NICE National Institute for Health and Care Excellence

Medical technologies advisory committee (MTAC)

31 October 2024

Information pack for draft guidance considerations on Robot assisted surgery for orthopaedic procedures: early value assessment

This product was selected for early value assessment in 2023. Clinical and economic evidence has been submitted to NICE by the companies, and an external assessment centre report has been completed.

This pack presents the information required for the MTAC to make draft recommendations on this topic. The consultation period on these draft recommendations is scheduled to take place between 10 December 2024 and 7 January 2025.

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Papers included in pack:

1. Front sheet
2. Scope
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4. EAG assessment report overview (ARO)
5. Stakeholder comments on the EAR and EAG responses
6. Register of interest

NICE National Institute for Health and Care Excellence

HealthTech Programme

GID-HTE10043 Robot-assisted surgery for orthopaedic procedures

Scope

1 Introduction

The topic has been identified by NICE for consideration for early value assessment (EVA). The objective of EVA for MedTech is to identify the most promising technologies in health and social care where there is greatest need and where the evidence base is still emerging. It will provide an early indication to the system whether they could be used while evidence is generated. The process may enable the technologies to be recommended for use only if further data is collected before NICE makes a final evaluation. NICE's Prioritisation Board ratified robot-assisted surgery for orthopaedic procedures as potentially suitable for an EVA by the HealthTech programme.

Consideration of robotic-assisted surgery (RAS) for orthopaedic procedures in this EVA will utilise the existing evidence to assess the clinical and cost-effectiveness across a range of procedures and indications. The EVA will further assess what gaps there are in the evidence base to facilitate evidence generation and a future full clinical and cost-effectiveness evaluation. The evidence gap analysis may inform the development of the RAS outcomes registry (MedTech strategy: One year on (2024).

A list of abbreviations is provided in appendix B.

2 Description of the technologies

2.1 Purpose of the medical technology

Approximately 1 in 10 people undergo a surgical procedure in the UK each year. Robotic-assisted surgery (RAS) is a type of surgery where robotic platforms are used to help enhance the work of the surgeon. These technologies enable surgeons to perform many procedures with more precision, flexibility and control than is possible with conventional techniques. The 'Future of Surgery' report by the Royal College of Surgeons (RCS) predicted the rapid expansion of RAS across the UK and the impact it will have in facilitating the more widespread use of minimally invasive surgery for many patients. This is due to the proposed advantages in ergonomics and operative precision, as well as its potential for improving training and service practices. The RCS estimated that between 2021 and 2022 over 1.8 million RAS procedures were done internationally and that RAS was available in more than 100 UK hospitals (RCS, 2023).

In orthopaedic procedures, RAS systems usually integrate pre-operative planning with real-time intraoperative guidance. The systems generally incorporate robotic arms controlled by the surgeon along with computer-assisted navigation systems. Computer-assisted navigation provides real-time tracking and 3D visualisation to guide surgical instruments. The RAS systems also have data collection features.

The RAS systems are expensive and require specific training. Additionally, the use of RAS requires the procurement of supplementary procedure packs for each operation. Supplementary procedure packs for RAS devices include additional sterile instruments, disposable items, implant components, consumables, imaging tools, and calibration tools necessary to support and enhance RAS. This requirement incurs additional costs, with these single-use items potentially representing a significant percentage increase relative to the cost of the implants. There is also potential for surgical complexity and increased operating times during the learning curve when adopting RAS (MacDessi et al. 2022). The impact of RAS on surgical outcomes and the

broader implications for healthcare systems such as the NHS are not yet clear (BOA, 2024). There may be potential benefits of using RAS compared with manually performed surgery with increased accuracy and precision. For example, in implant placement for total knee arthroplasty procedures, with improved functional benefit for patients. But, there is limited evidence available to determine whether the benefits of RAS are clinically significant (BOA, 2024).

People may prefer RAS if it enables a quicker return to normal activities, such as driving and work, compared to conventional surgery. People who are at higher surgical risk such as those who are older, have obesity or a high BMI, or with multimorbidity, may benefit from an increased access to surgery. Studies indicate that obesity may complicate the technical aspects of orthopaedic surgeries due to poor visualisation and an increased risk of complications (Si et al., 2023). RAS has the potential to enhance precision in these surgeries, particularly in challenging scenarios including those involving obese patients, where conventional surgery is more difficult.

There may be benefits to the surgeon such as reduced physical strain and reduced cognitive demand when using RAS during a procedure compared with conventional surgery. There may also be benefits for the wider NHS such as reduced length of stay, fewer readmissions, fewer revisions, and fewer complications which could contribute to cost savings. Improved patient outcomes may also result in less need for secondary clinical interventions such as physiotherapy, pain management, reoperation and revision surgery. This could reduce workload and drive efficiencies in service delivery. RAS may also support the adoption of partial knee replacements in place of total knee replacements by reducing the 'learning curve' associated with manual partial knee replacement. This is in line with NICE's guideline on joint replacement (primary): hip, knee and shoulder which suggests that partial knee replacements could have the added advantage of quicker recovery, shorter length of stay and fewer complications compared to total knee replacements.

The role of RAS in the future of surgery has also been noted across the Department of Health and Social Care (The Topol Review: Preparing the healthcare workforce to deliver the digital future, 2019) and Association of British HealthTech Industries (ABHI RAS network white paper, 2022). The MedTech strategy: One year on (2024) reported that the development of an implementation plan for a RAS registry is a key milestone for 2024 to 2025. This will form part of the wider NHS England Outcome and Registries Programme.

2.2 Product properties

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts and information available in the public domain. NICE has not carried out an independent evaluation of this description.

Robotic systems for orthopaedic surgery are increasingly used in operating theatres. RAS systems encompass a range of technologies that allow the patients specific anatomy to be mapped during the operation and translated into a computer model that can be viewed and manipulated in real time by the operating surgeon. This allows enhanced surgical 3D planning and delivery of the developed plan using assistive technologies. RAS devices enable the technology to follow the 3D plan and execute the cuts on the bone either with a saw or burr (a cutting tool) with varying degrees of surgeon control of surgical instruments.

Robotic systems also vary in their navigation and registration of the patient's anatomy and limb alignment. Some use image-based methods (such as plain radiographs, CT, or MRI scans) that aid pre-operative planning, where specified landmarks are mapped during the operation to match the image to the patient's anatomy. There are also image-less systems available, which use surface mapping techniques based on established navigation systems, with intra-operative mapping of the joint line and establishing limb alignment (BOA, 2024).

RAS systems are complex and require dedicated training programmes for the whole operating team. Some systems have in-built data collection capabilities which can be used for performance tracking, service operational audits and registry data collection purposes. Many of the robotic systems are 'closed systems' that work with components from the same company. This means that most orthopaedic RAS devices only allow for the use of implants from their respective manufacturers.

For this EVA, NICE will consider robotic platforms that are used for orthopaedic surgery which meet the following criteria:

- are intended for use for orthopaedic procedures in adult or paediatric populations
- meet the relevant regulatory standards such as having a CE or UKCA mark and the digital technology assessment criteria (DTAC) standards where required
- are available for use in the NHS.

The following robotic platforms have been identified for orthopaedic surgeries:

ApolloKnee (Corin)

The ApolloKnee robot-assisted surgical platform has recently been launched and is indicated for total knee arthroplasty. The system features the BalanceBot, a dynamic knee balancer used to capture soft tissue data throughout the full range of flexion and extension, assisting with the precise alignment and balancing of joints. The OMNIBotics system is the predecessor technology to the ApolloKnee system.

CORI Surgical System (Smith+Nephew)

The CORI Surgical System is used for total knee arthroplasty, partial knee arthroplasty and total hip arthroplasty. CORI does not require preoperative imaging; it uses real-time data and intraoperative imaging to create a virtual 3D model of the patient's anatomy. The CORI system is designed to be portable with a small operating room footprint. The system controls the

surgical cut based on how close it is to the planned bone surface, offering real-time feedback and visual indicators throughout the procedure. The Navio Surgical System is the predecessor technology to the CORI Surgical system.

MAKO SmartRobotics System (Stryker)

The Mako SmartRobotics System is indicated for partial knee arthroplasty including patellofemoral knee replacement, total knee arthroplasty and total hip arthroplasty, facilitated through a robotic arm. The Mako system provides CT-based anatomical models and software-defined spatial boundaries for precise implant placement. It is used in surgical knee and hip procedures where stereotactic surgery is appropriate.

ROSA Knee System (Zimmer Biomet)

ROSA is a robotic system designed to assist surgeons and is indicated as a stereotaxic instrumentation system for total knee arthroplasty and hip arthroplasty. It allows the surgeon to control and execute cutting with support from the robotic arm, which uses intra-operatively captured patient-specific metrics such as range of motion, alignment, and soft tissue laxity. The system facilitates intra-operative planning, including gap balancing and implant positioning, without the need for pre-operative images, but it can also be used with pre-op imaging.

SkyWalker (MicroPort MedBot)

The SkyWalker system is indicated for assisting in total knee arthroplasty surgeries. Its preoperative planning system generates personalised prosthetic implantation plans based on patient-specific anatomical characteristics using preoperative CT scan data. The company is in the process of obtaining CE marking for partial knee arthroplasty and for total hip arthroplasty and are planning to introduce the technology to the NHS.

VELYS Robotic-Assisted Solution (Johnson & Johnson)

The VELYS Robotic-Assisted Solution is indicated for total knee arthroplasty using the ATTUNE total knee system. This semi-active robotic system is imageless as it relies on an infrared camera to track reflective arrays on the

patient’s femur and tibia during surgery. The system maintains the saw blade within planned resection planes and allows bone resections without cutting blocks.

Table 1. Included orthopaedic robotic platforms

Technology (Company)	Indications	Robotic arm or handheld	Direct cutting or indirect	Image based or image-less	Open or closed system	Regulatory approval
ApolloKnee (Corin)	TKA	Arm	Indirect	Image-less	Closed	CE mark
CORI (Smith+Nephew)	TKA, PKA	Handheld	Direct	Image-less	Closed	CE mark
Mako Smart-Robotics (Stryker)	TKA, PKA, THA	Arm	Direct	Image	Closed	CE mark
ROSA Knee (Zimmer Biomet)	TKA, THA	Arm	Indirect	Image-less	Closed	UKCA, CE mark
SkyWalker (MicroPort MedBot) *	TKA, THA	Arm	Direct	Image	Open	CE mark
VELYS (Johnson & Johnson)	TKA	Arm	Direct	Image-less	Closed	UKCA, CE mark

Abbreviation: PKA: partial knee arthroplasty, THA: total hip arthroplasty, TKA: total knee arthroplasty
* Request for information not returned by the company

3 Target surgical procedures

For this EVA, the target population is people having a surgical procedure using RAS in the following specialties:

- Orthopaedic including but not limited to the following procedures:
    - total knee replacement
    - partial knee replacement including patellofemoral knee arthroplasty
    - total hip replacement
    - shoulder replacement
    - revision knee replacement
    - revision hip replacement

3.1 Diagnostic and care pathway

The diagnostic and care pathways vary between different specialties and indications for the procedures. There is little national guidance on the use of RAS for orthopaedic procedures. The NICE guideline on primary joint replacement (hip, knee and shoulder) does not explicitly mention RAS. Interventional procedure guidance for minimally-invasive total hip replacement does not mention RAS either, but this is because RAS is considered a minor modification of an existing procedure.

For orthopaedic procedures, there are some differences in care before and after the surgery. Imaging prior to routine manual knee replacement mainly relies on X-rays and occasional CT or MRI scans. Additional imaging appointments, particularly MRI and CT scans, are a key capacity constraint for RAS. But, not all RAS systems need these scans, as some are image-free. The impact of imaging appointments on capacity can be reduced by scheduling dedicated sessions, as they are generally shorter and do not require extensive radiologist involvement. But, this may add further costs and potential radiation exposure when CT scans are used. If robotic surgery is beneficial, these additional costs might be offset by reduced inpatient stays, reduced post-discharge care, or reductions in highly expensive complications

including revision surgery. A reduced length of stay and potential reduction in readmissions can also be influenced by changes to patient pathways and recovery programmes within NHS Trusts. For example, some NHS centres are establishing day case protocols for knee and hip replacements without the use of RAS.

The National Joint Registry (NJR) for England, Wales, Northern Ireland, the Isle of Man and states of Guernsey, is a mandatory audit of joint replacement procedures with over 95% capture of primary procedures. The primary outcome measures are revision surgery and 90-day mortality. In shoulder surgery the NJR also collects various Patient Reported Outcome Measures (PROMS) to assess the quality of care and outcomes for joint replacement surgeries delivered to people having NHS funded treatment. People undergoing elective inpatient surgery for hip and knee replacement are asked to complete questionnaires before and after their operations. PROMS collected by NHS Digital through the national PROMS programme can be linked to the National Joint Registry (NHS Digital, 2023).

Orthopaedic procedures

Traditional replacement without computer assisted navigation usually relies on templating on 2D X-rays and using a standardised operative technique to place extra medullary or intra medullary jigs (guides used to ensure precise bone cuts) to achieve the cuts at a pre-determined angle. The surgeon manually performs the bone cuts and places the implant, using alignment guides and tools to achieve the best possible fit. This process is reliant on the surgeon's skill and judgement, which may result in some variability in precision and alignment. Standard imaging techniques such as X-rays, CT or MRI scanning may be used for clarification of diagnosis or to assist in more complex cases. There were approximately 125,000 knee procedures and over 100,000 hip replacements last year with approximately 95% being done without RAS and without computer assisted navigation (NJR, 2024).

3.2 Patient issues and preferences

People should be supported by healthcare professionals to make informed decisions about their care. Shared decision making should be supported so that people are fully involved throughout their care (see the NICE guideline on shared decision making).

People may prefer RAS if it is associated with better outcomes, earlier discharge or in complex cases with poorly defined anatomy. The availability of RAS may introduce additional options, which can be considered a benefit. NICE's guideline on joint replacement estimates that 40% of all total knee replacements may be suitable for partial knee replacement. But, adoption of this in the NHS is estimated to be around 12% of all knee replacement surgery. If the use of robotic systems can help address this barrier it may enable clinicians and hospital providers to increase the mix of partial knee replacements in knee arthroplasty. In hip replacement surgery, RAS may reduce the options available to surgeons and patients as only cementless acetabular components are compatible with the system. These are generally more expensive and used in younger patients although evidence for improved revision estimates and cost-effectiveness is yet to be proven. The HIPPY trial is an ongoing trial aimed at determining the most preferred hip implant focusing on revision rates and failures.

The RACER trials are significant studies aimed at evaluating the clinical and cost-effectiveness of robotic-assisted replacement using Mako SmartRobotics, and the associated implant system compared to conventional methods. The RACER-Hip trial's primary objective is to determine if robotic-assisted replacement improves joint awareness and function at 12 months post-surgery. The RACER-Knee trial's outcome measures include the Forgotten Joint Score at 12 months, pain intensity, blood loss, opioid use, time to discharge and long-term patient-reported outcome measures. The trials aim to analyse whether the precision of robotic systems justifies their higher costs by potentially offering better clinical outcomes, such as fewer complications and more accurate implant placements.

4 Comparator

Conventional manual surgery without computer-assisted surgical navigation is the most used technique in the UK. So, the comparator for this assessment is conventional manual surgery.

Scope of the assessment

Table 3. Scope of the assessment

Populations	People having a joint replacement or revision procedure in an area with a RAS option available
Interventions (proposed technologies)	• RAS with ApolloKnee • RAS with CORI Surgical System • RAS with Mako SmartRobotics System • RAS with ROSA Knee • RAS with SkyWalker • RAS with VELYS Robotic-Assisted Solution
Comparator	Conventional manual surgery
Healthcare setting	Admitted patient services including emergency and elective surgery
Outcomes	**Primary outcomes:** Patient level • Patient Reported Outcome Measures • Frequency and grade of complication Surgeon level • Learning curve Organisation level • Revision surgery • Cost of additional equipment including the device and single use instrumentation, maintenance and servicing costs, training costs • Volume of procedures / operating time • Case mix for example proportion of partial knee replacements rather than total knee replacements **Secondary outcomes:** Patient level • Need for further imaging with associated radiation exposure (CT scans) • Mortality • Health related quality of life

	Surgeon level • Loss of experience with manual techniques • Precision / accuracy measures such as alignment on imaging • Career longevity and musculoskeletal injury • Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Organisation level • Staff requirements including time to undergo training • Length of hospital stay • Readmission to hospital at 30 days • People in whom the procedure without the use of RAS may not be feasible • Adverse events related to equipment • Requirement for transfer of images to industry to allow planning which can introduce delays • Environmental costs of additional disposable equipment and associated packaging, manufacture, and distribution.
Time horizon	The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

5 Other issues for consideration

Characteristics of technologies

- Some technologies can only be used for some of the procedures in scope.

- As most devices are 'closed systems', surgeons using RAS from a specific company must also use the same company's implant system for manual procedures. This means considering the implant design and its long-term use in both robotic and conventional surgeries, as surgeons will not always use RAS exclusively.

- Robotic surgical systems are connected devices, often requiring connectivity to internal or external networks through the internet. They may collect and store sensitive data. Data ownership, access, privacy, and storage should be compliant with UK law.

Evidence

- Different technologies have different levels of evidence and usage, across the NHS and within different specialties.
- Evidence associated with the implant system is also relevant to this assessment.

Safety

- Surgical teams must be familiar with the RAS system and patient positioning as insufficient training or experience with RAS can lead to errors and complications.
- There may be risks associated with the technical failures of the technology such as malfunctions or breakdowns.

Training

- RAS may improve outcomes by providing consistency in surgical procedures and reducing variability among surgeons. This technology may be particularly beneficial for low-volume surgeons or those with less experience.
- For surgeons operating with RAS, there may be less physical burden which may improve the diversity of orthopaedic surgeons such as increasing the number of female surgeons.

Costs

- All of the RAS technologies included in the scope are part of national procurement framework.
- RAS platforms are sold using various models, the most common being the volume commitment discount that is achieved once an agreed-on number of cases is reached.

- Various procurement options are available such as leasing and usage-based agreements.

- Many of the robotic systems are “closed systems”, which means when using a RAS from a specific company, you must also use the same company's implant system for manual procedures. There is a long-term consideration for surgeons and hospitals using the implant system from a company for both manual and RAS procedures. The economic modelling should take into account the cost of the implants and consumables associated with each robotic system.

6 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Age, sex, socioeconomic status, disability, race, sexual orientation, pregnancy and religion or belief are protected characteristics under the Equality Act 2010.

People who are at higher surgical risk such as those who are older, have obesity or a high BMI, or with multiple comorbidities may benefit from increased access to surgery. Age is a protected characteristic, and many people may be covered by the Equality Act if their condition has had a substantial adverse impact on normal day to day activities for over 12 months or is likely to do so.

There may be some inequalities in access to RAS. Robotic platforms are expensive and if the placement of robotic systems is limited to larger hospitals with more resources to procure and maintain the system and staff needed to use the system, access to RAS may increase existing regional inequalities.

7 Potential implementation issues

National level support is anticipated as a requirement for the implementation of RAS. Some technologies are already in use in many hospitals across the UK whilst others are newer.

Most robotic systems are 'closed systems' that work with specific company implant systems. The preference for implant systems may significantly influence a department's decision to adopt a RAS from a specific company, as implementing RAS requires hospitals to commit to purchasing a single company's equipment and implant systems.

Despite the substantial number of orthopaedic procedures conducted within the NHS, it may be challenging to achieve a significant increase of these procedures using robotic systems due to limitations in capacity, infrastructure, and cost. But adopting RAS may reduce surgical errors and potentially lower the time-consuming and demanding revision burden. This could lead to increased numbers of 'Getting it Right the First Time.'

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Appendix A. Related NICE Guidance

Interventional procedures guidance

NICE's Interventional procedures guidance IPG363 on Minimally invasive total hip replacement (2010)

NICE guidelines

NICE's guideline NG157 on Joint replacement (primary): hip, knee and shoulder (2020)

NICE's guideline NG197 on Shared decision making (2021)

NICE's guideline CG124 on Hip fracture: management (2011, updated 2023)

Quality standards

NICE's Quality standard QS206 on Joint replacement (primary): hip, knee and shoulder (2022)

Appendix B. Abbreviations

BMI	Body mass index
CT	Computer tomography
DTAC	Digital technology assessment criteria
EVA	Early value assessment
MRI	Medical Resonance Imaging
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
RAS	Robot-assisted surgery
RCS	Royal College of Surgeons

Document cover sheet

Assessment report: Robot-assisted surgery in orthopaedics

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Version number	Brief description of changes	Author/reviewer (for example, J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
0.01	Template creation Adding summary of technologies Adding studies included/excluded from Company submissions Adding economic evidence summary	K Keltie E Blacklock K Keltie R O'Leary	20/06/2024 21/06/2024 21/06/2024	
0.02	Adding tables from literature sifting (clinical and economic) Reformatting tables	K Keltie R O'Leary Elliot Blacklock	16/07/2024 19/07/2024	
0.03	Review adding narrative Adding to economics section Updating technology and cost sections (incorporating Company feedback) Adding to ongoing studies Adding to table of exclusions and non-key evidence	K Keltie R O'Leary E Blacklock E Blacklock K Keltie, P Leslie	29/07/2024 30/07/2024	
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	Adding detail of included studies Adding to economic model section QA of studies included/excluded from Company submissions Updating technology and cost sections (incorporating Company feedback) Updating technology section Updating ongoing studies Updating Costs table Reviewing special considerations Review of economics section QA Adding to clinical context, adding to adverse events section Adding results to clinical evidence section	D Muir R O'Leary P Leslie E Blacklock L Vale D Muir P Leslie K Keltie	06/08/2024 07/08/2024	
0.05	Adding input from Experts Oversight review	K Keltie A Sims	09/08/2024	
0.06	Addressing review comments Adding data extraction of included studies Review of economics section	K Keltie R O'Leary K Keltie P Leslie L Vale	12/08/2024	
0.07	Review of economics section Addressing review comments Added expert questions correspondence log QA	L Vale K Keltie E Blacklock P Leslie R O'Leary E Blacklock E Blacklock, P Leslie, K Keltie	14/08/2024	
0.08	Adding summary narrative to summary clinical evidence sections QA Adding base case economic results Adding expert responses	K Keltie E Blacklock, P Leslie R O'Leary E Blacklock	15/08/2024 16/08/2024 19/08/2024 19/08/2024	

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0.09	Adding Company responses to questions QA Checking references Checking Tables and Figures Adding latest expert responses to questions	K Keltie E Blacklock, P Leslie K Keltie	20/08/2024 21/08/2024	
0.10	Presubmission checklist Drafting summary section Adding threshold analysis	D Muir K Keltie R O'Leary	21/08/2024	
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

HTE10043 Robot-assisted surgery for orthopaedic procedures

External Assessment Group report

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Purpose of the assessment report

The purpose of this External assessment group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical or economic evidence. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

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Responsibility for report

The views expressed in report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

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Abbreviations

Term	Definition
AKSS	American Knee Society Score
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
CI	Confidence interval
CUSUM	Cumulative Sum
DTAC	Digital Technology Assessment Criteria
EAG	External assessment group
EMEA	Europe, Middle East and Africa
ERAS	Enhanced Recovery After Surgery
FJS	Forgotten Joint Score
HKA	Hip-knee-ankle
HES	Hospital Episode Statistics
HRG	Healthcare Resource Group
HR	Hazard ratio
ICER	Incremental Cost-Effectiveness Ratio
IQR	Interquartile range
KOOS	Knee injury and Osteoarthritis Outcome Score
KOOS-JR	Knee injury and Osteoarthritis Outcome Score for Joint Replacement
KSFS	Knee Society Function Score
KSKS	Knee Society Knee Score
KSS	Knee Society Score
LC-CUSUM	learning curve cumulative summation
LEAV	Lower exposure action value
MCID	Minimally clinically important difference
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines & Healthcare products Regulatory Agency
N/A	Not applicable
NICE	National Institute for Health and Care Excellence
NJR	National Joint Registry
NuTH	The Newcastle upon Tyne Hospitals NHS Foundation Trust
NR	Not Reported

Term	Definition
NRS	Numerical Rating Score
OHS	Oxford Hip Score
OKS	Oxford Knee Score
OPCS	Operating Procedure Codes Supplement
PACU	Post-Anaesthesia Care Unit
PKA	Partial Knee Arthroplasty
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMs	Patient Reported Outcome Measures
QALY	Quality-adjusted life year
RAS	Robotic Assisted Surgery
RCT	Randomised controlled trial
ROM	Range of Motion
SD	Standard deviation
SEA	Supplier equipment agreement
SMR	Standardised mortality ratio
SURG-TLX	Surgery task load index
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
UCLA	University of California Los Angeles activity-level
UKA	Unicompartmental Arthroplasty
VAS	Visual analogue scale
WOMAC	Western Ontario and McMaster Universities Arthritis Index
WTP	Willingness to pay

Executive summary

The purpose of this early value assessment is to identify evidence for 6 robotic systems used in joint replacement surgery (ApolloKnee, CORI, Mako, ROSA Knee, SkyWalker, VELYS) when compared with conventional surgery, identify evidence gaps to help direct further research and data collection, and develop a model to inform future economic evaluations.

Quality and relevance of the clinical evidence

The EAG prioritised 26 comparative studies,15 of which were conducted in a UK setting. The EAG noted that the quantity and quality of clinical evidence varied by joint replacement procedure and by technology:

- The majority of evidence included total knee arthroplasty (TKA); N=16 studies of which the EAG considered 5 RCTs and 3 prospective cohorts with comparator arms with matched baseline characteristics to be the highest quality evidence. RCT evidence from the UK has broadly shown clinical non-inferiority of the Mako robotic system when compared with conventional TKA. Improvements in alignment were observed in the UK RCT evidence for Mako and non-UK RCT evidence for CORI, and the EAG considered it plausible that this may lead to increased patient activity levels and lower revision rates. Randomised non-UK evidence for CORI and its predecessor NAVIO, as well as prospective cohorts with matched comparator arm using ROSA Knee gave similar results. The EAG did not identify any UK studies, RCT or observational studies with matched comparator arms (adjusting for differences in baseline characteristics between patients undergoing robotic or conventional surgery) for ApolloKnee, VELYS or SkyWalker in TKA; therefore there remains uncertainty regarding the effectiveness of these technologies in robotic TKA.
- Evidence in partial knee replacement was limited to Mako and CORI robotic systems, total of 6 studies which included 3 RCTs, 1 retrospective UK cohort with a matched comparator arm and a subgroup analysis. Two studies reported from the same RCT, which compared robotic unicompartmental arthroplasty

(UKA) against conventional TKA as a comparator and used different prostheses across arms; generalisability of these results is unclear.

- Evidence in total hip arthroplasty was limited to 5 observational studies, of which only 1 had patient characteristics matched across intervention and comparator arms. All studies used Mako. Trends in results appear similar to TKA in that no statistical differences in utility, VAS, satisfaction were observed between arms at 1 year, however differences in Forgotten Joint Score, Oxford Hip score and alignment were reported. Due to the lack of randomised evidence in this area, it is unclear how robust these findings are.
- The EAG note that ApolloKnee, ROSA Knee, SkyWalker and VELYS are not indicated for use in partial knee or total hip surgery.
- None of the technologies are currently indicated for shoulder replacement, and only CORI is explicitly indicated for revision TKA surgery. No comparative evidence was identified for these indications.

Across 8 RCTs considered key evidence, none reported a statistical difference in patient reported outcome measures at 1 year between robotic surgery and conventional surgery. However, there was large heterogeneity in the patient reported outcome measures (PROMs) reported across included studies and utilities were only available for Mako compared with conventional surgery. From the available randomised evidence, rates of adverse events did not appear different between robotic and conventional surgery, however none of the RCTs were powered to detect a difference in this outcome. Of note, all RCTs were for TKA and UKA procedures, with THA procedures supported only by limited evidence from observational studies, only 1 of which was with matching of patient characteristics between arms. Device-specific adverse events such as robotic failure or conversion to manual surgery, were considered rare by Clinical Experts, and rates could not be estimated reliably from secondary outcomes of efficacy studies because of small sample sizes. The learning curve associated with robotic surgery was considered short, between 7 and 30 cases, but the training required for staff involved in the procedure to achieve competency

differs between manufacturers. Delivery of adequate procedural volume within a centre to maintain competency, and ongoing training to maintain skills in conventional techniques in circumstances where conversion to manual surgery is required, are also considerations. After the learning curve phase, operation time appears comparable between robotic and conventional surgery. When considering UK RCT evidence, robotic surgery was associated with improvements in alignment assessed radiologically (CORI, Mako) and a reduction of inflammatory markers (Mako). However, the clinical impact on patient quality of life and economic impact on healthcare resource usage remains uncertain. The real-world data show differences in patient characteristics with those receiving robotic surgery being typically younger than those receiving conventional surgery. This aligns with guidance from the Royal College of Surgeons of England which recommends that surgeons learning robotic surgery should start with more straightforward cases, patients without severe comorbidities and patients with a BMI below 35. These baseline cohort differences may affect clinical outcomes and should be corrected for in future analysis, if they are available. Clinical outcomes should be considered when surgeons are beyond the learning curve to ensure that there is a fairer comparison of relative effectiveness and facilitate continuous audit and feedback on surgical performance.

Quality and relevance of the economic evidence

The EAG identified 22 published economic evaluations, including 7 with economic models which compared robotic joint replacement with conventional surgery. Four published economic models (3 Mako, 1 NAVIO) from a UK perspective reported an incremental cost per QALY of between £1,170 and £13,078. These models were sensitive to changes in annual procedure volume, cost of revision surgery and cost of the robotic technology. The EAG developed a de novo Markov model with a lifetime time horizon which included revision and mortality health states, the structure of which applies to total knee, partial knee, total hip replacement, and could apply to total shoulder replacement if evidence becomes available. The aim of this model was to determine the impact of univariate changes in clinical and cost parameters and explore uncertainties in the evidence base. The EAG created a base case for Mako using the

best publicly available clinical parameters and utilities, and costs, supplied by the Company. The EAG assumed the same length of stay, revision and mortality outcomes between robotic and conventional surgery. The EAG considered a volume-based lease option in the base case as this is the most used across consulted Clinical Experts. The EAG assumed 250 procedures per year using median procedure volumes of primary procedures from the National Joint Registry (NJR)'s 20th annual report. Most per patient procedure costs were attributed to the cost of the implant and the EAG note that robotic systems are only compatible with implants from the same manufacturer. Most per patient costs, in both robotic and conventional arms, were accrued in the first year and attributed to the initial orthopaedic procedure. Cost differences in the economic model between the robotic and conventional arms were broadly attributable to lower implant costs associated with volume-based contracts with manufacturers. The base case analysis, where many clinical outcomes are assumed to be the same, is sensitive to changes in utilities, where applying the upper and lower confidence interval from RCTs led to the ICER for RAS changing from being dominated to almost being dominant, as the ICER generated is low. Given the lack of data on revision and mortality outcomes these were assumed to be the same but changes in these parameters would affect estimates of cost-effectiveness.

Evidence gap analysis

A number of evidence gaps were identified, however the EAG would consider that 3 key evidence gaps could be filled pragmatically in a UK NHS setting: 1) procedural costs using robotics including consumables, implant used and number of times the robot is used at a hospital level which were key drivers in the economic model; this information could be collected via a large audit, 2) prospective data collection of revisions and rare adverse events across robotic and conventional surgeries, which could be collected via the NJR and linked to Hospital Episode Statistics for outcomes after discharge. Furthermore, the relative effectiveness of ApolloKnee, SkyWalker and VELYS remains unknown. There is limited evidence in THA and no evidence in shoulder replacement. 3) a thorough assessment of impacts on health (for patients and

clinicians) measured in a form suitable for use in the modelling, this might be derived from PROMs data already collected by NHS Digital and future prospective studies.

1. Decision problem

The decision problem as described in the Final Scope is described in Table 1.

Table 1: Summary of decision problem

Decision problem	Scope	EAG comment
Population	People having a joint replacement or revision procedure in an area with a robotic-assisted surgery (RAS) option available	The EAG focused on the following orthopaedic procedures which were listed in the Final Scope: • Total knee replacement • Partial knee replacement • Total hip replacement • Shoulder replacement The EAG considered evidence relating to revision (secondary joint replacement) surgeries separately, where data was available.
Intervention	• RAS with ApolloKnee • RAS with CORI Surgical System • RAS with Mako SmartRobotics System • RAS with ROSA Knee • RAS with SkyWalker • RAS with VELYS Robotic-Assisted Solution	The EAG also considered earlier versions of the devices which may have longer-term evidence. The EAG note that ROSA Hip is not available in the UK currently and therefore this was not considered within this assessment. The EAG note that currently only CORI is explicitly indicated for use in revision knee surgery (furthermore ROSA has revision listed as a contraindication).
Comparator(s)	Conventional manual surgery	Single arm studies (that is, studies with no comparator) were considered for those reporting learning curve and device-related adverse event outcomes. If safety concerns were identified by the Experts or published literature, this may affect future evidence generation.
Outcomes	**Primary outcomes:** Patient level: • Patient Reported Outcome Measures • Frequency and grade of complication	Due to the size of the evidence base and time/resource constraints the EAG focused on highest quality evidence (prioritising UK, prospective

Decision problem	Scope	EAG comment
	Surgeon level • Learning curve Organisation level • Revision surgery • Cost of additional equipment including the device and single use instrumentation, maintenance and servicing costs, training costs • Volume of procedures / operating time • Case mix for example proportion of partial knee replacements rather than total knee replacements **Secondary Outcomes** Patient level • Need for further imaging with associated radiation exposure (CT scans) • Mortality • Health related quality of life Surgeon level • Loss of experience with manual techniques • Precision / accuracy measures such as alignment on imaging • Career longevity and musculoskeletal injury • Procedure-related discomfort and ergonomics (for example, surgery task load index - SURG-TLX) Organisation level • Staff requirements including time to undergo training • Length of hospital stay • Readmission to hospital at 30 days • People in whom the procedure without the use of RAS may not be feasible • Adverse events related to equipment • Requirement for transfer of images to industry to allow planning which can introduce delays • Environmental costs of additional disposable equipment and associated packaging, manufacture, and distribution.	designs with largest sample size) and primary outcomes.

Abbreviations: EAG, External Assessment Group; RAS, Robotic assisted surgery

Terminology

The EAG will use the term 'conventional' surgery when referring to surgery conducted without robotic assistance or computer navigation. Conventional surgery is also referred to as manual or mechanical surgery in the literature. To provide further context, mechanical surgery may refer to use of mechanical tools, as is the EAG's intended meaning, or mechanical alignment of the joint.

The National Joint Registry (NJR) has standard definitions for the types of knee and hip surgery carried out in the UK as outlined below (Achakri et al., 2023). Joints may be totally replaced or only have specific compartment(s) replaced. The EAG uses the NJR descriptors and the specific terms reported by manufacturers and in the literature as appropriate.

Total knee replacement: replacing the lateral (outside) and medial (inside) compartments with new implants to both tibial and femoral condyles (with or without patella resurfacing). This may be referred to as total knee arthroplasty (TKA) in the literature.

Unicompartmental knee replacement: replacing either the lateral, medial or patellofemoral (under the kneecap) compartment with one tibial condyle and one femoral condyle (with or without patella resurfacing). This may be referred to as unicompartmental knee arthroplasty (UKA), partial knee replacement or partial knee arthroplasty (PKA) in the literature. Multicompartmental knee replacement: typically replacing 2 compartments. This may also be referred to as partial knee replacement or partial knee arthroplasty (PKA) in the literature. The NJR note that in some rare cases, lateral, medial and patellofemoral compartments can be replaced with separate unicompartmental devices.

Total hip replacement: replacing the femoral head with a stemmed femoral prosthesis and insertion of an acetabular cup, with or without cement. This may be referred to as total hip arthroplasty (THA) in the literature.

2. Overview of the technology

Robotic-assisted surgery (RAS) is a type of surgery where robotic platforms are used to help enhance the work of a surgeon. These technologies are intended to enable surgeons to perform a variety of procedures with more precision, flexibility and control compared with conventional techniques.

In orthopaedic procedures, RAS systems may integrate pre-operative planning with real-time intraoperative guidance. The systems generally incorporate a robotic arm controlled by the surgeon that holds and aligns cutting tools, computer-assisted navigation and registration systems, and also provide a platform for imaging to be viewed by the surgical team. The RAS systems may also have data collection features that can be used to verify and score the accuracy of bone resections and placement of implants.

Robotic platforms can be categorised as follows (Chen et al., 2018):

- Passive: guide surgeons, and robotic instrumentation must be directed by the surgeon to perform a task;
- Semi-active: constrain surgical manipulation through intraoperative feedback to the surgeon;
- Active: capable of independently performing tasks without human manipulation using preprogrammed algorithms and defined parameters.

Other categories for describing a feature set are commonly used and will be referred to in the assessment report as outlined below.

- Direct or indirect cutting: with direct cutting systems the robot cuts the bone into the preplanned shape, with indirect cutting systems the robot places or holds a cutting jig with cuts made by surgeon. Direct and indirect robotic cutting systems can be further described as:

    - Autonomous: the robot cuts the bone with no controlling human hand, the device moves and cuts based on instructions provided by the surgeon.
    - Haptic: human interaction is required to move the robot to cut, and as it approaches the preplanned boundary, feedback (visual or vibrational) is triggered to the surgeon who deactivates the device.
    - Boundary control: human interaction is required to move the robot to cut, and cutting is deactivated or prevented by the device if travelling beyond a preprogrammed boundary.

- Pre-operative imaging: Some systems use pre-operative imaging, for example 3-dimensional computed tomography (3DCT), to aid preoperative planning and provisional implant alignment. The model created is verified intraoperatively during registration of multiple anatomical landmarks. Other systems are considered “image-free” and rely on surface mapping technologies with intraoperative identification of landmarks (Robotics-in-the-NHS-Knees).

- Open or Closed platforms: Closed platforms limit the surgeon to specific proprietary implants and, potentially, tools and other peripherals such as scanners. Open systems allow the surgeon to consider multiple implants or tools from different Companies according to their preference (Mancino et al., 2020).

- Near or Remote surgery: Near surgery has the surgical platform in the same room as the procedure whereas remote would indicate that the platform is contained in another room or location. The EAG notes that no remote systems have been identified within this assessment's scope.

2.1 Included technologies

There are 6 robotic platforms from 6 different manufacturers which fall within the scope of the assessment (narrative summary available in the Final Scope). Not all identified robotic systems can be used for all the procedures of interest, see Table 2 for an overview of the indications and procedures of each device. The EAG note that all 6

robotics systems listed are considered as semi-active with different levels of automation, and all are closed platforms. A summary of the technologies and their components are summarised in Table 2 and Table 3 respectively.

Microport Medbot has not submitted information to NICE about the SkyWalker device and so the EAG have relied on information in the public domain about this technology.

The EAG were supplied with the following summary statement from NICE regarding the regulatory approval of the 6 devices within the scope of this assessment: *"NICE has confirmed that 5 Companies have submitted documentation that their technology has regulatory approval. All 5 devices were classified as class IIa. No regulatory information was received about the SkyWalker robot".*

All 6 devices have indicated Digital Technologies Assessment Criteria (DTAC) certification status as below:

- 3 Companies have submitted documentation in relation to DTAC (relating to CORI, ROSA, VELYS devices)
- 2 Companies state that DTAC is not required (relating to Mako and ApolloKnee devices, the latter stating that DTAC is not presently requested by hospitals).
- 1 Device have not indicated DTAC status (SkyWalker).

The EAG notes that of the devices within the scope of this assessment, only the CORI device is currently indicated for revision total knee arthroplasty. Clinical Experts confirmed that revision surgery is typically performed using conventional (non-robotic) techniques. One Clinical Expert stated use of the CORI system in primary and revision total knee replacement, another Clinical Expert stated using robotics in revision of partial to total knee replacement in the absence of infection.

