery. A goniometer will be used to measure ROM by a blinded researcher (EM, GL) prior to surgery (baseline), at discharge (immediately post-surgery prior to discharge home), at three- and 12-month clinic review appointments (scars from surgery will be concealed). Three measurements will be recorded for extension and flexion of the knee and a mean average will be documented.
7. The cost-effectiveness of the two interventions from a UK NHS perspective up to 12 months following knee arthroplasty. A health service resource use questionnaire will be completed by the patient at the three-, six-, and 12-month research assessment. The questionnaire collects data on primary, secondary, and community care associated with the knee arthroplasty over the previous months. Inpatient and surgical data will be collected on the case report forms (CRFs) and complications will be recorded at each visit. A ten-year time span with a disutility of 3.5% will be employed.[32]
8. Knee stability and power will be assessed at baseline and three, six, and 12 months following knee arthroplasty surgery. This will only be performed on a subgroup of the patients. A stress will be applied to the knee, and the joint space opening will be measured using an ultrasound probe, which will be used as a marker of knee stability. The power of the knee joint will be assessed using a standardized power rig. Specific assessment of the patient's power output will be evaluated by a Leg Extensor Power Rig (Nottingham, UK), well validated for use with this population group.[33]

Trial participants

Overall description of trial participants

Patients listed for routine primary mTKA for osteoarthritis under the care of participating surgeons at the study institution.

Inclusion criteria

- Listed for elective primary mTKA for end-stage (Kellgren-Lawrence grade 3 or 4)[34] medial compartment OA
- Intact anterior cruciate ligament
- Full-thickness and good-quality lateral cartilage[35]
- Correctable intra-articular varus deformity and intact medial collateral ligament
- American Society of Anesthesiologists (ASA)[36] grades I and II
- Male or female, aged 50 to 75 years at the time of listing for surgery
- Suitable candidate for a cruciate-retaining TKA (Triathlon prosthesis; Stryker, USA) or a UKA

Exclusion criteria

The patient may not enter the study if any of the following apply:

- Varus deformity of > 20°
- Fixed flexion of > 10°
- Patient is unable to comply with the study protocol (including refusal for CT scan) or functional assessments
- Female patients who are pregnant, lactating, or planning pregnancy during the course of the study
- Requires patella resurfacing (bone loss), or lateral compartment has significant OA (full-thickness lateral cartilage preserved)[35]
- Inability to understand the patient information for the study, provide written informed consent, or answer study questionnaires for cognitive or language reasons
- Inflammatory disorder, e.g. rheumatoid arthritis
- Symptomatic foot, hip, or spine pathology
- Prior surgery (other than arthroscopy) or septic arthritis of the knee
- Any other significant disease or disorder which, in the opinion of the investigator, may either put the patients at risk because of participation in the study, or may influence

the result of the study, or the patient's ability to participate in the study.

Study procedures

Assessment timepoints

Baseline sceening

Patients due to attend the pre-assessment clinic will be screened for suitability (inclusion/exclusion criteria) for recruitment into the study approximately two to six weeks prior to attendance. Eligible patients will be sent the PIL (see PIL V2.0: Supplementary Material) to make them aware of the study, and the research team will contact them via telephone to answer any questions they may have about the study prior to their planned pre-assessment appointment.

Routine pre-assessment clinic

All individuals at the study centre attend a routine face to face pre-assessment clinic four to six weeks preoperatively to assess fitness for surgery. Pre-assessment staff will be notified of the patient's potential inclusion in the study. Patients who wish to be part of the study will be asked to provide written informed consent, and complete a CRF and the preoperative questionnaires recording their knee function, expectations, and general health. Additionally, a subgroup of patients will have their knee stability and power assessed. Randomization will take place during this episode. Participants randomized to the robotic-assisted surgery group will be required to have an additional CT scan, which may be arranged to coincide with this appointment. To try and ensure blinding, participants will not be made aware that only those undergoing robotic surgery will have a CT scan – they will simply be made aware that some patients will need a CT scan to plan their surgery (see PIL V2.0: Supplementary Material).