Table 2: Summary of Technology

Device [predecessor]; manufacturer	Device Indication	Contraindications	Requires Pre-Op imaging	Open/Closed	Deployment of Robot	Cutting Type
ApolloKnee [OmniBotics]; Corin	TKA	Use with implants or procedures other that TKA with Apex Knee, Unity Knee or HLS KneeTec, use by a doctor that has not been duly trained, any other contraindications outlined for the Apex Knee, Unity Knee, or HLS KneeTec.	No	Closed - Recommended usage of OMNIBotics pins and screws. Use of other implants is specifically contraindicated	Robotic positioning system is affixed directly to the patient by a fixation system	Indirect (no haptics or boundaries, aligns with guide)
CORI [NAVIO]; Smith+Nephew	TKA, PKA, THA, Revision TKA	Children, pregnant women, patients who have mental or neuromuscular disorders that do not allow control of the knee joint.	No	Closed - Recommended use of Smith + Nephew implant systems JOURNEY II, JOURNEY UNI, JOURNEY II UK UNI, LEGION Revision Knee Femur and Tibia components and LEGION TKS	Handheld	Direct (boundary control)
Mako [RIO, Acrobot]; Stryker	TKA	No specifically listed contraindications, surgeon should consider the following: Articulation of the hip joint is necessary to complete bone registration, Metal in the operative or non-operative leg can lead to the creation of accuracy reducing artifacts in the CT scan which can adversely affect the operative plan, The presence of infection (including history of infection), acute or chronic, local or systemic should be ruled out, Poor bone quality may affect the stability of the implant, Patient size may complicate the resection procedure. Body Mass Index should be considered.	CT	Closed - Compatible with following Stryker implant system Triathlon Total Knee implant systems (Cemented and Cementless primary)	Arm: Moveable base station	Direct (haptic)
Mako [RIO, Acrobot]; Stryker	PKA	No specifically listed contraindications, surgeon should consider the following: Articulation of the hip joint is necessary to complete bone registration, metal in the operative or non-operative leg can lead to the creation of accuracy-reducing artifacts in the CT scan which can adversely affect the operative plan, the presence of infection (including history of infection), acute or chronic, local or systemic must be considered, Insufficient bone quality may affect the stability of the implant, patient size may complicate the resection procedure. Body Mass Index should be considered, loss of ligament structures may prevent creation of an ideal intra-operative plan, the significance of the deformity (Hyperextension, Flexion Contracture or Varus/Valgus) must be considered, patients with inflammatory arthritis or tricompartmental disease are not candidates for the procedure	CT	Closed - Compatible with following Stryker implant system RESTORIS MCK System	Arm: Moveable base station	Direct (haptic)
Mako [RIO, Acrobot]; Stryker	THA	No explicit contraindications listed, surgeon should consider the following: Metal in the operative or non-operative leg can lead to the creation of accuracy-reducing artifacts in the CT scan, which can adversely affect the patient plan, the presence of infection (including history of infection), acute or chronic, local or systemic must be considered.	CT	Closed - Compatible with following Stryker implant systems, Trident II Tritanium, Trident Tritanium, Trident II PSL, Trident PSL, Trident II Hemispherical, Trident Hemispherical, Accolade II, Secur Fit Advanced, Anato, Exeter.	Arm: Moveable base station	Direct (haptic)
ROSA; Zimmer Biomet	TKA	Hip pathology with significant bone loss (for example, avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum), Hip pathology severely limiting range of motion (for example, arthrodesis, severe contractures, chronic severe dislocation), Active infections of the knee joint area, Knee replacement revision surgery, presence of strong infrared sources or infrared reflectors in the vicinity of the NavitrackER devices, Implants that are not compatible with the system, contraindications for the implant as given by the implant manufacturer	Optional	Closed - should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible with ROSA Knee System	Arm: Moveable base station	Indirect (no haptics or boundaries, aligns with guide)
SkyWalker; Microport MedBot	TKA, THA	No information supplied. No information available in the public domain.	CT	Closed - Compatible with the Evolution Medial-Pivot Knee Implant	Arm: Moveable base station	Direct (additional information not provided)
VELYS; Johnson & Johnson	TKA	Patients for whom a hip centre of rotation cannot be established using the VELYS Robotic-Assisted acquisition protocols, Patients in whom the necessary bony landmarks needed for acquisition are not present or accessible, where ligament deficiency requires additional constraint beyond that achieved with the compatible ATTUNE Total Knee System implants.	No	Closed - Compatible with the ATTUNE Total Knee System	Arm: Stored and moved on satellite station and is then affixed to patient's bedrail	Direct (boundary control)

Abbreviations: PKA, Partial Knee Arthroplasty; THA, Total Hip Arthroplasty; TKA, Total Knee Arthroplasty;

Table 3: Summary of Technology Components

Device	System Components (Dimensions)	Instrumentation Kits	Tracking reference arrays and fixation method	Types of data collected	Device Lifetime	Planned updates to technology
ApolloKnee	1x OMNIBotics Station consisting of: Laptop, Camera, OMNIBot motor, Enclosure, Monitor, Foot switch, Wheelbase, Drawer, Mast, Camera arm and Docking station, stored across 4 cases. Unpacked dimension: 78 x 20 x 20 inches (HxWxD) Approximate weight 68kg 1x OMNIBot 1x BalanceBot	OMNIBotics instrument set that includes instruments required for use One of the following (dependent in implant choice) • OMNIBotics instruments, Apex Knee • OMNIBotics instruments, HLS KneeTec • OMNIBotics instruments, Unity Knee OMNIBotics/BalanceBot disposable kits including segregated screws and pins, USB for case report storage and 20 single use sterile packed reflective markers	Tibia - Two-pin bicortical fixation system, comprised of: 2 bone pins (3.2mm), Two Pin Universal Fixation bracket with Universal Reattachable Array Holder Femur - Two-pin bicortical fixation system, comprised of: 2 Bone pins (4.0mm), OMNIBot Fixation base, 45-degree angled reattach able Adaptor to which the robotic system is attached.	Intra operatively collects bone morphing data points and soft tissue data through full flexion extension, Patient's name and details	10 years for system with calibration at 12 months or 100 cases. Consumables are single use sterile packed reflective markers for attaching to tibial and femoral arrays – these are 5 year shelf life for sterility	-
CORI	1x Computer cart, 1x Camera cart used to communicate relative positioning of handpiece, femur, and tibia (via tracker arrays) to computer cart, 1x Hand piece used to undertake bone resection Computer and camera carts can be nested together when not in use.	CORI Instrument Kit - 2 Level tray that contains required instrumentation for surgery using CORI system 1 Tray for knee procedures and 1 for hips.	Two-pin 4.0mm and 3.2mm bicortical fixation for engagement but not penetration of the second cortex, with intra-incisional options available, comprised of: 2 bone pins, Tissue protector, tracking array clamps that allow the attachment of the bone tracking arrays to be attached to both femur and tibia	Intra-operative case-specific data related to use of the robotic system including but is not limited to: State timing, Intra-operative case information, Planning information and parameters, Surgical targets, Case review screen for each procedure. This information is housed on the CORI unit and is maintained on the unit itself.	Robotic Drill Attachment - 15 uses Robotic Drill and Tracker - 75 uses (until service and maintenance - then can be continually reused as part of the service plan offering) Bone and Checkpoint Pins - 10 uses (Replaced as appropriate until no longer sharp / threaded as part of service plan offering) Console, Robotics Cart and base, Tracking Camera, Tablet, Monitor and foot pedal - 5 years minimum	[redacted]
Mako (TKA)	1x Robotic Arm 1x Camera Stand 1x Guidance Module	Mako Instrumentation including: Mako knee tray, Mako power tray, Sterile disposables: Mako drape kit, Mako blade, VIZADISC knee tracking kit, femoral and tibial knee tracking kit, bone pins, leg positioners (optional)	Reference array is attached to an array clamp construct affixed to the Femur and Tibia requiring 2 Bone pins for each array clamp. (4.0 and 3.2mm)	[redacted]	[redacted]	[redacted]
Mako (PKA)	1x Robotic Arm 1x Camera Stand 1x Guidance Module	Mako Instrumentation including: Mako Knee Tray, MCK Uni Only Tray or MCK PF Tray (Both trays are required when performing Bicompartmental Only procedure) Sterile disposables: Mako Drape Kit, ball burr, Mako blade, VIZADISC,	Reference array is attached to an array clamp construct affixed to the Femur and Tibia requiring 2 Bone pins for each array clamp. (4.0 and 3.2mm)	[redacted]	[redacted]	[redacted]

Device	System Components (Dimensions)	Instrumentation Kits	Tracking reference arrays and fixation method	Types of data collected	Device Lifetime	Planned updates to technology
		femoral and tibial knee tracking kit, bone pins, leg positioners				
Mako (THA)	1x Robotic Arm 1x Camera Stand 1x Guidance Module	Mako Instrumentation including: Mako hip array kit, Mako hip power equipment kit, Mako hip acetabular, reamer basket kit Sterile disposables: Mako drape kit, VIZADISC hip kit, check points, cortical or variable angle screws, bone pins	No Reference arrays	[redacted]	[redacted]	[redacted]
ROSA	1x Robotic Unit consisting of: Robotic Arm, Computer and software, Foot pedal Touchscreen display, Optional storage area Dimensions: 1500 x 650 x 1205mm (HxWxD) Weight: 320kg 1x Optical Unit consisting of: Optical camera, Camera positioning arm, Touchscreen display. Dimensions: 1945 x 761 x 845mm (HxWxD) Weight: 140kg	No specific mention of predefined kits or collections of instruments. IFU lists the reusable and disposable instrumentation designed to be used with the ROSA System	Tibia - The Tibial reference frame is secured to 2 fixed fluted pins (3.2 x 80 mm) set near bicortically either inside or outside the exposing incision Femur -The Femoral reference frame is secured to 2 fixed fluted pins (3.2x150 mm) set bicortically either inside or outside the exposing incision.	[redacted] ROSA Knee system is DTAC Certified and cyber essentials qualified.	ROSA lifetime is 10 years or 2000 cycles The reusable instruments of the ROSA Knee System have a lifetime expectancy of five years under normal use, estimated at 240 surgeries over five years. All other disposables are single use A maintenance agreement is established between the customer and Zimmer Biomet. It covers the frequency of the preventive maintenances and list the different checks and tests performed.	[redacted]
SkyWalker	1x Robotic arm trolley 1x Surgical console consisting of Camera, 1 surgeon screen 1 operator screen, 1 operator console	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.
VELYS	1x Base station (92kg) with touchscreen and foot pedal control. I/O in the rear of device compromising Display Port connector for the connection of 3rd display, Ethernet Port for network connection, USB Port for using USB solid state flash drives ONLY 1x Satellite Station (89kg) with touchscreen and robotic arm transfer holding arm (11kg) that assist in the movement and attachment of Robotic Assisted Device (7kg)	Array Set Knee - Single use sterile instrumentation including saw array, tibia array, femur array, device array and pointer probe Array Drill Pins - Single use sterile instrumentation available in 100, 125 or 175mm lengths ATTUNE and INTUITION CAS Ligament Tensor Kit - Reusable Instrumentation kit including ATTUNE patella/femoral lug drill, patellar calliper, CAS Tensor spacer, CAS Ligament Tensor and handle.	Arrays are attached and detached from an Array clamp that is rigidly fixed to 2 array drill Pins that are fixed to the femur and tibia at the beginning of the procedure.	Collected data includes: Surgery date, Hospital identifier Patient identifiers, Surgeon identifiers, Surgical profile settings Initial assessment – hip-knee-ankle angle (alignment), range of movement, flexion and extension gaps on balance graph, Planned resections, alignment, and implant position. Post-resection flexion and extension gaps on balance graph (dependent on chosen workflow) Final assessment – alignment, range of movement, flexion and extension gaps on balance graph, femoral implant size, femoral implant type, tibial insert thickness, workflow timestamps. Anonymised data is also collected for analysis by field service engineers for the purpose of maintenance and fault resolution.	Minimum of 7 years or 1800 Cases. Components should be serviced at intervals to achieve this lifespan Base and Satellite Station - 300 Cases Robot Device - 1800 Cases Holding Arm - 300 Cases Saw Handpiece 200 Cases per handpiece (assuming 1 cycle per surgical procedure) Consumables Sterile Shelf-life (all single use) PURESIGHT Array Set): 3 years Oscillating Saw Blade: 5 years Array Drill Pins: 10 years Device Sterile Drapes: 3 years Satellite Station Sterile Drapes: 3 years Device Sterile Drapes, CE Mark: 3 years	Development of a new indication for the VELYS Robotic-Assisted solution is in progress which would allow for the system to be used for unicondylar knee replacement (UKR) procedures. Additional software updates planned for 2024 Clinical interface: Formatted case report with ability to capture screenshots and hip-knee-ankle angle at different positions of flexion, Ability to select custom rotation points on planning screen, Addition of universal surgeon identifier, Additional required patient information fields for case reports. Automatic verification of checkpoints prior to first tibia and femur cuts regardless of cut sequence Service care features: New diagnostic application for fault finding and system testing, Additional maintenance/service logs, Remote service access for updates System updates: Full hard drive encryption, Enhanced password rules for case report exports, Additional patient identifier fields on export case report screen, Cybersecurity and operating system updates

Device	System Components (Dimensions)	Instrumentation Kits	Tracking reference arrays and fixation method	Types of data collected	Device Lifetime	Planned updates to technology
					Satellite Station Sterile Drapes, CE Mark: 3 years	

Abbreviations: DTAC, Digital Technology Assessment Criteria; HxWxD, HeightxWidthxDepth; IFU, Instructions for Use; PKA, partial knee arthroplasty; THA, total hip arthroplasty; TKA, total knee arthroplasty;

2.2 Training

Robotic systems are complex and need dedicated training programmes for the whole operating team and support services. Each company and system have varied levels of mandatory training required by the organisation before they deploy a system for use in addition to any previous training, qualifications and experience in conventional orthopaedic surgery. This typically covers the system's use in navigation and registration of patient limb anatomy, use of the robotic system, sterile field preparation and cadaveric training. The requirements have been outlined in Table 4 by device as outlined in information provided by the Companies. At the Scoping Workshop representatives from Medtronic, Stryker and Zimmer Biomet confirmed that costs associated with training were included within their costs. Smith and Nephew confirmed in their request for information response that training is included in their costs.

The learning curve of Robotic assisted surgery is usually defined as at least 10 cases to gain competency. One Company (CORIN) have suggested that completing at least 10 cases per year would be considered sensible to stay current with the system. One Company (Smith and Nephew) have suggested around 30 cases per year is appropriate for safe and effective use of any robotic system. One Company (ZimmerBiomet) have suggested that the number of cases needed to remain competent would be similar for both robotic and conventional surgery.

The EAG notes that each robotic platform has training requirements to be considered competent in that system and that proficiency in one platform does not necessarily give transferable competency to a another platform.

Table 4: Overview of training requirements as reported by Companies.

Device	Surgeon	Nurse or Theatre Team	Sterile Services
ApolloKnee	Surgeons and senior theatre staff are trained with a mix of locally provided dry bone workshops and lab based cadaveric, hands-on simulations.	Regular theatre staff training is provided by drybone workshop and a web based 'flight simulator' is provided.	No information supplied
CORI	CORI will not deploy a device to any facility unless or until Health Care Practitioners have completed minimum training. • Blended learning journey with courses at London Academy • Online learning through Medical Education Training Pathway Additional support through diploma (Robotic Assisted Surgical Systems-Knee (Smith & Nephew) (PG Dip RASS)) which is intended to certify surgeons level of technical knowledge of CORI robotic assisted system and the application into clinical practice	None explicitly stated however there are modules on the online Medical Education Training Pathway that are relevant and PGcert RASS for Nurses.	Sterile services training provided in UK by Robotics technical field specialists upon installation of system and upon additional request with no additional cost
Mako	• Physician is qualified and experienced in orthopaedic surgery • Sawbone demonstration, hands on experience with Mako product specialist • Surgical observation. • Online training modules, along with the surgical technique and planning guides • Mandatory Mako certification course to qualify before performing cases • Arrange first cases. Discuss and plan approach.	Training is provided by the Mako launch team. Training takes 1-4 hours depending on application. • Instrument/consumable preparation. • Setting up and draping the Robotic-Arm • Mako surgical workflow • Guidance for an efficient launch • It may be necessary to register the Robotic-Arm Assisted surgery into the local/national joint registry forms dependent on country. It may be necessary to register the Robotic-Arm Assisted Surgery into local/national registries dependant on location	Central sterile services department staff training on Mako instrumentation requirements
ROSA	Mandatory certification is required from the surgeon to use the ROSA Knee System. Certification: 1. On Site Certification using a dedicated knee model 2. Surgeon to Surgeon Visit with a ROSA Knee expert Preparation for the 1st cases: 1. On site training for the entire care team 2. Guided preparation for the entire care team Support during the learning curve: 1. On site support and plan to gain independence 2. Further on-demand training as requested Once surgeon is certified they can work independent of Zimmer Biomet	Customised training provided.	None explicitly stated
SkyWalker	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.	No information supplied. No information available in the public domain.
VELYS	• Completed 20 conventional manual ATTUNE total knee replacement cases prior to VELYS Robotic Assisted Solution training. • Online training modules and simulator • Sawbones training on demo system • Full day cadaveric training with full case run through including hands-on training covering: Connecting and powering on, System initialization, Draping Sawblade registration, Docking and undocking from table, Pin and array placement, Landmarking and registration, Surgical planning, making robotic saw cuts, checking accuracy and trialling, Troubleshooting, Assistant positioning, powering down and disconnection, Classroom sessions covering details of system functionality, landmarking and registration, surgical planning and troubleshooting • Local refresher training conducted locally prior to first cases, including a dry run in operating theatres • Hypercare support from Johnson and Johnson surgical proctor and VELYS Robotic-Assisted Solution clinical specialists for all cases during first two weeks of use with ongoing support from VELYS Robotic-Assisted Solution clinical specialists and local sales representatives.	• Trained and signed off on 20 conventional manual ATTUNE total knee replacement cases • Online training modules • Hands on training with demo system covering: Connecting and powering on System initialization Draping Sawblade registration Docking and undocking from table Assistant positioning Powering down and disconnection • Full dry run in local operating theatre with surgeons prior to 1st case	Requirements for sterilization of reusable instruments

3. Clinical context

Joint surgery is a complex intervention that places physical and cognitive demands on the surgical team, particularly the operating surgeon. Musculoskeletal pain is an occupational hazard due to the long procedures requiring strength to manoeuvre and support limbs and implants, prolonged standing, and tiring postures. A survey of 586 arthroplasty surgeons in the US, of which 521 were actively practicing surgeons, assessed the prevalence of musculoskeletal pain and the impact on the surgeons (McQuivey et al., 2021). The mean number of years in practice for those responding to the survey was 19 years (range 1 to 51 years), with mean annual caseload of 413 cases (interquartile range between 300 and 500). After one day in the operating theatre 96.5% of respondents reported pain. A third reported high levels of pain (defined as greater than 5 out of 10 on the Numerical Rating Scale), most commonly reported in the lower back (32.4%), hands (24.8%) and neck (21.2%). Chronic pain (of greater than 30 days duration) was reported by 44.5% of respondents. Joint surgery involves exposure to noise, vibration, and the cognitive burden associated with a complex procedure. These challenges apply to both conventional surgery and RAS.

3.1 Conventional surgery

National guidance on the use of RAS for orthopaedic procedures is limited because care pathways involve different specialties and indications for procedures. Traditional joint surgery usually relies on 2D X-ray images which allow the surgeon to map out the target site for the implant and what it will look like after implantation. This operative technique uses extra medullary or intra medullary jigs (guides used to ensure precise bone cuts) to achieve the cuts at a pre-determined angle. The surgeon manually performs the bone cuts and places the implant, using alignment guides and tools to achieve the best possible fit. The process is reliant on the surgeon’s skill and judgement for the specific patient, which may result in some variability in precision and alignment.

3.2 Robotic assisted surgery (RAS)

RAS is not a direct replacement for all conventional joint replacement surgery given the complexity and range of procedures. The use of imaging before, during, and after surgery may be affected by the use of RAS which needs consideration for radiology department capacity. All patients undergo standard planar X-ray before and after surgery. Some RAS systems are image free while some robotic systems require additional imaging (on top of the standard planar X-ray used before both conventional and robotic surgery). For example, Mako requires an additional CT scan for pre-operative planning, therefore incurs additional cost and increased radiation exposure. Additional costs associated with robotics may be offset by reduced inpatient stays, reduced post-discharge care, or reductions in highly expensive complications including revision surgery. A reduced length of stay and potential reduction in readmissions can also be influenced by changes to patient pathways and recovery programmes within NHS Trusts. For example, some NHS centres are establishing day case protocols for knee and hip replacements without the use of RAS.

Guidance has been produced by the Royal College of Surgeons of England (Royal College of Surgeons of England, 2023) and the Robotic And Digital Assisted suRgery (RADAR) working group (RCS MSK RADAR Working Group, 2024) comprising members of the British Orthopaedics Association and the Royal Colleges of Surgeons of England and Edinburgh. Both sets of guidance address the complexity of developing services, the need for multidisciplinary input from the design to implementation phases, the establishment of a training pathway and the importance of robust governance structures. The EAG note that the good practice guide by the Royal College of Surgeons of England advises that careful consideration is required for case selection, and that learners start with easier cases, non-severely comorbid patients, and train on patients with a BMI below 35. The EAG consider that this case selection may intrinsically result in differences in patient characteristics between those receiving robotic and conventional surgery, which should be considered when evaluating results from real-world evidence.

The Companies provided information regarding their use in the NHS in their completed Requests for Information:

- CORIN advised that due to COVID-19 pandemic and supply chain delays the ApolloKnee system is being prepared for use at 1 NHS hospital with a predicted start date of August 2024;
- Smith and Nephew advised that 12 NHS hospitals have used CORI or NAVIO in either total or partial knee arthroplasty in the last 2023/24 year;
- Stryker advised that [redacted];
- Johnson & Johnson advised that VELYS is used in 1 private hospital (but treats NHS patients within that hospital);
- Zimmer Biomet advised that [redacted] ROSA Knee System.

The EAG note that of 5 Clinical Experts who responded to the first set of questions from the EAG, sent 01 August 2023: 1 did not have access to a robotic system, 1 had access to robotic systems from a single manufacturer, 2 had access to robotic systems from multiple manufacturers within their organisation and 1 had access to multiple robotic systems however it was unclear if this was from the same or different manufacturers.

3.3 The National Joint Registry (NJR)

The National Joint Registry (NJR) holds almost 3.7 million records and is widely regarded as the international exemplar of robust information and expertise. Data entry has been mandated in private organisations since 2003, and NHS organisations since 2011, and currently covers England, Guernsey, the Isle of Man, Northern Ireland, and Wales. The Registry is linked to the Personal Demographics Service (NHS England) twice a year for implant survivorship and mortality data, and was last linked in February 2024. From the 20th NJR annual report (Achakri et al., 2023), the registry contains

details on almost 1.5 million hip procedures, 1.5 million knee procedures, 64 thousand shoulder procedures, over 8 thousand elbow procedures, and over 8 thousand ankle procedures. NJR estimates that approximately half of the procedures entered are from the private sector (that is either conducted in an independent healthcare setting, or private patients treated in an NHS hospital). Current data completeness is over 97% which is exceptionally high for a national registry, indicating close engagement with clinicians. Such a comprehensive data source enables healthcare professionals and researchers to identify safety concerns such as those associated with the use of metal-on-metal hip implants. The NJR has close links with patients and produced the NJR Patient Decision Support Tool: helping patients to understand potential benefits and costs of surgery, leading to more informed choice of treatment in discussions with clinicians.

The NJR hip and knee component database contains information provided by manufacturers. In 2020 this was updated to require additional attribute data to help identify the exact implant model rather than the broad family or brand of device. The classification system used will form the basis of the International Prosthesis Library. Entry of information on new components may lag behind availability in clinical use, resulting in recent additions to the NHS procurement list having limited information in the database.

The NJR shared data with the EAG from 2004 to 2024 (noting a partial dataset for the final year) which demonstrates that the number of hip and knee procedures is substantially higher than the number of shoulder procedures; for example in 2023 there were 129,349 hip (including total hip replacement and resurfacing), 124,906 knee (including total and partial) and 9,105 shoulder procedures. The use of computer-assisted navigation has remained stable in hips and knees but increased in shoulders (6.0% in the partial year of 2024). In 2019, the NJR added a data field for "robotic surgery used" for hip and knee primary forms. From the partial year of 2024 (as of August 2024), 2.3% and 6.0% of hip and knee procedures used a robotic system; robotic surgery is not currently recorded in the NJR for shoulder replacement procedures.

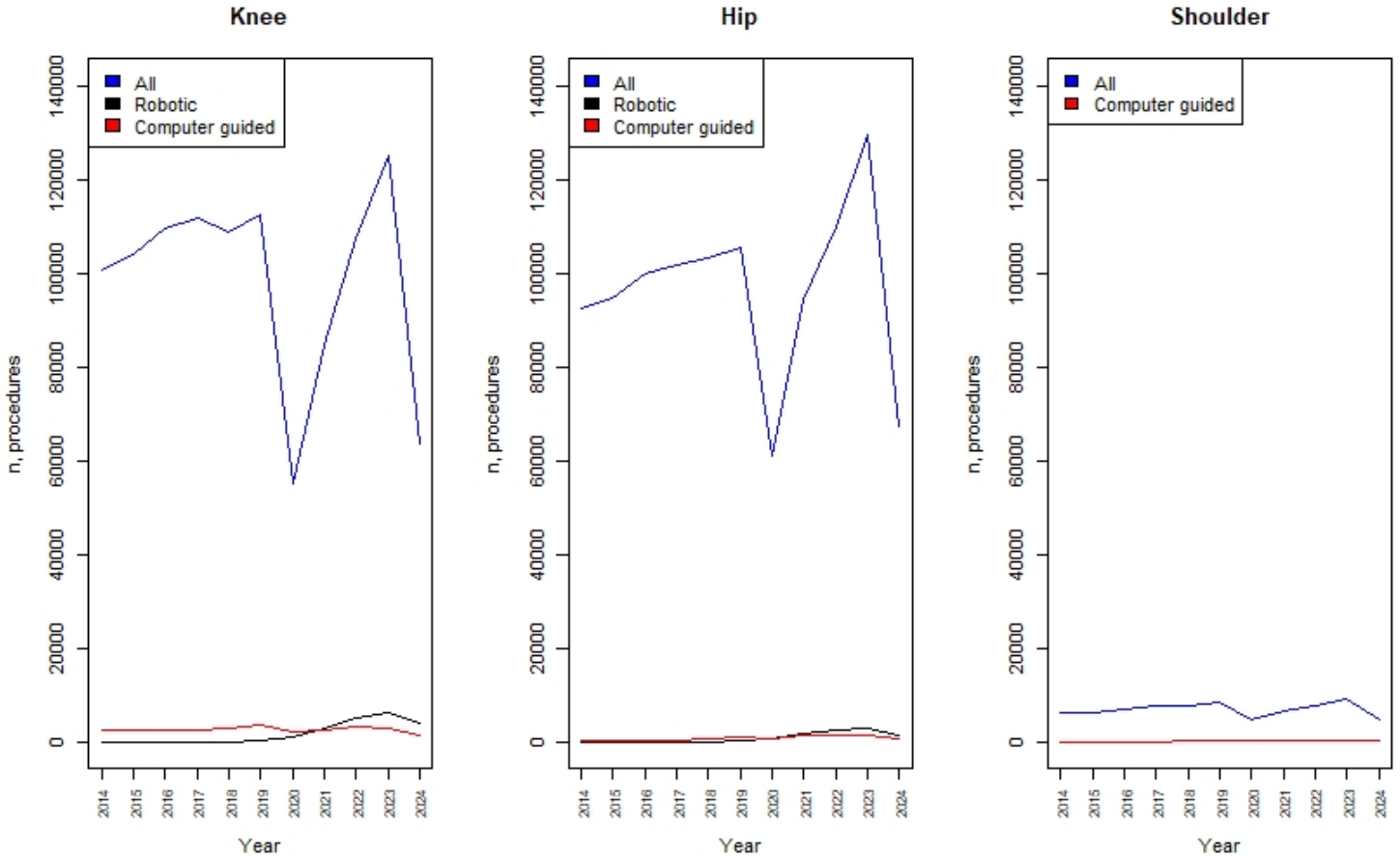
Computer navigation relates specifically to a set of methods that utilise computer technologies for planning and guiding surgical interventions in particular to track position of bones and instrumentation in a 3D space. Clinical Experts have stated that computer navigation is not routinely adopted in orthopaedics across the NHS.

The NJR advised that the Registry between 01 January 2021 and 11 September 2024 contained:

- 15,426 robotic primary total knee procedures: [redacted]
- 4,283 robotic primary partial knee procedures: [redacted] and
- 7,409 robotic primary hip procedures: [redacted].

Additional detailed data from NJR is described in section 5.10.

Figure 1: Number of knees, hips and shoulder replacements recorded in the National Joint Registry by year.
[Note: partial year for 2024, and decrease in activity in 2020 related to the COVID-19 pandemic]



3.4 Special considerations including issues related to equality

In addition to the equality considerations listed in the Final Scope the EAG note that the following contraindications of some robotic systems should also be considered:

- Any mental or neuromuscular disorder that affects the control of knee joint, insufficient bone quality, insufficient bone mass to allow fixation of sensors.

- Any condition that prevents full articulation of the hip joint, in order for systems to complete bone registration (a step which registers the position of the femur and tibia in a 3D space which allows real time positing feedback to be sent to the surgical monitors) the surgeon needs to take the patients leg through a full and preset range of motion which can include adduction, abduction and rotation of the hip joint as well as flexion and extension of the knee.

- For robotic systems which require CT scan for plan development, related considerations such as pregnancy, allergies, kidney disorders (in relation to contrast medium) and those with pre-existing metal work which can affect the accuracy of the CT scan (pre-existing implants, screws and plates). The EAG note that not all robotic systems in scope require prior imaging. However, two Clinical Experts advised that for robotic systems which require CT scan for plan development, a potential benefit is incidental pathology discoveries from this additional scan that would otherwise have been missed.

- Robotic assisted surgery has purported benefits in TKA where it has *"demonstrated significant advantages for obtaining accurate limb alignment and implant position in the Asian population, given that conventional jigs and guides are susceptible to malpositioning due to the unique anatomical features of the Asian population"* (Jung et al., 2023). An Asian population with severe osteoarthritis has a high prevalence (88%) of lateral bowing, a type of femoral deformity (Lasam et al., 2013). The Asian population has on average, smaller femoral anteroposterior and aspect measurements which may have an impact on implant options. This is not an issue specific to robotic systems in orthopaedic

procedures, however, could have an impact on lower margins of error for resectioning, which the robotic systems could help with (Kim et al. 2017).

One Clinical Expert also advised that there has been a large uptake of robotics in private hospitals, which has the potential to increase health inequalities.

4. Clinical evidence selection

4.1 Evidence search strategy and study selection

The clinical effectiveness search strategy was designed to find 1) results that explicitly named the robotic systems (or associated manufacturers), from the last five years (or last two years for conference abstracts), and 2) robotic orthopaedic surgery results that did not name one of the relevant technologies in the database record (but might in the full text), limited to systematic reviews or UK results, published in the last two years. Validated search filters were used to identify the systematic reviews and UK results. Economic results were identified using the same base searches with economic filters, and results were limited to the last five years. An English language limit was applied to all results. Search strategies were developed by information specialists and run on 07 July and 08 July 2024 on Ovid Embase, Ovid Medline, and Cochrane Library CENTRAL, with simpler searches (necessitated by the interfaces, using either device names or terms covering the general concept of robotic assisted surgery of the knee, hip or shoulder) on clinical trial registries (Clinicaltrials.gov, with Scanmedicine covering a range of registries), NIHR Library, EngRxiv, MedRxiv, CEA Registry, RePEC IDEAS and INAHTA. All results were limited to those from the last five years. See Appendix A1 for full search details. The EAG identified a total of 750 records for the clinical search, and 196 for the economic search.

Due to the quantity of evidence, the EAG excluded all conference abstracts and posters where published full papers were available for the manufacturer and procedure of interest (where Companies provided abstracts or posters or under review, the EAG searched for full papers and included them for review where possible). Taking a pragmatic approach, systematic reviews were restricted to those exclusively including

technologies in scope only, reporting meta-analysis of primary outcomes (as listed in the Final Scope); primary evidence included in the systematic reviews were not retrieved or checked for relevance to the scope. Clinical evidence records (N=750) plus relevant records from the economic database search (N=39) were reviewed by title and abstract and 619 were excluded by a single reviewer (PL). The remaining 170 records had full papers reviewed of which 40 were considered in scope by a single reviewer (PL, EB, KK). Manufacturers provided 100 studies of which 62 were already identified in the EAG literature search. Full paper review of the remaining 38 records resulted in 17 papers considered in scope by two reviewers (PL, KK). The EAG logged all papers identified during scoping and hand searching, then crosschecked these against the database literature search. A limitation of database searches is that consistent reporting of the robotic system used is required and many publications lacked this information in the title or abstract. Due to this, an additional 70 relevant papers were identified by the EAG at scoping and from hand searching (identified by reference trawling of identified papers, including recent systematic reviews) that were not otherwise identified by the literature search. A total of 143 full papers were reviewed and excluded by the EAG; the reasons for exclusion are summarised in Appendix A4. This included 53 systematic reviews, 31 of which included evidence from ROBODOC (which is not currently available in the UK) and 22 systematic reviews which included evidence where the device was not specified.

Across all sources, the EAG identified a total of 127 studies as being relevant to the decision problem. Details of sifting and selection of the clinical evidence are given in the PRISMA diagram in Appendix A2. Due to the volume of device specific evidence and following the EVA Final Protocol, the EAG prioritised comparative evidence conducted in a UK setting as the most generalisable to the NHS.

The Royal College of Surgeons of England recommended that surgeons learning robotic surgery should start with more straightforward cases; which may lead to patient selection and influence cohort comparison, the EAG considered that study designs with

matched patient demographics were most robust. Evidence from outside a UK setting was considered because of the lack of relevant UK studies across device types. Comparative evidence was prioritised in the order of RCTs, prospective comparative cohort studies and then retrospective comparative cohort studies. The EAG only considered single arm studies for the learning curve outcome.

The EAG prioritised data extraction for primary outcomes as defined in the Final Scope. Where outcomes were reported at multiple time points, the EAG extracted the longest timepoint available. Results from meta-analyses were only extracted where numerical values were reported; narrative summary descriptions of general trend were excluded. Study characteristics of other evidence, which was deemed in scope but not prioritised by the EAG using the hierarchy described, were tabulated. The EAG extracted data on secondary outcomes (as defined in the Final Scope) for RCTs and comparative UK studies only. The exception to this were papers describing device-related adverse events as their primary focus, as device-related adverse events were expected to be rare and difficult to capture in small studies. The EAG narratively summarised studies which focused on device-related adverse events (see section 6); these were described as incidental findings as these outcomes were not prioritised for data extraction. The EAG did not complete any formal critical appraisal checklists for clinical or economic evidence identified.

The eligible population as outlined in the Final Scope included those undergoing knee and hip revision surgery which is a different procedure to primary interventions. The EAG note that only CORI is currently indicated for revision TKA surgery; this may change in future. The EAG identified 1 paper in scope where the patients underwent revision knee replacement surgery exclusively (Cochrane et al., 2024); however this was not included as key evidence due to study design (retrospective single-arm cohort with 115 patients treated with CORI, conducted in US setting). No studies exclusively reporting on revision hip replacement were identified.

The EAG note that only 4 records related to robotic shoulder replacement were identified during the literature search, however none reached the eligibility for full paper

review and none included a device in scope. No evidence was received from the manufacturers relating to robotic shoulder surgery.

4.2 Included and excluded studies

The EAG considered a total of 127 papers as relevant to the decision problem, and prioritised a total of 26 comparative studies (15 UK and 7 non-UK studies) as key evidence with an additional 3 studies included for learning curve outcome only (Summary in Table 5, detailed study characteristics in Appendix B1). This included:

- 15 studies on total knee replacement,
- 5 studies on partial knee replacement (all medial compartment osteoarthritis),
- 5 studies on total hip replacement,
- 1 study reported on total and partial knee replacements as separate subgroups.

A total of 101 additional studies (Appendix B2) were considered relevant to the decision problem but were not prioritised by the EAG when the hierarchy described in the protocol was applied. The EAG note that this included 14 studies which described comparisons between robotic systems listed in the Final Scope (10 total knee replacement, 3 in partial knee replacement, 1 total hip replacement); 1 of which was conducted in a UK setting.

Table 5: Summary of studies selected by the EAG as the evidence base (N=26)

[Note: ordered by device, procedure, study design and then sample size. Ages reported in years, BMI in kg/m2, both reported as mean (SD) or median [Q1,Q3 or range, as stated]]

Author (journal, year); country (N number of centres)	Study design [duration of follow-up]	Procedure	Intervention (n patients allocated)	Comparator (n patients allocated)	Demographics (intervention arm)	Demographics (comparator arm)	Outcomes extracted
Vermue (Int Orthop, 2023; 503-509) Belgium (N=1 surgeon)	Prospective cohort with historical comparator [procedural]	TKA	OMNIBot (n=30)	Conventional (n=30)	Age: 63.4 (11.8) Male: 23% BMI: 28.7 (5.2) ASA: NR	Age: 68.5 (9.4) Male: 27% BMI: 28.5 (5.8) ASA: NR	Learning curve Operating time
Fary (Arthroplasty, 2023; 62); International (N=NR)	Prospective propensity matched [up to 1 year]	TKA (primary unilateral)	ROSA (n=216)	Conventional (n=216)	Age: 62.6 (8.12) Male: 39.4% BMI: 31.9 (6.12); median 29.8 [range: 15.6,52.7] ASA III: 33.5% ASA IV: 0.5%	Age: 62.6 (8.82) Male: 39.4% BMI: 31.7 (6.39); 30.9 [range: 18.6,51.7] ASA III: 26.9% ASA IV: 0.5%	PROMs Complications Revision surgery
Kenanidis (Eur J Orthop Surg Traumtol, 2023; 1231-1236); Greece (N=1)	Prospective matched comparative cohort (age, sex, BMI) [6 months]	TKA (primary unilateral)	ROSA (n=30)	Conventional (n=30)	Age: 69.3 (6.8) Male: 20% BMI: 27.8 (3.2)	Age: 69.1 (7.0) Male: 20% BMI: 27.9 (2.7)	PROMs Complications
Vanlommel (J Exp Orthop, 2021; 119); Belgium (N=1)	Retrospective cohort [90 days]	TKA (primary)	ROSA (n=90)	Conventional (n=90)	Age: 68.7 (8.1) Male: 51% BMI: 31.32 (5.20) ASA I: 8% ASA II: 51% ASA III: 42%	Age: 69.8 (8.2) Male: 48% BMI: 30.49 (4.80) ASA I; 13% ASA II: 61% ASA III: 26%	Learning curve
He (Orthop Surg, 2022; 1681-1694); China (N=1)	Retrospective cohort [3 months]	TKA (primary)	SkyWalker (n=30)	Conventional (n=30)	Age: 71.3 (7.2) Male: 23% BMI: 26.8 (4.2)	Age: 66.8 (6.5) Male: 22% BMI: 27.6 (3.6)	PROMs Complications Operating time
(Leslie et al., 2024 - *Academic in Confidence*) [Full paper academic in confidence, however abstract available online] US (N=5)	Prospective cohort [[redacted]; Online abstract reporting outcomes to 3 months]	TKA (primary)	VELYS (n=100)	Conventional (n=100)	Age: 66.6 (8.28) Male: 52% BMI: 31.7 (5.45)	Age: 64.4 (9.05) Male: 47% BMI: 33.5 (5.42)	PROMs Complications Learning curve Operating time
Morrisey (Cureus, 2023; e38872); US (N=1)	Retrospective cohort [Up to 6 months]	TKA (primary)	VELYS; kinematically aligned (n=66)	Traditional; mechanically aligned (n=99)	Age: 68.21 (6.91) Male: 47% BMI: 30.27 (4.62) ASA: NR	Age: 69.52 (7.17) Male: 43.4% BMI: 30.88 (5.28) ASA: NR	Learning curve
Adamska (Medicina, 2023; 236); Poland (N=1)	RCT (3-arm) [1 year]	TKA	CORI (n=71) and NAVIO (n=76)	Conventional (n=68)	NAVIO Age: 66 (7.5) Male: 36% BMI: 25.8 (3.3) CORI Age: 69 (6.8) Male: 49% BMI: 25.5 (2.9)	Age: 65 (8.2) Male: 46% BMI: 26.0 (3.2)	PROMs Complications Revision surgery Operating time Secondary outcomes: length of stay, ROM, alignment
Thiengwittayaporn (Int Orthop, 2021; 2851-2858); Thailand (N=1)	RCT [procedural]	TKA (primary)	NAVIO (n=75)	Conventional (n=77)	Age: 69.0 (8.3) Male: 8% BMI: 28.0 (4.9) ASA ≥2: 96%	Age: 69.1 (7.3) Male: 19% BMI: 27.7 (4.6) ASA ≥2: 99%	Learning curve Operating time Secondary outcomes: alignment
Khan (Int J Med Robot, 2021; e2308); UK	Retrospective cohort [procedural]	TKA (primary) or UKA (primary)	NAVIO (n=50 TKA, n=50 UKA)	Conventional (n=50 TKA, n=50 UKA)	TKA: Age: 74.0 [IQR 66.8,82] Male: 26% BMI: 30.7 [IQR 27.4,33.3] ASA III: 20% UKA: Age: 67 [IQR 53.2,80.7]	TKA: Age: 71.5 [IQR 66,77.3] Male: 26% BMI: 31.9 [IQR 27.6,35.6] ASA III: 36% UKA: Age: 67 [IQR 51,83]	Complications

Author (journal, year); country (N number of centres)	Study design [duration of follow-up]	Procedure	Intervention (n patients allocated)	Comparator (n patients allocated)	Demographics (intervention arm)	Demographics (comparator arm)	Outcomes extracted
					Male: 40% BMI: 29.8 [IQR 27.8,33.5] ASA III: 36%	Male: 40% BMI: 29.4 [IQR 26.3,33.5] ASA III: 22%	
Clement (Bone Joint J, 2024; 450-459); UK	RCT [up to 1 year]	TKA (primary)	Mako (n=50)	Conventional jig based (n=50)	Age: 67.0 (8.6) Male: 51.2% BMI: 31.2 (5.4)	Age: 66.5 (8.6) Male: 42.1% BMI: 31.5 (7.0)	PROMs Complications
Ajekigbe (J Biomechanics, 2024); UK	RCT [1 year]	TKA	Mako (n=50)	Conventional (n=50)	NR	NR	Secondary outcomes: gait and sway analysis
Kayani (Bone Joint J, 2021; 113-122); UK	RCT [up to 28 days]	TKA (primary)	Mako (n=15)	Conventional jig based (n=15)	Age: 67.9 (8.6) Male: 40% BMI: 27.0 (3.0) ASA III: 3 (20%)	Age: 68.7 (9.6) Male: 47% BMI: 27.5 (3.7) ASA III: 4 (27%)	Secondary outcomes: inflammatory markers, length of incision, temperature of skin, alignment
Ng (J Orthop, 2024; 77-81); Singapore (N=1)	Prospective cohort with propensity score matching [6 months]	TKA (Primary unilateral)	Mako (n=42) with ERAS protocol	Conventional (n=42) with ERAS protocol	Age: 65.7 (8.9) Male: 29% BMI: 27.3 (4.3) ASA >2: 7%	Age: 65.6 (7.5) Male: 26% BMI: 26.7 (4.1) ASA >2: 14%	PROMs Complications Revision surgery Operating time
Kayani (Knee Surg Sports Traumatol Arthrosc, 2023; 5453-5462); UK	Prospective cohort [up to 5 years]	TKA (primary)	Mako (n=60)	Conventional jig-based (n=60)	Age: 67.6 (7.6) Male: 46.7% BMI: 27.2 (3.6) ASA I: 21 (35.0%) ASA II: 34 (56.7%) ASA III: 5 (8.3%)	Age: 68.7 (6.1) Male: 45.0% BMI: 26.1 (3.6) ASA I: 24 (40.0%) ASA II: 32 (53.7%) ASA III: 4 (6.7%)	PROMs
Kayani (Knee Surg Sports Traumatol Arthrosc, 2019; 1132-1141); UK	Prospective cohort [up to 30 days]	TKA (primary)	Undefined; shared by Stryker, assumed Mako (n=60)	Conventional jig based (n=60)	Age: 67.6 (7.6) Male: 46.7% BMI: 27.2 (3.6) ASA I: 21 (35%) ASA II: 33 (55%) ASA III: 6 (10%)	Age: 68.7 (6.1) Male: 45.0% BMI: 26.1 (3.6) ASA I: 24 (40%) ASA II: 32 (53%) ASA III: 4 (7%)	Learning curve Secondary outcomes: surgical team anxiety levels
Banger (Bone Joint J, 2022; 433-443); UK	RCT [1 year]	Bi-UKA (intervention); TKA (comparator)	Mako (n=42)	Conventional (n=34)	Age: 70.4 (7.1) Male: error in reporting BMI: 32.6 (5.5)	Age: 68.7 (7.7) Male: error in reporting BMI: 32.4 (6.7)	Secondary outcomes: gait and sway analysis
Banger (Bone Joint J, 2020; 1511-1518); UK	RCT [post-procedure]	Bi-UKA (intervention); TKA (comparator)	Mako (n=32)	Conventional (n=38)	Age: 68.7 (7.8) Male: 47% BMI: 31.7 (17)	Age: 70.5 (7.1) Male: 47% 32.6 (5.8)	Secondary outcomes: alignment
Banger (Bone Joint J, 2021; 1088-1095); UK	RCT [up to 5 years]	UKA	Mako (n=69)	Conventional (n=70)	NR	NR	PROMs Complications Revision surgery Secondary outcomes: ROM
Clement (Bone Joint Res, 2020; 15-22); UK	Prospective cohort with propensity matching [up to 6 months]	UKA	Mako (n=30)	Conventional (n=90)	Age: 65.9 (12.0) Male: 9.3% BMI: 30.5 (8.4)	Age: 67.8 (8.3) Male: 14.8% BMI: 29.7 (4.9)	PROMs
Kayani (Bone Joint J, 2019; 24-33); UK	Prospective cohort [up to 90 days]	UKA	Mako (n=73)	Conventional jig based (n=73)	Age: 65.3 (8.6) Male: 43.8% BMI: 28.7 (4.1) ASA III or IV: 1 (1.4%)	Age: 66.1 (5.8) Male: 46.6% BMI: 27.9 (2.3) ASA III or IV: 1 (1.4%)	PROMs Pain
Clement (Bone Joint Res, 2021; 22-30); UK	Prospective cohort with propensity matching [up to 12 months]	THA	Mako (n=40)	Conventional (n=80)	Age: 59.8 (7.5) Male: 70.0% BMI: 30.1 (4.6) ASA I: 20 (50.0%) ASA II: 19 (47.5%) ASA III: 1 (2.5%)	Age: 60.0 (11.7) Male: 67.5% BMI: 30.2 (5.3) ASA I: 32 (40.0%) ASA II: 45 (56.3%) ASA III: 3 (3.8%)	PROMs Secondary outcomes: alignment
Kayani (Bone Joint J, 2019; 11-18); UK	Prospective cohort [6 weeks]	THA (primary)	Mako (n=25)	Conventional (n=50)	Age: 67.5 (5.8) Male: 52% BMI: 26.9 (2.2) ASA III or IV: 2 (8%)	Age: 69.4 (5.2) Male: 52% BMI: 27.4 (2.1) ASA III or IV: 6 (12%)	Secondary outcomes: alignment
Ammori (Orthop Procs, 2024; 6);	Prospective database	THA (primary)	Mako (n=NR)	Conventional (n=NR)	NR	NR	PROMs

Author (journal, year); country (N number of centres)	Study design [duration of follow-up]	Procedure	Intervention (n patients allocated)	Comparator (n patients allocated)	Demographics (intervention arm)	Demographics (comparator arm)	Outcomes extracted
UK [*Abstract only]*	[1 year]						
Fontalis (Bone Joint J, 2024; 24-30); UK	Retrospective cohort [30 days]	THA	Mako (n=267)	Conventional (n=1,465)	Age: 64.5 (11.6) Male: 42.3% BMI: 27.7 [24.3, 32.0 IQR] ASA I: 36 (13.7%) ASA II: 169 (64.5%) ASA III: 55 (21%) ASA IV: 2 (0.8%)	Age: 61.3 (15.8) Male: 37.7% BMI: 27.5 [24.1, 32.1 IQR] ASA I: 156 (11.5%) ASA II: 880 (64.8%) ASA III: 308 (22.7%) ASA IV: 15 (1.1%)	Secondary outcomes: length of stay, readmission
Kong (Int J Surg, 2020; 174-180); NR	Retrospective cohort [3 months]	THA	Mako (n=100)	Conventional (n=100)	Proficient cases (cases 15 to 100): Age: 51.93 (10.87) Male: 52.2% BMI: 24.98 (3.26) ASA: NR	Age: 51.89 (12.64) Male: 50% BMI: 24.24 (3.03) ASA: NR	Learning curve

Abbreviations: ASA, American Society of Anaesthesiologists; BMI, body mass index; ERAS, Enhanced Recovery After Surgery; IQR, interquartile range Q1,Q3; NR, not reported; PROM, Patient Reported Outcome Measure; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty

5. Clinical evidence review

5.1 Quality assessment of included studies

The EAG summarised the quantity and quality of included evidence in Table 6. Practical challenges of the evidence included aspects such as: limited blinding to procedure (which is not feasible); different implants being used across the intervention and comparator arms (due to compatibility with robotic systems); short duration of follow-up (particularly for the latest robotic systems); randomised or intended allocation not being followed due to patient or surgeon preference and experience of the surgeon and team, leading to potential imbalance between groups (for detailed appraisal see Appendix B1).

The 26 studies included the following study designs:

- 8 RCTs (6 UK, and 2 international) (Adamska et al., 2023; Ajekigbe et al., 2024; Banger et al., 2021; Banger et al., 2022; Banger et al., 2020; Clement et al., 2024; Kayani et al., 2021; Thiengwittayaporn et al., 2021), 2 of which were powered to detect differences in patient reported outcomes: minimal clinically important difference in KOOS, WOMAC function; 2 powered for differences in alignment: outlier of mechanical axis, 1 degree difference in tibial sagittal positioning; 2 for differences in gait: proportion with biphasic gait, biphasic gait knee flexion moment during gait, 1 C-Reactive Protein level, and 1 had no a priori power analysis undertaken,

- 12 prospective comparative cohorts (Ammori et al., 2024; Clement et al., 2020; Clement et al., 2021; Fary et al., 2023; Kayani et al., 2023; Kayani et al., 2019a; Kayani et al., 2019b; Kayani et al., 2019c; Kenanidis et al., 2023; Leslie et al., 2024 - *Academic in Confidence;* Ng et al., 2024; Vermue et al., 2023); 5 of which (2 UK and 3 international) included a matched comparator arm to achieve similar baseline characteristics between arms; the number of variables included in matching varied across studies, and 7 did not match characteristics between arms (5 UK and 2 international).