This CT scan will be anonymized using a dedicated study code, and transferred to Stryker using an encrypted data drop box. The CT scan will be reconfigured and transferred back, also using an encrypted data drop box. These data will be used by the Mako technician to plan the individuals' surgeries. This process is standard practice in hospitals across the UK that are already using the Mako for robotic-assisted knee surgery.[37]

Inpatient admission for surgery

All participants will be admitted in line with routine practice. Surgical data and hospital discharge data will be collected from source data to complete the CRF during the inpatient stay. No additional research assessments will be carried out at this point.

Routine clinical three-month follow-up clinic

All participants will attend a routine assessment with the clinical team. Participants will also be seen by the research team to complete the relevant patient-reported questionnaires, have their ROM assessed, and complete a health service resource use and complications data form. Additionally, a subgroup of patients will have their knee stability and power assessed. If patients are not able to attend this clinic, a virtual option will be available with postal questionnaires.

Additional six-month postal questionnaire follow-up

All participants will be asked to complete the relevant patient-reported questionnaires, and health service resource use and complications data forms.

Routine clinical 12-month follow-up clinic

All participants will attend a routine outpatient assessment with the clinical team including knee radiographs. Participants will also be seen by the research team to complete the relevant patient-reported questionnaires, have their ROM assessed, health service resource use and complications data forms. Also, a subgroup of patients will have their knee stability and power assessed. If patients are not able to attend this clinic, a virtual option will be available with postal questionnaires.

Screening and eligibility assessment

Patients listed for a routine primary mTKA under the care of the participating surgeons will be screened by a member of the research team and treating clinician. A screening form will be completed to confirm patient details:

- Name
- Hospital number
- Listed for routine primary knee arthroplasty
- Suitable candidate for a cruciate retaining TKA or a UKA
- Capacity to provide informed consent
- Age
- No pre-existing condition that limits function and potential outcome of surgery

Eligible participants will be sent a PIL (see PIL V2.0: Supplementary Material) and will be contacted via telephone by a member of the research team to discuss the study in more detail and confirm eligibility. Patients will be encouraged to take the study information and discuss it with their family and friends before making a decision to participate.

The research team will reconfirm the eligibility criteria below and record that: 1) the patient is able to comply with the study protocol (including refusal for CT scan); and 2) female participants are not pregnant, lactating, or planning pregnancy during the course of the study.

All eligible patients who are interested or agree to participate in the study will be reviewed at the preassessment clinic, where written informed consent and completion of baseline assessments will be undertaken by a member of the research team.

Informed consent

Written and verbal versions of the patient information and informed consent will be presented to the patients by the research team. This will explain no less than: the exact nature of the study; the implications and constraints of the protocol; and any risks involved in taking part. It will be clearly stated that the patient is free to withdraw from the study at any time, for any reason, without prejudice to future care, and with no obligation to give the reason for withdrawal. The patient will be encouraged to take the study information home and have the opportunity to question the investigator, their general practitioner, or other independent parties to decide whether they will participate in the study.

Patients who decide to take part will be approached in their preassessment clinic for their written informed consent.

This will be obtained by means of the patient's dated signature and the dated signature of the person who presented and obtained the informed consent. The person who obtained the consent will be a suitably qualified and experienced member of the research team, and will have been authorized to do so by the Principal Investigator. Copies of the signed informed consent will be given to the participants and also filed in the medical notes. The original signed form will be retained at the study site in the trial master file (TMF).

The patient must personally sign and print their name, and date the latest approved version of the informed consent form before any study-specific procedures are performed. If for whatever reason the patient is unable to print their name or date the consent form, this can be completed by the researcher taking consent, at the patient's request. It must be fully documented on the consent form that the researcher has taken this action, with the reason why also documented. However, the researcher must not sign the consent form on the patient's behalf; the patient must always sign the consent form.

Randomization

Participant numbers will be assigned sequentially as each patient enters the study. Participants will be randomized on a 1:2 (raUKA:mTKA) ratio after consent and baseline data collection is complete to reduce the risks of selection bias. Participants will not be told to which treatment arm they have been assigned and will be blinded until the end of study. However, it will not be possible to conceal the allocation of treatment from the surgeon. Research staff completing follow-up assessments and data analysts will be blinded to the participant's allocation in order to reduce potential bias.