- 6 retrospective comparative cohorts (2 UK and 4 international) (Fontalis et al., 2024; He et al., 2022; Khan et al., 2021; Kong et al., 2020; Morrisey et al., 2023; Vanlommel et al., 2021); the last 3 of which were considered for the learning curve outcome only, and treated as single arm studies.

One of the included UK observational studies was available as an abstract only (Ammori et al., 2024). The EAG noted differences in characteristics between arms (including age, implants used, liners, rehabilitation recommendations, use of general anaesthesia, day case, number of surgeons and their surgical experience, hospital where the procedures were conducted and their procedural volume) which may influence results. One study reported across two papers also compared robotic bilateral robotic UKA with conventional TKA (Banger et al. 2020); (Banger et al., 2022) therefore differences in results may not be directly attributable to the robotic system.

A total of 15 studies were conducted in a UK setting. The longest follow-up for total knee replacement was 5 years (Kayani et al., 2023), partial knee replacement 5 years (Banger et al., 2021), and total hip replacement 1 year (Clement et al., 2021); (Ammori et al., 2024); all using the Mako robotic system.

Of the 26 studies, 20 studies included osteoarthritis as the only indication for surgery, 2 studies included two or more indications (Fontalis et al., 2024; Leslie et al., 2024 - *Academic in Confidence*) and the remaining 4 studies did not report an indication for surgery (Ammori et al., 2024; Kong et al., 2020; Morrisey et al., 2023; Ng et al., 2024).

A total of 16 different implant types were used across the included studies; 15 studies used the same implant for both arms, 7 studies used different implant types between arms and 3 studies did not report the type of implant used.

Of the primary outcomes listed in the decision problem of the Final Scope:

- 12 studies reported on 14 different PROMs (Appendix C) and additional measures of patient satisfaction. The EAG asked the Clinical Experts (see Correspondence Log) which PROMs were routinely used in UK practice, and all 5 Clinical Experts agreed on forgotten joint score (FJS) for total and partial knee and total hip

replacement (one Clinical Expert noted that this scoring system had less of a ceiling effect than the Oxford Scores). The EQ-5D as well as specific Oxford Shoulder Score, Oxford Knee Score (OKS) and Oxford Hip Score (OHS), were the next most frequently suggested.

- Complications and absence of complications were reported in 9 studies ((Adamska et al., 2023); (Leslie et al., 2024 - *Academic in Confidence*); (Banger et al., 2021); (Clement et al., 2024); (Fary et al., 2023); (He et al., 2022) (Kenanidis et al., 2023); (Khan et al., 2021); (Ng et al., 2024)), however none of the included studies were powered to detect a difference in complication outcomes.

- Learning curve was reported in 6 studies ((Kayani et al., 2019c); (Kong et al., 2020); (Morrisey et al., 2023); (Thiengwittayaporn et al., 2021); (Vanlommel et al., 2021); (Vermue et al., 2023)). However, the description of initial training prior to study commencement varied across studies, this included: 2 hours training on specific robotic system, cadaver training, experience with other robotic systems across studies, prior experience with computer-navigation systems and procedural volume. One study reported that surgeons had “extensive experience”, another that they included high volume surgeons conducting more than 200 procedures each year, others not reported. Five of the six studies reporting on learning curve outcome included a single surgeon only. The generalisability of findings in this outcome are unknown.

- Revision surgery was reported in 4 studies ((Adamska et al., 2023); (Banger et al., 2021); (Fary et al., 2023); (Ng et al., 2024)); only one study differentiated septic and aseptic revisions. The EAG note that additional interventions were captured in some studies, debridement for infection and manipulation under anaesthesia, which were not included in the definition of revision. The EAG note that revision rates are implausibly low in studies with short follow-up periods, and none of the included studies were powered to detect a difference in this outcome.

- Operating time was reported in 6 studies ((Adamska et al., 2023); (Leslie et al., 2024 - *Academic in Confidence*); (He et al., 2022); (Ng et al., 2024);

(Thiengwittayaporn et al., 2021); (Vermue et al., 2023)) however the EAG note that the definition of operating time varied across studies, including total theatre time defined as wheels in to wheels out, total surgical time from skin incision to skin closure, tourniquet time or the definition of operation time was not explicitly reported. The EAG note that some studies included learning curve; which may influence results. One Clinical Expert advised that total theatre time, including set up time which is longer with RAS, may impact the number of procedures that can occur on a theatre list per day.

Table 6: Methodologies and quality assessment of clinical evidence by joint replacement procedure

Technology	Clinical Evidence Quality: Total Knee	Clinical Evidence Quality: Partial Knee	Clinical Evidence Quality: Total Hip	Clinical Evidence Quality: Shoulder
ApolloKnee or OMNIBotics	Limited evidence: 1 non-UK prospective cohort (n=60 patients, reporting intraoperative outcomes)	Not indicated	Not indicated	Not indicated
ROSA Knee	Limited evidence: 2 non-UK prospective cohorts (with matched comparator); longest follow-up 6 months and 1 non-UK retrospective cohort (included for learning curve outcome only)	Not indicated	Not indicated	Not indicated
SkyWalker	Limited evidence: 1 retrospective cohort (n=60, follow-up to 3 months)	Not indicated	Not indicated	Not indicated
VELYS	Limited evidence: 1 prospective comparator cohort, and 1 non-UK retrospective cohort (included for learning curve outcome only)	Not indicated	Not indicated	Not indicated
CORI or NAVIO	2 non-UK RCTs (longest follow up 1-year, largest n=215 patients) and 1 UK retrospective cohort	Limited evidence: 1 UK retrospective cohort (procedural outcomes only, n=200 patients)	Lack of evidence	Not indicated
Mako	5 UK RCTs (longest follow up 5 years with n=120 patients), 2 UK prospective cohorts, 1 non-UK prospective (with matched comparator)	1 UK RCT (longest follow-up 5 years with n=139 patients), 2 UK prospective cohorts (1 with matched comparator)	Limited evidence: 3 UK prospective cohort (1 with matched comparator), 1 UK retrospective cohort; longest follow-up 1 year, 1 non-UK retrospective cohort	Not indicated

Abbreviations: RCT, randomised controlled trial

5.2 ApolloKnee (formerly OMNIBotics) by Corin

The EAG did not identify any studies using ApolloKnee or OMNIBotics conducted in a UK setting, no RCTs and no prospective cohort studies with matching of population differences between arms were identified. The EAG considered 1 prospective cohort study as relevant for the learning curve outcome only, but other available evidence (1 retrospective cohort, see Appendix B2) did not meet the hierarchy for inclusion for extraction of results. Both studies addressed total knee arthroplasty procedures. This technology is not indicated for partial knee, total hip or shoulder replacement.

5.2.1 PROMs

The included study did not report on this outcome.

5.2.2 Complications

The included study did not report on this outcome.

5.2.3 Learning curve

The prospective cohort study reported on learning curve (Vermue et al., 2023), Table 7. This reported learning curve of 16 cases or less across various components of the total operation time. The study reported no change in alignment during the learning phase.

Table 7: Summary of OMNIBotics studies reporting on learning curve

Author (year); country	Study design	Procedure	Key findings
(Vermue et al., 2023); Belgium	Prospective cohort	TKA	Time for positioning of the femoral resection guide combined with the femoral resection, mean (SD): Significant difference between the first 10 cases (16.4 (3.7) mins) compared with the last 10 cases (12.6 (2.8) mins; p=0.02). Total surgical time (skin incision to surgical closure), mean (SD): Significant difference between first 10 cases (115.0 (14.8) mins) compared with last 10 cases (101.1 (10.8) mins; p=0.03).

Author (year); country	Study design	Procedure	Key findings
			No difference in tibial array, femoral array, registration, kinematic assessment, tibial block and resection, planning femur, gap validation times between the first 10 cases and the last 10 cases. CUSUM inflexion points were reported for tibial array (1 case), femoral array (4 cases), registration (7 cases), tibial guide and resection (3 cases), gap assessment (3 cases), femoral guide and resection (16 cases), total surgical time (9 cases). No inflexion point was reported for kinematic assessment, planning femoral component, or plan validation. Alignment: During learning curve, no clear inflexion points on CUSUM analysis for HKA, femoral or tibial coronal implant alignment, with mean (SD) deviation of the post-operative alignment compared to intra-operative planned alignment of 0.0° (2.5), 0.5° (1.7), 0.3° (1.3) respectively.

Abbreviations: CUSUM, cumulative summation; HKA, hip-knee-ankle; SD, standard deviation; TKA, total knee arthroplasty.

5.2.4 Revision surgery

The included study did not report on this outcome.

5.2.5 Operating time

One prospective cohort study (Vermue et al., 2023) reported a statistical difference in total operative time (not explicitly defined) between the last 10 robotic cases and last 30 conventional surgery conducted by the same surgeon using the same implant, Table 8.

Table 8: Summary of OMNIBotics studies reporting on operation time

Author (year); country	Study design	Procedure	Robotic: Total operative time, minutes, mean (SD)	Conventional: Total operative time, minutes, mean (SD)	p-value
(Vermue et al., 2023) Belgium	Prospective cohort	TKA	For the last 10 cases: 106.4 (13.8)	For the last 30 cases: 84.8 (15.8)	0.0001

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty

5.3 ROSA Knee by Zimmer Biomet

No studies conducted in a UK setting were identified, no RCTs were identified. The EAG prioritised 2 prospective comparative cohort studies with matched comparator arms and 1 retrospective cohort study for learning curve outcome only; all conducted in total knee arthroplasty. This technology is not indicated for partial knee, total hip or shoulder replacement. An additional 12 studies were identified as relevant to the scope but not prioritised by the EAG (see Appendix B2).

5.3.1 PROMs

Two prospective comparative cohort studies both with matching of patient characteristics and both on TKA ((Fary et al., 2023); (Kenanidis et al., 2023)) reported on 7 PROMs, Table 9. Significant differences were observed in four of them at 6 months follow-up.

Table 9: Summary of ROSA studies which reported PROMs

Note: reported as mean (SD) unless stated otherwise

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (ROSA)	Comparator (conventional)	p-value	Favours intervention or comparator
EQ-5D-5L	1 year	(Fary et al., 2023); NR	Prospective cohort (with propensity matching)	TKA	0.86 (0.19)	0.85 (0.19)	0.6210	-
FJS-12	6 months	(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	71.6 (8.3)	61.9 (8.1)	0.001	Intervention
KOOS-JR	1 year	(Fary et al., 2023); NR	Prospective cohort (with propensity matching)	TKA	78.61 (13.64)	79.49 (15.7)	0.6576	-
OKS	6 months	(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	37.8 (3.8)	34.8 (4.0)	0.006	Intervention
Satisfaction Are you satisfied with your knee?	6 months	(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	29/30 (96.7%)	27/30 (90%)	0.301	-
Satisfaction Would you have this operation again?	6 months	(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	30/30 (100%)	26/30 (86.7%)	0.038	Intervention
VAS	6 months	(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	1 (2)	2 (2)	0.025	Intervention

Abbreviations: FJS, Forgotten Joint Score; KOOS-JR, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement; NR, Not reported; OKS, Oxford Knee Score; TKA, total knee arthroplasty; VAS, visual analogue scale.

5.3.2 Complications

Two prospective comparative cohort studies with matching of patient characteristics ((Fary et al., 2023); (Kenanidis et al., 2023)) reported on adverse events, **Table 10**. (Fary et al., 2023) reported a significant difference in opioid use and wound complications with fewer events in the robotic arm; no complications were observed in the other study.

Table 10: Summary of ROSA studies which reported complications

Author (year); country	Study design	Procedure	Key results
(Fary et al., 2023); NR	Prospective cohort (with propensity matching)	TKA	Opioid use at 1 month was significantly different between robotic and conventional surgery arms; 31.2% compared with 42.6%, p=0.017. No difference was observed at 3 months (p=0.703). Fewer wound complications were observed in the robotic arm; 2.8% compared with 8.3%, p=0.0234. No statistical difference observed in post-operative deep knee infection, stiffness, pain, or other knee related adverse events
(Kenanidis et al., 2023); Greece	Prospective cohort (with matching)	TKA	No complications recorded in either arm.

Abbreviations: NR, not reported; TKA, Total Knee Arthroplasty.

5.3.3 Learning curve

The retrospective cohort study reported a learning curve (Vanlommel et al., 2021), Table 11; of between 6 and 11 cases across 3 high-volume surgeons.

Table 11: Summary of ROSA studies reporting on learning curve

Author (year); country	Study design	Procedure	Key findings
(Vanlommel et al., 2021); Belgium	Retrospective cohort	TKA	Operation time: Initial learning curve for total operative time was 10 cases, 6 cases and 11 cases across 3 different high-volume (>200 cases per year) arthroplasty surgeons. First 10 cases for all surgeons combined were associated with longer surgical time, robotic set up time, bone registration, joint balancing,

Author (year); country	Study design	Procedure	Key findings
			bone preparation, implant trialling. Statistical difference in least square mean (SE) between learning compared with mastered: 15.89 (2.26) mins; p=0.001.

Abbreviations: SE, standard error; TKA, total knee arthroplasty.

5.3.4 Revision surgery

One prospective comparative cohort study with matching of patient characteristics (Fary et al., 2023) reported on revision surgery, Table 12, reported no difference in revision between arms.

Table 12: Summary of ROSA studies reporting revision

Author (year); country	Study design	Procedure	Revision (%)	p-value
(Fary et al., 2023); NR	Prospective cohort (with propensity matching)	TKA	Septic revisions [1 year] 0.5% in robotic arm, 0.9% in conventional surgery arm Aseptic revisions [1 year] 0% in robotic arm, 0.9% in the conventional surgery arm	0.5623 N/A

Abbreviations: N/A, not applicable; NR, not reported; TKA, total knee arthroplasty.

5.3.5 Operating time

Operating time was not reported in the prioritised evidence.

5.4 SkyWalker by MicroPort

The EAG did not identify any studies using SkyWalker in a UK setting, no RCTs and no prospective cohort studies with matching of population differences between arms. The EAG did include 1 retrospective comparative cohort. One additional prospective single-arm study was also identified, however did not meet the hierarchy for inclusion for extraction of results. Both identified studies addressed total knee arthroplasty procedures. This technology is not indicated for partial knee, total hip or shoulder replacement.

5.4.1 PROMs

The included retrospective comparative cohort study (He et al., 2022) reported no statistical difference in 2 PROMs between SkyWalker and conventional surgery at 3 months, Table 13.

Table 13: Summary of SkyWalker studies which reported PROMs

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (SkyWalker) Mean (SD)	Comparator (Conventional) Mean (SD)	p-value
KSS	3 months	(He et al., 2022) China	Retrospective cohort	TKA	84.4 (3.9)	88.1 (2.2)	0.095
WOMAC	3 months	(He et al., 2022) China	Retrospective cohort	TKA	19.5 (3.5)	18.2 (3.0)	0.496

Abbreviations: KSS, Knee Society Score; SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario & McMaster Universities Score

5.4.2 Complications

The included retrospective comparative cohort (He et al., 2022) reported that blood loss was statistically lower in the SkyWalker arm than conventional surgery, Table 14. However, the clinical significance of this difference is unclear.

Table 14: Summary of SkyWalker studies which reported complications

Author (year); country	Study design	Procedure	Key results
(He et al., 2022) China	Retrospective cohort	TKA	Intraoperative blood loss, ml: mean (SD) of 192.3 (23.1) in robotic arm and 203.7 (29.8) in conventional arm; p=0.039

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty;

5.4.3 Learning curve

The included study did not report on this outcome.

5.4.4 Revision surgery

The included study did not report on this outcome.

5.4.5 Operating time

The retrospective comparative cohort study (He et al., 2022) reported no statistical difference in operation time, defined as skin incision to completion of suturing of operative area, between SkyWalker and conventional surgery. However, a statistical difference in tourniquet time was reported, defined as the time from the start of the application to the completion of the capsular suture, Table 15.

Table 15: Summary of SkyWalker studies reporting operating time

Author (year); country	Study design	Procedure	Operating time, minutes, mean (SD)	p-value
(He et al., 2022) China	Retrospective cohort	TKA	Skin incision to completion of suturing time: SkyWalker: 128.4 (18.8) Conventional: 119.5 (22.5) Total tourniquet time: SkyWalker: 96.0 (15.3) Conventional: 74.4 (17.3)	0.419 0.000

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty;

5.5 VELYS by Johnson & Johnson

The EAG did not identify any studies using VELYS in a UK setting, no RCTs and no prospective cohort studies with matching of population differences between arms were identified. The EAG considered 1 [redacted] study [redacted] which was provided as AiC by the Company with an associated abstract which is available on the Company website, and 1 retrospective cohort study as relevant for the learning curve outcome only. Other available evidence (3 retrospective cohort studies) did not meet the hierarchy for inclusion for extraction of results. All evidence was conducted in total knee arthroplasty procedures. This technology is not indicated for partial knee, total hip or shoulder replacement.

5.5.1 PROMs

One prospective cohort in TKA (Leslie et al., 2024 - *Academic in Confidence*) reported on PROMs, **Table 16**. [redacted].

Table 16: Summary of VELYS studies which reported PROMs

PROM	Timepoint	Procedure	Intervention (VELYS)	Comparator (conventional)	p-value
EQ-5D-5L	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
FJS	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
[redacted]	1 year	TKA	[redacted]	[redacted]	[redacted]
Pain at rest	1 year	TKA	[redacted]	[redacted]	[redacted]
Pain at activity	1 year	TKA	[redacted]	[redacted]	[redacted]
Satisfaction with procedures (10-point scale)	1 year	TKA	[redacted]	[redacted]	[redacted]

Abbreviations: FJS, Forgotten Joint Score; [redacted] PROMs, patient reported outcome measures; TKA, total knee arthroplasty

5.5.2 Complications

One prospective comparative cohort (Leslie et al., 2024 - *Academic in Confidence*) reported on [redacted] adverse events, Table 17.

[redacted]

Table 17: Summary of VELYS studies which reported complications

Author (year); country	Study design	Procedure	Key results
(Leslie et al., 2024 - *Academic in Confidence*)	Prospective comparative cohort	TKA (primary)	[redacted]

Author (year); country	Study design	Procedure	Key results
[Abstract available online]; US			[redacted]

Abbreviations: RAS, robotic assisted surgery; TKA, Total Knee Arthroplasty.

5.5.3 Learning curve

One prospective cohort compared [redacted] Table 18. Additionally, one retrospective cohort reported on learning curve and compared range of motion, pain and operative times between the first 20 cases and subsequent 46 cases (conventional) surgery, (Morrisey et al., 2023); no significant differences were reported. The authors reported that the operation times were significantly longer for the first 2 cases and then not significantly different thereafter.

Table 18: Summary of VELYS studies reporting on learning curve

Author (year); country	Study design	Procedure	Key findings
(Leslie et al., 2024 - *Academic in Confidence*) US	Prospective cohort	TKA (primary)	[redacted]
(Morrisey et al., 2023); US	Retrospective cohort	TKA	Operative time: No statistical difference in mean (SD) tourniquet times (66.0 (17.21) compared with 64.01 (8.16); p=0.42) between first 20 procedures and the subsequent 46 procedures. Compared to conventional surgery the mean (SD) tourniquet time (63.46 (10.62) mins) as a reference, there was a statistical difference in tourniquet time with the first 2 robotic operations (91.0 (7.07) mins; p=0.0004), but no statistical difference in operations 3-10 (65.63 (5.53 mins); p=0.57) or operations 11-66 (63.48 (8.11) mins; p=0.99). Range of motion: No statistical difference in mean (SD) flexion (110.25 (24.45) compared with 110.10 (11.98); p=0.53) or extension (1.43 (1.77) compared

Author (year); country	Study design	Procedure	Key findings
			with 2.07 (3.28); p=0.88) between first 20 procedures and the subsequent 46 procedures. Pain: No statistical difference in pain as determined by mean (SD) VAS (1.75 (1.77) compared with 1.82 (2.27); p=0.83) between first 20 procedures and the subsequent 46 procedures. No difference in the use of assistive devices at 6 weeks (11 (55%) and 15 (32.6%); p=0.09). No statistical difference in the number of patients attending emergency department or admission to hospital within 6 weeks (3 (15%) compared with 10 (21%); p=0.53) between first 20 procedures and the subsequent 46 procedures.

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty; VAS, visual analogue scale.

5.5.4 Revision surgery

None of the included studies reported on revision outcomes.

5.5.5 Operating time

One prospective cohort (Leslie et al., 2024 - *Academic in Confidence*) reported on [redacted] and total surgery time [redacted]Table 19.

Table 19: Summary of VELYS studies reporting operating time:

Author (year); country	Study design	Procedure	Operating time, minutes, mean (SD)	p-value
(Leslie et al., 2024 - *Academic in Confidence*) US	Prospective cohort	TKA (primary)	[redacted]	[redacted]

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty.

5.6 CORI (formerly NAVIO) by Smith & Nephew

One UK study and 2 non-UK studies were prioritised by the EAG using the CORI technology, or its predecessor NAVIO. This included 2 RCTs and one retrospective cohort study; 2 studies reported on total knee arthroplasty, and 1 included separate subgroups of total and partial knee arthroplasty. An additional 28 studies were identified

as relevant to the scope but not prioritised by the EAG (see Appendix B2). No evidence was identified in hip arthroplasty. This technology is not indicated for shoulder replacement.

5.6.1 PROMs

One RCT (Adamska et al., 2023) reported a difference in Knee injury and Osteoarthritis Outcome Score (KOOS) at 1 year between both CORI and conventional surgery, and NAVIO and conventional surgery, Table 20. However, the authors noted no difference in KOOS between NAVIO and CORI at 1 year, and no difference across any arms for the visual analogue scale (VAS) outcome measure for pain.

Table 20: Summary of CORI/NAVIO studies reporting on PROMs

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (NAVIO/CORI) Mean (SD)	Comparator (Conventional) Mean (SD)	p-value	Favours intervention or comparator
KOOS	1 year	(Adamska et al., 2023); Poland	RCT (three arms)	TKA	NAVIO: 87.0 (7.7) CORI: 85.5 (8.0)	81.7 (8.9)	NAVIO: 0.0498 CORI: 0.0382	Intervention Intervention
VAS	1 year	(Adamska et al., 2023); Poland	RCT (three arms)	TKA	NAVIO: 2 (1.3) CORI: 2.3 (1.0)	2.1 (1.2)	NAVIO: 0.1852 CORI: 0.6498	-

Abbreviations: KOOS, Knee injury and Osteoarthritis Outcome score; RCT, randomised control trial; SD, standard deviation; TKA, total knee arthroplasty; VAS, visual analogue scale

5.6.2 Complications

One RCT (Adamska et al., 2023) and one retrospective cohort study conducted in a UK setting (Khan et al., 2021) which matched to a control group based on age and sex, reported on blood loss between arms, Table 21. Significant differences in blood loss

were reported in TKA but not UKA. The RCT by (Adamska et al., 2023) also reported no statistical difference in complications at 1 year follow-up.

Table 21: Summary of CORI/NAVIO studies reporting on complications

Study (year); country	Study design	Procedure	Key finding
(Adamska et al., 2023); Poland	RCT (three arms)	TKA	Blood loss (defined as Hb level difference before and after surgery: Differences between NAVIO (n=76; 1.74 (1.26) g/dL), CORI (n=71; 1.51 (1.12) g/dL) and conventional surgery (n=68; 2.52 (1.01) g/dL); p=0.042 (one statistical test comparing 3 arms). Post-operative complications (1 year): No events in NAVIO, CORI and conventional surgery arms.
(Khan et al., 2021); UK	Retrospective cohort (with matched control)	TKA	Blood loss: Difference between mean calculated blood loss between robotic surgery arm (911 range [663,2021] ml) and conventional (1193 range [164,2634] ml); p<0.01. A total of 2 patients in robotic arm required a blood transfusion, compared to 12 in the control arm; p=0.01.
(Khan et al., 2021); UK	Retrospective cohort (with matched control)	UKA	Blood loss No statistical difference in mean calculated blood loss between arms; 821 range [0, 1608] ml in robotic surgery arm, and 854 range [10,1895] ml in conventional arm, p=0.69. No patients in robotic or control arm required a transfusion.

Abbreviations: RCT, randomised controlled trial; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

5.6.3 Learning curve

One RCT reported a learning curve (Thiengwittayaporn et al., 2021), Table 22; of 7 cases when monitoring operative time (defined as from initial surgical incision to a final would closure).

Table 22: Summary of CORI/NAVIO studies reporting on learning curve

Author (year); country	Study design	Procedure	Key findings
(Thiengwittayaporn et al., 2021); Thailand	RCT	TKA (primary)	Operative times: CUSUM analysis showed sharp inflexion point after 7 cases with two distinct phases: Phase 1- learning segment, Phase 2 - proficiency stage in robotic TKA. Total operative times were significantly longer in learning phase compared with proficiency phase (100.7 min compared with 67.4 min; p<0.001).

Abbreviations: CUSUM, cumulative summation; RCT, randomised controlled trial; TKA, total knee arthroplasty.

5.6.4 Revision surgery

One RCT (Adamska et al., 2023) reported that no revisions occurred across CORI, NAVIO and conventional surgery arms at 1 year, Table 23.

Table 23: Summary of CORI/NAVIO studies reporting on revision

Author (year); country	Study design	Procedure	Revision (%)	p-value
(Adamska et al., 2023); Poland	RCT (3 arms)	TKA	1 year: NAVIO: 0/76 (0%) CORI: 0/71 (0%) Conventional: 0/68 (0%)	N/A

Abbreviations: N/A, not applicable; RCT, randomised controlled trial; TKA, total knee arthroplasty.

5.6.5 Operating time

Two RCTs reported a longer operation or surgical time for robotic surgery ((Adamska et al., 2023), (Thiengwittayaporn et al., 2021)) when compared to conventional surgery, Table 24. However, (Thiengwittayaporn et al., 2021) included the learning curve for surgeons new to using the robotic system and (Adamska et al., 2023) reported that the surgeon conducted 15 robotic procedures using NAVIO before starting the study, but that no training was conducted on CORI as it was an updated version by the same manufacturer. The RCT by (Thiengwittayaporn et al., 2021) reported that there was no significant difference between operative times (defined as from initial surgical incision to

a final would closure) between the last 10 cases of NAVIO (when proficiency had been achieved) and all cases of the conventional arm; however, no p-value was reported. The definition of surgical time was not explicitly reported in (Adamska et al., 2023) .

Table 24: Summary of CORI/NAVIO studies reporting on operation time

Author (year); country	Study design	Procedure	Robotic: Operating time, minutes, mean (SD)	Conventional: Operating time, minutes, mean (SD)	p-value
(Adamska et al., 2023); Poland	RCT (3 arms)	TKA	NAVIO: 105 (8.17) CORI: 111 (11.5)	66.5 (9)	0.003 (one statistical test comparing 3 arms)
(Thiengwittayaporn et al., 2021); Thailand	RCT	TKA (primary)	All cases NAVIO: 70.1 (12.1) First 10 cases NAVIO: 95.0 (14.1) Last 10 cases NAVIO: 66.6 (5.3)	All cases 61.9 (10.0)	All cases <0.001

Abbreviations: RCT, randomised controlled trial; SD, standard deviation; TKA, total knee arthroplasty.

5.6.6 Secondary outcomes

The EAG also summarised 2 RCTs which reported on secondary outcomes (as defined in the Final Scope), Table 25. No differences in hospital stay or range of motion were reported. Both RCTs reported statistical differences in alignment outcomes, however the clinical significance of each individual outcome is unclear.

Table 25: Summary of CORI/NAVIO RCTs that reported on secondary outcomes

Author (year); country	Procedure	Study design (n, patients)	Key findings; reported as mean (SD)
(Adamska et al., 2023); Poland	TKA	RCT, 3 arms (n=215, including 76 NAVIO, 71 CORI, 68 conventional surgery)	Hospital stay: No difference between NAVIO (4.4 (1.0) days), CORI (4.8 (1.26) days) and conventional surgery (4.2 (1.4) days); p=0.447 ROM in extension: No difference between NAVIO, CORI and conventional surgery arms: 1.5 (3.8), 1.8 (1.7) and 1.5 (1.3) respectively; p=0.98

Author (year); country	Procedure	Study design (n, patients)	Key findings; reported as mean (SD)
			ROM in flexion: No difference between NAVIO, CORI and conventional surgery arms: 126.3 (14.2), 132.1 (9.0) and 124.3 (12.6) respectively; p=0.06 Femoral component rotational alignment: Difference between NAVIO 1.48 (1.11), CORI 1.33 (1.01) and conventional surgery arms 3.15 (1.21); p=0.0013.
(Thiengwittayaporn et al., 2021); Thailand	TKA (primary)	RCT (n=152; 75 NAVIO, 77 conventional)	Alignment: Significant difference in: - hip-knee-ankle angle, degrees: NAVIO 178.4 (1.0) compared with conventional surgery 177.9 (1.1); p=0.009, - coronal tibial component angle, degrees: NAVIO 88.5 (1.1), conventional surgery 87.9 (1.6); p=0.012, - sagittal femoral component angle, degrees: NAVIO 1.9 (1.8), conventional surgery 5.4 (2.5); p<0.001, - sagittal tibial component angle: NAVIO 86.0 (2.1), conventional surgery 85.1 (3.4); p=0.035, - change in joint line, mm: NAVIO 3.6 (0.3), conventional surgery 5.5 (0.4); p=0.004, - change in posterior femoral offset, mm: NAVIO 4.4 (0.4), conventional surgery 6.5 (0.7); p=0.001. No difference in tibiofemoral angle (p=0.723), coronal femoral component angle (p=0.199), posterior femoral angle (p=0.127) between arms.

Abbreviations: RCT, randomised controlled trial; ROM, range of motion; SD, standard deviation; TKA, total knee arthroplasty.

5.7 Mako (formerly RIO, Acrobot) by Stryker

A total of 14 UK and 1 non-UK studies using the Mako robotic system were prioritised by the EAG. This included 6 RCTs, 8 prospective comparative cohort studies (3 with a matched comparator arm) and 1 retrospective cohort study. This included 8 studies in TKA, 3 in UKA and 4 THA. This technology is not indicated for shoulder replacement. The EAG considered one additional retrospective cohort study in THA for the learning curve outcome only. An additional 43 studies were identified as relevant to the scope but were not prioritised by the EAG (see Appendix B2).

5.7.1 PROMs

From a UK setting, two RCTs ((Banger et al., 2021); (Clement et al., 2024)), and five prospective cohort studies ((Ammori et al., 2024); (Clement et al., 2021); (Clement et al., 2020); (Kayani et al., 2023); (Kayani et al., 2019a)) and one additional prospective cohort study from Singapore (Ng et al., 2024) reported PROMs when using the Mako robotic system, Table 26. The EAG note that it was only observational studies that reported significant differences in PROMs and utilities between robotic and conventional surgery arms. Two RCTs found no significant difference in utilities between robotic and conventional surgery at any timepoint. The abstract by (Ammori et al., 2024) also reported that robotic assistance was an independent predictor of greater Oxford Hip Score at 12 months from multivariate linear regression analysis (p=0.001); however no other details were reported.

Table 26: Summary of Mako studies reporting on PROMs

Note: reported as mean (SD) or median [Q1,Q3]

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (Mako)	Comparator (conventional)	p-value	Favours intervention or comparator
EQ-5D	1 year	(Clement et al., 2024); UK	RCT	TKA	Difference from baseline: 0.292 (0.297)	Difference from baseline: 0.276 (0.331)	p=0.823	-
EQ-5D	6 months	(Clement et al., 2020); UK	Prospective cohort (with propensity matching)	UKA	0.913 (0.126)	0.764 (0.248)	p=0.002	Intervention
EQ-5D-3L	5 years	(Banger et al., 2021); UK	RCT	UKA	0.72 [0.59, 1.00]	0.80 [0.69, 1.00]	p=0.353	-
EQ-5D	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	0.883 (0.150)	0.866 (0.157)	p=0.562	-
EQ-5D-3L	1 year	(Ammori et al., 2024); UK	Prospective cohort [Abstract only]	THA	5 [5,7] Unclear whether adjusted for case mix, and how scored	6 [5,8] Unclear whether adjusted for case mix, and how scored	p=0.002	Comparator
EQ-VAS	1 year	(Clement et al., 2024); UK	RCT	TKA	Difference from baseline: 3.09 (21.4)	Difference from baseline: 8.1 (18.7)	p=0.268	-
EQ-VAS	5 years	(Banger et al., 2021); UK	RCT	UKA	80.3 (16.4)	76.3 (18.2)	p=0.316	-
EQ-VAS	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	88.6 (9.5)	86.1 (15.0)	p=0.355	-
EQ-VAS	1 year	(Ammori et al., 2024); UK	Prospective cohort [Abstract only]	THA	90 [75,95]	80 [70,90]	p=0.003	Intervention
FJS	1 year	(Clement et al., 2024); UK	RCT	TKA	Difference from baseline: 62.5 (32.4)	Difference from baseline: 57.7 (35.6)	p=0.527	-
FJS	5 years	(Kayani et al., 2023); UK	Prospective cohort	TKA (primary)	78 [72.5,86.7]	75.5 [70.2, 80.7]	p=0.025	Intervention
FJS	6 months	(Clement et al., 2020); UK	Prospective cohort (with propensity matching)	UKA	77.1 (25.9)	52.9 (32.6)	p<0.001	Intervention
FJS	5 years	(Banger et al., 2021); UK	RCT	UKA	50 [23,85]	52 [28, 73]	p=0.784	-
FJS	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	78.0 (24.2)	56.9 (28.0)	p<0.001	Intervention
AKSS	5 years	(Banger et al., 2021);	RCT	UKA	167 [range: 139.75, 185]	177 [range: 145, 188.25]	p=0.532	-

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (Mako)	Comparator (conventional)	p-value	Favours intervention or comparator
		UK						
KSFS	6 months	(Ng et al., 2024); Singapore	Prospective cohort (with propensity score matching)	TKA	74 (18)	73 (18)	0.836	-
KSKS	6 months	(Ng et al., 2024); Singapore	Prospective cohort (with propensity score matching)	TKA	88 (11)	85 (14)	0.289	-
KSS	5 years	(Kayani et al., 2023); UK	Prospective cohort	TKA (primary)	86 [80, 90.7]	84 [79.2, 90]	NS	-
MCS	6 months	(Ng et al., 2024);l Singapore	Prospective cohort (with propensity score matching)	TKA	56 (8)	57 (12)	0.430	-
NRS	Day 0,1,2, and discharge	(Kayani et al., 2019a); UK	Prospective cohort	UKA	Day 0: 2.3 (1.0) Day 1: 3.3 (0.8) Day 2: 2.6 (0.7) Discharge: 2.5 (0.6)	Day 0: 4.3 (1.0) Day 1: 6.0 (1.1) Day 2: 5.6 (1.3) Discharge: 4.2 (1.4)	0.001 0.001 0.001 0.001	Intervention Intervention Intervention Intervention
OHS	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	44.4 (5.0)	41.9 (6.6)	0.038	Intervention
OHS	1 year	(Ammori et al., 2024); UK	Prospective cohort [Abstract only]	THA	46 [42,48]	43 [36,47]	0.001	Intervention
OKS	6 months	(Ng et al., 2024); Singapore	Prospective cohort (with propensity score matching)	TKA	41 (5)	40 (5)	0.381	-
OKS	1 year	(Clement et al., 2024); UK	RCT	TKA	Difference from baseline: 19.7 (10.0)	Difference from baseline: 20.2 (9.6)	0.814	-
OKS	5 years	(Kayani et al., 2023); UK	Prospective cohort	TKA (primary)	40 [36,42]	39 [36,41.5]	NS	-
OKS	6 months	(Clement et al., 2020); UK	Prospective cohort (with propensity matching)	UKA	44.2 (4.4)	36.5 (9.4);	<0.001	Intervention
OKS	5 years	(Banger et al., 2021); UK	RCT	UKA	40 [35,40]	41 [35,44]	0.812	-
PCS	6 months	(Ng et al., 2024); Singapore	Prospective cohort (with propensity score matching)	TKA	48 (9)	48 (8)	0.941	-
UCLA	5 years	(Kayani et al., 2023); UK	Prospective cohort	TKA (primary)	6 [6,7]	6 [6,7]	NS	-

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (Mako)	Comparator (conventional)	p-value	Favours intervention or comparator
VAS - pain	6 months	(Clement et al., 2020); UK	Prospective cohort (with propensity matching)	UKA	93.6 (12.3)	76.4 (24.8)	<0.001	Comparator
VAS - pain	5 years	(Banger et al., 2021); UK	RCT	UKA	18.6 (22.6)	15.9 (22.8)	0.454	-
VAS - pain	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	88.9 (16.1)	85.5 (21.4)	0.370	-
VAS - stiffness	5 years	(Banger et al., 2021); UK	RCT	UKA	19.1 (22.3)	23.1 (26.4)	0.443	-
WOMAC - total	1 year	(Clement et al., 2024); UK	RCT	TKA	Difference from baseline: 41.0 (19.3)	Difference from baseline: 37.6 (19.7)	0.437	-
Satisfaction	1 year	(Clement et al., 2024); UK	RCT	TKA	Knee – Satisfied 93.0% Activities – Satisfied 93.0% Pain – Satisfied 93.0%	Knee – Satisfied 86.8% Activities – Satisfied 84.2% Pain – Satisfied 89.5%	0.464 0.293 0.701	-
Satisfaction	6 months	(Clement et al., 2020); UK	Prospective cohort (with propensity matching)	UKA	Satisfied with knee: 100% Have this operation again? 100%	Satisfied with knee 94.0% Have this operation again? 91%	0.210 0.109	-
Satisfaction	5 years	(Banger et al., 2021); UK	RCT	UKA	Daily living - very satisfied 52.7% Recreational activities – very satisfied: 32.7%	Daily living - very satisfied 38.8% Recreational activities – very satisfied: 20.4%	0.157 0.160	-
Satisfaction	Mean 10 months (robotic), mean 1 year (conventional)	(Clement et al., 2021); UK	Prospective cohort (with propensity matching)	THA	Satisfied with hip 100% Have surgery again? 97.4%	Satisfied with hip 92.4% Have surgery again? 87.3%;	0.176 0.165	-

Abbreviations: AKSS, American Knee Society Score; FJS, Forgotten Joint Score; KSS, Knee Society Score; RCT, Randomised control trial; TKA, total knee arthroplasty; OHS, Oxford Hip Score; OKS, Oxford Knee Score; UKA, unicompartmental knee arthroplasty; THA, total hip arthroplasty; UCLA, University of California and Los Angeles activity-level; VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

5.7.2 Complications

Three studies which controlled for differences in baseline characteristics between arms, including two RCTs ((Banger et al., 2021); (Clement et al., 2024)) and one prospective cohort study with matching (Ng et al. 2024), reported no differences in complications between arms at 5 years, 1 year and 30 days respectively, Table 27. One prospective cohort study (without matching) reported a difference in pain between robotic and conventional surgery at day 0, 1, 2 and at discharge.

Table 27: Summary of Mako RCTs reporting complications

Author (year); country	Study design	Procedure	Key results
(Banger et al., 2021); UK	RCT	UKA	Reported no differences in postoperative complications between the two groups at 5 years. No difference in the number of attendances to the hospital outpatient clinic. Numeric values not reported.
Kayani et al., 2019a); UK	Prospective cohort	UKA	Pain: Patients in robotic arm experienced less pain as measured by NRS ($p<0.001$ at day 0, 1, 2 and discharge, see section 5.4.1) and opiate analgesia consumption ($p<0.001$ at day 0, 1, 2 and discharge). Complications: No statistical difference in blood loss was observed between arms ($p=0.64$), and no patients in either group required a blood transfusion following surgery.
(Clement et al., 2024); UK	RCT	TKA (primary)	Total of 19 complications reported. Of those followed up at 12 months, 6 patients (2 robotic, 4 conventional) reported ongoing pain with knee. No difference in overall number of complications across arms ($p=0.611$).
(Ng et al., 2024); Singapore	Prospective cohort	TKA	One readmission within 30 days in robotic arm (due to mechanical fall at home). No cases of infection within 30 days in either arm.

Abbreviations: RCT, randomised controlled trial; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

5.7.3 Learning curve

One prospective cohort study (Kayani et al., 2019) and one retrospective cohort study (Kong et al., 2020) reported a learning curve of 7 to 14 cases when monitoring operating times, and 8 cases when considering alignment, Table 28.

Table 28: Summary of Mako studies reporting learning curve

Author (year); country	Study design	Procedure	Key findings; reported as mean (SD)
(Kayani et al., 2019c); UK	Prospective cohort	TKA (primary)	Operating times: CUSUM analysis showed sharp inflexion point after 7 cases with two distinct phases: Phase 1- learning segment, Phase 2 - proficiency stage in robotic TKA. Operative times were significantly longer in learning phase compared with proficiency phase (89.2 (4.2) min compared with 66.8 (3.5); p=0.01).
(Kong et al., 2020); NR	Retrospective cohort	THA	Operating times: LC-CUSUM shows turning point at the 14th procedure, downward trend in operating time thereafter. Statistical difference in mean (SD) operating times between phases (122.98 (13.07; range [98,145]) mins compared with 91.52 (10.88; range [68-125]) mins; p<0.001). Statistical difference in acetabular registration (12.21 (3.07; range [7,20]) mins compared with 9.65 (3.84; range [3-21]); p=0.011) and cup implantation (8.71 (1.86 range [5,14]) mins compared with 4.69 (1.11 range [2-11]) mins; p<0.001) between phases. No difference in pelvic array or reaming times (both reported in minutes) between phases. Alignment: From CUSUM analysis no trend above unacceptable was observed in robotics arm for cup positioning, leg length discrepancy and offset. The surgeon achieved better proficiency after the 8th case.

Abbreviations: CUSUM, cumulative summation; LC-CUSUM, learning curve cumulative summation; NR, not reported; SD, standard deviation; THA, total hip arthroplasty; TKA, total knee arthroplasty.

5.7.4 Revision surgery

One RCT (Banger et al., 2021) and one prospective cohort study with matching (Ng et al., 2024) reported revisions, Table 29; the latter reporting no revisions, the former

reporting no statistical difference between arms, however the number of events was small (2 in the comparator group).

Table 29: Summary of Mako studies reporting revision

Author (year); country	Study design	Procedure	Revision (%)	p-value
(Banger et al., 2021); UK	RCT	UKA	5 years Mako: 0/55 (0%) Conventional: 2/49 (4%); both conversion to TKA one for tibial loosening at 2.5 years due to fall, one for pain time unspecified.	0.476
(Ng et al., 2024); Singapore	Prospective cohort with matching	TKA	6 months No cases of reoperation in either Mako or conventional arm.	N/A

Abbreviations: N/A, not applicable; RCT, randomised controlled trial; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

5.7.5 Operating time

One prospective cohort study with matched comparator arm (Ng et al., 2024) reported on surgical duration (not further defined), Table 30. The authors explained that the longer surgical duration associated with the robotic arm could be attributed to the insertion and removal of additional femoral and tibial pins, registration of anatomical landmarks and intra-operative planning, but no difference in length of hospital stay was reported between arms.

Table 30: Summary of Mako studies reporting operating time

Author (year); country	Study design	Procedure	Surgical duration, minutes, mean (SD)	p-value
(Ng et al., 2024); Singapore	Prospective cohort with propensity score matching	TKA	Mako: 109.8 (13.5) min Conventional: 85.6 (20.7) min	0.0001

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty.

5.7.6 Secondary outcomes

The EAG also summarised 10 UK studies ((Ajekigbe et al., 2024); (Banger et al., 2022); (Banger et al., 2021); (Banger et al., 2020); (Clement et al., 2021; Fontalis et al., 2024; Kayani et al., 2019a; Kayani et al., 2019b; Kayani et al., 2019c; Kayani et al., 2021)) which reported on other secondary outcomes, Table 31.