Subsequent assessments

All participants will attend routine orthopaedic outpatient clinic appointments at three months and 12 months following surgery, with an additional postal questionnaire assessment at six months. At each of these timepoints, the research team will repeat the patient-reported outcome measures (PROMs) carried out at baseline with the addition of a validated patient satisfaction questionnaire, completion of the health usage questionnaire, and a complications report form.

Additional PROMs

A health service resource use questionnaire will be completed at the three-, six-, and 12-month assessment points. Participants will be provided with a health service use patient diary to record community and secondary care visits to assist with recall for the completion of the questionnaire.

Complications

The incidence of complications, dislocation, and revision rates will be collected at each assessment.

Definition of end of trial

The end of trial is the date of the 12-month follow-up visit of the last participant.

Discontinuation/withdrawal of participants from study treatment

Each participant has the right to withdraw from the study at any time. In addition, the investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason, including:

- Ineligibility (either arising during the study or retrospective, having been overlooked at screening)
- Significant protocol deviation, i.e. intervention not used as intended at time of surgery
- Significant non-compliance with treatment regimen or study requirements
- An adverse event which requires discontinuation of the study medication, or results in inability to continue to comply with study procedures
- Consent withdrawn
- Lost to follow-up

Participants who wish to withdraw consent for the trial, or whose participation in the trial is discontinued, will have anonymized data collected up to the point of that withdrawal of consent included in the analyses unless the participant specifically asks for all data collected to be destroyed. No additional data will be collected from the participant. The reason for withdrawal will be recorded in the CRF. Participants who withdraw once they have been randomized will not be replaced. If the participant is withdrawn due to an adverse event, the investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilized.

Source data

Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history may be summarized into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, radiographs, and correspondence. CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). In this study the CRF will be used as the source document for PROMs and health economic data. All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

Treatment of trial participants

Description of study interventions

All participants will attend a routine preassessment clinic (routine blood tests, electrocardiogram, consent) to optimize fitness for surgery and a knee arthroplasty education session prior to admission for surgery. The mTKA arm will receive a cemented Triathlon prothesis with a cruciate-retaining polyethylene insert. This is the current standard care for all participating surgeons. Patients in the raUKA will receive a cemented Restoris MCK (Mako; Stryker). All participants will receive standard postoperative nursing and rehabilitation care. Prior to discharge from hospital, patients will undergo the routine physiotherapy (according to Enhanced Recovery After Surgery Society recommendations)[38] and occupational assessments for activities of daily living and equipment will be provided as routine care.

Table II. Mako knee CT scan protocol.

Category	Details			
Position/landmark	Supine, feet first			
Topogram (scout) direction	Craniocaudal; AP and lateral scout view			
kVp	120 to 140 kV (recommended 120 kVp)			
mA (if available)	Auto exposure control (200 to 400 mA)			
Pitch	1:1 (no gaps)			
Helical set	**Region**	**Thickness**	**Spacing**	**Algorithm**
Slice thickness, spacing, algorithm	Hip	2 to 5 mm	2 to 5 mm	Bone
	Knee	0.5 to 1 mm	0.5 to 1 mm	Bone
	Ankle	2 to 5 mm	2 to 5 mm	Bone
Image resolution	512 × 512 matrix: image must be square			
DFOV	Hip = 500 mm, knee = 250 mm, ankle = 500 mm; do not exceed limits			
Scan plan	Scan in the axial plane, for all three regions (hip, knee, and ankle)			
Scan start/end locations	Begin scan at the hip, through the knee ending at and including the ankle joint			
Hip region	Include the entire femoral head and motion rod; centre around the femoral head			
Knee region	Scan a region a minimum of 10 cm above and 10 cm below the distal femoral condyles; include margin above the patellofemoral joint, margin below the distal boundary of the tibial tuberosity, and the motion rod; centre around the joint line			
Angle region	Include the medial and lateral malleoli and the motion rod; centre around the ankle joint			
Images required for transfer	Transfer all axial bone images of the hip, knee, and ankle including the AP topogram in DICOM format, to PACS or CD.			

AP, anteroposterior; DFOV, display field of view; DICOM, digital imaging and communications in medicine; PACS, picture archiving and communications system.