Table 31: Summary of UK Mako studies that reported on secondary outcomes

Author (year)	Procedure	Study design (n, patients)	Key findings
(Kayani et al., 2021)	TKA	RCT (n=30)	Inflammatory markers: Robotic arm associated with transient reduction in multiple serum markers of inflammation and muscle injury (interleukin-6, TNF-alpha, C-reactive protein, erythrocyte sedimentation rate, lactate dehydrogenase and creatinine kinase) compared to conventional surgery. However, at 28 days only differences in interleukin-6 (9.7 (8.0) compared to 28.0 (21.2); p=0.006) and neutrophils (55.8 (8.6) compared to 63.1 (7.2); p=0.019) were observed. Length of incision: No statistical difference in length of incision was observed between arms: 12.1 (2.6) cm compared to 11.1 (2.3) cm; p=0.222. Temperature of skin: No statistical difference in skin temperature was observed between arms pre-operative, or at 6 hours, 1, 2, 7, 28 days post-operatively.
(Kayani et al., 2019c)	TKA	Prospective cohort (n=120)	Surgical team anxiety levels: CUSUM analysis of pre-operative stress levels in robotic arm as assessed by the state-trait anxiety inventory, state-trait anxiety inventory questionnaire, showed sharp inflexion point at 7 cases (similar trend as operative time) for all surgical team members (including anaesthetist, circulating nurse, ODP, scrub nurse, surgeon). Anxiety was significantly higher in learning phase than proficiency phase, p=0.02.
(Banger et al., 2021)	UKA	RCT (n=104)	ROM: No difference in range of motion (at 5 years; p=0.856) or change in range of motion (from pre-operation to 5 years; p=0.208) observed.
(Ajekigbe et al., 2024)	TKA	RCT (n=100)	Gait analysis (26 robotic, 23 conventional): Conventional surgery showed a statistically greater decrease in foot flat time, mid-stance time compared with robotic arm. Robotic arm showed a statistically greater decrease in propulsion time. Sway analysis (25 robotic, 22 conventional): No difference in sway was observed between arms.
(Banger et al., 2022)	Robotic: Bi-UKA	RCT (n=76)	Gait analysis (bi-UKA robotic, TKA conventional): No significant differences in the proportion of patients with biphasic gait between arms pre-operatively (p=0.69) or at

Author (year)	Procedure	Study design (n, patients)	Key findings
[Overlap with Banger et al. 2020]	Conventional: TKA		1 year (p=0.55). No difference between arms at any point in gait cycle. Sway (bi-UKA robotic, TKA conventional): Statistical difference in proprioception between arms at 1 year (p=0.005, favouring robotic bi-UKA). Worsening in proprioception observed between baseline and 1 year in conventional TKA (p=0.006), but no statistical difference observed in robotic bi-UKA arm. No difference in eyes closed, single-leg sway test for area of pressure, length (mm) or length of trajectory time normalized (mm/s) of centre of pressure between arms.
(Kayani et al., 2019a)	UKA	Prospective cohort (n=146)	Physiotherapy: The robotic arm was associated with decreased number of physiotherapy sessions (median [Q1,Q3] 5 [5,6] compared to 9 [8,10]; p<0.001), reduced time to straight leg raise (18.7 (3.4) compared to 24.9 (4.3); p<0.001) and increased maximum knee flexion at discharge (98.5 (8.8) compared with 93.3 (4.9); p<0.001). One patient in conventional arm required CPM machine due to limited knee flexion, no patients in robotic arm required CPM (p=0.22). Length of stay: Robotic arm was associated with shorter time to discharge (42.5 (5.9) hours compared with 71.1 (14.6); p<0.001).
(Fontalis et al., 2024)	THA	Retrospective cohort (n=1,607 including 1,732 procedures)	Length of stay: Median [Q1,Q3] was shorter in robotic arm (54 [34,78] hours) compared to conventional surgery arm (60 [IQR 51, 100] hours; p<0.001). The total staying in hospital more than 3 days was significant different between arms (29.2% in robotic arm, 46.5% in conventional arm; p<0.001). From binary logistic regression analysis, female sex, Age, PACU admission, use of conventional THA, ASA grade greater than II were all significantly associated with a length of stay greater than 2 days. Post-anaesthesia care unit (PACU) admission: No statistical difference in the proportion of people needing PACU admission between arms: 5.2% in robotic, 7.2% in conventional; p=0.238. No difference in days spent in PACU, p=0.488. Readmission within 30 days: No statistical difference in readmissions within 30 days between arms: 4.9% in robotic, and 6.1% in conventional; p=0.441.
(Kayani et al., 2021)	TKA	RCT (n=30)	Alignment: Statistical improvements in accuracy were reported in the robotic arm (root mean square error, SD) across planned limb alignment (1.2 (0.7) compared with 3.1 (1.3); p<0.001), femoral coronal alignment (1.1 (0.5) compared with 3.8 (1.1); p<0.001), femoral sagittal alignment (1.4 (1.0) compared with 3.2 (1.0); p<0.001), tibial coronal alignment (1.3 (0.9) compared with 3.9 (0.8); p<0.001), and tibial sagittal alignment (1.0 (0.4) compared with 3.1 (1.1); p<0.001).

Author (year)	Procedure	Study design (n, patients)	Key findings
(Kayani et al., 2019a)	UKA	Prospective cohort (n=146)	Alignment: No difference in overall post-operative limb alignment was observed between arms (mean (SD) varus: 1.88° (0.72°) compared to 1.72° (0.69 degrees); p=0.62).
(Banger et al., 2020)	Robotic: Bi-UKA Conventional: TKA	RCT (n=70)	Alignment (32 bi-UKA robotic, 38 TKA conventional): For 6 parameters of alignment (three femoral and three tibial), 47% of bi-UKA and 24% TKA had a change of less than 2° (p=0.045). Changes in HKA towards neutral in varus and valgus knees was significantly less in patients undergoing bi-UKA compared to those undergoing TKA (p<0.001).
(Clement et al., 2021)	THA	Prospective cohort (with propensity matching) (n=120)	Radiological alignment: Statistical differences in mean horizonal centre of rotation (0.2 (1.3) compared to -2.2 (4.5); p<0.001), mean acetabular offset (0.2 (1.1) compared to -2.1 (4.4); p<0.001), and mean leg length (2.3 (3.0) compared to 5.9 (6.0); p<0.001) between robotic and conventional surgery arms. No significant differences were observed between arms for vertical centre of rotation, mean combined offset, accuracy of component inclination, component anteversion or overall component position.
(Kayani et al., 2019b)	THA	Prospective cohort	Radiological alignment: Robotic arm was associated with improved restoration of the native horizontal centre of rotation (root mean square error (SD): 1.9 (1.3) compared with 3.7 (1.7) in the conventional arm; p<0.001), improved vertical centre of rotation (0.9 (1.1) compared with 2.2 (0.9) in conventional arm; p<0.001) and combined offset (1.7 (1.1) compared with 2.6 (0.9); p<0.001). Robotic arm had reduced outliers from both pre-defined horizontal (4% and 28%, p<0.001) and vertical (4% and 20%, p<0.001) centres of rotation. Robotic arm was associated with improved accuracy of overall component positioning within safe zones of inclination and anteversion defined by Lewinnek (96% compared with 68% in the conventional arm; p=0.02) and Callanan (92% compared with 64%, p=0.01). No difference in leg-length discrepancy was observed between arms (p=0.46).

Abbreviations: ASA, American Society of Anaesthesiologists; bi-UKA, bi-unicompartmental knee arthroplasty; HKA, hip-knee-ankle angle; PACU, Post-Anaesthesia Care Unit; RCT, randomised controlled trial; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, Unicompartmental Arthroplasty

5.8 The National Joint Registry (UK)

Several outcomes listed within the decision problem (NICE, Final Scope, 2024) are recorded routinely in the UK National Joint Registry, who shared feedback and shared data to the EAG to support this early value assessment:

- Intra-operative complications; NJR advised that these are poorly completed and therefore not considered reliable.

- revision surgery; NJR shared data with the EAG that showed:

    - within 3 years of 8,903 robotic TKA procedures [redacted] a total of 59 revisions (0.7%) were recorded,

    - within 3 years of 2,674 robotic UKA [redacted] a total of 27 revisions (1.0%) were recorded,

    - within 3 years of 5,771 robotic THA [redacted] a total of 31 revisions (0.5%) were recorded.

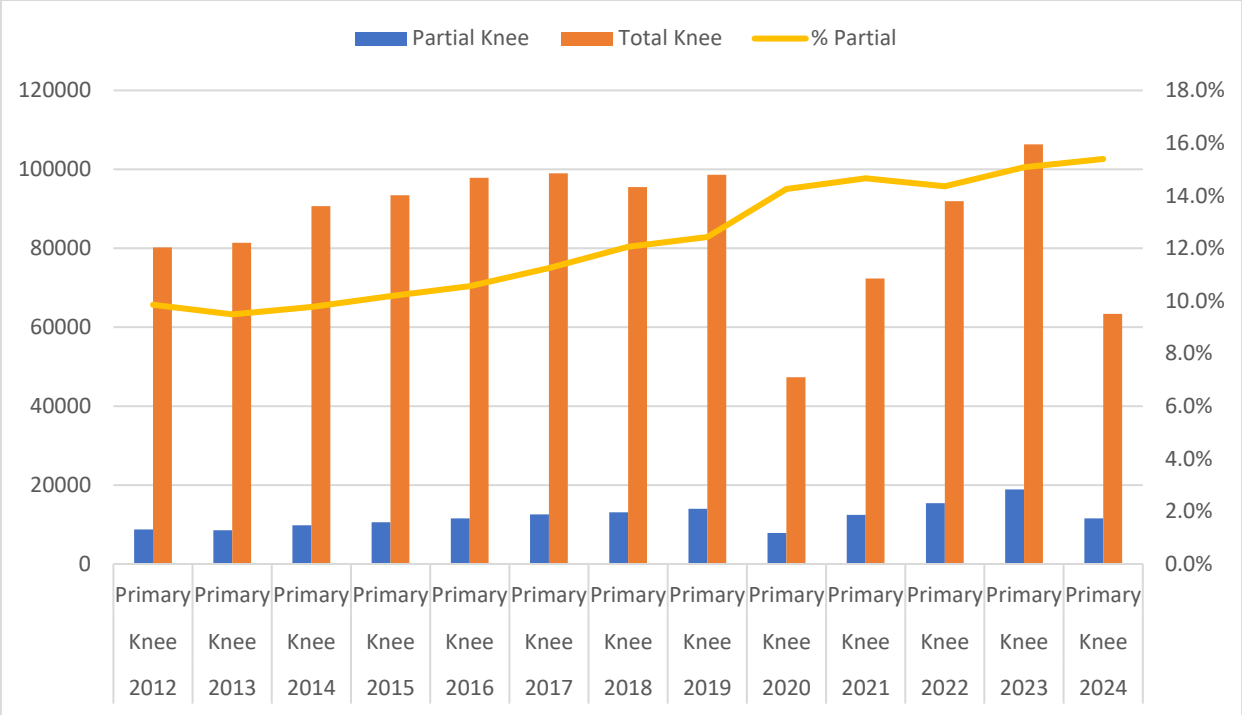
  Given the low number of revisions, and limited duration of follow up, it was considered not practical to differentiate revision rate by robotic system or consider that revisions differed by robotic or conventional surgery. The NJR 20th Annual Report (Achakri et al., 2023) reported that 1.45% of primary TKA procedures, 3.49% of primary UKA procedures, and 1.44% of primary THA procedures had been revised at 3 years. This includes both robotic and conventional surgery, but the exact breakdown between the two were not provided by the NJR. The NJR also advised that non-revision reoperations were recently introduced in the Registry data collection, however data is currently insufficient for analysis.

- mortality; NJR shared data on mortality, excluding patients who received a revision and then subsequently died, across both robotic and conventional total hip, total knee and partial knee joint replacement providing a more robust estimation of survival than standardised mortality ratio (SMR) (see section 9, which describes use of data from the NJR 20th Annual Report (Achakri et al., 2023)).

- centre volume of procedures; median procedure volumes for primary joint replacement procedures were obtained from the NJR 20th Annual report, however the EAG note that this includes a large number of private centres (which may skew the median value).

- Case mix; for example, proportion of partial knee replacements rather than total knee replacements. The NJR provided on 01 August 2024 a breakdown of the total number total and partial knee replacements recorded in the Registry between 2014 and the partial year of 2024, Figure 2; which demonstrated a steady increase in partial knee replacement from 9.8% (in 2014) to 15.4% (in the partial year of 2024).

Figure 2: The number of total and partial primary knee arthroplasty procedures recorded in the National Joint Registry between 2014 and 2024



- PROMs data for shoulder replacements. The NJR advised that the Registry does not currently capture use of robotic systems for shoulder procedures, indicating that this is not widely adopted in the UK. However, the NJR does record PROMs in conventional shoulder replacement; making it ideally placed to monitor outcomes

before and after adoption of robotic shoulder replacement when this occurs. The EAG note that national data collection of PROMs for hip and knee replacement is collected separately by NHS England (previously NHS Digital) and therefore not recorded in the NJR. The EAG note that from the NJR 20th annual report that PROMs data has not been provided by NHS England to NJR for 2 years (Achakri et al., 2023). The EAG consider linkage of NJR to HES with PROMs data represents a procedural and clinically rich dataset which could be explored to answer multiple research questions in the future.

5.9 The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

One Clinical Expert highlighted that revision rates following robotic and non-robotic TKA and UKA procedures were reported in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) within their 2023 annual report, with adjustment of baseline characteristics to account for confounding. The 2024 annual report has since been published, and provides similar results.

For TKA, the mean age was 68.5 years, with a total of 71,906 robotic assisted TKA procedures recorded since 2016, representing 35.7% of primary TKA conducted in 2023. The registry noted that there were 5 robotic systems used with a small number of prostheses and acknowledged that many of the systems had short follow-up. Whilst revisions up to 6 years were lower in the robotic arm (1.2%; 886/71,505) than TKA procedure without technology assistance (2.3%; 4,058/174,394), the registry reported that when adjusting for age, gender, ASA, BMI, bearing surface, patella component usage, and stability that there was no evidence of a difference in rate of revision between arms, hazard ratio (HR) 1.04 (95%CI 0.96 to 1.13); p=0.332.

For UKA, the mean age was 65.5 years, with a total of 9,760 robotic assisted UKA procedures recorded since 2015, representing 48.1% of UKA conducted in 2023. Revisions up to 8 years were lower in the robotic arm (3.4%; 331/9,760) compared to non-robotic arm (4.7%; 789/16,799) and when adjusting for age, gender, ASA, BMI and

mobility, there was no evidence of a difference in rate of revision between arms; HR 0.90 (95%CI 0.77 to 1.05); p=0.171.

To consider the generalisability of results from the Australian registry to procedures taking place the NHS, the EAG compared key demographics for UKA and TKA procedures. The age distribution appeared to differ between procedures between countries: mean age of 68.5 years in AOANJRR versus median age of 70.0 years in NJR for TKA, and mean age of 65.5 years in AOANJRR versus median age of 64.0 years in NJR for UKA. Differences in ASA were also seen across all knee replacement procedures, with 5.6% in AOANJRR recorded as class 1, versus 11.0% in NJR, and 1.3% in AOANJRR recorded as class 4, compared with 0.3% in NJR. Although limited data did not allow for statistical testing, the EAG considers it plausible that these differences could point towards the patient selection for each procedure being different by country, and therefore not generalisable. Robotic surgery for total hip and shoulder replacement were not reported in the 2024 annual AOANJRR report.

5.10 Summary and interpretation of the clinical evidence

From a systematic search, supplemented by information provided by the Companies and hand searching by the EAG during scoping, a total of 26 studies were prioritised by the EAG; 15 of which were conducted in a UK setting. The EAG considered RCT and prospective comparative evidence with matched comparator arm to account for population differences between robotic and conventional surgery to be the most robust study methodology when considering effectiveness. The EAG note that none of the RCTs were powered to detect differences in adverse events or revision rates. The National Joint Registry was considered the most robust source when considering hospital procedural volume, robotic uptake, revision and mortality due to national coverage and also due to low frequency of outcomes.

Most evidence available was in TKA procedures (N=16 studies, which included 5 RCTs, and 3 prospective cohorts with matched comparator arms). Studies were identified for all technologies listed in the Final Scope (ApolloKnee, CORI, Mako, ROSA Knee, SkyWalker, VELYS):

- Mako had the highest quality evidence base in TKA (including 3 RCTs and 3 prospective cohort studies with comparator arms including 1 with matched baseline characteristics). The randomised evidence broadly reported clinical non-inferiority of the Mako system when compared with conventional surgery; with no significant difference in length of hospital stay, complications, PROMs, utilities or revisions between robotic and conventional TKA. No statistical difference in range of motion at 5 years (secondary outcome) was also reported from the randomised evidence. However, improvements in alignment were consistently reported, and the EAG considers it plausible that this may lead to improvements in activity and reduction in revisions. Differences in gait analysis were also observed – greater decrease in propulsion time, and reduction in serum markers of inflammation noted for Mako when compared with conventional surgery arms.

- CORI and predecessor NAVIO had the next highest quality evidence with 2 non-UK RCTs in TKA including a three-armed RCT which demonstrated similar results between CORI and NAVIO, and 1 retrospective cohort study. Randomised evidence demonstrated significant differences in one PROM (KOOS) and alignment, however utilities were not reported and no differences in complications, length of hospital stay, range of motion, were observed between arms.

- ROSA Knee had 2 non-UK prospective cohort studies with matched comparator arms to account for confounders which demonstrated short term differences in PROMs following TKA at 6 months, but no statistical difference in utility at 1 year and no statistical difference in revision reported. Fewer wound complications were reported in the robotic arm, and lower opioid use at 1 month, however no statistical difference in opioid use was reported at 3 months.

- There was limited non-UK evidence for ApolloKnee, SkyWalker and VELYS, which lacked randomised and prospective comparative studies which

adequately account for population differences between patients receiving robotic and conventional TKA surgery.

Five studies and 1 subgroup analysis reported on UKA procedures. Whilst this included 3 RCTs and 1 retrospective cohort study with a matched comparator arm, 2 of these RCTs overlapped in patient recruitment and compared robotic UKA against conventional TKA, using a different prosthesis across arms. Evidence in UKA was limited to CORI and Mako devices (the only devices indicated for this procedure).

- From randomised evidence on Mako comparing robotic and conventional UKA, no significant difference in utility, VAS, patient satisfaction, complications, range of motion or revisions were observed at 5 years.

- One retrospective cohort with a matched control group for CORI demonstrated no difference in blood loss between groups, however no other outcomes of interest were reported.

Five studies reported on THA, however no randomised evidence was identified. Evidence was limited to Mako only (CORI and SkyWalker are also indicated for this procedure, but no evidence was identified).

- Focusing on one prospective cohort study with a propensity matched comparator arm, no difference in utility, VAS or patient satisfaction were observed at 1 year between robotic and conventional arms. However, differences in Forgotten Joint Score, Oxford Hip Score, and alignment were observed.

6. Adverse events and clinical risk

6.1 MHRA Field Safety Notices

On 26 June 2024, the EAG searched the Medicines and Healthcare products Regulatory Agency (MHRA) database from 1 January 2019 to 26 June 2024, using the

device names listed in the Final Scope (applying speciality limits of general surgery OR orthopaedics).

Two field safety notices were identified for Mako. One was specific to total and partial knee surgery in which a straight or angled saw is attached to the MICS Handpiece, which described a programming error may result in unsuccessful attempts to verify the location of the saw blade before bone preparation. This may result in a discrepancy between bone preparation and pre-operative plans, and the actual cuts made in surgery. One advised of possible loss of function requiring restart or conversion to manual surgery if the robotics system was not shutdown or restarted when switching between applications (that is, TKA to THA). This may extend surgery time and increase risk of complications.

One field safety notice was identified for CORI, which was a Marker Registration Error which may cause tracker arrays to flicker on screen. Best case scenario: the user adjusts the camera position or uses a backup device to continue use of the CORI Surgical System, with minimal to no delay, with no hazardous situation or harm. Worst-case scenario: a surgical delay of greater than 30 minutes. If the flickering occurs during bone removal and the surgeon is moving faster than the recommended cutting velocity, a bone gouge can occur. The gouge in the cut surface can be filled with cement and does not negatively affect implant fixation.

No relevant field safety notices were identified for ApolloKnee, ROSA Knee, SkyWalker or VELYS.

6.2 Noise

The EAG's literature search incidentally identified 2 papers which evaluated noise exposure to the staff using robotic systems (both were considered as in scope but non-key evidence due to device-related complication being listed as a secondary outcome in the Final Scope). In a prospective UK study of 19 TKA and 11 THA procedures using Mako, the surgeon and assistant had statistically significantly greater noise exposure than other staff (Goffin et al., 2024). The equivalent continuous sound pressure level

(L_{Aeq}) was over 80 dB, exceeding the lower exposure action value (LEAV) set out by the Control of Noise at Work Regulations 2005 (HSE, 2005). A prospective German study assessed noise levels during TKA from 8 Mako, 7 NAVIO and 6 CORI procedures (Hönecke et al., 2023). Average measured L_{Aeq} exceeded the LEAV for Mako but not NAVIO or CORI which may relate to the continuous ventilation system unique to that device. When a calculation was applied to allow for microphone placement being remote from the surgeon's ear, all devices exceeded LEAV. Measured and calculated peak sound pressures (LC_{peak}) when using high power instruments such as saws or reamers were highest for NAVIO, and all devices were lower than the LEAV. The authors acknowledged that relatively high sound exposure also occur during conventional surgeries. Three Clinical Experts reported that robotic surgery was noisier than conventional surgery, and three Clinical Experts reported no difference between robotic and conventional surgery. Three Clinical Experts noted noise levels in orthopaedic surgery is associated with saw and laminar flow, which are related to the procedure and not specific to the robotic systems.

6.3 Fracture

The EAG also incidentally found the study by (Torre et al., 2023), which described two case studies of early fracture of the tibial baseplate after UKA with a Stryker Restoris MultiCompartmental Knee System implant with Mako robotic assistance, both cases required revision to total knee arthroplasty. Several factors may influence surgical failure including implant integrity, patient weight and activity level, cementation techniques, or implant positioning. The authors caution that awareness of this complication and improved positioning of implants with RAS may help to reduce such events in future. The number of procedures that occurred before these device-related adverse events were reported is unknown which makes it difficult to put these results into context.

6.4 Ergonomics

Orthopaedic surgery is a physically and mentally demanding activity with body positions held for several hours by operating staff. Three papers were identified that addressed

the broad issue of ergonomics of staff (Gorce & Jacquier-Bret, 2023; Haffar et al., 2022; Shugaba et al., 2022). The study by (Haffar et al., 2022), using the ROSA Knee system, reported that despite operating times for total knee arthroplasty being on average 16.4 minutes longer in robotic surgery compared with conventional surgery, the time spent in a demanding flexion position, calorie expenditure, heart rate, and minute ventilation of staff was lower. The systematic review and meta-analysis by (Gorce & Jacquier-Bret, 2023) of 77 studies (which included 35 focused on robotic and video-assisted surgery but did not break these down by technology, 48 in surgery without video or robotic assistance) across 17 specialties (not specific to joint replacement) reported that the prevalence of work-related musculoskeletal disorder was highest in the neck, back, lower back and shoulders.

6.5 Other considerations

The EAG also note that the Mako device requires additional pre-operative CT imaging, and that pre-operative imaging is optional when using the ROSA Knee system. The EAG consulted with the Head of Imaging Physics & Radiation Safety at the Newcastle upon Tyne Hospitals NHS Foundation Trust who advised that one additional CT looking at three anatomical areas (to determine the angle between the hip, knee and ankle which is used to measure the knee alignment in knee osteoarthritis) had a measured dose in the order of 2 mSv which is under a year of natural background radiation in the UK. They advised that there is a possibility of this needing to be repeated if images are not adequate for surgery.

7. Evidence synthesis

It was not feasible to undertake meta-analysis for evidence within any of the technologies in this EVA because of study heterogeneity (populations, interventions, comparator, and definition and timing of outcomes). Issues with heterogeneity in published literature was previously highlighted by the umbrella review (Hasan et al., 2020) and overview (Kort et al., 2022) which identified critical flaws in the quality of the

included systematic reviews impacted by the large range of outcomes and the paucity of patient related safety measures. Adoption of an international core outcome set for the evaluation of robotic assisted surgery from a patient, surgeon, organisational and population level, as recommended by the RoboCOS study (Robertson et al., 2023), may introduce standardisation in reporting in robotic assisted surgeries and may support future evaluations.

8. Ongoing studies

The EAG identified 6 ongoing studies being conducted in a UK setting (Appendix D). The largest is the national REINFORCE trial (funded through NIHR Health and Social Care Delivery Research; ISRCTN18320267) which is using an observational stepped wedge study design to measure the impact of robot-assisted surgery as it is introduced and scaled up across NHS hospitals currently performing robotic surgery. This study includes but is not exclusive to orthopaedic surgery and includes all robotic systems. The primary outcome measures are patient level (covering disease-specific quality of life, overall quality of life measured using EQ-5D, and complications), surgeon or team level (covering precision or accuracy, and visualisation measured using the Surgeon Task Load Index on the day of surgery), organisation level (covering equipment failure using a surgery form on the day of surgery, standardisation of operative quality measured using process evaluation interviews, overall economic or cost-effectiveness measured using Health Economic review throughout the study) and population level (covering equity of access). As of June 2024, REINFORCE has opened 16 NHS sites, and recruited over 2,100 patients (target recruitment of 2,560, with an estimated completion date of April 2025).

Several Companies provided information regarding ongoing studies as academic in confidence:

- Zimmer Biomet [redacted].
- Johnson & Johnson [redacted]

[redacted].

- CORIN have an ongoing multi-site trial in the US gathering data and follow up patients by developing a large database.
- Smith and Nephew have provided [redacted]
- Stryker have 13 ongoing studies based in the UK.

9. Economic evidence

9.1 Published economic evidence

The EAG conducted an independent literature search for economic evidence (Appendix A1) where 196 records were identified. This was supplemented by economic references provided by the Companies. The EAG only included economic studies explicitly naming a technology (or a predecessor) in the final scope, or incorporating threshold analysis such that the device was not specified (included by the EAG so that they could review economic modelling methodology). Details of sifting and selection of papers for inclusion are given in the PRISMA diagram in Appendix A3. The EAG considered that 22 economic papers each comparing a robotically assisted joint replacement and conventional joint replacement were relevant to the decision problem (Appendix B3); 7 included a Markov economic model ((Burn et al., 2020); (Clement et al., 2019); (Maldonado et al., 2021); (Nherera et al., 2020); (Vermue et al., 2021); (Yeroushalmi et al., 2022); (Zhang et al., 2023)) and remaining 15 were costing or cost utility analyses ((Alexander et al., 2024); (Barsoum et al., 2023); (Christen et al., 2022); (Clement et al., 2022); (Clement et al., 2023); (Cool et al., 2019); (Cotter et al., 2022); (Ezeokoli et al., 2023); (Fang et al., 2022); (Goh et al., 2022); (Huang et al., 2024); (Kolessar et al., 2022); (Tompkins et al., 2022a); (Tompkins et al., 2022b); (Varughese et al., 2024)). The EAG also briefly reviewed the structure of 4 Markov models

presented in excluded publications (Hua & Salcedo, 2022; Ong et al., 2024; Rajan et al., 2022; Zhang et al., 2024). These either did not name a technology, or named a technology that was out of scope. These publications were reviewed to identify any key features and economic modelling methodologies that may be appropriate for use in the model developed as part of this EVA.

Of the 22 included papers, the following robotic systems were used:

- 15 Mako
- 1 Mako RIO
- 3 NAVIO
- 1 Mako and NAVIO
- 1 VELYS
- 1 with no technology reported (UK threshold analysis with results applicable to any technology).

The 22 economic studies were conducted in the following procedures:

- 10 in TKA only
- 5 in UKA only
- 3 in TKA and UKA
- 3 in THA only
- 1 in TKA and THA
- 0 in shoulder replacement, revision knee arthroplasty or revision hip arthroplasty.

The time horizon of the studies ranged from procedure only, to a lifetime. The one study considering threshold analysis for costs for TKA and THA provides a useful gauge for centres considering adopting robotic technologies in these procedures (Burn et al., 2020), to be able to calculate costs based on their anticipated annual case volume, preferred robotic system, and price negotiated.

The EAG have narratively summarised the 4 economic evaluations which included economic modelling conducted from a UK perspective (Clement et al., 2019; Clement

et al., 2023; Clement et al., 2022; Nherera et al., 2020). A tabular summary of model inputs and key results are in Table 32. The EAG note that only 1 study included servicing costs for the robotics system, none included cost of the implants (with the proposed assumption that the same implant is used in both intervention and comparator arms; which may not be the case with these closed systems being compatible with only manufacturer specific implants, see Table 2), all 3 studies using Mako appropriately included CT imaging costs pre-procedure in the robotic arm only (noting that CT costs are not required when using NAVIO). The published economic models were sensitive to procedure volume, length of stay, follow up duration and cost of revision.

Table 32: Summary of 4 economic evaluations conducted in UK setting

Author (year)	Procedure	Starting age of model, years	Purchasing option	Procedural volume (annually)	Robotic cost per patient (in addition to procedure costs)	Cost of procedure	Cost of revision	Incremental utility gain for robotic surgery	Incremental cost per QALY: discounted (undiscounted)
(Clement et al., 2022)	THA with Mako	69	Monthly rental: £9,600 Annually: £115,200, consumables £278 per patient	100	£1,516 (robotic system, consumables, CT scan)	£6,207	Aseptic (87%): £11,897 Septic (13%): £21,937	0.091 compared to conventional THA	£2,349 (£1,910) at 10-year horizon, and £1,432 (£980) at lifetime horizon compared to conventional THA.
(Clement et al., 2019)	UKA with Mako	65	Monthly rental: £9,600 Annually: £115,200, consumables £626 per patient	100	£1,866 (robotic system, consumables, CT scan)	£5,010	Aseptic: £9,655 Septic: £30,011	1.39 compared to conventional UKA and 1.80 compared to conventional TKA	£1,170 compared to conventional UKA and £1,395 compared to conventional TKA from lifetime model.
(Clement et al., 2023)	UKA with Mako	66	Annual rental £115,200, consumables £626 per patient	400	£1,070 (robotic system, consumables, CT scan)	£5,721	Aseptic: £9,655 Septic: £30,011	0.012 [95%CI -0.413, 0.437]	£13,078 compared to conventional UKA at 5 years; which changed to £52,155 when the cost of a single

Author (year)	Procedure	Starting age of model, years	Purchasing option	Procedural volume (annually)	Robotic cost per patient (in addition to procedure costs)	Cost of procedure	Cost of revision	Incremental utility gain for robotic surgery	Incremental cost per QALY: discounted (undiscounted)
									septic revision case was removed from analysis.
(Nherera et al., 2020)	UKA with NAVIO	65	Capital purchase £358,000 with 5-year lifespan, with service contract (2-5 years) of £21,500 per year, consumables £260 per patient	100	£1,225 (robotic system, service contract consumables)	£6,267 (additional £289 rehabilitation)	£10,390	9.47 compared to conventional	£2,831 compared to conventional UKA at 5 years

Abbreviations: CI, confidence interval; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental arthroplasty.

9.1.1 Mako

A cost utility analysis compared robotically assisted, with conventional, total hip arthroplasty over a lifetime time horizon using data from a prospective cohort (Clement et al., 2022). Although all surgeries were performed by the same group of surgeons, all RAS using Mako were completed under a private provider, and all conventional surgeries were completed under the NHS. The authors acknowledge differences in patient characteristics between groups, with the robotic arm having a higher proportion of male patients, younger patients, and better pre-operative EQ-5D and EQ-VAS scores. Furthermore, the EQ-5D responses were reported post-operatively at 6 to 12 months, but utility scores were very low compared with those in the other economic evidence. Therefore, there are concerns about both the internal validity of the study and the generalisability of the evidence to the decision problem. Analytically, differences in utility favoured the robotically assisted group. These differences were essentially extrapolated over the longer term in the economic model. Collectively these issues result in critical biases against conventional surgery. However, it is noted that all cost and clinical parameters used in the analysis were applicable to an NHS population. Further bias is possible as it was stated that patients in the robotically assisted surgery group were recruited consecutively, and the same was not stated for the conventional surgery group. The analysis assumed a monthly rental cost of the Mako device of £9,600, or £115,200 annually, which was spread across an average procedure volume of 100 cases per year. The cost of implants was not included and therefore assumed to be the same across intervention and comparator arms. The authors adjusted for confounding factors between arms (age and pre-operative EQ-5D) and reported a 0.091 improvement in EQ-5D for robotically assisted surgery, compared with conventional surgery. The 10-year time horizon undiscounted incremental cost per QALY was £1,910 for robotically assisted surgery relative to conventional surgery, and when discounted at 5% per year the incremental cost per QALY was £2,349, assuming 100 robotically assisted surgeries were completed each year. At the 10-year time point, a centre performing at least 10 surgeries each year would remain under the willingness to pay threshold of £20,000 per QALY.

A Markov decision analysis from an NHS perspective with lifetime time horizon reported that robotically assisted UKA had an incremental cost of £1,395 per QALY compared with conventional TKA, and £1,170 compared with conventional UKA (Clement et al., 2019). The base case assumed an annual rental with a centre volume of 100 patients treated with robotic assistance each year, with incremental costs per QALY rising to £7,170 when compared with conventional TKA, and £8,604 when compared with conventional UKA, for a centre completing only 10 cases per year. Improved cost-effectiveness was shown to be achievable for high volume centres completing 200 surgeries per year, as capital cost can be spread over more participants, and more so if length of hospital stay could be reduced from 2 days to 1 day. Input parameters were consistent with those reported in other studies, however it is unclear what adjustments were made, if any, to account for differences in patient populations between studies that provided input parameter values. In particular, it is unclear about comparability of utility values used, assumptions made about recovery periods and differences in length of stay. The model structure was appropriate, allowing patients to remain in the stable state, have a single surgical revision, and die.

An incremental cost utility analysis (Clement et al., 2023) used RCT data with 55 patients in the intervention arm, and 49 in the comparator arm, to report that RAS UKA was associated with an overall 0.012 [95% CI-0.413, 0.437] QALY gain at 5 years. This corresponded to an incremental cost per QALY of £13,078 for a centre with an annual rental of robotic equipment completing 400 surgeries each year. The authors reported that at least 300 cases each year were needed for the incremental cost per QALY to remain below £20,000. The costs associated with one septic revision in the conventional surgery group were driving the analysis in favour of RAS, and when excluded, the incremental cost per QALY of RAS was £52,155. With this case removed, RAS was cost neutral if more than 900 cases were done each year and if consumable costs were zero. The authors justified exclusion of this case because septic revisions are an infrequent and random event and would not be expected to differ between surgery types. An absolute cost difference of less than £240 was needed to maintain a cost per QALY of less than £20,000. The study was limited by short follow

up and impacts on both costs and QALYs resulting from any difference in future revision may alter the cost-effectiveness. This aspect could be explored using threshold analysis. The authors acknowledged that the study was not powered to detect a statistically significant difference in QALYs between groups and would have needed close to 10,000 patients in each arm. There was also no probabilistic sensitivity analysis reported. Costings did not account for smaller centres operating on fewer than 400 cases per year or take into account the robot being used for cases in addition to UKA, to bring the cost down.

The EAG notes these 3 studies are in different procedures, so evidence is limited. The study authors argue that in each analysis robotic surgery could be cost-effective. The EAG note concerns with these analyses such that the EAG are unable to comment on the likely cost-effectiveness of Mako with any confidence.

9.1.2 NAVIO

A Markov model study using NAVIO reported improved cost-effectiveness of robotically assisted UKA, when compared with conventional UKA (Nherera et al., 2020). This study included an annual service cost which is applicable between year 2 and year 5 following capital purchase of the robotics system and did not include CT costs because a CT is not needed for the NAVIO system. A higher incremental cost per QALY (£2,831) was found than for Mako (Clement et al., 2019), for the same centre volume. However, the EAG notes the model structure was different, allowing 2 surgical revisions before assuming that further intervention would be a TKA, a health state that the authors did not model. Results were more favourable for younger patients and were sensitive to centre volume and the follow up period. The ICER was different between male (£3,374/QALY) and female (£2,332/QALY) patients; a consequence of the slightly higher mortality for males compared with females. All input parameters were from publicly available sources, making the model replicable.

9.1.3 VELYS

No published economic evaluations were identified for VELYS, however the Company submitted a bespoke economic model developed in Excel. [redacted]. The EAG did not attempt to replicate or critically appraise this bespoke economic model, however notes that when the WTP was changed to [redacted].

9.1.4 Generic device

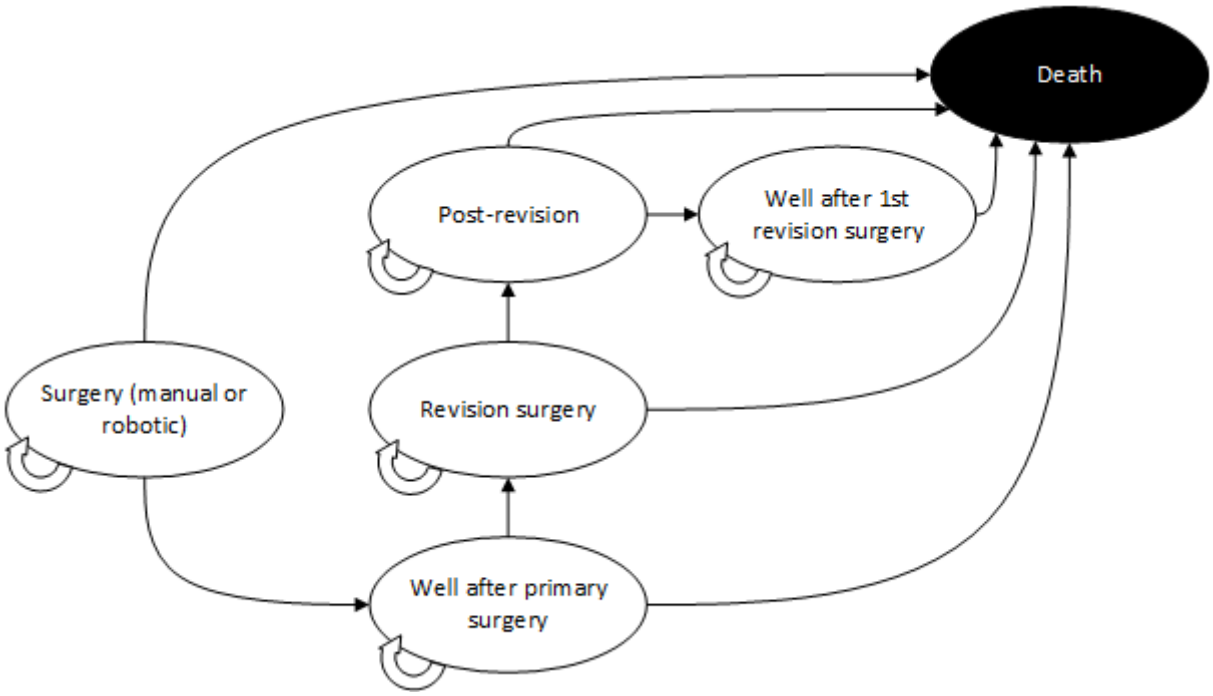
The EAG also considered one additional study which used a Markov model framework with lifetime time horizon to estimate changes in costs and quality of life, assuming a generic RAS technology for hip and knee replacements, compared with conventional surgery (Burn et al., 2020). It was assumed that RAS would lead to a relative reduction in risk of revision of 50%, and a 5% improvement in quality of life after the procedure. In particular, the EAG considers that the 50% reduction in revision risk may be optimistic, given that the Clinical Experts consulted have suggested it would be reasonable to assume no difference in revision rates between conventional surgery and RAS. Using these assumptions, threshold analysis gave costs of £11,182 [£10,691 to £11,721] for knee replacement, and £12,134 [£11,616 to £12,701] for hip replacement, above which

the ICER would be greater than the £20,000 cost-effectiveness threshold. Assuming a 50% reduction in revision rate alone and no improvement in quality of life, threshold costs were £1,094 [£788 to £1,488] for knee replacement and £1,347 [£961 to £1,842] for hip replacement. Assuming a 5% improvement in quality of life alone (and no improvement in revision rate) gave threshold prices of £9,911 [£9,476 to £10,296] and £10,578 [£10,171 to £10,982]. Probabilities of transitions to revision and death states were based on real-world linked Clinical Practice Research Datalink and HES Admitted Patient Care and Office for National Statistics data over a 17-year period, so are likely to be the most representative of NHS practice. It is unclear whether the PROMs collected before and after surgery were mandatory, or whether this may be a source of bias if patient characteristics differ between the groups with and without PROMs recorded. Values for costs and utilities used in the base case were not explicitly reported and therefore not replicable.

9.2 Economic modelling

The EAG considered that the Markov model structure applied by 3 UK studies (Burn et al., 2020; Clement et al., 2019; Nherera et al., 2020) was sufficiently generalisable to all procedures and devices in the scope. To use the latest evidence and costs available, the EAG developed a cohort Markov model (Figure 3), using the R package, '*rdecision'*, with each Markov state representing a health state experienced by a patient. Each transition represents an event which causes patients to change health states. The starting point is a hypothetical cohort of 1,000 patients who need a primary TKA, UKA or THA procedure; each procedure was modelled separately. Due to the lack of published evidence the EAG did not include shoulder replacement within the economic modelling, however, note that the model structure is appropriate for this indication when evidence becomes available. The EAG notes that the base case should be considered illustrative, and the results should be interpreted in light of the limitations detailed in section 9.3.3 **Limitations of economic modelling**.

Figure 3: Economic model



Costs and QALYs are accrued as patients enter (excluding 'Surgery' state) and leave (excluding 'Death' state) the following different health states in the model:

- 'Surgery': the state patients start in and remain in this state until they are discharged well from hospital or die. To avoid including non-Markov tunnel states in the model, which introduce a dependency on cycle duration, the EAG have modelled the transition from this state assuming 95% of remaining patients leave it within one month. The cost of the procedure was associated with making a transition from this state.
- 'Death': an absorbing state that can be transitioned to from any other state in the model.
- 'Well after primary surgery': a state that a patient may remain in after their primary surgery unless they need revision surgery or die. A patient may not return to this state from another state.
- 'Revision surgery': a state entered when a patient has the first revision surgery after their primary surgery. As in the 'Surgery' state, the EAG have assumed that 95% of remaining patients leave the state within one month and move to either 'death' or

'post-revision'. Due to the low revision rate as demonstrated by the UK NJR, see section 5.8, the EAG did not separate aseptic and septic revisions as separate health states in the economic model in the base case, but instead assumed weighted average costs using activity levels from NHS Reference costs.

- 'Post-revision': patients move into this state from 'revision surgery' and spend an average of 1 year in the state, to allow a utility decrement to be applied for the first year after revision surgery.
- 'Well after 1st revision surgery': a state that a patient may remain in after their revision surgery, until they die.

Per-cycle transition probabilities were calculated from event rates and cycle duration, accounting for the presence of multiple states and the possibility of making more than one transition in a single cycle. Rates were estimated on a per-cycle basis to account for reported time-dependency of clinical parameters (see Table 33).

The EAG did not identify any evidence which suggested that acute complications such as wound infection, deep vein thrombosis and nerve or vessel damage, were significantly different between robotic and conventional joint replacement surgeries. Therefore, adverse events were not included in the economic model, but this could be amended should such evidence become available. The EAG did consider including conversion to manual surgery as an outcome in the economic model, however this outcome was not reported in the included studies, is not routinely recorded by the NJR, and four Clinical Experts advised that this is extremely unlikely to occur. Due to the rarity of event, and lack of data the EAG omitted conversion to manual surgery from the economic model. Three Clinical Experts also advised including dislocation as an outcome specifically in THA. However, in the evidence prioritised for inclusion in this report, the EAG did not identify any reporting a difference in this outcome between conventional and robotic surgery. Therefore, dislocation was not included in the economic model, however this could be amended should such evidence become available. Additional outcomes suggested by Clinical Experts included activity reporting, robotic surgery in conjunction with radiostereometric analysis (RSA) to predict revision

rates, and objective laxity assessment. However, the EAG did not identify any evidence related to these outcomes during this early value assessment. The EAG acknowledge that evidence for these outcomes may become available in the future and may therefore inform future modelling.

In line with the NICE reference case (PMG36), both costs and outcomes were discounted at 3.5% annually, and were considered from a UK NHS and personal social services perspective. Three Clinical Experts estimated lifetime of total knee implants of 20 years and greater, two Clinical Experts estimated a lifetime of 20 years or greater for total hip implant, two Clinical Experts estimated up to 15 years for partial knee implant. Using a cycle length of 1 month, the EAG have applied a lifetime time horizon to the base case, assuming a maximum life expectancy of 100 years to align with available standardised mortality data. The EAG considers this best reflects the life expectancy of a joint replacement and its consequences and best represents the rate of revision surgeries which includes both early revisions due to complications and late revisions due to implant longevity.

Several assumptions were made in developing the model:

- Clinical parameters, revision rate and mortality rate, were assumed to be the same for robotic and conventional surgery due to lack of evidence demonstrating a difference in these outcomes between arms. Revision and mortality rates were derived from UK data from the NJR 20th annual report (Achakri et al., 2023); where robotic and non-robotic procedures are aggregated together.
- Utilities used in the economic model were derived from best available data for Mako; RCT evidence for TKA and UKA, and a prospective cohort study with adjustment for confounding variables (sex, age, pre-operative PROMs) for THA. It is plausible that utilities may be similar for other robotic systems, and because clinical parameters are the same, the EAG have done modelling only for Mako, but have adjusted the per patient costs using the costs of each other technology and presented these in Table 39.

- Minor complication events, such as deep vein thrombosis, nerve or vessel damage, or infection, experienced in hospital after surgery are not considered as separate Markov health states. Instead, these acute complications are considered as being incorporated within the Healthcare Resource Group (HRG) procedure cost. The EAG acknowledge that complications may have an impact on quality of life, but because no evidence was identified to suggest a difference between robotic and conventional surgery, have assumed that this is resolved before discharge from hospital, therefore not affecting utilities (or costs) used in the model
- Clinical experts reported that the robotic systems currently being used have not yet been licensed to be used for revision surgery, so it is assumed that all revision surgery is completed using conventional surgery.
- There is a low rate of revision captured in the NJR following robotic surgery, and evidence from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) suggests that the rate of revision is not significantly different between robotic and conventional TKA when adjusting for differences in baseline characteristics between arms. Therefore, because no difference can be established between revisions after conventional and robotic surgery, the EAG assumed that only a single revision surgery takes place during the time horizon, and any further revisions would apply equally to both arms. Three Clinical Experts advised that more than 1 revision was possible, one noting that revisions can lead to more revisions; however, 2 Clinical Experts acknowledged lack of data regarding multiple revisions following robotic surgery. Of a retrospective cohort of 1,193,830 primary knee arthroplasty (TKA and UKA combined) documented in the UK National Joint Registry (NJR), 75,881 underwent revision knee arthroplasty, and of these 33,292 patients had both their primary and revision surgery documented in the UK National Joint Registry. Analysis of this cohort identified that male patients and younger patients were at higher risk of multiple revisions, and that 19.9% of first revisions (n=3,575 patients) were revised again within 13 years, 20.7% of second revisions (n=574 patients) were revised again within 5 years and 20.7% of third revisions (n=114 patients) were revised again within 3 years (Deere et al., 2021). Similar

results were reported in the retrospective analysis of 29,010 patients with primary and revision THA (Deere et al., 2022).

The EAG also noted that studies by (Clement et al., 2019) in UKA, and (Clement et al., 2022) in THA used different costs for septic and aseptic revision. The EAG also assumed that the cost of revision surgery reflected a weighted average of septic and aseptic revisions as per NHS reference costs (using activity levels from the National schedule of NHS costs 2021 to 2022) and was the same for all indications.

- The EAG also assumed in the base case that all revision procedures are single stage procedures and incur costs only once. The NJR Annual Report indicates that between 2003 and 2022, there were 98,791 TKA revision procedures, and that the majority (77,594 procedures, 78.5%) were single stage (Achakri et al., 2023). The EAG acknowledge this limitation and potential for higher costs associated with two-stage revisions.

9.2.1 Clinical parameters

The clinical parameters used for THA, TKA and UKA included in the economic model developed by the EAG are summarised in Table 33. Data obtained from the NJR included: median age of the patient, sex, median procedure volume across centres contributing data, revision and mortality rates subgrouped by procedure; all of which were kept the same between the robotic and conventional surgery arms. Median length of stay, obtained from NHS Digital Hospital Admitted Patient Care Activity (2022 to 2023) and supplemented by Clinical Expert opinion, was also kept the same between robotic and conventional surgery arms.

The EAG base case also assumed that the total surgical time and total theatre time were the same between conventional surgery and robotic surgery; and already captured in the Healthcare Resource Group (HRG) cost of the procedure. Three Clinical Experts acknowledged that the robotic systems in the scope have different capabilities which could potentially lead to differences in the length of time in theatre (one stating that some systems have a mechanical arm with more intuitive anatomy

mapping which can reduce time, one stating that larger systems need more advanced draping of the robotic arms, taking approximately 20 minutes of a nurse's time prior to the patient coming to theatre). However, two acknowledged that differences may not exist when the learning curve has been achieved. One Clinical Expert advised that robotic systems would have minimal or no clinically meaningful difference, and one Clinical Expert considered that surgical time would be similar between robotic and conventional surgery. Definitions of operation or theatre time were variable or not explicitly reported across the identified clinical evidence, which should be considered in future evidence generation.

Table 33: Main clinical parameters

Variable	Model arm	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Total knee replacement	-	-	-	-
Median start age, years	Conventional and robotic	72	NJR	NJR 20th Annual Report states median age for TKA of 70 years. EAG have used 72 to align with mortality data derived from NJR 20th Annual Report. (Achakri et al., 2023); the median age of a person receiving a cemented TKA was 70 years (IQR 64 to 76 years).
Male sex	Conventional and robotic	43%	NJR	NJR 20th Annual Report (Achakri et al., 2023);
Revision, annual proportion	Conventional surgery and robotic	1 year: 0.0043 5 years: 0.0028 10 years: 0.0020 15 years: 0.0025 19 years: 0.0033	NJR	Due to rarity of events, and none of the published RCTs being powered to detect difference in revision, the EAG have prioritised NJR as the primary source. A spline function was used to interpolate revisions between the timepoints available in the NJR 20th Annual Report, and beyond 19 years, the EAG have taken an average rate across the available 15 and 19 year data. Values presented are a subset of the annual rates used in the model. The 2023 AOANJRR annual report found no difference between revision rates of robotic surgery and non-robotic assisted TKA when adjusting for age, gender, ASA, BMI, bearing surface, patella component usage and stability; HR: 1.04 (95%CI 0.94 to 1.14); p=0.417.
Mortality, annual proportion	Conventional surgery and robotic	Male: 30 days: 0.0014 1 year: 0.0089 5 years: 0.0282 10 years: 0.0605 15 years: 0.1196 20 years: 0.1916 25 years: 0.2993 28 years: 0.3831 Female: 30 days: 0.0010 1 years: 0.0054 5 years: 0.0185 10 years: 0.0453 15 years: 0.0969 20 years: 0.1530 25 years: 0.2541 28 years: 0.3226	NJR	The EAG used mortality data at 1, 5, 10, 15 and 19 years from the NJR 20th Annual Report and standardised mortality lifetables, for males and females. The NJR report used 5 year age ranges, so the EAG used the midpoint of 72 years to extract appropriate standardised mortality. The hazard ratio between the two sources at the 19 year time point was used to derive mortality for conventional and robotic surgery from standardised mortality beyond 19 years. The EAG considered applying an average of the 15 and 19 year hazard ratios, but this resulted in visible discontinuity in the plotted curves. A spline function was used to interpolate mortality between the timepoints available in the NJR Annual Report. Overall mortality rates used for each cycle were adjusted to reflect the proportion of males (43%, NJR Annual Report) and females. Values presented are a subset of the annual rates used in the model. Values derived were broadly consistent with values used in published literature. Conventional surgery as reported by: - Clement et al. 2019: 30 days: 0.0024 90 days: 0.0047 1 year: 0.0088 4 years: 0.0444 8 years: 0.1148 Post-revision, annual: 0.011 - Clement et al. 2024 at 1 year was 0.025 (1/38) The EAG have not identified any randomised evidence which reported a difference in mortality between robotic and conventional surgery arms. Rates of mortality are low, therefore as above the EAG have prioritised NJR as evidence source and assumed no difference in mortality between arms. This is broadly consistent with published results (Clement et al. 2024: Mako 0/43 at 1 year) and the approach taken in other published economic models (Clement et al. 2019).
Annual procedure volume	Conventional and robotic combined	250	NJR	The NJR 20th Annual Report stated the median [Q1,Q3] number of primary TKA procedures over a 3-year period (01 January 2020 to 31 December 2022) was 421 [147, 704] per provider, which is the equivalent of 140 [49,234] primary TKA procedures per provider per year. Similarly the NJR reported the median [Q1,Q3] number of primary unicondylar knee procedures over a 3-year period (01 January 2020 to 31 December 2022) was 54 [18,118] per provider, which is the equivalent of 18 [6,40] per provider per year. The EAG note that this includes NHS and private providers, which may skew this estimate, and represents historical data, knowing that the uptake of robotic surgery is increasing over time. Therefore, the EAG assumed a centre volume of 250 procedures annually, combining UKA and TKA, that can be conducted using robotic system instead of conventional surgery. Five Clinical Experts advised that between 25% and 100% conventional procedures could be conducted with robotic systems, however all acknowledged that existing procedural volume, resource allocation and theatre utilisation (including sharing of the robot between theatres) will impact this.
Length of stay, days	Conventional, robotic	2	NHS Digital	Median length of stay for cemented total knee replacement (OPCS code W40.1) and uncemented (W41.1) was 2 days (Hospital Admitted Patient Care Activity 2022-23: Procedures). EAG assume same length of stay for both robotics and conventional arms. The EAG have explored reduction in length of stay with robotics arm between 10% and 30% in sensitivity analysis.
Partial knee replacement				
Median start age, years	Conventional and robotic	62	NJR	NJR 20th Annual Report states median age for UKA of 64 years. EAG have used 62 to align with mortality data derived from NJR 20th Annual Report. (Achakri et al., 2023); where patients receiving cemented unicondylar prostheses were typically six years younger (median age 64 years; IQR 57 to 71) compared with all types of knee replacement.
Male sex	Conventional and robotic	51%	NJR	NJR 20th Annual Report (Achakri et al., 2023);
Revision, annual proportion	Conventional surgery and robotic	1 year: 0.0098 5 years: 0.0093	NJR	Due to rarity of events, and none of the published RCTs being powered to detect difference in revision, the EAG have prioritised NJR as the primary source. A spline function was used to interpolate revisions between the timepoints available in the NJR 20th Annual Report, and

		10 years: 0.0112 15 years: 0.0128 19 years: 0.0150		beyond 19 years, the EAG have taken an average rate across the available 15 and 19 year data. The 2023 AOANJRR annual report found a difference between revision rates of robotic surgery and non-robotic assisted UKA when adjusting for age, gender, ASA, BMI, and mobility; however this was marginal; HR 0.83 (95%CI 0.70 to 0.99); p=0.034. Following findings of TKA, the EAG have assumed no difference in revision rates between robotic and conventional arms.
Mortality, annual proportion	Conventional surgery and robotic	Male: 30 days: 0.0006 1 year: 0.0028 5 years: 0.0077 10 years: 0.0158 15 years: 0.0311 20 years: 0.0662 25 years: 0.1150 30 years: 0.1991 35 years: 0.3102 38 years: 0.3961 Female: 30 days: 0.0001 1 year: 0.0013 5 years: 0.0050 10 years: 0.0103 15 years: 0.0236 20 years: 0.0473 25 years: 0.0862 30 years: 0.1591 35 years: 0.2636 38 years: 0.3339	NJR	As above. The EAG used mortality data at 1, 5, 10, 15 and 19 years from the NJR 20th Annual Report and standardised mortality lifetables, for males and females. The NJR report used 5 year age ranges, so the EAG used the midpoint of 62 years to extract appropriate standardised mortality. The hazard ratio between the two sources at the 19 year time point was used to derive mortality for conventional and robotic surgery from standardised mortality beyond 19 years. The EAG considered applying an average of the 15 and 19 year hazard ratios, but this resulted in visible discontinuity in the plotted curves. A spline function was used to interpolate mortality between the timepoints available in the NJR Annual Report. Overall mortality rates used for each cycle were adjusted to reflect the proportion of males (51%, NJR Annual Report) and females. Values presented are a subset of the annual rates used in the model. This is broadly consistent with values used in published literature. Conventional surgery as reported by: - Clement et al. 2019: 30 days: 0.0006 90 days: 0.0022 1 year: 0.0053 4 years: 0.0329 8 years: 0.1090 Post-revision, annual: 0.011 - Banger et al. 2021: 2/49 at 5 years. The EAG have not identified any randomised evidence which reported a difference in mortality between robotic and conventional surgery arms. Rates of mortality are low, therefore as above the EAG have prioritised NJR as evidence source and assumed no difference in mortality between arms. This approach has been taken in other published economic models (Clement et al. 2019). Mortality results from published literature included: - Banger et al. 2021: 1/55 at 5 years Nherera et al. 2020; NAVIO mean annual probability (95%CI) 0.0444 (0.0442 to 0.0447) following procedure. All-cause: 0.049
Annual procedure volume	Conventional and robotic combined	250	NJR	The NJR 20th Annual Report stated the median [Q1,Q3] number of primary TKA procedures over a 3-year period (01 January 2020 to 31 December 2022) was 421 [147, 704] per provider, which is the equivalent of 140 [49,234] primary TKA procedures per provider per year. Similarly, the NJR reported a median [Q1,Q3] number of primary unicondylar knee procedures over a 3-year period (01 January 2020 to 31 December 2022) was 54 [18,118] per provider, which is the equivalent of 18 [6,40] per provider per year. The EAG note that this includes NHS and private providers, and represents historical data, knowing that the uptake of robotic surgery is increasing over time. Therefore, the EAG assumed a centre volume of 250 procedures annually, combining UKA and TKA, that can be conducted using robotic system instead of conventional surgery.
Length of stay, days	Conventional, robotic	1	NHS Digital	As advised by 3 Clinical Experts. Cost associated with length of hospital stay are incorporated in HRG costs, however the same HRG has been applied for total and partial knee replacement (therefore an average length of stay has been included in costings). The EAG have explored reduction in length of stay with robotics between 10% and 30% in sensitivity analysis.
Total hip replacement				
Median start age, years	Conventional and robotic	67	NJR	NJR 20th Annual Report states median age for THA of 69 (IQR 61 to 76) years. EAG have used 67 to align with mortality data derived from NJR 20th Annual Report (Achakri et al., 2023).
Male sex	Conventional and robotic	40%	NJR	NJR 20th Annual Report (Achakri et al., 2023);
Revision, annual proportion	Conventional surgery and robotic	1 year: 0.0080 5 years: 0.0031 10 years: 0.0043 15 years: 0.0052 19 years: 0.0050	NJR	Due to rarity of events, and none of the published RCTs being powered to detect difference in revision, the EAG have prioritised NJR as the primary source. A spline function was used to interpolate revisions between the timepoints available in the NJR 20th Annual Report, and beyond 19 years, the EAG have taken an average rate across the available 15 and 19 year data. Values presented are a subset of the annual rates used in the model. This is broadly consistent with values used in published literature for conventional surgery: - Clement et al. 2022: 0.00389 annually Following TKA, the EAG have assumed that revision rates were the same between conventional and robotic arms for THA.
Mortality, annual proportion	Conventional surgery	Male: 30 days: 0.0015 1 year: 0.0094 5 years: 0.0178 10 years: 0.0352 15 years: 0.0674 20 years: 0.1119 25 years: 0.1940	NJR	As above. The EAG used mortality data at 1, 5, 10, 15 and 19 years from the NJR 20th Annual Report and standardised mortality lifetables, for males and females. The NJR report used 5 year age ranges, so the EAG used the midpoint of 67 years to extract appropriate standardised mortality. The hazard ratio between the two sources at the 19 year time point was used to derive mortality for conventional and robotic surgery from standardised mortality beyond 19 years. The EAG considered applying an average of the 15 and 19 year hazard ratios, but this resulted in visible discontinuity in the plotted curves. A spline function was used to interpolate mortality between the timepoints available in the NJR Annual Report. Overall mortality rates used for each cycle were adjusted to reflect the proportion of males (40%, NJR

		30 years: 0.3029 33 years: 0.3873 Female: 30 days: 0.0008 1 year: 0.0065 5 years: 0.0128 10 years: 0.0254 15 years: 0.0492 20 years: 0.0848 25 years: 0.1567 30 years: 0.2599 33 years: 0.3295		Annual Report) and females. Values presented are a subset of the annual rates used in the model. This is broadly consistent with values used in published literature. Conventional surgery as reported by: - Clement et al. 2022: 0.25 at 10 years The EAG have not identified any randomised evidence which reported a difference in mortality between robotic and conventional surgery arms. Rates of mortality are low, therefore as above the EAG have prioritised NJR as evidence source and assumed no difference in mortality between arms.
Annual procedure volume	Conventional and robotic combined	250	NJR	The NJR 20th Annual Report stated the median [Q1,Q3] number of primary hip procedures over a 3-year period (01 January 2020 to 31 December 2022) was 492 [208,833] per provider, which is the equivalent of 164 [69,277] per provider per year (Achakri et al., 2023). The EAG note that this includes NHS and private providers, and represents historical data, knowing that the uptake of robotic surgery is increasing over time. Therefore, in the base case the EAG will assume a centre volume of 250 procedures annually can be conducted using robotic system instead of conventional surgery.
Length of stay, days	Conventional, robotic	2.5	NHS Digital	Median length of stay for cemented total hip replacement (OPCS code W37.1) was 3 days across activity of 21,683 cases and uncemented (W38.1) was 2 days across activity of 25,778 cases (Hospital Admitted Patient Care Activity 2022-23: Procedures). Therefore, EAG assumed mid-point for base case applied to both intervention and comparator arms, and explored reduction in length of stay in the robotic arm between 10% and 30% in sensitivity analysis.

Abbreviations: AOANJRR, Australian Orthopaedic Association National Joint Replacement Registry; ASA, American Society of Anaesthesiologists; BMI, body mass index; CI, confidence interval; EAG, External Assessment Group; HR, hazard ratio; IQR, Interquartile range; NJR, National Joint Registry; OPCS, Operating Procedure Codes Supplement; RCT, randomised controlled trial; THA, Total hip arthroplasty; TKA, Total knee arthroplasty; UKA, Unicompartmental Arthroplasty

9.2.2 Resource use and cost

The costs of all technologies, as provided by the Companies are summarised in Appendix E, which demonstrated cost variation. This included information from Zimmer Biomet who indicated that they offer a 4th commercial model based on a pay-by-use model which is agreed on but has not yet been taken up in the UK. Additionally, Stryker indicated that a purchase lease option is available for the Mako device that is funded through a 3rd party. No information was provided for the SkyWalker robotic system. The EAG converted these costs from the Company to standardised per patient costs based on a capital purchase, Table 34, and lease option assuming 250 procedures each year based on mean primary procedure volumes described the NJR, **Table 35**. All calculated costs accounted for the intended lifetime of the system, as provided by the Companies.

The Clinical Experts estimated that between 25% and 100% of conventional TKA, UKA, THA surgeries could potentially be conducted with a robotic system. The EAG note that use of the technology across procedures decreases the per-patient costs. To illustrate the cost components of the per-patient costs, the EAG calculated that for a lease agreement of 250 procedures in a year (no optional extras), 9% to 18% of the per-patient costs are associated with the robotic system, and the majority of the costs are attributed to the implant (between 45% and 76%), with additional costs for consumables (between 9% and 28%), service plan (between 0% and 12%), Table 36.

The EAG developed a base case for Mako, using a 5-year volume-based lease purchase option, which is the most common purchasing option, as advised by 3 Clinical Experts using robotic systems in the UK. The EAG also presents indicative per patient costs and QALYs for the other technologies in scope, and available for volume-based purchasing, although this was not modelled, but calculated using the difference in technology costs between each technology and Mako. Because of the structure of the model and its transitions, some minor cost differences may have been observed if the other technologies were modelled. In each case, the EAG used the same consumable and implant costs as the capital purchase option, which was also explored in sensitivity

analysis (for Mako only) to assess which is likely to be the most cost effective for Trusts looking to adopt robotic technologies for orthopaedic surgeries.

Additional costs used in the economic modelling are summarised in

Table 37 including procedure costs and CT imaging costs applicable to Mako device only, see Table 2. The EAG note that all 6 systems included in this Early Value Assessment are “Closed” systems meaning that only implants from that manufacturer are indicated for use with the Robotic system. Due to the complexity of joint replacement, there are a range of implants available, with different implant sizes, fixation methods, bearing surfaces and liners used. Due to this, the EAG considered an average implant cost across all available for each manufacturer within the robotic arm. Five Clinical Experts considered this simplification as appropriate, however one Clinical Expert advised that for THA that cemented and reverse hybrid surgery would be used less with RAS due to differences in the mode of fixation between groups, and that for TKA posterior stabilised liners would be used less and cruciate retaining liners used more with RAS. One Clinical Expert advised that there may be local negotiations for implant costs. The EAG submitted a freedom of information request to the Newcastle upon Tyne Hospitals NHS Foundation Trust (13 August 2024) to determine the proportion of Healthcare Resource Group (HRG) costs associated with the protheses for the comparator arm. This prosthesis cost would be removed from the HRG in the robotics arm to avoid double counting of implant costs. The EAG conducted extreme value sensitivity analysis to determine the impact on results when the upper and lower limit of implant costs are considered. The EAG acknowledge that there may be costs included in the HRG which may differ between conventional and robotic surgery (for example sterilisation costs, number of drapes required, need for robotic technician), which could not be explored further without detailed micro-costing approach which was considered unfeasible within this early value assessment.

The EAG note that to date in 2024 the NJR records that 6% of knee and 2.8% of hip replacements were conducted using robotic systems (see Section 3). The Clinical Coding team within Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) also

advised that HRG codes assigned are unaffected by the inclusion of procedure code "Y45.2: Approach to organ under robotic control NEC" (OPCS). Therefore, the EAG assumed that costs associated with robotic surgery may be incorporated within existing HRG costs for joint replacement, however due to low proportion the EAG considered that this represented minimal double counting. The Clinical Coding team also advised that the HRG codes used in the economic model (HN12 and HN22) were associated with Best Practice Tariffs based on minimum patient reported outcome measures (PROMs) participation rate of 50%, minimum NJR compliance rate of 85%, NJR unknown consent rate below 15%, and for hip replacements in patients aged 70 or over the provider uses cemented or hybrid protheses for at least 80% of patients. The EAG note that the Best Practice Tariff is approximately 10% higher than the base HRG, which was explored in sensitivity analysis.

Clinical Experts advised that staffing would remain the same between conventional surgery and robotic surgery. Three Clinical Experts advised that Company representation would be present during the learning curve, however that this did not incur additional cost. One Clinical Expert advised that joint replacement in the conventional surgery arm could be conducted by a registrar, whereas joint replacement in the robotic arm would be conducted typically by a consultant surgeon, which would further increase costs in the robotic arm, when compared with conventional surgery. It is plausible that procedure duration could be different between conventional and robotic surgery, so this was explored by the EAG in sensitivity analysis.

Table 34: Device costs per patient calculated by EAG (capital purchase)

Parameter	ApolloKnee	CORI	Mako	ROSA	VELYS
Annual procedure volume	250	250	250	250	250
Lifetime of system, years	10	5	[redacted]	10	7
Device costs (assuming procedural volume and lifetime of robot above), per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for THA, per patient	-	[redacted]	[redacted]	-	-
Consumable costs for TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for UKA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for THA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Implant costs for UKA, per patient	-	[redacted]	[redacted]	-	-
CT imaging costs (pre-procedure), per patient	-	-	[redacted]	-	-
Service plan, per patient (assuming not applied in first year and included in 12-month warranty and that costs of 4 years spread across 5 years)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Optional extras, per patient	-	[redacted]	[redacted]	[redacted]	-
Total costs (THA)	**-**	[redacted]	[redacted]	**-**	**-**
Total costs (with optional extras)	**-**	[redacted]	[redacted]	**-**	**-**
Total costs (TKA)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total costs (with optional extras)	**-**	[redacted]	[redacted]	[redacted]	**-**
Total costs (UKA)	**-**	[redacted]	[redacted]	**-**	**-**
Total costs (with optional extras)	**-**	[redacted]	[redacted]	**-**	**-**

Abbreviations: THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

Table 35: Device costs per patient calculated by EAG (12-month contract, assuming 250 procedures each year, noting that this purchase option is not available for ApolloKnee)

Parameter	ApolloKnee	CORI	Mako	ROSA	VELYS
Annual procedure volume	-	250	250	250	250
Rental cost, per patient	-	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for THA, per patient	-	[redacted]	[redacted]	-	-
Consumable costs for TKA, per patient	-	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for UKA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for THA, per patient	-	[redacted]	[redacted]	[redacted]	[redacted]
Implant costs for TKA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for UKA, per patient	-	[redacted]	[redacted]	-	-
CT imaging costs (pre-procedure), per patient	-	-	[redacted]	-	-
Service plan, per patient	-	[redacted]	[redacted]	[redacted]	-
Optional extras, per patient	-	[redacted]	[redacted]	[redacted]	-
Total costs (THA)	**-**	[redacted]	[redacted]	-	-
Total costs (with optional extras)	**-**	[redacted]	[redacted]	-	-
Total costs (TKA)	**-**	[redacted]	[redacted]	[redacted]	[redacted]
Total costs (with optional extras)	**-**	[redacted]	[redacted]	[redacted]	-
Total costs (UKA)	**-**	[redacted]	[redacted]	-	-
Total costs (with optional extras)	**-**	[redacted]	[redacted]	-	-

Abbreviations: FoI, freedom of information; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty

Table 36: Breakdown of cost components (TKA, assuming 12 month contract, and 250 procedures each year, no optional extras)

Cost component	ApolloKnee	CORI	Mako	ROSA	VELYS
Rental	-	[redacted]	[redacted]	[redacted]	[redacted]
Consumables	-	[redacted]	[redacted]	[redacted]	[redacted]
Implant	-	[redacted]	[redacted]	[redacted]	[redacted]
CT imaging (pre-procedure)	-	-	[redacted]	-	-
Service plan	-	[redacted]	[redacted]	[redacted]	[redacted]
Total cost TKA, per patient	-	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: TKA, total knee arthroplasty

Table 37: Additional cost parameters

Parameter	Value	Source	Comment
Procedural cost, primary total knee and primary partial knee	[redacted]	National Schedule of NHS Costs (2021-2022)	[redacted]
Procedural cost, primary total hip	[redacted]	National Schedule of NHS Costs (2021-2022)	[redacted]
Procedural cost, revision knee or hip (no diagnosis of infection)	[redacted]	National Schedule of NHS Costs (2021-2022)	[redacted] The EAG have assumed that the cost of revision implant is included in this HRG. Three Clinical Experts highlighted the complexity of imaging and healthcare appointments prior to decision of revision. Therefore, the EAG have not included any additional costs associated with additional healthcare appointments prior to revision surgery within the economic model base case. The EAG will consider higher costs of revision within sensitivity analysis.
Procedural cost, revision knee or hip (infection)	[redacted]	National Schedule of	[redacted] The EAG have assumed that the cost of revision implant is included in this HRG. Three Clinical

Parameter	Value	Source	Comment
		NHS Costs (2021-2022)	Experts highlighted the complexity of imaging and healthcare appointments prior to decision of revision. Therefore, the EAG have not included any additional costs associated with additional healthcare appointments prior to revision surgery within the economic model base case. The EAG will consider higher costs of revision within sensitivity analysis.
Length of stay, bed day cost (per day)	[redacted]	NHS Reference Costs 2017-2018	[redacted]
Pre-operative CT scan knee or hip (robotic surgery only)	[redacted]	National Schedule of NHS Costs (2021-2022)	[redacted]

Abbreviations: EAG, External assessment group; HRG, Health Resource Group;

9.2.3 Health state utilities

Utilities were reported in all but one of the economic studies using Markov models described previously. The values for utilities associated with TKA, UKA and THA and revision, and temporary disutilities for 12 months, associated with revision used in the EAG economic model are described in Table 38. Differences in utilities between arms were obtained from 2 RCTs and 1 prospective cohort study with adjustment of confounding variables across arms. All values of utilities were derived from studies using the Mako system. The EAG considered that utilities were unlikely to differ much between robotic systems, although acknowledge that this is a limitation and differences might exist due to differences between the technologies, although such data is currently unavailable. The EAG has noted this as an evidence gap which could be addressed in the future (see section 11).

Table 38: Health state utilities and disutilities

Parameter	Model arm	Value	Source	Comment
Total knee replacement				
EQ-5D, mean (SD)	Conventional surgery	1 year, mean (95%CI): 0.752 (0.646 to 0.857)	Used in the economic model by (Clement et al., 2024) Pre-operative, n=38 patients: 0.476 (0.275) Differences from baseline: 2 months, n=41: 0.228 (0.263) 6 months, n=41: 0.232 (0.311) 12 months, n=38: 0.276 (0.331)	The RCT by Clement et al. 2024 showed no evidence of a statistical difference in EQ-5D-3L at 1 year, although the sample size was small. Because there is no data beyond 1 year, this value is used for the duration of a patient's stay in the 'primary surgery' and 'well after primary' states.
EQ-5D, mean (SD)	Mako	1 year, mean (95%CI): 0.750 (0.661 to 0.838)	Used in the economic model by (Clement et al., 2024) Pre-operative, n=43 patients: 0.458 (0.296) Differences from baseline: 2 months, n=46: 0.283 (0.316) 6 months, n=46: 0.240 (0.338) 12 months, n=43: 0.292 (0.297)	As above. For simplicity, the EAG have applied only full year utilities in the model. That is, utilities at 2 and 6 months have not been used, and the 1 year utilities have been applied for each of the twelve monthly cycles. Because there is no data beyond 1 year, this value is used for the duration of a patient's stay in the 'primary surgery' and 'well after primary' states.
Utility (tool not reported)	Conventional surgery, robotic surgery (Mako)	Post-revision: 0.565	Used in the economic model by (Clement et al., 2019), reported in text as an average from (Slover et al., 2006), (Slover et al., 2008) and (Moschetti et al., 2016)	Assumed TKA revised with further TKA has the same post-revision utility as UKA revised with TKA. This value is used for the duration of a patient's stay in the 'well after revision' state, and is used with the utility decrement below applied to it in the 'post-revision' state.
Utility (tool not reported)	Conventional surgery, Robotic surgery (Mako)	Septic revision: -0.2 for 12 months Aseptic revision: -0.1 for 12 months	Used in the economic model by (Clement et al., 2019), reported as being from (Slover et al., 2006), and (Moschetti et al., 2016)	Applied to UKA and TKA arm in Clement 2019. This value is used in the 'post-revision' state to adjust the utility used in the 'well after revision' state.
Partial knee replacement				
EQ-5D, mean (SD)	Conventional surgery	1 year, mean (95%CI): 0.728 (0.658 to 0.798) 2 years, mean (95% CI): 0.746 (0.682 to 0.809) 5 years, mean (95%CI): 0.729 (0.652 to 0.805)	Used in economic model by (Clement et al., 2023) Pre-operative: 0.427 (0.295) 3 months: 0.644 (0.261) 1 year, n=49 patients: 0.728 (0.250) 2 years, n=49 patients: 0.746 (0.228) 5 years, n=49 patients: 0.729 (0.273)	The RCT by Clement et al. 2023 showed no evidence of a differences in EQ-5D-3L at any timepoint, although the sample size was small. For simplicity, the EAG have applied only full year utilities in the model. That is, utilities at 3 months have not been used, and the 1 year utilities have been applied for each of the twelve monthly cycles in year 1. The 2 year values are used in years 2, 3 and 4, and because there is no data beyond 5 years, this value is then used for the rest of a patient's stay in the 'well after primary' state. Sensitivity analysis will use data by Banger et al. 2021, with 5 year data of 0.80 [0.69, 1.00]. The RCT by Banger et al. 2021 also showed no evidence of a difference in EQ-5D at 5 years.
EQ-5D, mean (SD)	Mako	1 year, mean (95%CI): 0.744 (0.673 to 0.814) 2 years, mean (95% CI): 0.749 (0.675 to 0.822) 5 years, mean (95%CI): 0.704 (0.620 to 0.787)	Used in economic model by (Clement et al., 2023) Pre-operative: 0.466 (0.297) 3 months: 0.713 (0.241) 1 year, n=55 patients: 0.744 (0.266) 2 years, n=55 patients: 0.749 (0.279) 5 years, n=55 patients: 0.704 (0.315)	As above. Sensitivity analysis will use data by Banger et al. 2021, with 5-year data in Mako RIO arm of 0.720 [0.587, 1.000]. The RCT by Banger et al. 2021 also showed no evidence of difference in EQ-5D at 5 years.

Parameter	Model arm	Value	Source	Comment
Utility (tool not reported)	Conventional surgery, Robotic surgery (Mako)	Post-revision: 0.565	Used in the economic model by (Clement et al., 2019), reported in text as an average from (Slover et al., 2006), (Slover et al., 2008) and (Moschetti et al., 2016)	Post-revision utility assumed from UKA revised with TKA. This value is used for the duration of a patient's stay in the 'well after revision' state, and is used with the utility decrement below applied to it in the 'post-revision' state.
Utility (tool not reported)	Conventional surgery, Robotic surgery (Mako)	Septic revision: -0.2 for 12 months Aseptic revision: -0.1 for 12 months	Used in the economic model by (Clement et al., 2019), reported as being from (Slover et al., 2006), and (Moschetti et al., 2016)	Applied to UKA and TKA arm in Clement 2019. This value is used in the 'post-revision' state to adjust the utility used in the 'well after revision' state.
Total hip				
EQ-5D, mean (SD)	Conventional surgery	1 year, mean (95%CI): 0.754 (0.731 to 0.776)	Used in the economic model by (Clement et al., 2022) Pre-operative, n=512 patients: 0.384 (0.320) Post-operative (6-12 months): 0.754 (0.263)	Prospective cohort (with propensity matching) adjusting for differences in sex, age, preoperative PROMs). Used EQ-5D-3L.
EQ-5D, mean (SD)	Mako	1 year, mean (95% CI): 0.845 (0.740 to 0.949)	Used in the economic model by (Clement et al., 2022) Pre-operative, n=48 patients: 0.384 (0.320) Post-operative (6-12 months): change in EQ-5D 0.091 (0.009 to 0.173)	Prospective cohort (with propensity matching adjusting for differences in sex, age, preoperative PROMs). Used EQ-5D-3L, sample size small in robotics arm.
EQ-5D, mean (SD)	Conventional surgery	Post-revision, mean (95%CI): 0.754 (0.731 to 0.776)	EAG assumption	The EAG found no data for post-revision utilities in THA, so assumed that post-revision utility is the same as post-primary surgery utility. This value is used for the duration of a patient's stay in the 'well after revision' state and is used with the utility decrement below applied to it in the 'post-revision' state.
EQ-5D, mean (SD)	Mako	Post-revision, mean (95% CI): 0.845 (0.740 to 0.949)	EAG assumption	The EAG found no data for post-revision utilities in THA, so assumed that post-revision utility is the same as post-primary surgery utility. This value is used for the duration of a patient's stay in the 'well after revision' state and is used with the utility decrement below applied to it in the 'post-revision' state.
Utility (tool not reported)	Conventional surgery, Robotic surgery (Mako)	Septic revision: -0.2 for 12 months Aseptic revision: -0.1 for 12 months	Used in the economic model by (Clement et al., 2019), reported as being from (Slover et al., 2006), and (Moschetti et al., 2016)	Applied to UKA and TKA arm in Clement 2019, assume also applicable to total hip procedures. This value is used in the 'post-revision' state to adjust the utility used in the 'well after revision' state.

Abbreviations: CI, confidence interval; RCT, Randomised controlled trial; SD, Standard deviation; TKA, Total Knee Arthroplasty; UKA, Unicompartmental Arthroplasty.

9.2.4 Approach to analysis

The EAG developed a Markov model in R, using the '*rdecision'* package, to carry out cost-utility analysis reporting net benefit at the willingness to pay threshold of £20,000 per QALY gained. Using the best available evidence, the EAG modelled (or calculated costs for) all technologies using utilities from the Mako technology for total and partial knee arthroplasty, and total hip arthroplasty procedures. Other clinical parameters were the same between robotic and conventional surgery, including revision rate, mortality, length of stay, procedure time. Only technology costs were different between robotic systems. The EAG then conducted threshold analysis to explore the difference in utilities that would enable the Mako robotic system to be cost-effective at a WTP of £20,000.

To explore uncertainties further the EAG also conducted the following sensitivity analysis for the Mako base case only:

- Capital purchase option applied instead of rental.
- Rental option based on 400 procedures a year.
- Cost of the primary procedure (via HRG codes) increased by 10% to account for Best Practice Tariff. This was not applied to revision procedures.
- Cost of the implant in the robotic arm changed to the upper and lower limit (as provided by Stryker), noting that because these are not broken down by procedure type, they reflect the absolute minimum and maximum values possible for implant cost, with more favourable results expected for procedures using the cheaper implants.
- Length of stay: reduce length of stay in robotic arm by 10%, 20%, 30% when compared with conventional surgery to cover plausible limits advised by Clinical Experts.
- Utility gain using alternative values from published literature (Banger et al., 2021), UKA only.
- Zero revisions in the robotic arm.

- A plausible best case, combining 20% reduction in revisions, 20% reduction in length of stay, and use of the cheapest possible implant, in the robotic arm.

Two-way analysis was also conducted for combinations of revision rate, procedural volume and per-patient technology costs, to identify the parameter values that resulted in an ICER below the £20,000 WTP threshold.

9.3 Results from the economic modelling

9.3.1 Base case

Results from the base case comparing robotic systems with conventional surgery for TKA, UKA and THA are reported in Table 39. In TKA procedures, costs accrued in the first year accounted for 94.6% of overall costs for conventional procedures, versus 95.2% of overall costs for robotic procedures. In UKA, with a higher revision rate, the first-year costs were only 77.8% of the total for conventional procedures, and 79.8% for robotic procedures. In THA, costs in the first year were 92.4% of overall costs for conventional procedures, versus 93.0% for robotic procedures. The results show that robotic surgery in TKA and UKA was dominated by conventional surgery which was because of fewer total QALYs gained in the robotic arm. For context, the difference in QALYs between robotic and conventional surgery be equivalent [redacted] (range between [redacted], and [redacted]) in full health for TKA performed robotically. For UKA, the difference in QALYs is equivalent to [redacted] (range [redacted] and [redacted]) in full health, for RAS. For THA, this value would be [redacted] with a range between [redacted] and [redacted] in full health. It is important to note that these results are limited because only utility values were different between conventional and robotic surgery (with revision rates and mortality the same across arms), which may explain why authors of published evidence have concluded that RAS using Mako is cost-effective, whereas the EAG, based on their modelling results, have not. The EAG notes that the point estimates lie in a region of the cost effectiveness plane close to the y axis (small differences in QALYs) and not far from the x axis (relatively small differences in costs), where being “dominated” or “dominant” is strongly influenced by

uncertainties in model parameters. The EAG have used this base case only to illustrate the impact of other changes when exploring uncertainty in later sensitivity analysis.

The EAG note that only the point estimate of robotic THA appears cost-effective at a willingness to pay threshold (WTP) of £20,000, however this was not the case when the lower confidence interval of utilities was applied in the economic model. The EAG note that the lack of cost-effectiveness demonstrated for TKA and UKA is likely because of the utility values used. The limitations of the utility data are reported in detail in section 5 (for each device) and section 9.2.3. The cost-effectiveness point estimate for THA was close to the willingness to pay threshold, but with utility values from a study of lower quality design, the certainty of these conclusions is limited. Also, the post-utility revision for THA was assumed to be the same as after the primary procedure, due to lack of utility data for THA revision; which may overestimate the QALYs gained. The EAG also note that when upper and lower confidence intervals of utilities were applied in the base case, this resulted in marked changes in the ICER, with the robotic arm changing from being dominated to nearly dominant, as the ICERs obtained using extreme values from the confidence intervals can be substantially lower than a £20,000 threshold value. The EAG note that in addition to the differences in study design, the studies had sample sizes too small to detect a statistical difference, and the assumptions made by the EAG explains the observed difference in total QALYs associated with the partial and total knee replacement and hip replacement procedures. Therefore, the EAG would consider these base case results as simply demonstrating the model sensitivity to changes in utility. Future larger, controlled comparative studies capturing utilities would reduce uncertainties in this area.

9.3.2 Sensitivity analysis

From threshold analysis, if the cost of the robotic system was held fixed as in the base case, a difference in total QALYs of [redacted] (CORI), [redacted] (Mako), [redacted] (ROSA Knee), and [redacted] (VELYS) over an average patient lifetime between robotic and conventional surgery would be required for the robotic technologies to be cost-effective for TKA at a willingness to pay (WTP) threshold of £20,000. A larger difference in total QALYs of [redacted] (CORI), [redacted] (Mako) between robotic and conventional surgery is required for the

robotic system to be cost-effective in UKA. Using the currently available data, the EAG question the clinical meaningfulness of the magnitude of these QALY differences over a lifetime time horizon. However, the EAG also notes that the available utility data is sparse and imprecise.

The results of the univariate sensitivity analysis for TKA, UKA and THA when considering the Mako device only are summarised in Table 40, Table 41 and Table 42 respectively. Changes to the upper implant cost (as provided by Stryker) made the greatest proportional change to the incremental cost across all 3 procedures.

The EAG note that the sensitivity analyses show that absolute changes in costs and QALYs over a lifetime time horizon from the base case are small, highlighting that the sensitivity of the economic model to initial procedural costs which contribute most of the total costs. Similar trends were observed across all 3 orthopaedic procedures. This further highlights the need for better understanding of consumables, implant and pathway costs which may differ between robotic and conventional surgery in an NHS setting.

The EAG included utilities from (Banger et al., 2021), in UKA, in the sensitivity analysis which resulted in an incremental difference in QALYs of -1.098 when compared with conventional surgery over a lifetime time horizon. Utilities in the robotic arm were greater than in the conventional arm, only when revision rate was set to 0%. Whilst revisions are rare, the EAG acknowledge that this scenario is clinically implausible, however this sensitivity analysis does demonstrate that in the current analysis, revisions have little impact on the difference in average QALYs over a lifetime. Additional utility decrements associated with adverse events could be considered if differences between robotics and conventional orthopaedic procedures were identified; however, the EAG acknowledge that severe adverse events are rare, and that small comparative studies are unlikely to be powered to detect statistical differences in rare complication outcomes.

The EAG also considered a combination of multiple sensitivity analysis, reflecting a best plausible case, to determine the impact on outcome. This case assumed a 20%

reduction in revisions, and length of stay, in the robotic arm compared with conventional surgery, and that the cheapest possible implant was used. For TKA and UKA, although per patient costs were similar in the robotic and conventional arms, the robotic arm was still dominated because of a decrease in QALYs. For THA, the robotic arm achieved a lower cost per patient when compared with the conventional arm, therefore dominating conventional surgery.

Table 39: Base case results (noting that ApolloKnee is omitted because a leasing option is not available, and SkyWalker is omitted because the Company did not provide any costing information)

*[Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *]*

	Total costs, per patient	Total QALY, per patient	Difference in cost (compared with conventional)	Difference in QALY (compared with conventional) [difference when using the lower and upper confidence interval of utilities]	Incremental cost effectiveness ratio (ICER) [difference when using the lower and upper limit of utilities]
Total knee arthroplasty					
Conventional	[redacted]	8.406 [7.243, 9.559]	-	-	-
Robotic: CORI	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	**Dominated** [**Dominated**, [redacted]*]
Robotic: Mako	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	**Dominated** [**Dominated**, [redacted]*]
Robotic: ROSA	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	**Dominated** [**Dominated**, [redacted]*]
Robotic: VELYS	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	**Dominated** [**Dominated**, [redacted]*]
Partial knee arthroplasty					
Conventional	[redacted]	10.998 [9.982, 12.001]	-	-	-
Robotic: CORI	[redacted]	10.769 [9.654, 11.869]	[redacted]	-0.229 [-1.343, 0.872]	**Dominated** [**Dominated**, [redacted]*]
Robotic: Mako	[redacted]	10.769 [9.654, 11.869]	[redacted]	-0.229 [-1.343, 0.872]	**Dominated** [**Dominated**, [redacted]*]
Total hip arthroplasty					
Conventional	[redacted]	9.871 [9.569, 10.159]	-	-	-
Robotic: CORI	[redacted]	11.063 [9.687, 12.426]	[redacted]	1.192 [-0.183, 2.555]	[redacted]* [**Dominated**, [redacted]*]
Robotic: Mako	[redacted]	11.063 [9.687, 12.426]	[redacted]	1.192 [-0.183, 2.555]	[redacted]* [**Dominated**, [redacted]*]

Abbreviations: QALY, quality-adjusted life years.