Treatment group 1: Standard care

On admission for surgery, participants randomized to this group will receive a conventional manual Triathlon (Stryker) TKA with a cruciate-retaining polyethylene insert. In a manually performed TKA, the surgeon will make an incision down the front of the knee and move the patella to one side to allow access to the knee joint. The surgeon will then make bone cuts using a manual jig and a handheld saw to prepare the bone surfaces for the implant. A measured resection technique will be employed, with 8 mm resection from the distal femur and 9 mm from the proximal tibia with a three-degree slope. The surgeons will use a conventional jig alignment technique with intramedullary referencing for the femur and extra medullary referencing for the tibia. Sizing of the femoral component and rotation (using Whiteside's line) will be performed manually after intraoperative assessment. Once the implant is in position the knee is then balanced by the "feel", although a full ROM and soft-tissue releases will be performed as required to balance the knee in flexion and extension.

Treatment group 2: Intervention group

Prior to admission for surgery, participants randomized to the intervention group will require a three-region (hip, knee, and ankle) preoperative CT scan as part of the planning process for robotic-assisted surgery (Table II). The information from the CT scan will be used to create a 3D model of the patient's bony anatomy to plan the positioning and sizing of the implant. The research team will make every effort to coordinate the CT scan with the patient's routine pre-assessment clinic to limit the requirement for additional hospital visits. The CT scan will be anonymized using a dedicated study code and transferred to Stryker using an encrypted data drop box. The CT scan will be reconfigured and transferred back using an encrypted data drop box. These data will be used by the Mako technician to plan the individual patient's surgery. On admission for surgery, participants will receive the cemented Restoris MCK (Mako; Stryker) with a highly crosslinked (X3) polyethylene insert through a similar surgical approach (less invasive) to the knee joint. Instead of using a manual jig and a handheld saw, a burr will be used to prepare the bone surfaces according to the planned alignment for the implant which is controlled by the Mako robotic arm with the supervision of the surgeon. During the operation, trackers (markers for the robot to assess where the knee is in space) will be positioned on the tibia and femur using two unicortical treaded pins (4 mm) through a small incision (2 cm) a hand's width above and below the joint. Once the trackers are in place, registration of the knee joint surface is performed. The specified bone cuts are then performed using the robotic arm. The robotic arm does not perform the surgery; the orthopaedic surgeon still performs the surgery and the implant is inserted by the surgeon.

Both groups

All patients will receive the same standard of inpatient care and rehabilitation and discharge advice to progress mobility

and standard exercises. Data will be collected from source data regarding length of stay and discharge details. Data regarding healthcare usage and equipment will be collected using the modified Client Service Receipt Inventory;[39] this will be completed at follow-up clinics and interim phone call follow-ups. The research team will contact the patient by phone and at scheduled research visits to optimize completion over the study period.

CT scan

CT is a procedure that uses x-ray equipment to create cross-sectional pictures of bony anatomy. During the scan, the participant will lie on a narrow platform bed as it slides through the scanner, which is shaped like a large doughnut. A CT scanner creates clear and detailed pictures of bones. CT scans involve radiation, and there are small risks associated with radiation exposure. These are described in the patient information leaflet (see PIL V2.0: Supplementary Material). The CT scan is an essential component of the research study, and provides the anatomical information required for the Mako robot to accurately perform the bone cuts during surgery. If a patient is unable to undergo a CT scan for any reason, then they will be unable to participate in the research study.

Maintenance and storage of device

The Mako robot is stored in the orthopaedic theatres where the research procedures will take place. The device will be sterilized as standard sterilizing procedures for the theatre. Sterile single-use drapes will be used throughout the procedure. The Mako robot will undergo regular maintenance by a robotic technician who will also be present for all surgeries where the Mako is used in both clinical and research cases. The device is CE-marked for this purpose.

Safety reporting

Potential risks

The risks for the two groups are those particular to TKA and those incurred during an operative intervention. These include infection, thrombosis, stiffness, instability, pain, scar sensitivity, loss of function, nerve or vessel injury, and requirement for revision with attendant time off work. General risks include cardiorespiratory risk, angina, myocardial infarction (MI), stroke, pneumonia, risks from prolonged recumbency, urinary infection, and skin ulcers. Potential risks and steps taken to minimize these risks are outlined in the PIL (see PIL V2.0: Supplementary Material).