Table 40: Results of sensitivity analysis for TKA (Mako)

*[Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *]*

Changes to economic model	Robotic: Total costs, per patient	Robotic: Total QALY, per patient	Conventional: Total costs, per patient	Conventional: Total QALY per patient	Incremental cost (% of robotic total cost)	Incremental QALY	Incremental cost effectiveness ratio (ICER)
Base case: rental option (assuming 250 per year)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Capital purchase option (assuming 250 per year)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Rental option (assuming 400 per year)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.022	**Dominated**
HRG costs increased by 10% to account for Best Practice Tariff	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Lower limit of implant costs, [redacted] (robotic arm)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Upper limit of implant costs, [redacted] (robotic arm)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Length of stay reduced by 10% (robotic arm)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Length of stay reduced by 20% (robotic arm)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Length of stay reduced by 30% (robotic arm)	[redacted]	8.385	[redacted]	8.406	[redacted]	-0.021	**Dominated**
Zero revisions (robotic arm only)	[redacted]	8.442	[redacted]	8.406	[redacted]	0.036	[redacted]*
Combination of 20% reduction of revisions, 20% reduction in LoS, and lower limit of implant costs	[redacted]	8.396	[redacted]	8.406	[redacted]	-0.010	**Dominated**

Abbreviations: QALY, quality-adjusted life years; TKA, total knee arthroplasty

Table 41: Results of sensitivity analysis for UKA (Mako)

*[Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *]*

Changes to economic model	Robotic: Total costs, per patient	Robotic: Total QALY, per patient	Conventional: Total costs, per patient	Conventional: Total QALY per patient	Incremental cost (% of robotic total cost)	Incremental QALY	Incremental cost effectiveness ratio (ICER)
Base case: rental option (assuming 250 per year)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Capital purchase option (assuming 250 per year)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Rental option (assuming 400 per year)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
HRG costs increased by 10% to account for Best Practice Tariff	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Lower limit of implant costs, [redacted] (robotic arm)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Upper limit of implant costs, [redacted] (robotic arm)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Length of stay reduced by 10% (robotic arm)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Length of stay reduced by 20% (robotic arm)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Length of stay reduced by 30% (robotic arm)	[redacted]	10.769	[redacted]	10.998	[redacted]	-0.229	**Dominated**
Utility difference from Banger et al. 2021 applied	[redacted]	10.830	[redacted]	11.928	[redacted]	-1.098	**Dominated**
Zero revisions (robotic arm only)	[redacted]	11.036	[redacted]	10.998	[redacted]	0.038	**Dominant**
Combination of 20% reduction of revisions, 20% reduction in LoS, and lower limit of implant costs	[redacted]	10.818	[redacted]	10.998	[redacted]	-0.180	**Dominated**

Abbreviations: QALY, quality-adjusted life years; UKA, unicompartmental knee arthroplasty

Table 42: Results of sensitivity analysis for THA (Mako)

*[Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *]*

Changes to economic model	Robotic: Total costs, per patient	Robotic: Total QALY, per patient	Conventional: Total costs, per patient	Conventional: Total QALY per patient	Incremental cost (% of robotic total cost)	Incremental QALY	Incremental cost effectiveness ratio (ICER)
Base case: rental option (assuming 250 per year)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Capital purchase option (assuming 250 per year)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Rental option (assuming 400 per year)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
HRG costs increased by 10% to account for Best Practice Tariff	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Lower limit of implant costs, [redacted] (robotic arm)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Upper limit of implant costs, [redacted] (robotic arm)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Length of stay reduced by 10% (robotic arm)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Length of stay reduced by 20% (robotic arm)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Length of stay reduced by 30% (robotic arm)	[redacted]	11.063	[redacted]	9.871	[redacted]	1.192	[redacted]*
Zero revisions (robotic arm only)	[redacted]	11.072	[redacted]	9.871	[redacted]	1.201	**Dominant**
Combination of 20% reduction of revisions, 20% reduction in LoS, and lower limit of implant costs	[redacted]	11.065	[redacted]	9.871	[redacted]	1.194	[redacted]*

Abbreviations: QALY, quality-adjusted life years; THA, total hip arthroplasty

9.3.3 Limitations of economic modelling

Key limitations considered by the EAG include:

- Utilities included in the economic model were for the Mako robotic system only, because there was no evidence of differences in utilities in the evidence prioritised for the other technologies. The EAG acknowledge that differences in technology features may lead to differences in utilities between robotic systems. As evidence becomes available for the other technologies, this should be considered.
- Utility data were derived from RCTs for TKA and UKA procedures, and a prospective cohort study with propensity matching for THA. Furthermore, due to lack of data in THA, the same utility after revision was applied as after the primary surgery, which may inflate results and explain the differences between procedures modelled.
- Revision and mortality data was taken from the NJR 20th Annual Report and was aggregated across all robotic devices and considered the same between robotic and conventional surgery. However, the EAG would consider that the economic model could be rerun for other procedures and other robotic systems when additional data becomes available.
- The economic model does not explicitly account for differences in accuracy of implant or differences in range of motion, gait analysis or time to return to normal function between robotic and conventional surgery. However, both aspects would contribute to changes in EQ-5D scores; acknowledging that EQ-5D, whilst being the preferred tool for NICE may be relatively insensitive to small changes in health and it can be difficult to capture changes in health within a trial that are of short duration or occur unpredictably. The EQ-5D scores have been incorporated into an economic evaluation but these come from small RCTs, or prospective cohort studies with matching in the case of THA, and hence are imprecise and potentially unreliable as even modest amounts of additional data could change both point estimates and distributions. There is currently no randomised evidence available which demonstrates a difference in EQ-5D

between arms, but study sample sizes have been small and confidence intervals in EQ-5D wide which could include economically important differences favouring either robotic or conventional surgery. Additional information on utilities from a larger population would reduce this uncertainty in future economic modelling. Furthermore, in the economic model the EAG used utility values at 1 yearly intervals, where available, but these data do not reflect any difference in speed of recovery following surgery. Further data over the post-surgery recovery period is needed.

- The economic model does not account for incidental pathological discoveries from additional CT imaging, which is required for Mako device only, that would otherwise have been missed. The incidence and relevance of this is currently unclear.

- The economic model does not account for changes in quality of life for the operating staff. Robotic systems reducing the physical burden of operators in orthopaedic procedures was highlighted by Clinical Experts at the Scoping Workshop as potentially leading to a longer surgical career.

- The economic model does not account for NHS system benefits of robotic systems in expanding capacity of joint replacement surgeries, the impact on current NHS waiting lists or reduction in variation amongst surgeons or centres. This would need a different model for the economic evaluation.
- The economic model also does not consider the additional staff time costs associated with operating room staff attending training and maintaining their competency; noting that additional training may be needed for systems that use pre-operative analysis of image-based plans, and ongoing training needed as teams change.
- Due to the current robotic systems being considered ‘closed’, that is only compatible with implants from the same manufacturer, there were differences in implant costs applied for conventional and robotic surgery arms in the economic model. One Clinical Expert also advised of potential efficiency savings

associated with not requiring as many manual knee systems. Future audits across multiple centres could explore uncertainties in implant and consumable costs across both arms.

- Conversion from robotic to manual surgery was not included in economic model. This outcome was not captured by NJR nor in any of the published literature identified. Clinical Experts advised the EAG that in their experience this would be a very rare event. Future analysis of national databases including routine administrative databases could quantify frequency and costs associated with this adverse event and others such as dislocation, blood loss and transfusion rates, where data is available.
- Other limitations to consider are the lack of probabilistic sensitivity analysis so there is no full exploration of statistical imprecision in the model inputs. This in part also reflects that distributions based upon existing data may be not accurately reflect the full level of imprecision as in many cases too few data are available and even relatively modest amounts of additional data could change both point estimates and distributions. To compensate for this the EAG have explored key uncertainties across a range of sensitivity analysis.

9.4 Summary and interpretation of the economic modelling

The EAG considered the randomised evidence available, data from NJR and 5 published economic evaluations conducted in a UK setting to develop a Markov model with a general structure that was applied to TKA, UKA and THA procedures. The base case model was populated using clinical evidence and utilities from Mako due to lack of available data for other technologies, highlighting that the only difference between robotic technologies included in this report was the technology costs per patient. For all technologies, the base case assumed a 5-year lease purchase option assuming 250 procedures per year. Length of hospital stay, revision rate and mortality were assumed to be the same between robotic and conventional surgery arms because no robust evidence from the UK was identified to suggest differences in these outcomes; however these assumptions limited the ability of the economic model to demonstrate benefits of

robotics. Due to uncertainties, the EAG conducted a range of sensitivity analysis. The analysis showed that the model was sensitive to changes in short term in-hospital costs associated with the initial orthopaedic joint replacement procedure which made up most of the total costs accrued over a lifetime time horizon. Specifically changes in implant costs had the largest impact, which is relevant to the decision problem as each robotic system can only be used with compatible prosthesis from the same manufacturer, and the implant cost contributed 45% to 76% of the technology costs. Additional sensitivity analysis demonstrated that annual procedure volume of a hospital is important as this reduces the per patient costs of robotics. Across the 3 procedures in scope, an additional 150 robotic procedures each year reduces the cost per patient by [redacted]. A greater [redacted] per patient is achieved by using a capital purchase option; assuming 250 procedures each year, this is [redacted] than the rental option. The EAG note that a lease purchasing option is negotiated based on annual procedure volumes which may vary across hospitals. When applying the upper and lower confidence intervals of utilities from RCTs in the economic model, the incremental cost effectiveness ratio changed direction from dominated to almost being dominant, as the ICER calculated is very low. This is a consequence of small comparative studies, with wide confidence intervals, and highlights that larger studies of utilities across all technologies are needed.

The base case model assumed no difference in revision or mortality, an approach which is justified from the evidence identified. However, should differences in adverse events exist between arms this would result in both cost and utility differences. Linkage of the NJR to the PROMs data (as collected by NHS Digital) may also support future analysis to determine whether there are differences in utilities between robotic and conventional surgery. Given the lack of data on adverse events, data from the UK National Joint Registry, with potential linkage to Hospital Episode Statistics would help to identify differences in adverse event rates. Should such data become available their impact on cost-effectiveness should be explored. However, due to learning curve of theatre staff and different patient selection between robotic and conventional surgery

whilst learning, all future economic analysis should use data from studies where patient baseline characteristics are matched between arms.

10. Integration into the NHS

The data from the NJR suggests that use of RAS in orthopaedics is increasing over time (see Section 3). Practical considerations from the EAG in reviewing the published literature, and from Clinical Experts include:

- all robotic systems being 'closed' such that they are only compatible with implants from the same manufacturer. Whilst volume-based contracts reduce the immediate cost to hospitals, stating a fixed number of procedures within volume-based contracts may limit implant variety, patient access and fair competition,
- the ability for robotic systems to decrease physical and cognitive burden for operators, with ergonomic and career longevity outcomes which cannot be easily captured in the literature. It is plausible that a reduction in physical burden for operating staff, and increased planning with systems using pre-operative imaging could provide theatre slot efficiencies and enable additional procedures over time,
- the size of the robotics system when considering currently available operating theatre space,
- the mobility of the robot, which may be shared between multiple theatres, this should be considered when discussing feasibility of annual procedure volumes,
- the need for pre-operative CT imaging for the Mako system, for example whether a lead-lined theatre room is needed and consideration of the additional radiation exposure for patients and staff,
- training requirements have been outlined, see Section 2.2, with the learning curve in the literature stated as approximately 7 procedures, Company recommendations ranged between 10 and 30 procedures, and one Clinical Expert estimated approximately 10 procedures. One Clinical Expert advised that the overall learning curve was less for partial knee replacement than total hip or total knee replacement. Two Clinical Experts advised that the learning curve was

expected to be similar across robotic systems, two Clinical Experts felt that there would be an expected difference in learning curve between systems one noting the requirement of pre-operative analysis of the image-based plan, and two Clinical Experts reported that differences in learning curve between systems was currently unknown.

- the impact on trainee development of manual skill set which is still needed for surgeries, maintaining competency in conventional surgery considering that robotic surgeries can convert to manual in some clinical and emergency situations, and staff time required for training and maintaining competency in robotic surgery. Clinical Experts advised that competency for conventional surgery is through peer-review, local audit, possibly at trust and surgeon level, and national audit through the NJR figures on revision, mortality, and PROMs. Clinical Experts advised that competency for robotic surgery would be similar, and may additionally include training programmes for example online, face-to-face, cadaveric, in theatre, refresher course and a minimum number of cases to maintain skill.

Guidance from Royal College of Surgeons of England (Royal College of Surgeons of England, 2023) and the Robotic And Digital Assisted suRgery (RADAR) working group (RCS MSK RADAR Working Group, 2024) discuss training pathways when implementing robotic technologies in the NHS.

11. Evidence gap analysis

11.1 Summary and conclusions of evidence gap analysis

Referring to the decision problem, a number of evidence gaps have been identified by the EAG. Key gaps included:

Population gaps:

- Lack of randomised evidence for total hip replacement.
- No evidence on shoulder replacement using robotics systems in scope.
- Lack of evidence in revision procedures, however only CORI is indicated for revision TKA and ROSA Knee is explicitly contraindicated for revision surgery.

Intervention gaps:

- No UK evidence for ApolloKnee, ROSA Knee, SkyWalker or VELYS robotic systems.
- No randomised evidence or prospective cohort studies with matched comparator arm to account for differences in baseline patient characteristics (within the last 5 years) for ApolloKnee, SkyWalker or VELYS robotic systems.

Outcome gaps:

- Availability of evidence for primary outcomes is summarised in Table 43.
- Lack of evidence of utility outcomes, including comparative utilities relative to conventional surgery, for ApolloKnee, CORI, ROSA knee, SkyWalker and VELYS technologies; requiring reliance on utility data from Mako to populate economic models. Studies reporting utilities using Mako were of small sample size, and observed differences in utilities were small; additional information on utilities from a larger population would reduce the uncertainty.

- Lack of reported adverse events in UK setting, for example conversion to manual surgery, dislocation, which may be rare events and difficult to capture in randomised studies.
- Lack of reporting of procedure duration and total theatre time; not captured in NJR or HES; which may support future economic evaluations considering the number of patients in a theatre list per day, and the feasibility of RAS increasing the cases per week or month.
- Limited comparative evidence for reduction in physical stress and strain on surgeons and theatre staff for RAS versus conventional surgery, which may support future economic evaluations which include the capacity of surgical units.
- Clarity is needed on how many times the robotic system is used, as this will influence the cost per patient.
- Lack of reporting of length of stay; not captured in NJR but is captured in HES.
- Lack of randomised evidence to determine whether there are differences in subsequent physiotherapy appointments, or readmission within 30 days between arms.

Other considerations:

- The published economic evaluations based on real world evidence had to adjust for observed differences in patient characteristics between RAS and conventional surgery arms. Therefore, future analysis should account or adjust for differences in population characteristics between RAS and conventional surgery.
- The National Joint Registry (NJR) captures procedural information of conventional and robotic knee and hip replacement. NJR also records the specific robotic systems used. The NJR also routinely links to NHS Personal Demographics Service twice per year to get data for revision surgery and mortality outcomes. This may support future analysis

including surveillance of uptake in the NHS, and longitudinal analysis of outcomes.

- PROMs data is recorded by NHS Digital for knee and hip replacement. This data should be linked to NJR data to support future analysis to determine cost-effectiveness of robotic systems used in the NHS.
- Multiple cost components were provided by the manufacturers, with uncertainty in implant and consumable costs, for conventional and robotic arms, due to negotiations based on procedural volume and contract duration.

Table 43: Availability of evidence for primary outcomes across 26 included studies

Device: procedure	PROMs	Complications	Learning curve	Revision Surgery	Operating time
ApolloKnee: TKA	RED	RED	GREEN	RED	AMBER
CORI: TKA	GREEN	GREEN	GREEN	GREEN	GREEN
Mako: TKA	GREEN	GREEN	GREEN	GREEN	GREEN
ROSA Knee: TKA	GREEN	GREEN	GREEN	GREEN	RED
SkyWalker: TKA	AMBER	AMBER	RED	RED	AMBER
VELYS: TKA	AMBER	AMBER	GREEN	RED	AMBER
CORI: UKA	RED	GREEN	RED	RED	RED
Mako: UKA	GREEN	GREEN	RED	GREEN	RED
CORI: THA	RED	RED	RED	RED	RED
Mako: THA	GREEN	RED	GREEN	RED	RED

Key: **GREEN** RCT or comparative observational study with matched baseline characteristics (or single-arm study for learning curve outcome only); **AMBER** comparative observational study with unmatched baseline characteristics. **RED** single-arm only or no evidence. Abbreviations: THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental arthroplasty

11.2 Key areas for evidence generation

Considering the quality and quantity of evidence identified (see Table 6, Table 43), the EAG considered 9 specific evidence generation recommendations in Table 44. Suggestions 1 to 4 are related to effectiveness, safety and cost-effectiveness. Suggestions 5 to 9 are related to service delivery and organisation of care to better explore the costs associated with implementing robotics in the NHS.

Table 44: Evidence generation recommendations

#	Research question	Recommended study design	Outcomes
1	Are ApolloKnee, SkyWalker, VELYS clinically effective and cost-effective in a UK setting?	RCT or prospective real-world evaluation with matching of patient characteristics between arms, in a UK setting	Key outcomes
2	Is there a difference in revision rate (implant survivorship), mortality or other adverse events (conversion to manual, dislocation) between robotic technologies (ApolloKnee, CORI, Mako, ROSA Knee, SkyWalker, VELYS) and conventional procedures longitudinally?	NJR linked to HES with longer follow-up with case-mix adjustment, to account for differences between robotic and conventional surgery population differences, across a national population to capture the rare events. Revision rates could be reported by device by the NJR, in a similar way to the AOANJRR 2024 annual report.	Revision or failure rates, mortality, conversion to manual surgery, dislocation
3	Is there a difference in patient utility between robotic technologies (ApolloKnee, CORI, Mako, ROSA Knee, SkyWalker, VELYS) and conventional procedures longitudinally?	As part of an RCT if one is conducted for clinical effectiveness purposes or alternatively using a longitudinal follow-up of patients conducted either prospectively or retrospectively, if data allow, with matching of patient characteristics between arms, with longer follow-up	Disease-specific and generic HRQoL tools
4	Is there a difference in quality of life for the surgical staff when implementing robotic technologies (ApolloKnee, CORI, Mako, ROSA Knee, SkyWalker VELYS)?	Real-world evidence supplemented with a stated preference technique like contingent valuation to ask operators the value for the ergonomics benefits of robotic	QoL tools for staff, satisfaction, absences and time away from work
5	What is the annual hospital joint replacement procedure volume, and what number and proportion are conducted with robotic assistance over time?	Longitudinal study using NJR data	Cases per week/month/year Capacity constraints
6	Is the surgical time and total theatre time different between robotic assisted surgery and conventional orthopaedic surgery?	Multi-centre audit	Specific definition of surgical time (skin incision to skin closure) and total theatre time (wheels-in to wheels-out)
7	Is use of robotics changing the proportion of patients undergoing partial or total knee replacement?	Longitudinal study using NJR data	Procedure type over time
8	What cost components differ between conventional and robotic surgery in practice, and what is the variation in these costs? How many times does a single robot get used, for which procedures, and how does this impact on costs?	Multi-centre audit and micro-cost analysis	Implants and consumables used, sterilisation, staff involved with maintenance, procedure duration, length of stay, frequency of use of robot
9	What are the clinical and cost implications of revision joint replacement in a UK setting?	Care pathway analysis	Diagnostic imaging used (before and after procedure), healthcare resource usage, readmission rates, A&E attendances, orthopaedic review, physiotherapy sessions, pain team review, GP appointments, walking aids

Abbreviations: HES, Hospital Episode Statistics; NJR, National Joint Registry; RCT, randomised control trial.

12. Conclusions

12.1 Conclusions from the clinical evidence

The EAG prioritised 26 key studies as most relevant to the decision problem. Most evidence included total knee arthroplasty procedures, with Mako having the most robust evidence base (including multiple UK RCTs). Whilst observational studies reported short-term increases in PROMs and utilities, none of the randomised evidence reported a statistically significant difference at 1 or 5 years. None of the robotic systems are currently indicated for shoulder replacement, only CORI is indicated for revision TKA. No differences in adverse events were identified, however small comparative studies were not powered to detect differences in rare outcomes. Broadly, RAS seems clinically non-inferior to conventional TKA surgery. There was a similar trend for UKA, but a lack of randomised evidence in THA.

In terms of relevance to the decision problem, the EAG note that differences between treatment arms were commonly reported in the included evidence, including differences in implant used and surgical technique, which may limit generalisability of results. Key uncertainties included the limited evidence on the effectiveness of ApolloKnee, SkyWalker and VELYS robotic systems, for which RCT and comparative prospective observational studies are lacking.

12.2 Conclusions from the economic evidence

The EAG identified 4 published economic evaluations conducted from a UK perspective which reported robotic orthopaedic surgery to have an incremental cost per QALY of between £1,170 and £13,078. The EAG developed a Markov model, informed by the published economic evaluations, which enabled the EAG to explore the impact of cost and utility changes for the different indications for robotic surgery compared with conventional surgery. For TKA and UKA, all robotic arms were dominated in the base case by the conventional surgery arm, because QALYs per patient were higher in the conventional arm. For THA, the ICERs for robotic surgery were between [redacted] and [redacted], relative to conventional surgery. The main limitation of the model was a lack of data to underpin it, especially in terms of differences in revision and mortality outcomes

between conventional and robotic arms. No high quality comparative evidence from the UK has been found to suggest they are different, which was supported by Clinical Experts, but if differences did exist, they would not be reflected in the model. This is likely to be the main reason why the EAG's results are inconsistent with previously published economic studies, in which fewer revisions have been assumed in the robotic arm. In the EAG's sensitivity analysis, both TKA and UKA were found to be cost-effective when it was assumed that robotic surgery resulted in no revision procedures. Due to the lack of data available for all technologies, only clinical data and utilities for Mako were used; with only technology costs varied for other robotic systems. Key uncertainties include consumable and implant costs which are major contributors to technology costs, and uncertainties in utilities due to small sample size and lack of precision in estimates derived from the available studies.

12.3 Conclusions on the gap analysis

There is a need for further data to understand the variation in procedural and technology costs associated with robotics, including the procedural volume per hospital, use of consumables, implants across the NHS. The EAG only considered rental options for 250 and 400 procedures a year, and a capital purchase option for 250 procedures a year, in their analysis. Further work could consider higher and lower volume centres, further consideration of consumables, and more options of implant price to reflect costs incurred in current NHS usage of robotic systems across the UK. Future data collection should also focus on reducing uncertainties in the clinical effectiveness data and hence in the EAG cost-effectiveness results. Robust effectiveness evidence is missing for some technologies, and additional real-world analysis of the National Joint Registry linked to Hospital Episode Statistics and PROMs, as collected by NHS Digital, may assist with filling these gaps. In addition, a more thorough assessment of impacts on health-related quality of life and estimation of health state utilities to inform the model is needed. Ideally this should come from larger studies to minimise imprecision and maximise generalisability to the NHS patient population and may also consider quality of life of theatre staff.

Future publications should also list the robotic system in the title or abstract to assist with future literature searching.

13. References

Achakri, H., Ben-Shlomo, Y., Blom, A., Boulton, C., Bridgens, J., Brittain, R., Clark, E., Dawson-Bowling, S., Deere, K., Esler, C., Espinoza, O., Evans, J., Goldberg, A., Gregson, C., Hamoodi, Z., Howard, P., Jameson, S., Jones, T., Judge, A., . . . Young, E. (2023). *The National Joint Registry 20th Annual Report 2023*. njrcentre.org.uk. https://www.hqip.org.uk/wp-content/uploads/2023/10/NJR-20th-Annual-Report-2023.pdf

Adamska, O., Modzelewski, K., Szymczak, J., Swiderek, J., Maciag, B., Czuchaj, P., Poniatowska, M., & Wnuk, A. (2023). Robotic-Assisted Total Knee Arthroplasty Utilizing NAVIO, CORI Imageless Systems and Manual TKA Accurately Restore Femoral Rotational Alignment and Yield Satisfactory Clinical Outcomes: A Randomized Controlled Trial. *Medicina (Kaunas, Lithuania)*, *59*(2), 236. https://doi.org/10.3390/medicina59020236

Ajekigbe, B., Ramaskandhan, J., Clement, N., Galloway, S., Gabrov, N., Smith, K., Weir, D., & Deehan, D. (2024). Robotic-arm assisted versus manual total knee arthroplasty: Functional gait analysis from a randomised controlled trial. *Journal of Biomechanics*, *169*, 112112. https://doi.org/https://dx.doi.org/10.1016/j.jbiomech.2024.112112

Alexander, K., Karunaratne, S., Sidhu, V., Fritsch, B., Gupta, S., Horsley, M., Guzman, M., Boyle, R., McBride, K., & Steffens, D. (2024). Evaluating the cost of robotic-assisted total and unicompartmental knee arthroplasty. *J Robot Surg*, *18*(1), 206. https://doi.org/10.1007/s11701-024-01932-8

Ammori, M., Hancock, S., Talukdar, P., Munro, C., & Johnston, A. (2024). Robotic-assisted versus manual total hip arthroplasty: patient-reported outcome measures at 12 months. *Orthopaedic Proceedings*. https://boneandjoint.org.uk/Article/10.1302/1358-992X.2024.4.006

Banger, M., Doonan, J., Rowe, P., Jones, B., MacLean, A., & Blyth, M. J. B. (2021). Robotic arm-assisted versus conventional medial unicompartmental knee arthroplasty: five-year clinical outcomes of a randomized controlled trial. *Bone Joint J*, *103-B*(6), 1088-1095. https://doi.org/10.1302/0301-620X.103B6.BJJ-2020-1355.R2

Banger, M. S., Doonan, J., Jones, B. G., MacLean, A. D., Rowe, P. J., & Blyth, M. J. G. (2022). Are there functional biomechanical differences in robotic arm-assisted bi-unicompartmental knee arthroplasty compared with conventional total knee arthroplasty? A prospective, randomized controlled trial. *Bone and Joint Journal*, *104*(4), 433-443. https://doi.org/https://dx.doi.org/10.1302/0301-620X.104B4.BJJ-2021-0837.R1

Banger, M. S., Johnston, W. D., Razii, N., Doonan, J., Rowe, P. J., Jones, B. G., MacLean, A. D., & Blyth, M. J. G. (2020). Robotic arm-assisted bi-unicompartmental knee arthroplasty maintains natural knee joint anatomy compared with total knee arthroplasty: A prospective randomized controlled trial. *Bone and Joint Journal*, *102 B*(11), 1511-1518. https://doi.org/doi.org/10.1302/0301-620X.102B11.BJJ-2020-1166.R1

Barsoum, W., Gregory, D., Needham, K., Mont, M., Sodhi, N., Coppolecchia, A., & Jacofsky, D. (2023). Advantages of robotic arm-assisted total hip arthroplasty: a 90-day episode-of-care clinical utility and cost analysis. *J Comp Eff Res*, *12*(5), e220208. https://doi.org/10.57264/cer-2022-0208

Burn, E., Prieto-Alhambra, D., Hamilton, T. W., Kennedy, J. A., Murray, D. W., & Pinedo-Villanueva, R. (2020). Threshold for Computer- and Robot-Assisted Knee and Hip Replacements in the English National Health Service. *Value Health*, *23*(6), 719-726. https://doi.org/10.1016/j.jval.2019.11.011

Chen, A. F., Kazarian, G. S., Jessop, G. W., & Makhdom, A. (2018). Robotic Technology in Orthopaedic Surgery. *J Bone Joint Surg Am*, *100*(22), 1984-1992. https://doi.org/10.2106/JBJS.17.01397

Christen, B., Tanner, L., Ettinger, M., Bonnin, M. P., Koch, P. P., & Calliess, T. (2022). Comparative Cost Analysis of Four Different Computer-Assisted Technologies to Implant a Total Knee Arthroplasty over Conventional Instrumentation. *J Pers Med*, *12*(2). https://doi.org/10.3390/jpm12020184

Clement, N. D., Bell, A., Simpson, P., Macpherson, G., Patton, J. T., & Hamilton, D. T. (2020). Robotic-assisted unicompartmental knee arthroplasty has a greater early functional outcome when compared to manual total knee arthroplasty for isolated medial compartment arthritis. *Bone Joint Res*, *9*(1), 15-22.

Clement, N. D., Deehan, D. J., & Patton, J. T. (2019). Robot-assisted unicompartmental knee arthroplasty for patients with isolated medial compartment osteoarthritis is cost-effective: a markov decision analysis. *Bone Joint J*, *101-B*(9), 1063-1070. https://doi.org/10.1302/0301-620X.101B9.BJJ-2018-1658.R1

Clement, N. D., Fraser, E., Gilmour, A., Doonan, J., MacLean, A., Jones, B. G., & Blyth, M. J. G. (2023). Cost-utility analysis of robotic arm-assisted medial compartment knee arthroplasty. *Bone Jt Open*, *4*(11), 889-899. https://doi.org/10.1302/2633-1462.411.BJO-2023-0090.R1

Clement, N. D., Galloway, S., Baron, J., Smith, K., Weir, D. J., & Deehan, D. J. (2024). Patients undergoing robotic arm-assisted total knee arthroplasty have a greater improvement in knee-specific pain but not in function. *Bone Joint J*, *106-B(5)*, 450-459.

Clement, N. D., Gaston, P., Bell, A., Simpson, P., Macpherson, G., Hamilton, D. F., & Patton, J. T. (2021). Robotic arm-assisted versus manual total hip arthroplasty. *Bone Joint Res*, *10*(1), 22-30. https://doi.org/10.1302/2046-3758.101.BJR-2020-0161.R1

Clement, N. D., Gaston, P., Hamilton, D. F., Bell, A., Simpson, P., Macpherson, G. J., & Patton, J. T. (2022). A Cost-Utility Analysis of Robotic Arm-Assisted Total Hip Arthroplasty: Using Robotic Data from the Private Sector and Manual Data from the National Health Service. *Adv Orthop*, *2022*, 5962260. https://doi.org/10.1155/2022/5962260

Cochrane, N. H., Kim, B. I., Stauffer, T. P., Hallows, R. K., Urish, K. L., Carvajal Alba, J. A., & Seyler, T. M. (2024). Revision Total Knee Arthroplasty With an Imageless, Second-Generation Robotic System. *J Arthroplasty*, *39*(8S1), S280-S284. https://doi.org/10.1016/j.arth.2024.02.018

Cool, C. L., Jacofsky, D. J., Seeger, K. A., Sodhi, N., & Mont, M. A. (2019). A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty. *J Comp Eff Res*, *8*(5), 327-336. https://doi.org/10.2217/cer-2018-0136

Cotter, E. J., Wang, J., & Illgen, R. L. (2022). Comparative Cost Analysis of Robotic-Assisted and Jig-Based Manual Primary Total Knee Arthroplasty. *J Knee Surg*, *35*(2), 176-184. https://doi.org/10.1055/s-0040-1713895

Deere, K., Whitehouse, M. R., Kunutsor, S. K., Sayers, A., Mason, J., & Blom, A. W. (2022). How long do revised and multiply revised hip replacements last? A retrospective observational study of the National Joint Registry. *Lancet Rheumatol*, *4*(7), e468-e479. https://doi.org/10.1016/S2665-9913(22)00097-2

Deere, K., Whitehouse, M. R., Kunutsor, S. K., Sayers, A., Price, A. J., Mason, J., & Blom, A. W. (2021). How long do revised and multiply revised knee replacements last? An analysis of the National Joint Registry. *Lancet Rheumatol*, *3*(6), e438-e446. https://doi.org/10.1016/S2665-9913(21)00079-5

Ezeokoli, E. U., John, J., Gupta, R., Jawad, A., & Cavinatto, L. (2023). Index surgery and ninety day re-operation cost comparison of robotic-assisted versus manual total knee arthroplasty. *Int Orthop*, *47*(2), 359-364. https://doi.org/10.1007/s00264-022-05674-w

Fang, C. J., Mazzocco, J. C., Sun, D. C., Shaker, J. M., Talmo, C. T., Mattingly, D. A., & Smith, E. L. (2022). Total Knee Arthroplasty Hospital Costs by Time-Driven Activity-Based Costing: Robotic vs Conventional. *Arthroplasty Today*, *13*, 43-47. https://doi.org/https://dx.doi.org/10.1016/j.artd.2021.11.008

Fary, C., Cholewa, J., Ren, A. N., Abshagen, S., Anderson, M. B., & Tripuraneni, K. (2023). Multicenter, prospective cohort study: immediate postoperative gains in active range of motion following robotic-assisted total knee replacement compared to a propensity-matched control using manual instrumentation. *Arthroplasty*, *5*(1), 62. https://doi.org/10.1186/s42836-023-00216-0

Fontalis, A., Wignadasan, W., Mancino, F., The, C. S., Magan, A., Plastow, R., & Haddad, F. S. (2024). Factors associated with decreased length of stay following robotic arm-assisted and conventional total hip arthroplasty. *Bone Joint J*, *106-B*(3 Supple A), 24-30. https://doi.org/10.1302/0301-620X.106B3.BJJ-2023-0569.R2

Goffin, J., MacRae, E., Farrow, L., Whittaker, D., Dixon, J., Rankin, I., Krishnamurthy, A., & Stevenson, I. (2024). Study on impact of robotic-assisted orthopaedic industrial noise (SIREN). *Arch Orthop Trauma Surg*, *144*(5), 2413-2420. https://doi.org/10.1007/s00402-024-05303-8

Goh, G. S., Haffar, A., Tarabichi, S., Courtney, P. M., Krueger, C. A., & Lonner, J. H. (2022). Robotic-Assisted Versus Manual Unicompartmental Knee Arthroplasty: A Time-Driven Activity-Based Cost Analysis. *J Arthroplasty*, *37*(6), 1023-1028. https://doi.org/10.1016/j.arth.2022.02.029

Gorce, P., & Jacquier-Bret, J. (2023). Effect of Assisted Surgery on Work-Related Musculoskeletal Disorder Prevalence by Body Area among Surgeons: Systematic Review and Meta-Analysis. *Int J Environ Res Public Health*, *20*(14). https://doi.org/10.3390/ijerph20146419

Haffar, A., Krueger, C. A., Goh, G. S., & Lonner, J. H. (2022). Total Knee Arthroplasty With Robotic Surgical Assistance Results in Less Physician Stress and Strain Than Conventional Methods. *Journal of Arthroplasty*, *37*(6 Supplement), S193-S200. https://doi.org/https://dx.doi.org/10.1016/j.arth.2021.11.021

Hasan, M. M., Zhang, M., Beal, M., & Ghomrawi, H. M. K. (2020). An umbrella review comparing computer-assisted and conventional total joint arthroplasty: quality assessment and summary of evidence. *BMJ Surg Interv Health Technologies*, *2*. https://doi.org/10.1136/bmjsit-2019-000016

He, R., Sun, M. L., Xiong, R., Yang, P. F., Lei, K., Liu, L. M., Yang, L., & Guo, L. (2022). A Newly Designed "SkyWalker" Robot Applied in Total Knee Arthroplasty: A Retrospective Cohort Study for Femoral Rotational Alignment Restoration. *Orthopaedic Surgery*, *14*(8), 1681-1694. https://doi.org/https://dx.doi.org/10.1111/os.13365

Hönecke, T., Schwarze, M., Wangenheim, M., Savov, P., Windhagen, H., & Ettinger, M. (2023). Noise exposure during robot-assisted total knee arthroplasty. *Archives of Orthopaedic and Trauma Surgery*, *143*(6), 2813-2819. https://doi.org/https://dx.doi.org/10.1007/s00402-022-04454-w

HSE. (2005). *Control of Noise at Work Regulations*. Retrieved 6 August 2024 from https://www.legislation.gov.uk/uksi/2005/1643/contents/made

Hua, Y., & Salcedo, J. (2022). Cost-effectiveness analysis of robotic-arm assisted total knee arthroplasty. *PLoS One*, *17*(11), e0277980. https://doi.org/10.1371/journal.pone.0277980

Huang, P., Cross, M., Gupta, A., Intwala, D., Ruppenkamp, J., & Hoeffel, D. (2024). Early Clinical and Economic Outcomes for the VELYS Robotic-Assisted Solution Compared with Manual Instrumentation for Total Knee Arthroplasty. *J Knee Surg*, 864-872. https://doi.org/10.1055/a-2343-2444

Jones, K. C., Weatherly, H., Birch, S., Castelli, A., Chalkley, M., Dargan, A., Forder, J. E., Gao, M., Hinde, S., Markham, S., Premji, S., Findlay, D., & Teo, H. (2023). *Unit Costs of Health and Social Care 2023 Manual* [Technical Report]. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York). https://doi.org/10.22024/UniKent/01.02.105685

Jung, H. J., Kang, M. W., Lee, J. H., & Kim, J. I. (2023). Learning curve of robot-assisted total knee arthroplasty and its effects on implant position in asian patients: a prospective study. *BMC Musculoskeletal Disorders*, *24*(1), 332. https://doi.org/https://dx.doi.org/10.1186/s12891-023-06422-w

Kayani, B., Fontalis, A., Haddad, I. C., Donovan, C., & TRajput, V. (2023). Robotic-arm assisted total knee arthroplasty is associated with comparable functional outcomes but improved forgotten joint scores compared with conventional manual total knee arthroplasty at five-year follow-up. *Knee Surg Sports Traumatol Arthrosc*, *31*(12), 5453-5462. https://doi.org/10.1007/s00167-023-07578-7

Kayani, B., Konan, S., Tahmassebi, J., Rowan, F. E., & Haddad, F. S. (2019a). An assessment of early functional rehabilitation and hospital discharge in conventional versus robotic-arm assisted unicompartmental knee arthroplasty: a prospective cohort study. *Bone Joint J*, *101-B*(1), 24-33. https://doi.org/10.1302/0301-620X.101B1.BJJ-2018-0564.R2

Kayani, B., Konan, S., Thakrar, R. R., Huq, S. S., & Haddad, F. S. (2019b). Assuring the long-term total joint arthroplasty: a triad of variables. *Bone Joint J*, *101-B*(1_Supple_A), 11-18. https://doi.org/10.1302/0301-620X.101B1.BJJ-2018-0377.R1

Kayani, B., Konon, S., Huq, S. S., Tahmassebi, J., & Haddad, F. S. (2019c). Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. *Knee Surg Sports Traumatol Arthrosc*, *27*, 1132-1141.

Kayani, B., Tahmassebi, J., Ayuob, A., Konan, S., Oussedik, S., & Haddad, F. S. (2021). A prospective randomized controlled trial comparing the systemic inflammatory response in conventional jig-based total knee arthroplasty versus robotic-arm assisted total knee arthroplasty. *Bone Joint J*, *103-B*(1), 113-122. https://doi.org/10.1302/0301-620X.103B1.BJJ-2020-0602.R2

Kenanidis, E., Paparoidamis, G., Milonakis, N., Potoupnis, M., & Tsiridis, E. (2023). Comparative outcomes between a new robotically assisted and a manual technique for total knee arthroplasty in patients with osteoarthritis: a prospective matched comparative cohort study. *Eur J Orthop Surg Traumatol*, *33*(4), 1231-1236. https://doi.org/10.1007/s00590-022-03274-3

Khan, H., Dhillon, K., Mahapatra, P., Popat, R., Zakieh, O., Kim, W. J., & Nathwani, D. (2021). Blood loss and transfusion risk in robotic-assisted knee arthroplasty: A retrospective analysis. *Int J Med Robot*, *17*(6), e2308. https://doi.org/10.1002/rcs.2308

Kolessar, D. J., Hayes, D. S., Harding, J. L., Rudraraju, R. T., & Graham, J. H. (2022). Robotic-Arm Assisted Technology's Impact on Knee Arthroplasty and Associated Healthcare Costs. *J Health Econ Outcomes Res*, *9*(2), 57-66. https://doi.org/10.36469/001c.37024

Kong, X., Yang, M., Jerabek, S., Zhang, G., Chen, J., & Chai, W. (2020). A retrospective study comparing a single surgeon's experience on manual versus robot-assisted total hip

arthroplasty after the learning curve of the latter procedure - A cohort study. *Int J Surg*, *77*, 174-180. https://doi.org/10.1016/j.ijsu.2020.03.067

Kort, N., Stirling, P., Pilot, P., & Muller, J. H. (2022). Robot-assisted knee arthroplasty improves component positioning and alignment, but results are inconclusive on whether it improves clinical scores or reduces complications and revisions: a systematic overview of meta-analyses. *Knee Surg Sports Traumatol Arthrosc*, *30*(8), 2639-2653. https://doi.org/10.1007/s00167-021-06472-4

Lasam, M. P., Lee, K. J., Chang, C. B., Kang, Y. G., & Kim, T. K. (2013). Femoral lateral bowing and varus condylar orientation are prevalent and affect axial alignment of TKA in Koreans. *Clin Orthop Relat Res*, *471*(5), 1472-1483. https://doi.org/10.1007/s11999-012-2618-7

Leslie, I., Alton, T., E, S., Ford, M., Lesko, J., Diaz, R., & Delanois, R. (2024 - *Academic in Confidence*). Accuracy and early outcomes from the adoption phase of a novel image-free robotic-assisted system for total knee arthroplasty. *TBD*.

Maldonado, D. R., Go, C. C., Kyin, C., Rosinsky, P. J., Shapira, J., Lall, A. C., & Domb, B. G. (2021). Robotic Arm-assisted Total Hip Arthroplasty is More Cost-Effective Than Manual Total Hip Arthroplasty: A Markov Model Analysis. *J Am Acad Orthop Surg*, *29*(4), e168-e177. https://doi.org/10.5435/JAAOS-D-20-00498

Mancino, F., Cacciola, G., Malahias, M. A., De Filippis, R., De Marco, D., Di Matteo, V., Gu, A., Sculco, P. K., Maccauro, G., & De Martino, I. (2020). What are the benefits of robotic-assisted total knee arthroplasty over conventional manual total knee arthroplasty? A systematic review of comparative studies. *Orthopedic Reviews*, *12*(1S), 15-22. https://doi.org/https://dx.doi.org/10.4081/or.2020.8657

McQuivey, K. S., Deckey, D. G., Christopher, Z. K., Rosenow, C. S., Mi, L., Spangehl, M. J., & Bingham, J. S. (2021). Surgical Ergonomics and Musculoskeletal Pain in Orthopaedic Surgery Residents: A Multicenter Survey Study. *J Am Acad Orthop Surg Glob Res Rev*, *5*(3), 3781-3787. https://doi.org/10.5435/JAAOSGlobal-D-20-00119

Morrisey, Z. S., Barra, M. F., Guirguis, P. G., & Drinkwater, C. J. (2023). Transition to Robotic Total Knee Arthroplasty With Kinematic Alignment is Associated With a Short Learning Curve and Similar Acute-Period Functional Recoveries. *Cureus*, *15*(5), e38872. https://doi.org/10.7759/cureus.38872

Moschetti, W. E., Konopka, J. F., Rubash, H. E., & Genuario, J. W. (2016). Can Robot-Assisted Unicompartmental Knee Arthroplasty Be Cost-Effective? A Markov Decision Analysis. *J Arthroplasty*, *31*(4), 759-765. https://doi.org/10.1016/j.arth.2015.10.018

Ng, E. C., Xu, S., Liu, X. E., Lim, J. B. T., Liow, M. H. L., Pang, H. N., Tay, D. K. J., Yeo, S. J., & Chen, J. Y. (2024). Enhanced recovery after surgery day surgery for MAKO robotic-arm assisted TKA; better outcome for patients, improved efficiency for hospitals. *Journal of Orthopaedics*, *56*, 77-81. https://doi.org/https://dx.doi.org/10.1016/j.jor.2024.05.013

Nherera, L. M., Verma, S., Trueman, P., & Jennings, S. (2020). Early Economic Evaluation Demonstrates That Noncomputerized Tomography Robotic-Assisted Surgery Is Cost-Effective in Patients Undergoing Unicompartmental Knee Arthroplasty at High-Volume Orthopaedic Centres. *Advances in Orthopedics*, *2020*, 3460675. https://doi.org/https://dx.doi.org/10.1155/2020/3460675

Ong, C. B., Buchan, G. B. J., Hecht, C. J., 2nd, Liu, D., Petterwood, J., & Kamath, A. F. (2024). Use of a fluoroscopy-based robotic-assisted total hip arthroplasty system resulted in greater improvements in hip-specific outcome measures at one-year compared to a CT-based robotic-assisted system. *Int J Med Robot*, *20*(3), e2650. https://doi.org/10.1002/rcs.2650

Rajan, P. V., Khlopas, A., Klika, A., Molloy, R., Krebs, V., & Piuzzi, N. S. (2022). The Cost-Effectiveness of Robotic-Assisted Versus Manual Total Knee Arthroplasty: A Markov Model-Based Evaluation. *J Am Acad Orthop Surg*, *30*(4), 168-176. https://doi.org/10.5435/JAAOS-D-21-00309

RCS MSK RADAR Working Group. (2024). *Development of new Robotic MSK surgical service within the NHS: A Best Practice Guide*. British Orthopaedic Association & Royal College of Surgeons of England & Royal College of Surgeons of Edinburgh.