In addition, it is anticipated that those patients who are randomized to use of the robotic instrumentation may require a longer procedure of up to ten minutes,[40] and there is a theoretical increased risk of infection. There is also a small risk of sustaining a fracture through a tracker pin (a threaded pin inserted into the bone so the robot can establish the position of the bone in time and place).[41,42] Tracker pins are routinely used for navigated TKA surgery and this increased risk is accepted to enable more accurate placement on the knee prosthesis. However, to our knowledge there is only one reported case of a fracture through a tracker pin site when used for robotic TKA surgery.[43] There is also a small risk of wound infection at the tracker pin site but, again, these are established and accepted in navigation TKA surgery.[44]

Definitions

Adverse event

An adverse event (AE) is any untoward medical occurrence in a patient or other clinical investigation participant taking part in a trial of a medical device, which does not necessarily have to have a causal relationship with the device under investigation. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the device, whether or not it is considered to be related to the device.

Adverse device effect

An adverse device effect is defined as all untoward and unintended responses to the medical device. The phrase 'responses to a medical device' means that a causal relationship between the device under investigation and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. All cases judged by either the reporting medically qualified professional or the sponsor as having a reasonable suspected causal relationship to the device qualifies as a device effect. This also includes any event resulting from insufficiencies or inadequacies in the instruction for use or deployment of the device, and includes any event that is a result of a user error.

Device deficiency

Inadequacy of a medical device related to its identity, quality, durability, reliability, safety, or performance, such as malfunction, misuse or use error, and inadequate labelling.

Serious adverse event

"Serious" means an adverse event resulting in:

1. Death
2. Inpatient hospitalization or prolonged hospitalization

   Note: defined as an inpatient admission, regardless of length of stay. Hospitalization for pre-existing conditions (including elective procedures that have not worsened) or additional elective hospitalization do not constitute a serious adverse event (SAE).
3. Life-threatening illness or injury

   Note: the term 'life-threatening' in the definition of 'serious' refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
4. Persistent or significant disability or incapacity
5. Congenital anomaly or birth defect
6. Other serious events that may jeopardize the patient, and may require medical or surgical intervention to prevent one of the other five listed outcomes

   Note: this includes device deficiencies that might have led to a SAE if suitable action had not been taken, the intervention had not been made, or if circumstances had been less fortunate.

Other events that may not result in death, are not life-threatening, or do not require hospitalization, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above. To ensure no confusion or misunderstanding of the difference between the

terms 'serious' and 'severe', which are not synonymous, the following note of clarification is provided.

The term 'severe' is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe MI); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as 'serious', which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a participant's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

Serious adverse device effects

A serious adverse device effect (SADE) is any untoward medical occurrence seen in a patient that can be directly related to the prosthesis implanted, resulting in any of the characteristics or led to characteristics of a serious adverse event. SADE is also any event that may have led to these consequences if suitable action had not been taken, the intervention had not been made, or if circumstances had been less fortunate. All cases are judged by either the reporting medically qualified professional or the sponsor.

Anticipated SADE

An anticipated SADE is a SADE which, by its nature, incidence, severity, or outcome, has been previously identified in the current version of the risk analysis report or investigator brochure.

Unanticipated adverse device effect

An unanticipated adverse device effect (UADE) is any SADE on health or safety, or any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application); or any other unanticipated serious problem associated with a device that related to the rights, safety, or welfare of the subject.

Expectedness

Expectedness will be assessed by the Principal Investigator or an appropriately trained designee using the list of expected events here. This list is based on current clinical knowledge of expected intra- and postoperative complications of TKA: intraoperative complications: not able to proceed with expected implant (in this case the triathlon TKA or the Mako restoris), soft-tissue damage, neurovascular damage, fracture, patients become medically unwell and cannot perform mTKA or raUKA, blood loss, and general medical complications, e.g. heart attack, stroke; and postoperative complications: infection (superficial and deep implant infection), deep vein thrombosis and pulmonary embolus, stiffness, swelling, numbness, neurovascular complications, wound breakdown, fracture, and general health problems, e.g. stroke, heart attack, kidney failure, and potential loss of limb and life.