Robertson, C., Shaikh, S., Hudson, J., Roberts, P. G., Beard, D., Mackie, T., Matthew, C., Ramsay, C., Gillies, K., & Campbell, M. (2023). The RoboCOS Study: Development of an international core outcome set for the comprehensive evaluation of patient, surgeon, organisational and population level impacts of robotic assisted surgery. *PLoS One*, *18*(3), e0283000. https://doi.org/10.1371/journal.pone.0283000

Royal College of Surgeons of England. (2023). *Robotic-assisted surgery: a pathway to the future*. Royal College of Surgeons of England. https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/robotic-assisted-surgery/

Shugaba, A., Lambert, J. E., Bampouras, T. M., Nuttall, H. E., Gaffney, C. J., & Subar, D. A. (2022). Should All Minimal Access Surgery Be Robot-Assisted? A Systematic Review into the Musculoskeletal and Cognitive Demands of Laparoscopic and Robot-Assisted Laparoscopic Surgery. *J Gastrointest Surg*, *26*(7), 1520-1530. https://doi.org/10.1007/s11605-022-05319-8

Slover, J., Espehaug, B., Havelin, L. I., Engesaeter, L. B., Furnes, O., Tomek, I., & Tosteson, A. (2006). Cost-effectiveness of unicompartmental and total knee arthroplasty in elderly low-demand patients. A Markov decision analysis. *J Bone Joint Surg Am*, *88*(11), 2348-2355. https://doi.org/10.2106/JBJS.E.01033

Slover, J. D., Tosteson, A. N., Bozic, K. J., Rubash, H. E., & Malchau, H. (2008). Impact of hospital volume on the economic value of computer navigation for total knee replacement. *J Bone Joint Surg Am*, *90*(7), 1492-1500. https://doi.org/10.2106/JBJS.G.00888

Thiengwittayaporn, S., Uthaitas, P., Senwiruch, C., Hongku, N., & Tunyasuwanakul, R. (2021). Imageless robotic-assisted total knee arthroplasty accurately restores the radiological

alignment with a short learning curve: a randomized controlled trial. *International Orthopaedics*, *45*, 2851-2858. https://doi.org/https://doi.org/10.1007/s00264-021-05179-y

Tompkins, G. S., Sypher, K. S., Griffin, T. M., & Duwelius, P. D. (2022a). Can a Reduction in Revision Rates Make Robotic Total Knee Arthroplasty Cost Neutral With Manual Total Knee Arthroplasty at Ten-Year Follow-Up? An Episode Cost Analysis *J Arthroplasty*, *37*, S777-S781.e773. https://doi.org/doi: 10.1016/j.arth.2021.10.030

Tompkins, G. S., Sypher, K. S., Li, H. F., Griffin, T. M., & Duwelius, P. J. (2022b). Robotic Versus Manual Total Knee Arthroplasty in High Volume Surgeons: A Comparison of Cost and Quality Metrics. *J Arthroplasty*, *37*(8S), S782-S789. https://doi.org/10.1016/j.arth.2021.12.018

Torre, B. B., Pavano, C., Connors, J. P., Silver, J., Bellas, N., Shekhman, M., & Solovyova, O. (2023). Early Tibial Baseplate Fracture after Medial Unicondylar Knee Arthroplasty: A Report of 2 Cases. *JBJS Case Connector*, *13*(3), A52. https://doi.org/https://dx.doi.org/10.2106/JBJS.CC.22.00733

Vanlommel, L., Neven, E., Anderson, M. B., Bruckers, L., & Truijen, J. (2021). The initial learning curve for the ROSA(R) Knee System can be achieved in 6-11 cases for operative time and has similar 90-day complication rates with improved implant alignment compared to manual instrumentation in total knee arthroplasty. *J Exp Orthop*, *8*(1), 119. https://doi.org/10.1186/s40634-021-00438-8

Varughese, I., Whitehouse, S. L., Donnelly, W. J., & Crawford, R. W. (2024). The Cost Effectiveness of Unicompartmental versus Total Knee Arthroplasty. *J Knee Surg*, *37*(1), 66-72. https://doi.org/10.1055/a-1967-2346

Vermue, H., Stroobant, L., Thuysbaert, G., de Taeye, T., Arnout, N., & Victor, J. (2023). The learning curve of imageless robot-assisted total knee arthroplasty with standardised laxity testing requires the completion of nine cases, but does not reach time neutrality compared to conventional surgery. *International Orthopaedics*, *47*(2), 503-509. https://doi.org/https://dx.doi.org/10.1007/s00264-022-05630-8

Vermue, H., Tack, P., Gryson, T., & Victor, J. (2021). Can robot-assisted total knee arthroplasty be a cost-effective procedure? A Markov decision analysis. *Knee*, *29*, 345-352. https://doi.org/10.1016/j.knee.2021.02.004

Yeroushalmi, D., Feng, J., Nherera, L., Trueman, P., & Schwarzkopf, R. (2022). Early Economic Analysis of Robotic-Assisted Unicondylar Knee Arthroplasty May Be Cost Effective in Patients with End-Stage Osteoarthritis. *Journal of Knee Surgery*, *35*(1), 39-46. https://doi.org/https://dx.doi.org/10.1055/s-0040-1712088

Zhang, S., Liu, Y., Ma, M., Cao, Z., Kong, X., & Chai, W. (2023). Is Robotic-Assisted Technology Still Accurate in Total Hip Arthroplasty for Fibrous-Fused Hips? *Journal of Arthroplasty*, *38*(1), 129-134. https://doi.org/https://dx.doi.org/10.1016/j.arth.2022.07.023

Zhang, Z., Luo, Y., Zhang, J., Zhang, C., Wang, X., Chen, J., & Chai, W. (2024). Can Robotic Arm-assisted Total Knee Arthroplasty Remain Cost-effective in Volume-based Procurement System in China? A Markov Model-based Study. *Orthop Surg*, *16*(6), 1434-1444. https://doi.org/10.1111/os.14078

14. Appendices

Appendix A – Literature searching

Appendix A1 – Search strategy (clinical and economic)

Embase <1974 to 2024 July 05>

#	Search terms	Results
1	robotic surgical system/ or robotic neurological surgical equipment/ or exp robotic orthopedic surgical system/	7335
2	medical robot/ or robot/	5317
3	robotic surgical device/ or robotic console/ or robotic navigation system/	1393
4	robot assisted surgery/	27088
5	robotics/	48965
6	computer assisted surgery/ and robot*.mp.	2085
7	robot*.ti,kf.	77181
8	robot*.ab. /freq=3	41503
9	(robot* adj2 assist*).ab.	37621
10	(or/1-9) and robot*.ti,ab.	95077
11	arthroplasty/ or exp hip arthroplasty/ or exp knee arthroplasty/ or exp shoulder arthroplasty/ or resection arthroplasty/ or resurfacing arthroplasty/ or exp revision arthroplasty/	106608
12	replacement arthroplasty/ or exp hip replacement/ or exp knee replacement/ or exp shoulder replacement/ or exp hemiarthroplasty/ or total arthroplasty/	51785
13	(knee or hip or shoulder).ti. and ((surger* or surgical).ti,kf,hw. or su.fs.) and (ortho* or arthro*).af.	86150
14	(exp hip injury/su or exp knee injury/su or exp shoulder injury/su or hip/su or hip joint/su or exp knee/su or shoulder/su or exp "joint of shoulder region"/su) and (ortho* or arthro*).af.	44912
15	(exp hip injury/ or exp knee injury/ or exp shoulder injury/ or hip/ or hip joint/ or exp knee/ or shoulder/ or exp "joint of shoulder region"/) and (surger* or surgical).hw. and (ortho* or arthro*).af.	52858
16	(hip surgery/ or exp knee surgery/ or shoulder surgery/) and (ortho* or arthro*).af.	79382
17	(arthroplas* or knee replacement* or hip replacement* or shoulder replacement* or joint replacement*).ti,kf,hw.	146341
18	((tka or uka or pka).ti,kf,hw. and knee arthroplas*.mp.) or (tha.ti,kf,hw. and hip arthroplas*.mp.)	4969
19	arthroplas*.ab. /freq=3 or tka.ab. /freq=3 or uka.ab. /freq=3 or pka.ab. /freq=3 or tha.ab. /freq=3	51943
20	or/11-19	251604
21	10 and 20	1887
22	(apolloknee* or apollo knee* or omnibotic* or balancebot* or balance-bot or balance-botr or balance-bottm or cori or corir or coritm or navio* or mako* or acrobot* or rio or rosa or rosar or rosatm or rosaknee or (skywalker* not MIT-skywalker*) or velys* or attune total knee*).mp. and robot*.af. and (knee* or hip or hips or shoulder* or musculoskelet* or patell* or arthroplas*).mp.	489

#	Search terms	Results
23	21 or 22	1929
24	limit 23 to (english language and yr="2019 -Current")	1227
25	limit 23 to (books or chapter or "conference review" or editorial or note or short survey or tombstone)	48
26	24 not 25 [baseline: named or unnamed, english, 2019-present, no editorials etc]	1210
27	limit 26 to (conference abstract or conference paper)	86
28	26 not 27 [baseline plus no conference abstracts: named or unnamed, english, 2019-present, no editorials etc]	1124
29	(corin or corinr or corintm or (smith adj2 nephew*) or stryker* or zimmer* or biomet* or microport* or medbot* or "Johnson and Johnson*" or "johnson & johnson*" or depuy*).in,mp.	210721
30	(22 or (29 and 21)) and 28 [results since 2019 with named devices]	457
31	(22 or (29 and 21)) and 27	27
32	limit 31 to (english language and yr="2022 -Current") [named device, conference abstracts since 2022]	17
33	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	689805
34	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	446820
35	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	20379
36	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	60288
37	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	55500
38	(handsearch* or hand search*).ti,ab,kf.	14191
39	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	51210
40	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	22380
41	(meta regression* or metaregression*).ti,ab,kf.	20264
42	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	816711
43	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	501383
44	(cochrane or (health adj2 technology assessment) or evidence report).jw.	32028
45	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	28157
46	(outcomes research or relative effectiveness).ti,ab,kf.	17005
47	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	8185
48	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	444
49	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	260
50	umbrella review*.ti,ab,kf.	2200
51	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	35
52	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	22
53	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	30

#	Search terms	Results
54	or/33-53 [CADTH SR filter https://searchfilters.cadth.ca/link/33]	1091762
55	(28 and 54) not 30	100
56	limit 55 to yr="2022 -Current" [results without relevant technologies named, systematic reviews from 2022 onwards]	66
57	limit 28 to review	125
58	57 and ((review or overview or literature).ti. or "this* review".ab. or "this* systematic review".ab.)	63
59	28 not 58	1061
60	limit 59 to yr="2022 -Current"	720
61	exp United Kingdom/	478357
62	(national health service* or nhs*).ti,ab,in,ad.	501658
63	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	65207
64	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jx,in,ad.	3865184
65	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in,ad.	3031824
66	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in,ad.	124937
67	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in,ad.	417151
68	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in,ad.	58391
69	or/61-68	4728361

#	Search terms	Results
70	(exp "arctic and antarctic"/ or exp oceanic regions/ or exp western hemisphere/ or exp africa/ or exp asia/ or exp "australia and new zealand"/) not (exp united kingdom/ or europe/)	3898838
71	69 not 70 [UK filter, from https://doi.org/10.1111/hir.12252]	4431032
72	(60 and 71) not 30 [results without relevant technologies named, (potential) primary research, from 2022 onwards, limited to UK]	68
73	30 or 32 or 56 or 72 [non-econ clinical results of various types]	602
74	Health Economics/	36629
75	exp Economic Evaluation/	370966
76	exp Health Care Cost/	355288
77	pharmacoeconomics/	13702
78	(econom$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab.	1483836
79	(expenditure$ not energy).ti,ab.	53128
80	(value adj2 money).ti,ab.	3129
81	budget$.ti,ab.	49703
82	or/74-81	1788007
83	letter.pt.	1328714
84	editorial.pt.	811567
85	note.pt.	992074
86	or/83-85	3132355
87	82 not 86	1666849
88	(metabolic adj cost).ti,ab.	1964
89	((energy or oxygen) adj cost).ti,ab.	5248
90	((energy or oxygen) adj expenditure).ti,ab.	38866
91	88 or 89 or 90	44820
92	87 not 91	1657708
93	animal/	1666954
94	exp animal experiment/	3207745
95	nonhuman/	7779738
96	(rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh.	6686887
97	93 or 94 or 95 or 96	10760070
98	exp human/	26746182
99	human experiment/	663871
100	98 or 99	26748893
101	conference abstract.pt.	5198224
102	92 not (97 not 100)	1490608
103	102 not 101	1203353
104	28 and 103 [econ papers since 2019]	161
105	30 and 104 [econ AND named]	61
106	104 not 105 [econ not named]	100
107	30 or 32 [named - abstracts last 2 yr, anything else last 5]	474

#	Search terms	Results
108	56 or 72 [not-named - SRs and UK, last 2yrs]	128

Link

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to July 05, 2024>

#	Search terms	Results
1	Robotic Surgical Procedures/	18755
2	Robotics/	29393
3	Surgery, Computer-Assisted/ and robot*.mp.	3069
4	robot*.ti,kf.	53373
5	robot*.ab. /freq=3	27517
6	(robot* adj2 assist*).ab.	21767
7	(or/1-6) and robot*.ti,ab.	60973
8	arthroplasty/ or anterior cruciate ligament reconstruction/ or bone-patellar tendon-bone grafting/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/ or arthroplasty, subchondral/ or posterior cruciate ligament reconstruction/	90665
9	(knee or hip or shoulder).ti. and ((surger* or surgical).ti,kf,hw. or su.fs.) and (ortho* or arthro*).af.	66950
10	(exp Hip Injuries/su or exp Knee Injuries/su or exp Shoulder Injuries/su or hip/su or knee/su or shoulder/su or exp hip joint/su or exp knee joint/su or shoulder joint/su) and (ortho* or arthro*).af.	70381
11	(exp Hip Injuries/ or exp Knee Injuries/ or exp Shoulder Injuries/ or hip/ or knee/ or shoulder/ or exp hip joint/ or exp knee joint/ or shoulder joint/) and (surger* or surgical).hw. and (ortho* or arthro*).af.	10416
12	(arthroplas* or knee replacement* or hip replacement* or shoulder replacement* or joint replacement*).ti,kf,hw.	108873
13	((tka or uka or pka).ti,kf,hw. and knee arthroplas*.mp.) or (tha.ti,kf,hw. and hip arthroplas*.mp.)	3847
14	arthroplas*.ab. /freq=3 or tka.ab. /freq=3 or uka.ab. /freq=3 or pka.ab. /freq=3 or tha.ab. /freq=3	44667
15	or/8-14	180279
16	7 and 15	1558
17	(apolloknee* or apollo knee* or omnibotic* or balancebot* or balance-bot or balance-botr or balance-bottm or cori or corir or coritm or navio* or mako* or acrobot* or rio or rosa or rosar or rosatm or rosaknee or (skywalker* not MIT-skywalker*) or velys* or attune total knee*).mp. and robot*.af. and (knee* or hip or hips or shoulder* or musculoskelet* or patell* or arthroplas*).mp.	252
18	16 or 17	1570
19	limit 18 to (english language and yr="2019 -Current")	1105
20	limit 19 to (address or autobiography or bibliography or biography or comment or dictionary or directory or editorial or news or newspaper article or observational study, veterinary or personal narrative or portrait)	27
21	19 not 20 [baseline: named or unnamed, english, 2019-present, no editorials etc]	1078

#	Search terms	Results
22	(corin or corinr or corintm or (smith adj2 nephew*) or stryker* or zimmer* or biomet* or microport* or medbot* or "Johnson and Johnson*" or "johnson & johnson*" or depuy*).in,mp.	113747
23	(17 or (22 and 16)) and 21 [results since 2019 with named devices]	281
24	(systematic review or meta-analysis).pt.	353042
25	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	394976
26	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	369719
27	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	17694
28	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	42998
29	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	45829
30	(handsearch* or hand search*).ti,ab,kf.	11653
31	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	38794
32	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13176
33	(meta regression* or metaregression*).ti,ab,kf.	16611
34	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	525862
35	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	386990
36	(cochrane or (health adj2 technology assessment) or evidence report).jw.	21958
37	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	19246
38	(outcomes research or relative effectiveness).ti,ab,kf.	11809
39	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4671
40	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	311
41	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	179
42	umbrella review*.ti,ab,kf.	2095
43	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	14
44	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
45	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	12
46	or/24-45 [CADTH SR filter from https://searchfilters.cadth.ca/link/33]	762854
47	(46 and 21) not 23	90
48	limit 47 to yr="2022 -Current" [results without relevant technologies named, systematic reviews from 2022 onwards]	54
49	limit 21 to ("review articles" or meta analysis or "systematic review")	171
50	49 and ((review or overview or literature).ti. or "this* review".ab. or "this* systematic review".ab.)	94
51	21 not 50	984
52	limit 51 to yr="2022 -Current"	687
53	exp United Kingdom/	396415

#	Search terms	Results
54	(national health service* or nhs*).ti,ab,in.	293792
55	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	129757
56	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in.	2565808
57	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in.	1850652
58	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in.	74925
59	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in.	272247
60	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in.	36191
61	or/53-60	3288821
62	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp united kingdom/ or europe/)	3439749
63	61 not 62 [UK filter from https://doi.org/10.1111/hir.12252]	3083873
64	(52 and 63) not 23 [results without relevant technologies named, (potential) primary research, from 2022 onwards, limited to UK]	85
65	Economics/	27535
66	exp "costs and cost analysis"/	271591
67	Economics, Dental/	1922
68	exp economics, hospital/	25883
69	Economics, Medical/	9288

#	Search terms	Results
70	Economics, Nursing/	4013
71	Economics, Pharmaceutical/	3141
72	(economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab.	1129606
73	(expenditure$ not energy).ti,ab.	39154
74	value for money.ti,ab.	2243
75	budget$.ti,ab.	37712
76	or/65-75	1297927
77	76 not (((energy or oxygen) adj cost) or (metabolic adj cost) or ((energy or oxygen) adj expenditure)).ti,ab.	1289583
78	77 not (letter or editorial or historical article).pt.	1248494
79	78 not (exp animals/ not humans/)	1168492
80	21 and 79 [econ, since 2019]	166
81	80 and 23 [econ, named devices, since 2019]	33
82	80 not 81 [econ not-named, since 2019]	133
83	23 [named, since 2019]	281
84	48 or 64 [not-named, SRs or UK, since 2022]	134

Link

Cochrane/Central

#	Search terms	Results
#1	MeSH descriptor: [Robotic Surgical Procedures] this term only	975
#2	MeSH descriptor: [Robotics] this term only	1202
#3	MeSH descriptor: [Surgery, Computer-Assisted] this term only	1113
#4	robot*:ti,kw,ab	7914
#5	#3 AND #4	73
#6	robot*:ti,kw	6397
#7	(robot* NEAR/3 assist*):ti,kw,ab	4498
#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7	8954
#9	#8 and robot*:ti,ab	7623
#10	MeSH descriptor: [Arthroplasty] explode all trees	8043
#11	(knee OR hip OR shoulder):ti AND (surger* OR surgical):ti,kw AND (ortho* OR arthro*)	8181
#12	MeSH descriptor: [Knee Injuries] explode all trees and with qualifier(s): [surgery - SU]	862
#13	MeSH descriptor: [Hip Injuries] explode all trees and with qualifier(s): [surgery - SU]	1335
#14	MeSH descriptor: [Shoulder Injuries] explode all trees and with qualifier(s): [surgery - SU]	526
#15	MeSH descriptor: [Hip] explode all trees and with qualifier(s): [surgery - SU]	91
#16	MeSH descriptor: [Knee] explode all trees and with qualifier(s): [surgery - SU]	249

#	Search terms	Results
#17	MeSH descriptor: [Shoulder] explode all trees and with qualifier(s): [surgery - SU]	248
#18	MeSH descriptor: [Hip Joint] explode all trees and with qualifier(s): [surgery - SU]	414
#19	MeSH descriptor: [Knee Joint] explode all trees and with qualifier(s): [surgery - SU]	1889
#20	MeSH descriptor: [Shoulder Joint] explode all trees and with qualifier(s): [surgery - SU]	430
#21	(#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20) AND (ortho* or arthro*)	4348
#22	MeSH descriptor: [Hip Injuries] explode all trees	2701
#23	MeSH descriptor: [Knee Injuries] explode all trees	1925
#24	MeSH descriptor: [Shoulder Injuries] explode all trees	1887
#25	MeSH descriptor: [Hip] explode all trees	545
#26	MeSH descriptor: [Knee] explode all trees	1109
#27	MeSH descriptor: [Shoulder] explode all trees	1019
#28	MeSH descriptor: [Hip Joint] explode all trees	1324
#29	MeSH descriptor: [Knee Joint] explode all trees	4988
#30	MeSH descriptor: [Shoulder Joint] explode all trees	1126
#31	(#22 OR #23 OR #24 IR #25 OR #26 OR #27 OR #28 OR #29 OR #30) AND (surger* OR surgical):ti,kw AND (ortho OR arthro*)	3799
#32	(arthroplas* OR ((knee OR hip OR shoulder or joint) NEXT1 replacement*)):ti,kw	30121
#33	((tka OR uka OR pka):ti,kw AND (knee NEXT1 arthroplas*):ti,kw,ab) or (tha:ti,kw and (hip NEXT1 arthroplas*):ti,ab,kw)	725
#34	#10 OR #11 OR #21 OR #31 OR #32 OR #33	35200
#35	#9 AND #34	253
#36	(apolloknee* or apollo-knee* or omnibotic* or balancebot* or balance-bot or balance-botr or balance-bottm or cori or corir or coritm or navio* or mako* or acrobot* or rio or rosa or rosar or rosatm or rosaknee or (skywalker* NOT MIT-skywalker*) OR velys* OR attune-total-knee*):ti,ab,kw AND robot* AND (knee* OR hip OR hips OR shoulder* OR musculoskelet* OR patell* OR arthroplas*)	74
#37	(corin or corinr or corintm or (smith NEAR/2 nephew*) or stryker* or zimmer* or biomet* or microport* or medbot* or (johnson NEAR/2 johnson*) or depuy*)	22989
#38	#35 AND #37	29
#39	#38 OR #36 with Publication Year from 2019 to present, in Trials	61
#40	#38 OR #36 with Cochrane Library publication date from Jan 2019 to present	67
#41	#40 OR #39	67
#42	#35 NOT #41 with Publication Year from 2022 to present, in Trials	90

(zero results on CDSR)

#41: trial registry results from registries other than ISRCTN removed, dates checked and trimmed, also deduplicated – 15 results

#42: all results from registries removed (only articles remain), deduplicated – 59 results

Clinicaltrials.gov

Other terms: (apolloknee OR apollokneetm OR "apollo knee" OR "apollo kneetm" OR omnibotics OR balancebot OR balancebottm OR "balance-bot" OR "balance-bottm" OR cori OR coritm OR navio OR naviotm OR mako OR makotm OR acrobot OR acrobottm OR rio OR riotm OR rosa OR rosatm OR rosaknee OR rosakneetm OR skywalker OR skywalkertm OR velys OR velystm OR "attune total knee" OR "attune total kneetm") AND (knee OR knees OR hip OR hips OR shoulder OR shoulders OR musculoskeletal OR patella OR arthroplastic OR arthropl

sty) | In United Kingdom | Study completion on or after 01/01/2019

Link

77 results

Scanmedicine

(apolloknee|apollokneetm|"apollo knee"|"apollo kneetm"|omnibotics|omniboticstm|balancebot|balancebottm|"balance-bot"|"balance-bottm"|cori|coritm|navio|naviotm|mako|makotm|acrobot|acrobottm|rio|riotm|rosa|rosatm|rosaknee|rosakneetm|skywalker|skywalkertm|velys|velystm|"attune total knee"|"attune total kneetm")+(knee|knees|hip|hips|shoulder|shoulders|musculoskeletal|patella|arthroplastic|arthroplasty)

Completion: 2019-present, Location: UK

Link

16 results but only one result not already in CT.gov or CENTRAL results: ISRCTN47889316

EngRxiv

(apolloknee OR apollokneetm OR "apollo knee" OR "apollo kneetm" OR omnibotics OR balancebot OR balancebottm OR "balance-bot" OR "balance-bottm" OR cori OR coritm OR navio OR naviotm OR mako OR makotm OR acrobot OR acrobottm OR rio OR riotm OR rosa OR rosatm OR rosaknee OR rosakneetm OR skywalker OR skywalkertm OR velys OR velystm OR "attune total knee" OR "attune total kneetm") AND (robot OR

robots OR robotic OR robotics) AND (knee OR knees OR hip OR hips OR shoulder OR shoulders OR musculoskeletal OR pate

la OR arthroplastic OR arthroplasty)

0 results

MedRxiv

Various ad hoc searches

0 results

CEA Registry

(robot OR robots OR robotic OR robotics) AND (((surgery OR surgical) AND (knee OR knees OR hip OR hips OR shoulder OR shoulders OR musculoskeletal OR patella)) OR (arthroplastic OR arthroplasty))

Link

9 results

RePEC IDEAS

(robot|robots|robotic|robotics)+(((surgery|surgical)+(knee|knees|hip|hips|shoulder|shoulders|musculoskeletal|patella))|(arthroplastic|arthroplasty))

Link

6 results

INAHTA

((apolloknee OR apollokneetm OR "apollo knee" OR "apollo kneetm" OR balancebot OR balancebottm OR "balance-bot" OR "balance-bottm" OR cori OR coritm OR navio OR naviotm OR mako OR makotm OR acrobot OR acrobottm OR rio OR riotm OR rosa OR rosatm OR rosaknee OR rosakneetm OR skywalker OR skywalkertm OR velys OR

velystm OR "attune total knee" OR "attune total kneetm") AND (knee OR knees OR hip OR hips OR shoulder OR shoulders OR musculoskeletal OR patella OR arthroplastic OR arthroplasty)) OR ((robot OR robot

OR robotic OR robotics) AND (((surgery OR surgical) AND (knee OR knees OR hip OR hips OR shoulder OR shoulders OR musculoskeletal OR patella)) OR (arthroplastic OR arthroplasty)))

Link

7 results (though four out of date remit, later removed)

Full numbers:

Clinical

Embase 602 (457 (articles) + 17 (conference abstracts) with potential named devices, 128 not-named)

Medline 415 (281 named, 134 not-named)

CENTRAL (after tidying) 74 (15 named, 59 not-named)

Clinicaltrials.gov 77

Scanmedicine 1 (16 results but only 1 added, after deduplication against CT.gov plus ISRCTN results on CENTRAL)

(Medrxiv/Engrxiv: both zero)

After total deduplication and tidy: 750

Economic

Embase 161 (61 named, 100 not-named)

Medline 166 (33 named, 133 not-named)

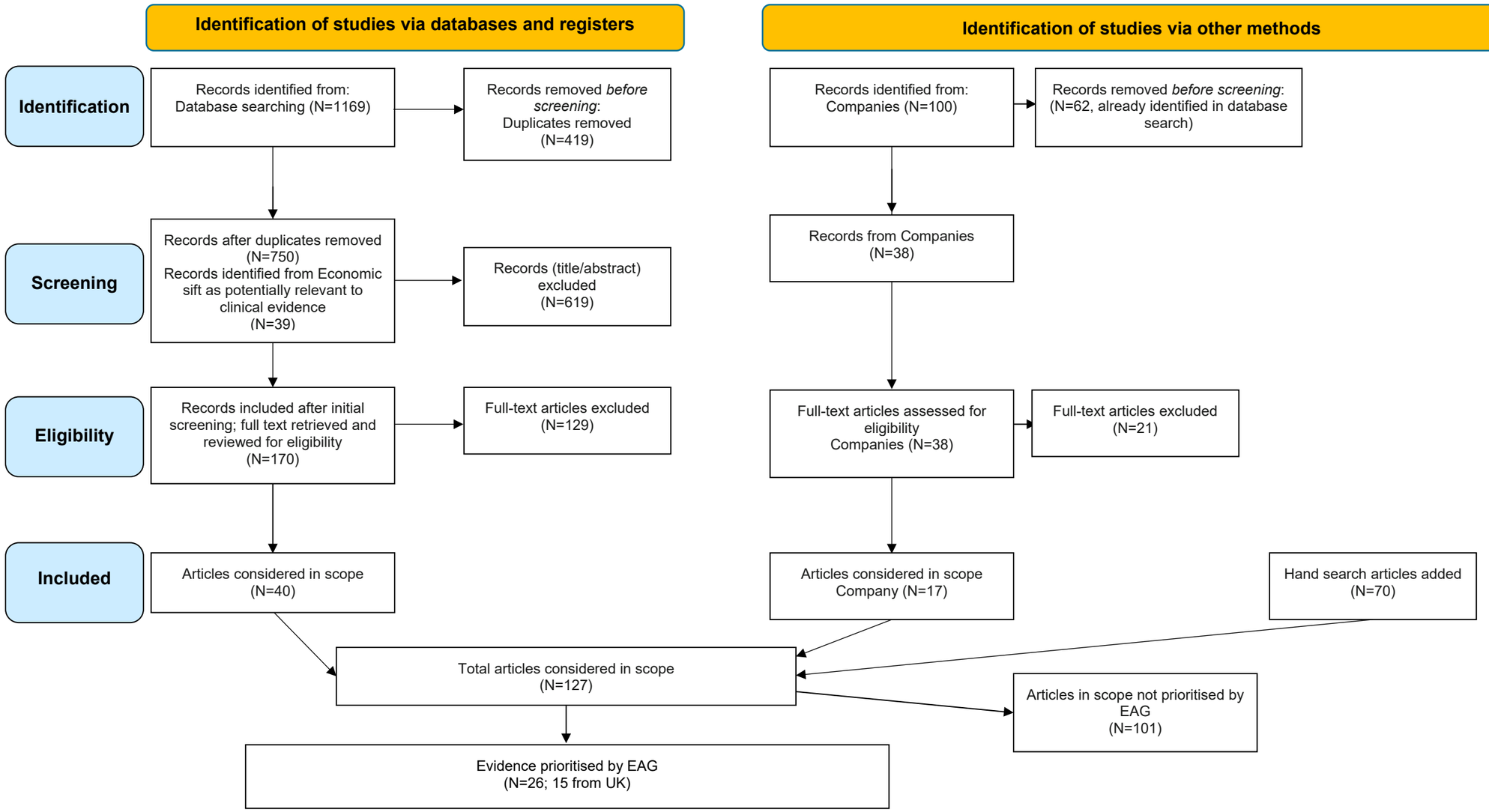
CEA registy 9

REPEC IDEAS 6

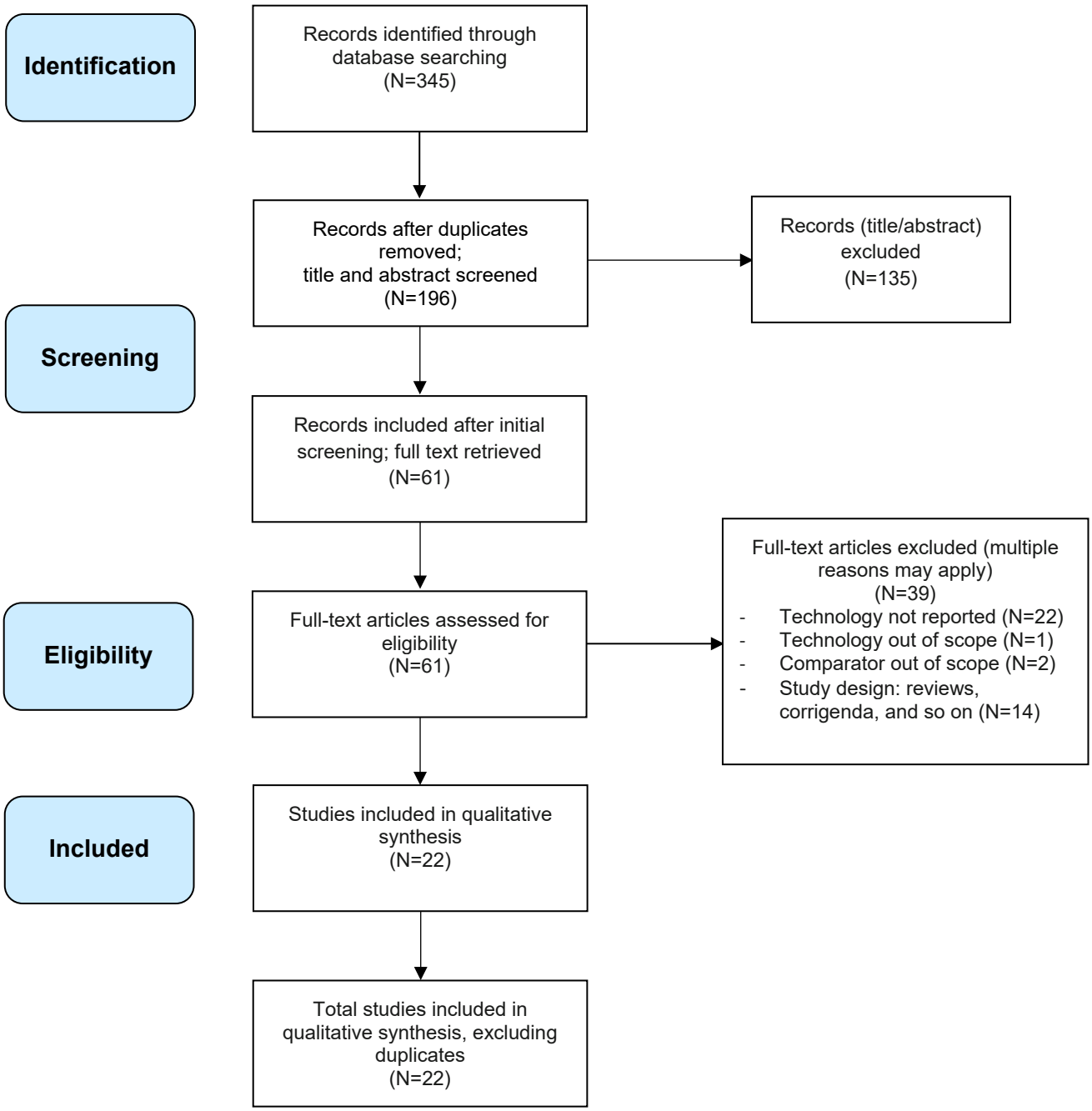
INAHTA 3 (after applying dates)

After total deduplication and tidy: 196

Appendix A2 – PRISMA diagram: clinical



Appendix A3 – PRISMA diagram: economic



Appendix A4 – Excluded studies

#	Source	Study reference	Reason
1.	Zimmer Biomet	2 CiC reports from the Australian Orthopaedic Association National Joint Registry Replacement	Intervention: Evidence focused on Zimmer implants, and not specifically on the ROSA Knee system.
2.	Stryker	Australian Orthopaedic Association National Joint Replacement Registry. Automated Industry Report 14218 Stryker Australia Restoris MCK/Restoris MCK Unicompartmental Knee. [accessed online May 8, 2024].	Design: Report not accessible.
3.	EAG literature searches	Agarwal (J Arthrop, 2020)	Intervention: Includes ROBODOC, CASPAR
4.	EAG literature searches	Aggarwal (Arch Orthop Trauma Surg, 2024; 2223-2227)	Intervention: technology not reported
5.	EAG literature searches	Alrajeb (Eur J Orthop Surg Traumatol, 2024)	Intervention: Includes ROBODOC
6.	EAG literature searches	Alshaharani (Eur Rev Med Pharma 2024)	Intervention: technology not reported
7.	EAG literature searches	Alton (Expert Rev Med Devices, 2023; 303-311)	Intervention: technology not reported
8.	EAG literature searches	Antonios (Arthroplast Today, 2019; 88-95)	Intervention: technology not reported
9.	EAG literature searches	Are (ERMPS, 2023; 2624-2633)	Study design: Included cadavers
10.	EAG literature searches	Bagaria (Arthroplasty, 2022)	Study design: review
11.	EAG literature searches	Bai (JEBM, 2022; 77-96)	Study design: review article
12.	EAG literature searches	Batailler (Arch Ortho Traum Surg, 2021; 2027-2034)	Study design: review article
13.	EAG literature searches / Stryker	Batailler (Knee Surg Sports Traumatol Arthrosc, 2021; 3585-3598)	Study design: Systematic review (N=26 studies, 14 were comparative case-control studies); all using Mako system. No meta-analysis (due to heterogeneity in outcome measures, follow-up period, patient population), included 4 cadaveric studies. Country of each study not explicitly reported; primary evidence not sifted due to time constraints.
14.	Stryker	Bell (J Bone Joint Surg, 2016; 627-635)	Year of publication: More than 5 years from time of search. Note: RCT with

#	Source	Study reference	Reason
			robotic (n=62) and conventional (n=58) unicompartmental knee arthroplasty.
15.	EAG literature searches	Bensa (Knee Surg Traumatol Arthro, 2023)	Intervention: Includes ROBODOC/ and Yuanhua
16.	EAG literature searches / Stryker	Bernard de Villeneuve (Arch Orthop Trauma Surg, 2021; 2129-2138)	Study design: review article
17.	EAG literature searches / Corin	Blum (Arch Orthop Trauma Surg, 2021; 2155-2164)	Comparator: 1) RAS cohort split into two groups by expectation fulfilment i.e. single arm RAS study, 2) RAS cf FORCE-TJR database cohorts not equivalent for age, sex, pre-op pain scores
18.	Stryker	Blyth (Bone Joint Res, 2017; 631-639)	Year of publication: More than 5 years from time of search. Note: secondary analysis of RCT with robotic (n=64) and conventional (n=65) unicondylar knee arthroplasty. UK setting
19.	EAG literature searches	Bouche (Knee, 2023)	Intervention: technology not reported
20.	EAG literature searches	Buchan (Arch OrthopTrauma Surg, 2024; 1843-1850)	Intervention: out of scope [redacted]
21.	EAG literature searches	Buchan (Arthroplasty, 2023; 56)	Intervention: out of scope [redacted]
22.	EAG literature searches; systematic review references	Buchan (Int J Med Robot, 2023; e2518)	Intervention: out of scope [redacted]
23.	EAG literature searches	Buchan (J Robot Surg, 2023; 2073-2079)	Intervention: out of scope [redacted]
24.	EAG literature searches	Buchlak (Eur J Orth Surg Trauma, 2022; 915-931)	Intervention: Includes ROBODOC, PRAXIM, devices not reported in all studies.
25.	EAG literature searches	Bullock (J Clin Med, 2022; 6674)	Study design: review article
26.	Smith & Nephew	Canetti (Arch Orthop Trauma Surg, 2018; 1765-1771)	Year of publication: More than 5 years from time of search. Note: prospective cohort robotic (n=11) and conventional (n=17) (25 patients) UKA.
27.	EAG literature searches	Chen (Surg Technol Int, 2022)	Study design: review article
28.	EAG literature searches	Chin (J Knee Surg, 2021;1064-1075)	Intervention: includes ROBODOC, CASPAR, and technology not reported in all studies
29.	EAG literature searches /	Clatworthy (Surg Technol Int, 2022; 315-320)	Comparator: TKA with navigation

#	Source	Study reference	Reason
	Johnson & Johnson		
30.	EAG literature searches	Clement (Bone Joint J, 2019; 1464)	Study design: corrigendum to Clement (Bone Joint J, 2019;1063-1070)
31.	EAG literature searches	Clement (EFORT Open Res. 2020)	Intervention: technology not reported Study design: included cadaver and saw bone studies.
32.	EAG literature searches / Stryker	Clement (The Knee, 2024; 94-104)	Duplicate: secondary analysis of RCT reporting outcomes at 6 months (separate study included in EAG report from same RCT reporting 12 month FU and same outcomes).
33.	EAG literature searches	Constantinescu (J Arthroplasty, 2024; 1512-1517)	Intervention: technology not reported
34.	EAG literature searches	Constantinescu (J Arthroplasty, 2024; 1771-1776)	Intervention: technology not reported
35.	EAG literature searches	Cool (J Arthroplasty, 2019; 926-931)	Intervention: technology not reported
36.	Corin	Corin Internal Study (no date)	Robotic system footprint data
37.	EAG literature searches / Stryker	Daffara (Int Orthop, 2023; 711-717)	Comparator: Robotic-assisted surgery in both arms, but comparison of cruciate retaining, or posterior-stabilised implants.
38.	Smith & Nephew	Davis (J Arthroplasty, 2015; 55-60)	Year of publication: More than 5 years from time of search. Note: prospective cohort robotic (n=50), THA.
39.	EAG literature searches / Smith & Nephew	Davis (JB JS Open Access, 2021; e21.00006)	Intervention: Main analysis is of computer-guided surgery versus non-computer-guided. Unlikely to include robotic systems, includes study of NJR data from 2003-2020 (robotic data fields only added in 2019).
40.	EAG literature searches / Johnson & Johnson	Doan (J Arthroplasty, 2022; 795-801)	Study design: cadaveric study
41.	EAG literature searches / Corin	Edelstein (Arthroplast Today, 2023; 101204)	Study design: Simulations
42.	EAG literature searches	Elliott (Arc Ortho Trama, 2021; 2099-2117	Intervention: Includes ROBODOC
43.	EAG literature searches	Emara (Int J Med Robots Comp Asst Surg, 2021)	Intervention: Includes ROBODOC
44.	EAG literature searches	Emara (Bone Joint J, 2021; 1488-1496)	Intervention: technology not reported

#	Source	Study reference	Reason
45.	EAG literature searches	Emara (JAAOS, 2021; e1328-e1342)	Intervention: technology not reported
46.	Corin	Forlenza (ISTA Conference, 2023)	Abstract only
47.	EAG literature searches	Fozo (Cureus, 2023)	Intervention: technology not reported
48.	EAG literature searches	Ghazal (Cureus, 2023)	Intervention: technology not reported
49.	EAG literature searches	Gorce (Int J Env Res Pub Health, 2023)	Intervention: technology not reported
50.	EAG literature searches	Gregory (J Knee Surg, 2023; 1077-1086)	Intervention: technology not reported
51.	EAG literature searches	Grosso (J Knee Surg, 2022; 8-803)	Intervention: technology not reported
52.	EAG literature searches / Corin	Grosso (Knee Surg Sports Traumatol Arthrosc, 2024; 1-9)	Comparator: RAS cohort split into groups by varus alignment (considered by EAG as single arm RAS study)
53.	EAG literature searches	Grosso (Knee Surg Sports Traumatol Arthrosc, 2024; 1516-1524)	Comparator: Not comparative - assessing complexity of knee anatomy and soft tissue identity
54.	EAG literature searches	Hecht, (J Robot Surg, 2024)	Intervention: technology not reported in all studies
55.	Smith & Nephew	Herry (Int Orthop, 2017; s00264-017-3633-9)	Year of publication: More than 5 years from time of search. Note: retrospective case control with matched robotic (n=40) and conventional (n=40) UKA;
56.	EAG literature searches	Hickey (Clin Orthop Relat Res 2023; 157-173)	Intervention: technology not reported
57.	EAG literature searches	Hoeffel (J Robot Surg, 2023; 2899-2910)	Intervention: includes ROBODOC, and technology not reported for all studies
58.	EAG literature searches	Hoveidaei (Tech Health Care, 2023)	Study design: 4 studies included in meta-analysis (EAG have already included the RCT and prospective study as key evidence; remaining 2 were retrospective studies).
59.	EAG literature searches	Hoveidaei (Int Ortho, 2024)	Intervention: Includes ROBODOC and technology not reported in all studies
60.	EAG literature searches	Hua (PLoS ONE, 2022; e0277980)	Intervention: technology not reported
61.	Johnson & Johnson	Hunter [AiC] [Poster] Full paper published Spitzer (2024)	Comparator: Comparison robotic-assisted surgery with or without soft tissue release.
62.	EAG literature searches	Iturriaga (Surg Tech Int, 2020)	Intervention: technology not reported

#	Source	Study reference	Reason
63.	Stryker	Kayani (Bone Joint J, 2018; 1033-1042)	Year of publication: More than 5 years from time of search. Note: UK study, prospective cohort with robotic (n=60) and conventional (n=60) UKA.
64.	Stryker	Kayani (Bone Joint J, 2018; 930-937)	Year of publication: More than 5 years from time of search. Note: UK study, prospective cohort with robotic (n=40) and conventional (n=40) TKA.
65.	EAG literature searches	Kayani (EFFORT Open Rev, 2019;611-616)	Intervention: technology not reported
66.	EAG literature searches / Corin	Keggi (Arch Orthop Trauma Surg, 2021; 2165-2174)	Comparator: Use of robotics with or without predictive plan
67.	Corin	Keggi (EPIC Series in Health Sci, 2020; 160-164)	Comparator: RAS cohort compared to registry data & historical literature, reported equivalent for WOMAC scores and UCLA activity scale, no detail on baseline characteristics
68.	Corin	Keggi (ICJR Conference, 2016)	Year of publication: More than 5 years from time of search.
69.	EAG literature searches	Khanna (Cureus, 2024; e57726)	Intervention: technology not reported
70.	EAG literature searches	Kim (Knee Surg Traumatol, 2023)	Intervention: Included Intellijoint/ KneeTrac/ PiGalielo and technology not reported in all studies
71.	EAG literature searches	Kirschner (JAAOS, 2021; 609-615)	Intervention: technology not reported
72.	Corin	Koenig (Arthroplast Today; 2022; 172-178)	Comparator: Main area of focus is digital balance tool.
73.	Corin	Koulalis (Knee, 2011; 436-442)	Year of publication: More than 5 years from time of search. Note: cadaveric.
74.	EAG literature searches	Kumar (Postgrad Med J, 2023)	Intervention: Includes ROBODOC
75.	EAG literature searches	Kunze (J Orthop, 2021; 212-219)	Study design: Included 4 robotic studies, all using Acrobot/Mako, all published prior to 2019
76.	EAG literature searches	Kunze (J AAOS Global Res & Rev, 2022)	Intervention: All included studies used ROBODOC/ORTHODOC
77.	Corin	Lawrence (Bone & Joint Orthop Proc, 2020; 1)	EAG could not retrieve source
78.	EAG literature searches / Corin	Lee (Bone Joint J, 2021; 67-73)	Comparator: RAS cohort split into groups by mediolateral ligament balance and tibial insert thickness, ie single arm RAS study

#	Source	Study reference	Reason
79.	EAG literature searches	Lei (Knee Surg, Sports Traumatol, Arthrosc, 2022; 721-733)	Intervention: Robotics system not reported
80.	EAG literature searches	Li (Asian J Surg, 2024)	Intervention: Includes TiRobot
81.	EAG literature searches	Lin (Int J Med Robot, 2020; 1-7)	Study design: review (no meta-analysis), all studies used Mako, no reporting of study designs. Primary evidence not reviewed due to time constraints.
82.	EAG literature searches	Liu (Arthroplasty, 2021; 15)	Study design: review article
83.	EAG literature searches / Stryker	Loomans (Arch Orthop Trauma Surg, 2023; 5501-5506)	Comparator: Navigation-assisted
84.	EAG literature searches	Ma (Chinese J Anat Clinics, 2024)	Study design: abstract only in English
85.	EAG literature searches	Maman (Knee Surg Traumatol Arthrosc, 2024; 1-7)	Comparator: TKA with navigation
86.	EAG literature searches	Mancino (Orthop Rev, 2020; 8657 15-22)	Intervention: Includes ROBODOC, iBlock, CASPAR
87.	EAG literature searches / Zimmer Biomet	Mancino (Arch Orthop Trauma Surg, 2023; 2701-2711)	Comparator: Navigated total knee arthroplasty (iAssist).
88.	EAG scoping searches	Mancino (Arch Orthop Trauma Surg, 2024; 393-404)	Comparator: Navigated total knee arthroplasty (iAssist).
89.	EAG literature searches	Mont (J Knee Surg, 2021; 328-337)	Intervention: technology not reported
90.	EAG literature searches	Mullaji (J Ortho, 2022; 31-39)	Intervention: Included HURWA, ROBODOC
91.	EAG literature searches / Smith & Nephew	Naito (BMC Musculoskeletal Dis, 2021; 1016)	Intervention: Main analysis is of navigation system (no mention of robot).
92.	EAG literature searches / Stryker	Ng (Bone Joint J, 2021; 1009-1020)	Study design: Systematic review with meta-analysis (N=17, including 16 observational and 1 study design not reported); all using Mako system. Included 3 matched cohorts (all retrospective design), and 11 studies published before 2019.
93.	EAG literature searches	Nogalo (Knee Surg Traumatol, 2023)	Intervention: Includes ROBODOC/Tsolution One, technology not reported for all studies.
94.	EAG literature searches	Ong (Clinicoecon Outcomes Res, 2022; 309-318)	Intervention: technology not reported