Relatedness

The relationship between the investigational medical device (including comparator treatments) and the occurrence of each AE must be assessed and categorized by the Principal Investigator (or delegate). Related events are those that are related to the administration of the medical device or study procedures. Each AE should be categorized as follows:

- Not related: no relationship with the investigational device; other factor(s) certainly or probably causative.
- Possibly related: the nature of the event, underlying medical condition, concomitant medication, or timing of the event in relation to use of the device make it possible that the AE has a causal relationship to the device.

Reporting of AE

All AEs occurring during the study observed by the investigator or reported by the participant, whether or not attributed to the device under investigation, will be recorded on the CRF as specified in the protocol. All ADEs will be recorded in the CRF. The following information will be recorded: description, date of onset and end date, severity, assessment of relatedness to device, other suspect drug or device, and action taken. Follow-up information should be provided as necessary. The relationship of AEs to the device will be assessed by a medically qualified investigator or the sponsor/manufacturer, and will be followed up until resolution or the event is considered stable. All ADEs that result in a participant's withdrawal from the study, or are present at the end of the study, should be followed up until a satisfactory resolution occurs.

Reporting procedures for all SAEs/SADEs/UADEs

All SAEs/SADEs/ASADEs/UADEs will be reported to the Principal Investigator in the first instance, who will determine seriousness, relatedness, and expectedness. The event will then be reported to the sponsor/legal representative R&D Regulatory Compliance Team at ACCORD NHS Lothian within one working day of the investigator team becoming aware of them. For a related SAE the investigator will complete a Stryker 'Product Experience Report' form or inform a Stryker employee. Reports of related and unexpected SAEs should be submitted to the Scotland B Research Ethics Committee within 15 days of the Principal Investigator becoming aware of the event, using the NHS HRA Non-CTIMP Safety Report to REC form (Report of Serious Adverse (non-CTIMP) Form).

Related and unexpected events must also be reported through the Lothian NHS Datix Incident Reporting System by a member of the research team. UADEs occurring in Lothian NHS sponsored studies must also be reported via the electronic incident reporting system, Datix. The incident type should be entered as 'Research Incident/Accident'; directorate as 'Medical Director's Directorate'; speciality as 'Research Development and Governance'; site as 'Regent Point'; and location as 'Research Buildings'. The event must also be assessed by the Principal Investigator to determine whether or not it constitutes a serious incident (SI). This is defined as an event or incident that results in unexpected or avoidable death, or serious harm, to one or more patients, staff, visitors, or members of the public. If the event has been classed as (or is suspected to be) a SI, an NHS manager will inform the Director of Quality and Effectiveness, via. the Clinical Governance and Risk Department (CGARD), as soon as possible by telephone.

Medical device quarantine

If an ADE is defined as serious (i.e. a SADE) or a DD that could have led to a SADE/UADE, the investigator must quarantine the device as soon as possible. This involves segregating the device from other equipment and labelling it as 'not for use' with relevant contact details. The device and all associated items (including relevant packaging materials) should be quarantined. They should not be repaired, discarded, or returned to the manufacturer without agreement from the sponsor.

The manufacturer has a legal obligation to report all events that need to be reported to the nominated competent authority immediately (without any unjustifiable delay) after a link is established between the event and the device, but no more than two days following the awareness of the event for a serious public health threat; ten days following awareness of the event for death or unanticipated serious deterioration in health; and 30 days following the awareness of the event for all other events meeting the SAE criteria.

Annual reports

In addition to the above reporting, the Principal Investigator will submit once a year, throughout the trial, or on request, a progress/safety report to the Research Ethics Committee (REC) and Research and Development department.

Statistical analysis

Description of statistical analysis

Statistical analysis will be performed using Statistical Package for Social Sciences v. 17.0 (SPSS, USA). Parametric and non-parametric tests will be used as appropriate to assess continuous variables for significant differences between groups. The difference in improvement from baseline to three, six, and 12 months in the outcome measures will be assessed using an independent-samples *t*-test. Changes in outcomes measures from baseline to three, six, and 12 months following surgery will be analyzed using repeated measures analysis of variance (ANOVA) and adjusted for multiple testing to assess improvement in the scores postoperative for each group. The data are expected to demonstrate a normal distribution, but this will be assessed prior to analysis. Categorical variables will be assessed using a chi-squared test or a Fisher's exact (in less than five in one cell) test.

Health economics

An economic evaluation will be conducted from an NHS perspective. Data collection from the study will also focus on estimating the cost of the interventions and subsequent use of services. Analyses will be carried out from an NHS perspective and will include the capture of resource use from secondary and primary/community care. All relevant costs associated with providing the interventions will be calculated, including length of stay. All unit costs will be derived using routine data sources and study-specific estimates. Costs in the follow-up period will include use of secondary care services, e.g. inpatient stays and outpatient visits; primary/community care services, e.g. GP visits, district nurse visits, and prescription costs incurred over the follow-up period. These data will be collected using a health service use patient diary. Data on the use of services will be combined with the appropriate unit costs to produce a cost for each trial participant. From these, a mean cost per intervention will be calculated. HRQoL will be measured using EQ-5D-3L, a simple measure which patients complete at the start and end of treatment. It comprises five dimensions of health: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, and anxiety and depression. The cost-effectiveness analysis of the two types of surgery will be based on incremental cost per QALY. The results will be presented as point estimates of mean incremental costs and QALYs. Deterministic and stochastic sensitivity analysis will be undertaken, and presented as point estimates and cost-effectiveness acceptability.

Number of participants

A power calculation was performed using the MCID in the OKS, which is defined as five points.[45] A 1:2 (raUKA:mTKA) block randomization will be used to limit the number needed in the robotic arm and will subsequently limit the costs of the study. Using a 2:1 randomization method, a MCID of five points with a SD of 10, an α of 0.05, and a power of 0.80 a sample size of 144 patients are required for a two-tailed study.[45] There will be a minimum of 48 in the raUKA arm and 96 in the mTKA arm. A presumed 10% dropout rate is anticipated in each arm and would require 159 patients to be randomized: 53 in the raUKA arm and 106 in the mTKA arm. Block randomization will be used to focus the number randomized to the robotic arm (robotic surgery to be completed over a 12-month period).

Statistical significance level

An α value of 0.05 will be used to power the study for the primary outcome measured at six months. Therefore, should a significant result be found, we are 95% confident it is real. Bonferroni correction will be performed for other outcome measures assessed at the different time points to account for multiple testing of data.

Criteria for the termination of the trial

The Principal Investigator, the sponsor, and the funder will discuss the options for terminating the trial if any of the following occur: failure of the Mako support technician to attend surgery/lack of Mako support; high incidence of pin site fractures (> three individual cases); and high incidence of deep infection in Mako arm (> three individual cases).

Procedure for accounting for missing, unused, and spurious data

Data completion rates will be provided for each outcome at baseline and each of the follow-up points. The number of patients lost to follow-up will be reported, and follow-up will be compared between groups using the median length of follow-up. A table showing the rates of missing data (as percentages) for all outcomes will be presented. The number of patients with missing data will also be reported. Multiple imputation will be used on missing data provided that rates are less than 20%, as described by Rubin.[46] This will be performed using SPSS v. 17 to create five datasets, and results will be pooled (more datasets may be created if missing data rates are high). The imputed dataset will be used in the base-case analysis. All data collected on data collection forms will be used, since only essential data items will be collected.

No data will be considered spurious in the analysis, since all data will be checked and cleaned before analysis.

Procedures for reporting any deviations from the original statistical plan

Data will be analyzed as intention to treat and per protocol. In any cases where patients do not receive their randomized intervention, they will be analyzed as intention to treat. All patients undergoing surgery will be included. Patients who are randomized but who did not undergo knee arthroplasty surgery will be withdrawn, and will not be included in the final analysis. Direct access will be granted to authorized representatives from the sponsor, host institution, and the regulatory authorities to permit trial-related monitoring, audits and inspections.

Data recording and record-keeping

Data will be collected by the site researcher (baseline collection), clinicians delivering the interventions, and participants (health utility and assessment questionnaires). All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, "ND" will be written. If the item is not applicable to the individual case, "NA" will be written. If the data item is unknown, "NK" will be written. If a data item has not been recorded on source data then "NR" will be written. All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error a single straight line should be drawn through the incorrect entry, and the correct data entered above it. All such changes must be initialled and dated, and errors should not be erased or whited out. For clarification of illegible or uncertain entries, the clarification should be printed above the item, then initialled and dated. All trial data will be entered on paper CRFs and subsequently inputted into the trial database by the research team. In accordance with the ICH GCP (Section 5.5),[47] electronic data entry systems will be validated and standard operating procedures for data entry will be maintained.

Quality control and quality assurance procedures

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations, and standard operating procedures. Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented, and reported in compliance with the protocol, GCP, and the applicable regulatory requirements. The Principal Investigator and other key staff will attend site initiation training, coordinated by the research team, which will incorporate elements of trial-specific training necessary to fulfil the requirements of the protocol. Training will consist of reviewing the trial protocol, recruitment, consent, randomization, follow-up, trial procedures, and intervention training as applicable, trial arrangements, data protection, and data handling.

Ethics

The investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.[48] The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.[47]

Approvals

The protocol, informed consent form, participant information leaflet, and any proposed advertising material will be submitted to an appropriate REC, and host institution(s) for written approval. The investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Participant confidentiality

The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participant ID number on the CRF and any electronic database. Participant-identifiable data will be stored separately from trial data and in accordance with standard operating procedures. The name and any other identifying detail will not be included in any trial data electronic file. All documents will be stored securely and only accessible by trial staff and authorized personnel. The study will comply with the Data Protection Act 1998, General Data Protection Regulation, and the Freedom of Information Act, which require data to be anonymized as soon as it is practical to do so and stored securely.

Financing and insurance

Financial funding is provided by Stryker for the material costs of the study to conduct the trial following a full peer-review process. They are assured of the quality of the trial; the research proposal is worthwhile, of high scientific quality, has an appropriate research infrastructure with expert clinical trial management, has the capacity to comply with the principles of good clinical practice, and represents good value for money.

Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If study participants are harmed while taking part in the trial because of negligence on the part of a member of the study team, the institutional (NHS Lothian) liability cover would apply.

Publication policy

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases, and any other publications arising from the trial. The authors will acknowledge that the trial was funded by Stryker. Authorship will be determined in accordance with the ICMJE guidelines, and other contributors will be acknowledged.

Limitations

The major limitation of this study is in blinding of the patient to their treatment group. In the original ethical application (2019), the protocol included a sham CT scan of the group undergoing mTKA in an effort to blind the patients to their randomization. However, this was not possible following the

COVID-19 pandemic, and resources at the study centre would not allow for the sham CT scan. A substantial amendment was then granted by the ethical committee (20/SS/0011) on 16 July 2024 for the change in the protocol and removal of sham CT scan in those undergoing mTKA. To try and retain blinding, we discussed the study design with a patient and public involvement (PPI) group, who agreed with simply stating that some patients will need a CT scan for operative planning, but not explicitly stating this will only be needed for the raUKA group only. Furthermore, there will be potential differences in the wounds between the groups with the addition of pin site wounds in those undergoing raUKA. An option was to undertake sham pin site wounds in those undergoing mTKA, but on discussing this with the PPI group, and given the potential risk of complications with these wounds in the larger mTKA group, it was not thought to be appropriate. Some members of the PPI group also felt that patients may well assume the pin site wounds are part of a normal mTKA. Conversely, for those with no pin site wounds, patients will be told that the pins were placed through the surgical wound, which is now commonplace with robotic TKA, in effect to maintain blinding.

Social media

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Supplementary material

Patient Information Leaflet.

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Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

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Ethical review statement

This study protocol received favorable ethical approval from the Scotland B Research Ethics Committee (20/SS/0011). The study will be conducted in accordance with the principles outlined in the Declaration of Helsinki, Good Clinical Practice guidelines, and all applicable regulatory and legal requirements. Written

informed consent will be obtained from all participants prior to their involvement in the study.

Trial registration number

Internal Reference No: NHS Lothian R&D AC19080
Ethics Ref: 20/SS/0011
IRAS project ID: 263001
Trial registration: ClinicalTrials.gov ID NCT05290818.