#	Source	Study reference	Reason
95.	EAG literature searches	Ong (Int J Med Robot, 2024; e2582)	Intervention: technology out of scope (ROSA Total Hip)
96.	EAG literature searches	Onggo (Arch Orthop Trauma Surg, 2020; 1533-1549)	Intervention: Includes ROBODOC
97.	EAG literature searches / Corin	Orsi (Arthroplast Today, 2022; 1-8)	Comparator: simulation
98.	EAG literature searches / Corin	Orsi (Arthroplast Today, 2023; 101090)	Comparator: Main area of focus is surgical approach/technique
99.	EAG literature searches / Corin	Orsi (Knee Surg Sports Traumatol Arthrosc, 2022; 2922-2930)	Comparator: Main area of focus is surgical approach/technique
100.	Corin	Orsi (Knee Surg Sports Traumatol Arthrosc, 2024; 1-14)	Comparator: RAS cohort split into groups by knee phenotype and alignment technique, considered as single arm RAS study
101.	EAG literature searches	Parel (J Arthro Joint Surg, 2022)	Intervention: Includes ROBODOC
102.	EAG literature searches	Pierce (Am J Manag Care, 2020; e205-e210)	Intervention: technology not reported
103.	EAG literature searches	Pierce (J Comp Eff Res, 2021; 1225-1234)	Intervention: technology not reported
104.	Corin	Plaskos (Orthop Procs, 2020; 1) [Poster]	Study Design: Case study
105.	EAG literature searches	Raj (J Ortho, 2023)	Intervention: Included ROBODOC
106.	EAG literature searches	Rajan (JAAOS, 2022; 168-176)	Intervention: technology not reported
107.	EAG literature searches	Remily (Arthroplast Today, 2021; 46-49)	Intervention: technology not reported
108.	Smith & Nephew	Renkawitz (Bone Joint J, 2015; 890-898)	Year of publication: More than 5 years from time of search. Note: RCT with robotic (n=66) and conventional (n=69) THA.
109.	EAG literature searches	Riantho (JB JS Open Access, 2023; e23.00010)a	Intervention: Includes ROBODOC/ HURWA/ YUANHUA
110.	EAG literature searches	Robinson (Bone and Joint, 2019)	Intervention: Includes Sculptor RGA
111.	EAG literature searches	Ruangsomboon (J Robot Surg, 2024)	Intervention: Includes ROBODOC and Trex-RS
112.	EAG literature searches	Ruangsomboon (Acta Ortho, 2023)	Intervention: Includes ROBODOC/ YUANHUA/ HURWA/Tsolution One
113.	EAG literature searches	Samuel (J Robot Surg, 2022)	Intervention: Includes ROBODOC

#	Source	Study reference	Reason
114.	EAG literature searches	Sarrel (J Comp Eff Res, 2024; e230040)	Study design: review article Intervention: technologies used not reported, primary evidence not reviewed due to time constraints
115.	EAG literature searches / Zimmer Biomet	Seidenstein (Knee Surg Sports Traumatol Arthrosc, 2021; 859-866)	Study design: cadaveric study
116.	EAG literature searches	Selvaratnam (J Knee Surg, 2022; 731-738)	Study design: single arm
117.	Smith & Nephew	Sendtner (Int Orthop, 2011; 809-815)	Year of publication: More than 5 years from time of search. Note: robotic device not mentioned; THA.
118.	EAG literature searches	Sephton (J Orthop, 2020; 223-228)	Study design: single arm
119.	EAG literature searches	Sephton (J Clin Orthop Trauma, 2020; S239-S245) UK (N=1)	Study design: mixed intervention
120.	EAG literature searches / Corin	Shady (Clin Orthop Relat Res, 2022; 1604-1615)	Study design: cadaveric study
121.	EAG literature searches	Shah (Surgery, 2021; 134-139)	Intervention: technology not reported
122.	EAG literature searches / Corin	Shalhoub (Arthroplasty Today, 2019; 334	Study design: No outcomes in Scope.
123.	EAG literature searches / Corin	Sharma (Med Eng Phys, 2022; 103881-)	Study design: No outcomes in Scope.
124.	EAG literature searches / Corin	Shatrov (Arch Orthop Trauma Surg, 2021; 2087-2096)	Study design: Literature review (N=13, but only 10 in detailed table, including 3 cadaveric, 6 retrospective cohort, 1 prospective cohort) of the 10 papers detailed 7 were from 2018 or earlier, no mention of matched comparator group
125.	EAG literature searches / Smith & Nephew	Shearman (Arch Orthop Trauma Surg, 2021; 2147-2153)	Comparator: UKA with computer navigation
126.	EAG literature searches / Johnson & Johnson	Spitzer (Knee, 2024; 52-61)	Comparator: RAS to conventional only for soft tissue release (or not) Outcomes: Out of Scope
127.	Johnson & Johnson	Spitzer et al. (2024) [Poster]	Study design: Poster only (full paper by Spitzer et al. 2024 reviewed by EAG)
128.	EAG literature searches	Steffens (Int Orthop, 2022; 481-488)	Comparator: TKA with navigation
129.	EAG literature searches	Sweet (JBJS Rev, 2021)	Intervention: Includes ROBODOC

#	Source	Study reference	Reason
130.	EAG literature searches	Thanabaien (Malaysian HTA, 2022)	Study design: review article
131.	EAG literature searches	Vermue (Arch Orthop Trauma, 2023; 3369-3381)	Intervention: Includes ROBODOC
132.	EAG literature searches / Corin	Vigdorchik (J Arthroplasty, 2022; 2035-2040 e5)	Comparator: RAS cohort split into groups by alignment technique and soft tissue release, ie single arm RAS study
133.	EAG literature searches / Corin	Wakelin (Knee Surg Sports Traumatol Arthrosc, 2022; 939-947)	Comparator: RAS cohort split into groups by joint gap balance across flexion, ie single arm RAS study
134.	EAG literature searches / Corin	Wakelin (Knee Surg Sports Traumatol Arthrosc, 2023; 5535-5545)	Comparator: RAS cohort split into groups by joint laxity and gap balance across flexion, ie single arm RAS study.
135.	EAG literature searches	Walgrave (Bone Jt Open, 2023; 13-18)	Study design: review article
136.	EAG literature searches	Wang (Int J Med Robot CAS, 2023)	Intervention: Includes ROBODOC, CASPAR
137.	EAG literature searches	Ward (J Clin Ortho Trauma, 2023)	Intervention: Technology not reported
138.	EAG literature searches	Yamamoto (J ISAKOS 8, 2023; S69) - Abstract	Intervention: unable to determine device
139.	EAG literature searches	Yasen (Cureus, 2023; 50852)	Study design: review article
140.	EAG literature searches	Zhang (Bone Joint J, 2022; 541-548)	Study design: systematic review (N=14), including 4 RCTs (3 published before 2019), 2 Markov decision models, 3 prospective cohorts (1 published before 2019, no mention of matching) and 5 retrospective cohorts. A total of 7 studies were published before 2019. All studies using Mako.
141.	EAG literature searches / Stryker	Zhang (Knee Surg Sports Traumatol Arthrosc, 2022; 2677-2695)	Study design: Systematic review with meta-analysis (N=16 studies, all observational, 5 retrospective) matching not reported, 4 published before 2019; all using Mako system. Three studies conducted in UK (Kayani et al. 2018a, Kayani et al. 2018b, Kayani et al. 2019); the later included in EVA report as published within the last 5 years.
142.	EAG literature searches	Zhang (J Arthroplasty, 2024; 568)	Study design: corrigendum to Zhang (J Arthroplasty, 2023; 1434-1437)
143.	EAG literature searches	Zhang (Orthop Surg, 2024; 1434-1444)	Intervention: technology not reported

Abbreviations: CiC, Commercial in confidence; EAG, external assessment group; FU, follow-up; NJR, National Joint Registry; RAS, Robotic Assisted Surgery; RCT, randomised controlled trial; THA, total hip arthroplasty; TKA, Total

Knee Arthroplasty; UCLA, University of California Los Angeles activity-level; WOMAC, Western Ontario & McMaster Universities Score.

Appendix B – Included studies

Appendix B1 – Key clinical evidence (N=26)

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
1.	Adamska (Medicina, 2023; 236) (Adamska et al., 2023) [NCT04611815; RATKA trial] *Funding:* Authors declared no funding received. *Declaration of interest*: Authors declared no conflicts of interest.	*Study design:* RCT three arms, triple blinded (care provider, investigator, outcomes assessor) using computer randomisation. *Procedure:* primary TKA *Intervention:* - NAVIO (n=76) - CORI (n=71) **GREEN** *Comparator:* convention (n=68) **GREEN** *Implants:* All patients received a cemented, fixed-bearing prosthesis with metal-bearing polyethylene (Journey II, Smith & Nephew).	*Inclusion:* Patients with knee osteoarthritis involving one or more compartments, listed for TKA, aged 18 years or older, willing to provide informed consent in Polish language. *Exclusion:* Primary stage of one-sided knee osteoarthritis, severe symptoms in the contralateral knee so as to require staged bilateral knee replacements within 6 months of the primary procedure, fixed flexion deformity of 15° or greater who will require excessive resection of the distal femur, clinically assessed as varus or valgus deformity of 15°or greater, any comorbidity which in the opinion of the investigator is severe enough to present an unacceptable risk to the patient's safety, inflammatory arthritis, unable to understand written and spoken Polish. **GREEN**	Surgery time, length of hospital stay, blood loss, complications (1 year), revision (1 year), functional outcomes (KOOS, ROM, VAS), alignment. **GREEN**	Surgeon conducted 15 NAVIO procedures prior to study, no training for CORI (updated system by same manufacturer). Authors acknowledge: surgeon did not reach the learning curve, while it was ongoing, short follow up period of 12 months, did not analyze cost-effectiveness of the operation, limited radiographic evaluation, patients not completely blinded to RAS or conventional which would need excessive pointless incisions of the skin, simulating pins fixation, only included femoral component rotational alignment from radiographic evaluation.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
			Recruitment period: Between 01 December 2021 and 31 July 2022. *Setting:* Poland (N=1, single surgeon) *Follow-up:* 1 year		
2.	Ajekigbe (J Biomechanics, 2024; 112112) [ISRCTN47889316] *Funding:* Funded by Stryker *Declaration of interests:* None	*Study design:* RCT *Procedure:* TKA *Intervention:* Mako, also used Verasense sensor (n=50) **GREEN** *Comparator:* Conventional (n=50) **GREEN** *Implants:* All patients received cemented Triathlon cruciate retaining TKA with a highly crossed linked (X3) polyethylene insert. Mako group also received the Verasense	*Inclusion:* Listed for elective primary total knee replacement for end-stage osteoarthritis, aged between 45 and 85 years of age at time of listing for surgery, and suitable for a cruciate retaining Triathlon prosthesis. *Exclusion*: Incompetent MCL (grade III in laxity) observed by consultant on examination, unable to comply with the study protocol, pregnant, lactating or planning pregnancy during the course of the study, requires patella resurfacing, any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at ability to participate in the study. **GREEN**	Functional gait analysis **RED**	Complete gait cycle data were available for only 26 patients in intervention and 23 in comparator arm. Demographics of patients included in analysis not reported. No *a priori* power analysis undertaken (no study comparing gait parameters was available at time of recruiting); post-hoc power calculation stated as 86.3% power for the effect size and number of patients included in analysis.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		device (Orthosensor inc., Dania Beach, Florida, US) temporarily inserted to measure intracompartmental pressures in knee flexion and extension).	*Recruitment period:* Between June 2019 and December 2021 (paused during March to June 2020 due to cessation of elective surgery during COVID pandemic). *Follow-up:* 1 year *Setting:* Newcastle upon Tyne, UK		
3.	Ammori (Orthop Procs, 2024; 6-6) *Abstract only* *Funding:* NR *Declaration of interests:* NR	*Study design:* prospective database (n=539 patients, 564 procedures) *Procedure:* Primary THA *Intervention:* Undefined (shared by Stryker, assumed Mako) (n=NR) **AMBER** *Comparator:* Conventional (n=NR) **GREEN** *Implants:* NR	*Inclusion:* consecutive patients undergoing primary THA identified from local prospective registry. *Exclusion*: NR **GREEN** *Recruitment period:* Between 01 May 2021 and 31 August 2022 *Follow-up:* 1 year *Setting:* Aberdeen, UK	Oxford Hip Score, EQ-5D-3L, EQVAS **GREEN**	Limited detail provided in abstract, for example: demographics of included participants, number of patient treated with robotic or conventional surgery and device used not explicitly reported.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
4.	Banger (Bone Joint J, 2022; 433-443) [ISRCTN 12151461; **TRUCK trial**] *Funding:* Not reported *Declaration of interests:* Not reported	*Study design:* RCT (double blinded) *Procedure:* bi-unicompartmental and total knee arthroplasty (different across arms) *Intervention:* robotic-assisted (Mako RIO) bi-unicompartmental knee arthroplasty, bi-UKA, with two Mako Restoris implants (n=34) **GREEN** *Comparator:* standard TKA, with Zimmer NexGen LPS implant (n=42) **AMBER** *Implants:* Intervention group received unicondylar fixed bearing MAKO Restoris MCK implants (Stryker, US)	*Inclusion:* Patients suitable for a standard TKA to treat medial and lateral compartment osteoarthritis with clinical intact cruciate and collateral ligaments. *Exclusion*: Patients with inflammatory arthropathies, varus or valgus deformities greater than 15°, fixed flexion contracture greater than 10°, single compartment osteoarthritis suitable for an isolated UKA procedure, or patellofemoral osteoarthritis greater than Kellgren and Lawrence grade III. **GREEN** *Recruitment period:* October 2014 to February 2018 *Follow-up:* 1 year *Setting:* Glasgow, UK	Functional gait analysis, sway analysis **RED**	Different procedure and different implants across arms which may confound results. Overlap with Banger et al. 2020.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Comparator group received Fixed-bearing, cruciate-sacrificing, posterior-stabilised Zimmer NexGen LPS TKA (Zimmer Biomet, US).			
5.	Banger (Bone Joint J, 2021; 1088-1095) [ISRCTN77119437] *Funding:* Institutional support grant from the Mako Surgical Corporation (now Stryker), who had oversight of the trial, but no influence on data analysis nor the publication of the findings. *Declaration of interests:* Multiple authors with Mako Surgical (Stryker)	*Study design:* RCT; online randomization software, double blinded. *Procedure:* UKA *Intervention:* Mako with Restoris implant (n=69) **GREEN** *Comparator:* Conventional with Zimmer Biomet implant (n=70) **AMBER** *Implants:* Intervention group received Restoris MCK (MAKO Surgical, US) Comparator group received Oxford phase 3 UKA (Zimmer Biomet, US)	*Inclusion:* Listed for UKA to treat medial osteoarthritis, provided informed consent, were willing to attend the scheduled follow-up appointments. *Exclusion:* ligament insufficiency, inflammatory arthritis, a deformity requiring augmentation, neurological movement disorders, pathology of the feet, ankles, hips, or opposite knee causing significant pain or gait alterations, and patients clearly requiring a TKA pre-operatively. **GREEN** *Recruitment period:* October 2010 to December 2012 *Follow-up:* up to 5 years *Setting:* Glasgow Royal Infirmary (N=1), UK	PROMs (OKS, AKSS, FJS, pain-VAS, stiffness-VAS, satisfaction) **GREEN**	Different implants across arms; which may confound results, surgeries carried out by high-volume UKA surgeons. Patients in robotic arm required pre-operative CT and additional incisions for registration pins, which may lead to unblinding.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
6.	Banger (Bone Joint J, 2020; 1511-1518) [ISRCTN 12151461; **TRUCK trial**] *Funding:* Funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. *Declaration of interests:* Multiple author with Stryker or Zimmer Biomet.	*Study design:* RCT *Procedure:* bi-unicompartmental and total knee arthroplasty (different across arms) *Intervention:* robotic-assisted (Mako) bi-unicompartmental knee arthroplasty, bi-UKA, with medial and lateral Restoris implants (n=32) **GREEN** *Comparator:* standard TKA, with NexGen LPS implant (n=38) **AMBER** *Implants:* Intervention group received Medial and lateral Restoris MCK (Multi-compartmental Knee) fixed-bearing onlay implants (Stryker,	*Inclusion:* On waiting list for knee arthroplasty, with medial and lateral compartment osteoarthritis suitable for treatment with a standard unconstrained TKA with clinically intact cruciate and collateral ligaments. *Exclusion*: Rheumatoid arthritis or other inflammatory arthropathies, varus or valgus deformities greater than 15°, a fixed flexion contracture greater than 10°, single-compartment osteoarthritis suitable for an isolated UKA, or patellofemoral osteoarthritis (greater than Kellgren and Lawrence grade III), patients who had undergone previous surgery to the knee, those with significant disease in other joints which might alter their gait. **GREEN** *Recruitment period:* NR *Follow-up:* post-procedure *Setting:* Glasgow (N=1), UK	Alignment parameters (radiological) **GREEN**	Different procedure and different implants across arms (Zimmer NexGen LPS in comparator, Mako Restoris MCK implants in intervention arm); which may confound results. Overlap with Banger et al. 2020. Authors acknowledge some patients lost to in-adequate CT scans. Outcomes for dynamically loaded knee behave differently to an unloaded knee.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Kalamazoo, Michigan, US), Comparator group received NexGen LPS implant (Zimmer, Warsaw, Indiana, US), a fixed-bearing bicruciate-sacrificing total condylar implant.			
7.	Clement (Bone Joint J, 2024; 450-459) [ISRCTN 47889316] *Funding:* Stryker *Declaration of interests:* All authors reported researcher-initiated research grant from Stryker	*Study design:* RCT; randomised using Sealed Envelope software (blinding not possible due to requirement of pre-operative CT for those in robotic arm). *Procedure: Primary TKA* *Intervention:* Mako (n=50) **GREEN** *Comparator:* Conventional jig-based (n=50) **GREEN** *Implants:* All patient received Triathlon with X-3	*Inclusion:* Aged 45 to 85 years at the time of listing for TKA. *Exclusion:* varus deformity exceeding 20°; inability to comply with the study protocol; female participants for whom exposure to radiation was contraindicated; requirement for patella resurfacing; inability to understand the patient information for the study, provide written informed consent, or answer study questionnaires; and any other serious disease or disorder. **GREEN** *Recruitment period:* May 2019 to December 2021. *Follow-up:* 1 year	*Primary:* WOMAC, OKS, FJS, satisfaction, EQ-5D, EQ-VAS, HSS *Secondary:* Complications **GREEN**	Powered to detect difference in WOMAC. Authors acknowledge that methods of placement of the components fundamentally different between arms; robotic arm underwent restrict kinematic alignment where relatively more bone is resected from the distal lateral femoral condyle. Different implants across arms; which may confound results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		highly cross-linked, polyethylene; Stryker, US	*Setting:* Newcastle, UK (N=1)		
8.	Clement (Bone Joint Res, 2021; 22-30) *Funding:* Collection of this data from the private centre was funded by a grant from Stryker. Benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non- profit organization with which one or more of the authors are associated. *Declaration of interests:* Multiple authors with Stryker.	*Study design:* Propensity score matched (1:2 ratio) cohort study (matched for age at operation, sex, BMI, ASA grade, and preoperative function), selecting closest matching controls. Powered to detect a MCID of 5 points in OHS (80% power). *Procedure:* THA *Intervention:* Mako (n=40) **GREEN** *Comparator:* conventional (n=80) **GREEN** *Implants:* Intervention group received uncemented Trident Acetabular Shell (Stryker) with a highly crosslinked polyethylene liner.	*Inclusion:* osteoarthritis of the hip (complete radiological joint space loss). *Exclusion*: Inflammatory arthritis; haemochromatosis; chondrocalcinosis; or haemophilia, immobility, or other neurological conditions affecting musculoskeletal function. **GREEN** Doesn't need to be highlighted *Recruitment period:* consecutive series of patients undergoing robotic surgery prospectively recruited during November 2017 to June 2019. Comparator arm had data collected over a 12 month period (timepoint undefined). *Follow-up:* Up to 12 months *Setting:* Edinburgh, UK (N=2)	PROMs (OHS, FJS, satisfaction), EQ-5D, EQ-VAS, radiological assessment (Lewinnek and Callanan safe zones, and restoration of leg length) **AMBER**	Private hospital performing robotic surgeries, NHS hospital conventional surgeries, duration of recruitment and duration of following in intervention and comparator arms different, which may confound results. Authors acknowledge non-randomization of patients (which was dependent on which hospital they presented to), propensity matching using a 1:2 ratio being dependent on data available at the recruiting centres and propensity matching not including patient comorbidities (authors state that propensity matching did include EQ5D however this is not explicitly reported in methods section).

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Comparator group received cemented crosslinked contemporary acetabular component (Stryker, Newbury, UK).			Different implants across arms; which may confound results.
9.	Clement 2020 (Bone Joint Res; 15-22) *Funding:* benefits received directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated. *Declaration of interests:* Multiple authors with Stryker	*Study design:* Prospective cohort with propensity matching (1:3 based on age at operation, sex, NMI and preoperative function scores) selecting the closest matching control. Powered to detect MCID 5 points on OKS (80% power). *Procedure:* UKA *Intervention:* Mako (n=30) **GREEN** *Comparator:* Conventional (n=90) **AMBER** *Implants:* Intervention group received cemented Restoris MCK implant	*Inclusion:* Isolated medial compartment osteoarthritis (complete radiological joint space loss), preservation joint space in other compartments of the knee joint; a varus deformity of less than 10° which is correctible, flexion deformity less than 15° and a minimum of 90° of knee flexion. *Exclusion:* Inflammatory arthritis, haemochromatosis, chondrocalcinosis, haemophilia, symptomatic knee instability or anterior cruciate ligament deficiency, multicompartment disease, previously failed correctional osteotomy or ipsilateral UKA, and immobility or other neurological conditions affecting musculoskeletal function. **GREEN** *Recruitment period:* Robotic arm included consecutive patients prospectively recruited from one	PROMs (OKS, FJS, pain-VAS, satisfaction), length of hospital stay, EQ-5D. **GREEN**	Different recruitment periods between arms, and intervention and comparator arms were at different hospitals (high-volume hospital for conventional arm, low-volume hospital for robotics arm), which may confound results. Different implants across arms; which may confound results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		(Stryker, Kalamazoo, Michigan, US) Conventional group received Triathlon (Stryker).	centre between May 2017 to February 2018. Conventional arm included patients from a different centre recruited over a 12-month period (dates not specified) *Follow-up:* Up to 6 months *Setting:* UK (N=2)		
10.	Fary et al. (J Arthroplasty, 2023; 62) [NCT03737149] *Funding:* Funded by Zimmer Biomet. *Declaration of interests:* Multiple authors employed by Zimmer Biomet, includes one paid consultant.	*Study design:* Prospective propensity matched 1:1 (based on age, sex, BMI, comorbidity index) *Procedure:* Unilateral primary TKA with Persona, Vanguard, NexGen, Natural-Knee system *Intervention:* RAS (n=216) with ROSA (Zimmer Biomet) **GREEN** *Comparator:* conventional (n=216) **AMBER**	*Inclusion:* Age 18 years or older, scheduled for procedure for osteoarthritis indication, capable of walking with minimal assistance (single walking stick or single crutch) pre-operatively. *Exclusion:* substance abuse as determined by surgeon, inflammatory arthropathies that would interfere with or compromise activity profiles, those undergoing other surgical intervention studies, those requiring simultaneous or staged bilateral knee arthroplasties less than 90 days apart, patients with less than 3-month follow-up, patients with missing pre-operative or 1 month follow-up data. **GREEN**	Length of hospital stay, ROM, PROMs (KOOS-JR, EQ-5D-5L), post-operative opioid use, adverse events, revision, patients prescribed physiotherapy at discharge, patients discharged to skilled nursing facilities. **AMBER**	Surgeons unaware of comparison of outcomes (31 surgeons performing conventional TKA only, 4 performing RAS only, and 11 combination); primary aim of trial was to evaluate mymobility (Zimmer Biomet) smartphone care management platform (not specific to evaluating RAS). Statistical difference in use of general anaesthesia between arms (63% in intervention arm, 52.8% comparator; p=0.04), and in components used (tibial articulating surface: cruciate retaining,

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Implants: All patients received either Persona Knee System (Zimmer Biomet,Warsaw, IN, US); Vanguard Knee System (Zimmer Biomet, Warsaw, IN, US); or NexGen Knee System (Zimmer Biomet, Warsaw, IN, US). In addition, the comparator group also may have received Natural- Knee System (Zimmer Biomet, Warsaw, IN, US)	*Recruitment period:* between August 2019 and April 2022 for intervention arm. *Follow-up:* range of motion up to 90 days, PROMs up to 1 year. *Setting:* Not explicitly reported (multiple centres, N=NR), however clinical trial registration for the mymobility platform is based in US, Australia, Italy, the Netherlands		posterior stabilized, ultra-congruent, medial congruent, constrained posterior stabilized; p<0.0001). Different implants across arms; which may confound results.
11.	Fontalis (Bone Joint J, 2024; 24-30) *Funding:* Authors stated that no financial or material support for research, authorship or publication of article. However, author contributions state "Funding acquisition" *Declaration of interests:*	*Study design:* Retrospective cohort (identified from prospective database) *Procedure:* THA (n=1607) *Intervention:* Mako (n=267 procedures) **GREEN** *Comparator:* Conventional (n=1,465 procedures)	*Inclusion:* All THA patients of any age undergoing THA for any indication (including osteoarthritis, osteonecrosis, inflammatory arthritis, and post-traumatic arthritis). *Exclusion*: NR **GREEN** *Recruitment period:* May 2019 and January 2023 *Follow-up:* 30 days	LoS, need for treatment in a post-anaesthesia care unit (PACU), readmission within 30 days **AMBER**	Authors acknowledge that allocation to the respective groups was based on the patients' choice, the expertise and confidence of the Surgeon. Analysis restricted to 2019 onwards to minimized learning curve confounding results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
	Multiple authors with Stryker, Smith & Nephew, Corin, MatOrtho, Zimmer, and AO Recon	**GREEN** *Implants:* NR	*Setting:* London (high-volume centre), UK (N=1)		
12.	He (Orthop Surg, 2022; 1681-1694) *Funding:* National Key R&D Program of China. *Declaration of interests:* Not reported	*Study design:* Retrospective cohort *Procedure:* TKA (primary) *Intervention:* SkyWalker (n=30) **GREEN** *Comparator:* Conventional (n=30) **AMBER** *Implants:* Intervention group received MP prosthesis (MicroPort Orthopedics Inc., Arlington, TN, US). Comparator group received LEGION Total Knee System posterior stabilised prosthesis	*Inclusion:* Age 80 years or less, patients with only deformity of the knee, varus deformity ≤15 degrees, and fixed flexion deformity ≤10 degrees, the Kellgren-Lawrence classification grade IV, availability of complete follow-up data in the medical records (including operation time, intraoperative blood loss, tourniquet time, length of stay, maximum knee flexion angle, KSS, WOMAC at 3 months postoperatively, complete full-length weight bearing radiography (anteroposterior and lateral views) and CT of the lower extremity, no severe dysfunction of the contralateral knee or Kellgren-Lawrence classification lower than Grade II. *Exclusion*: Patients with large bone defects around the knee, knee valgus deformities, severe extra-articular deformities, patients with periarticular soft tissue dysfunction and neuropathy, history of	Alignment, blood loss, operative time, tourniquet time, complications, length of stay, PROMs (WOMAC, KSS)	Power calculation based on 85% power and difference in proportions (however outcome unclear). Authors acknowledge different prostheses used across groups (robotic system requiring unique prosthetic system); which may influence results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		(Smith & Nephew, Memphis, TN, US)	autoimmune diseases prior to surgery such as rheumatoid arthritis and ankylosing spondylitis, involving lesions in multiple joints. *Recruitment period:* Between May 2019 and December 2020. *Follow-up:* 3 months *Setting:* China (N=1)		
13.	Kayani (Knee Surg Sports Traumatol Arthrosc, 2023; 5453-5462) *Funding:* None *Declaration of interests:* One author with Smith & Nephew.	*Study design:* prospective cohort study *Procedure:* primary TKA *Intervention:* Mako (n=60 consecutive patients) **GREEN** *Comparator:* conventional jig-based (n=60 consecutive patients) **GREEN** *Implants:* All patients received Cemented	*Inclusion:* Patients with symptomatic end-state knee arthritis undergoing primary TKA, aged between 18 and 80 years *Exclusion:* Conversion of unicompartmental knee arthroplasty to TKA, prior infection of knee joint, arthroplasty for fracture or previous osteotomy, and underlying neurological dysfunction compromising mobility. **GREEN** *Recruitment period:* Between January 2016 and May 2017	PROMs (KSS, FJS, UCLA, OK), complication (DVT, infections, debridement), manipulation under anaesthesia. **AMBER**	Powered to detect 12 point difference in FJS between arms (80% power). Same cohort as Kayani (Knee Surg Sports Traumatol Arthrosc, 2019; 1132-1141), different outcomes reported. Allocation based on installation of robotic system (comparator arm all prior to installation) and included the first cohort of patient to undergo robotic surgery by the surgeon. Authors acknowledged that the study was not

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, US) cruciate substituting knee system.	*Follow-up:* 5 years *Setting:* London, UK (N=1; single surgeon)		powered to assess for differences in functional outcomes, which may have introduced type II error, and that the population was relatively healthy with limited comorbidities and high functional demands after surgery, therefore the generalisability of results remains unknown.
14.	Kayani (Bone Joint J, 2021; 113-122) [NCT04192006] *Funding:* No funding for personal or professional use from a commercial party related directly or indirectly to the subject of this article, however benefits have been or will be received (as below) but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which	*Study design:* RCT (randomised using online number generator) *Procedure:* Primary TKA *Intervention:* Mako (n=15) **GREEN** *Comparator:* Conventional jig-based (n=15) **GREEN** *Implants:* All patients received Triathlon cruciate-retaining knee	*Inclusion:* Patients with osteoarthritis of the knee undergoing primary TKA, aged 18 and 80 years, able to tolerate general anaesthesia, and able to give informed consent. *Exclusion:* Inflammatory arthropathy, unable to tolerate general anaesthesia, with a previous infection of the knee joint, those undergoing conversion of unicompartmental to TKA, those undergoing TKA for fracture or with a previous osteotomy, those with neurological dysfunction compromising mobility. **GREEN**	*Primary:* Inflammatory response (serum makers), skin temperature over the operated knee, macroscopic soft tissue injury, femoral and tibial bone trauma *Secondary* Radiographic alignment, length of incision, operating time, change in haemoglobin concentration	Powered to detect a difference of 25 mg/L in CRP at 24 hours between groups with 80% power. Authors acknowledge that analysis restricted to short-term difference in CRP levels, however long-term impact remains unknown.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
	one or more of the authors are associated. *Declaration of interests:* Multiple authors with Smith & Nephew, Stryker, Digital Surgery, HCA, Springer, AO, Corin, MatOrtho.	system (Stryker) with patellar resurfacing using asymmetrical components	*Recruitment period:* NR *Follow-up:* up to 28 days *Setting:* London, UK (N=1)	**AMBER**	
15.	Kayani (Knee Surg Sports Traumatol Arthrosc, 2019; 1132-1141) *Funding:* None *Declaration of interests:* One author with Stryker.	*Study design:* prospective cohort study *Procedure:* Primary TKA *Intervention:* Undefined; shared by Stryker, assumed Mako (n=60 consecutive patients) **GREEN** *Comparator:* conventional jig-based (n=60 consecutive patients) **GREEN** *Implants:* All patients received Cemented Stryker Triathlon (Stryker	*Inclusion:* Patients with symptomatic knee osteoarthritis undergoing primary TKA, aged between 18 and 80 years. *Exclusion:* Conversion of unicompartmental knee arthroplasty to TKA, prior infection of knee joint, arthroplasty for fracture or previous osteotomy, and underlying neurological dysfunction compromising mobility. **GREEN** *Recruitment period:* between 2016 and 2017 *Follow-up:* Up to 30 days	Learning curve (operative times), surgical team anxiety levels, alignment, complications. **AMBER**	Allocation based on installation of robotic system (comparator arm all prior to installation), and included the first cohort of patient to undergo robotic surgery by the surgeon; therefore analysis includes learning curve. Authors acknowledge that radiological analyses were performed using plain radiographs (they advised that post-operative CT would have enabled more accurate assessment of radiological outcomes)

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Navigation, Kalamazoo, Michigan, US), cruciate substituting knee system	*Setting:* London, UK (N=1, and single surgeon)		
16.	Kayani (Bone Joint J, 2019; 11-18); UK *Funding:* Supported by the National Institute for Health Research University College London Hospitals Biomedical Research Centre *Declaration of interests:* One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article (Companies not explicitly stated)	*Study design:* Prospective cohort *Procedure:* primary cementless THA *Intervention:* Mako (n=25) **GREEN** *Comparator:* conventional (n=50) **GREEN** *Implants:* All patient received Accolade II femoral stem (Stryker, Mahwah, New Jersey) and Trident acetabular shell (Stryker).	*Inclusion:* Patients undergoing primary THA for symptomatic hip osteoarthritis (primary osteoarthritis or osteoarthritis secondary to osteonecrosis or rheumatoid arthritis), age between 18 and 80 years inclusive, and suitability to receive the planned study implants *Exclusion*: Patients in whom the planned hip biomechanics were in a different position to the contralateral hip (for example developmental dysplasia of the hip or protrusio acetabuli), revision THA, immobility or other neurological condition affecting musculoskeletal function. **GREEN** *Recruitment period:* September 2016 and January 2018 *Follow-up:* 6 weeks *Setting:* London, UK (N=1, and single high-volume surgeon)	Radiological alignment (horizontal centre of rotation, vertical cetnre of rotation, combined offset, component offset, component anteversion, overall component position, within Lewinnek's safe zone, within Callanan's safe zone, leg-length disprepancy) **AMBER**	Authors acknowledge that radiological analyses were performed using plain radiographs (they advised that post-operative CT would have enabled more accurate assessment of radiological outcomes) and that the robotic technology was not used to guide femoral preparation or stem insertion, which may have affected the observed study outcomes in the robotic group. Powered to detect minimum difference in horizontal centre of rotation between arms with 90% power. Robotic group was the first cohort of patients to undergo robotic-arm assisted THA by the operating surgeon, therefore learning curve may influence results. Allocation to robotic arm

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
					was based on device availability.
17.	Kayani (Bone Joint J, 2019; 24-33); UK *Funding:* NIHR University college London Biomed Research Centre. *Declaration of interests:* One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article (Companies not explicitly stated)	*Study design:* Prospective cohort (n=146) *Procedure:* UKA *Intervention:* Mako RIO (n=73 consecutive patients) **GREEN** *Comparator:* Conventional (n=73 consecutive patients) with Oxford mobile-bearing implant **AMBER** *Implants:* Intervention group received RESTORIS MCK (Mako Surgical Corporation, Kalamazoo, Michigan) fixed-bearing UKA system. Comparator group received Oxford mobile-bearing UKA (Zimmer	*Inclusion:* Patients with symptomatic medial compartment osteoarthritis undergoing primary UKA. Diagnosis of osteoarthritis or osteonecrosis limited to the medial compartment, preservation of the other compartments of the knee joint, passively correctible varus deformity of less than 10°, fixed flexion deformity less than 15°, maximum knee flexion greater than 90°, and patient between 18 to 80 years of age. *Exclusion*: diagnosis of inflammatory arthritis, haemochromatosis, chondrocalcinosis, or haemophilia, symptomatic knee instability or anterior cruciate ligament (ACL) deficiency, multi-compartment disease, previously failed correctional osteotomy or ipsilateral UKA, immobility or other neurological condition affecting musculoskeletal function. **GREEN**	Pain (numerical rating scale, analgesia), blood loss, length of stay, alignment, time to straight-leg raise, knee extension, knee flexion, physiotherapy sessions, continuous passive motion machine sessions. **AMBER**	Powered to detect a difference in pain of 2.17 points in the numerical rating scale (at 24 hours) with 80% power. Allocation based on installation of robotic system (comparator arm all prior to installation), and included the first cohort of patient to undergo robotic surgery by the surgeon; therefore analysis includes learning curve. Different implant used between arms; which may influence results. Authors acknowledge that all procedures were conducted under general anaesthesia.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Biomet, Bridgend, United Kingdom).	*Recruitment period:* Between February 2016 and February 2018. *Follow-up:* Up to 90 days *Setting:* London, UK (N=1, single high-volume surgeon)		
18.	Kenanidis et al. (Eur J Orthop Surg Traumatol, 2023; 1231-1236 2023) *Funding:* Authors declared no funding received. *Declaration of interests:* Authors declared no conflicts of interest.	*Study design*: prospective matched comparative cohort (based on age, sex, and BMI), patient choice on intervention or comparator. *Procedure:* primary unilateral TKA. *Intervention:* RAS (n=30) with ROSA (Zimmer Biomet) consecutive patients **GREEN** *Comparator:* conventional (n=30) **GREEN**	*Inclusion: a*dult patients suffering from symptomatic primary unilateral end-stage knee osteoarthritis. *Exclusion:* complex primary or revision TKA, different knee implant, **GREEN** *Recruitment period:* September 2020 to May 2021 *Follow-up:* 6 months *Setting:* Greece; academic orthopaedic hospital (N=1) by the same surgeon.	Intra- and postoperative complications, blood transfusion rate, LOS, and revision, PROMs (OKS, VAS, FJS-12, satisfaction) **GREEN**	Patient choice of robotic or conventional; which may influence results. Short follow-up, small sample size.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Implants: All patients received Posterior-stabilised prostheses (Nexgen Legacy, Zimmer Biomet, Warsaw, IN)			
19.	Khan (Int J Med Robot, 2021; e2308); UK *Funding:* not reported *Declaration of interests:* One author with Smith & Nephew	*Study design:* Retrospective cohort *Procedure:* Primary TKA (n=100), primary UKA (n=100) *Intervention:* NAVIO (n=50 TKA, n=50 UKA, consecutive patients) **GREEN** *Comparator:* Conventional (n=50 TKA, n=50 UKA); matched on age and sex. **AMBER** *Implants:* Intervention group received either, Accuris or Journey. Comparator group received either, Accuris, Journey or Oxford.	*Inclusion:* Patients with confirmed diagnosis of osteoarthritis, aged older than 18 year undergoing primary TKA or UKA. *Exclusion*: non-osteoarthritis patients with alternative indications for knee arthroplasty, patients undergoing bilateral procedures, patients with prior knee operations, haematological disease, and coagulopathies. **GREEN** *Recruitment period:* January 2016 to February 2020. *Follow-up:* Procedural. *Setting:* London, UK (N=1; multiple surgeons)	Blood loss, transfusion. **GREEN**	Allocation to robot and surgeon by operating surgeon preference. Powered to detect 20% reduction in blood loss (80% power). TKA and UKA reported separately. Different implants or different in proportion of implants between arm; which may influence results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
20.	Kong (Int J Surg, 2020; 174-180) *Funding:* Authors reported no funding *Declaration of interest:* Authors reported no declaration of competing interests.	*Study design:* Retrospective cohort *Procedure:* THA *Intervention:* Mako (n=100) **GREEN** *Comparator:* Conventional (n=100) **GREEN** *Implants:* All patient received Trident acetabular cup and Accolade II tapered stem (Stryker, Mahwah, US).	*Inclusion:* All surgeries performed by one experienced surgeon in conventional THA with Trident acetabular cup and Accolade II tapered stem (Stryker). *Exclusion:* Patients with incomplete clinical data or non-standard radiographs were excluded. **GREEN** *Recruitment period:* Between August 2018 and March 2019. *Setting:* NR (N=1, single surgeon) *Follow-up:* 3 months	Learning curve based on operating time, robotic complications, alignment **GREEN**	EAG have included the study for the learning curve outcome only. Historical comparator arm.
21.	(Leslie et al., 2024 - *Academic in Confidence*) Provided by Company. [NCT04730271] [Abstract available online] *Funding:* Funded by DePuy Synthes	*Study design:* prospective comparative cohort *Procedure:* Primary TKA *Intervention:* VELYS (n=100) **GREEN**	*Inclusion:* patients aged between 22 and 85 years old with osteoarthritis, post-traumatic arthritis or rheumatoid arthritis suitable for TKA. *Exclusion:* Pregnant, contra-lateral knee already enrolled in study, or had an amputation, previous partial knee arthroplasty, patellectomy,	[redacted] intraoperative complications, [redacted] total surgical time, alignment, PROMs. **GREEN**	Statistical difference in baseline BMI between arms (lower BMI in robotics arm). [redacted]

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
	Declaration of interests: Multiple authors with DePuy Synthes	*Comparator:* Conventional (n=100) **GREEN** *Implants:* All patients received Attune implant.	high tibial osteotomy or primary TKA in the affected knee. **GREEN** *Recruitment period:* [redacted] (study start date reported as 23 February 2021 on trial registration) *Follow-up:* [redacted] [Abstract reporting outcomes to 3 months] *Setting:* US (N=5); [redacted]		[redacted]
22.	Morrisey (Cureus, 2023; e38872) *Funding:* Authors reported no funding *Declaration of interest:* Single author from DePuy Synthes.	*Study design:* Retrospective cohort (identified from medical records) *Procedure:* TKA (primary), same implant used in all cases. *Intervention:* VELYS kinematically aligned (n=66) **GREEN**	*Inclusion:* Patients who received either robot-guided and kinematically aligned TKA procedures or traditionally instrumented mechanically aligned TKA procedures. *Exclusion:* Revision surgery, age below 30 or above 89, lack of six-week follow-up data in the form of a patient office of telemedicine visit note, prior major knee trauma or arthritis related to traumatic injury, unexpected major deformity to the knee, and unavailability of patient medical records. **GREEN**	Learning curve, complications (pain, use of assistive devices, infection), range of motion, tourniquet time, manipulation under anaesthesia **AMBER**	EAG have included the study for the learning curve outcome only. Historical comparator arm, different alignment between arms; may influence results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		Comparator: Conventional mechanically aligned (n=99) **AMBER** *Implants:* All patient received Depuy Attune Cruciate Retaining implant (DePuy Synthes, Warsaw, IN, US).	*Recruitment period:* Between January 2021 to October 2021 for the conventional comparator arm and between October 2021 and April 2022 for the robotic arm. *Setting:* US (N=1, single surgeon) *Follow-up:* 6 weeks, 6 months		
23.	Ng (J Orthop, 2024; 77-81) *Funding:* authors declared no funding received *Declaration of interests:* Multiple authors with Johnson & Johnson, Stryker and Zimmer Biomet	*Study design:* Prospective cohort with 1:1 propensity matched comparator group (matched on age, sex, operative site, Charlson Comorbidity Index, ASA grade, BMI, preoperative PROMs: KSFS, Knee Society Function Score; KSKS, Knee Society Knee Score; OKS) *Procedure:* TKA (primary) *Intervention:* Mako (n=42) with Enhanced Recovery After Surgery Protocol	*Inclusion*: patients undergoing primary unilateral TKA, with ASA grade ≤3 and agreeable for discharge home, all were listed as day surgery with aim of discharge within 24 h. *Exclusion*: NR **GREEN** *Recruitment period:* Between August 2020 and July 2021 (for both arms) *Follow-up:* Up to 6 months *Setting:* Singapore (N=1)	Surgical duration, length of hospital stay, successful 24 hour discharge, complications (pain, readmission, infection), PROMs and post-operative ROM **AMBER**	Authors acknowledge that the study was conducted within a single institution study with a limited sample size, and that follow-up period was relatively short at 6 months. The EAG note that all patients followed the Enhanced Recovery After Surgery (ERAS) protocol which includes multidisciplinary pre-operative patient optimization, intra-operative strategies and post-operative management and may have influenced results.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		GREEN *Comparator:* Conventional (n=42) with Enhanced Recovery After Surgery Protocol **GREEN** *Implants:* NR			
24.	Thiengwittayaporn (Int Orthop, 2021; 2851-2858); (Thiengwittayaporn et al., 2021) [NCT04307251] *Funding:* Supported by the Faculty of Medicine Vajira Hospital, Navamindradhiraj University Research Fund, Thailand (grant numbers 10-63). *Declaration of interest:* None declared by the authors	*Study design:* RCT *Procedure:* TKA (primary) *Intervention:* NAVIO (n=75) **GREEN** *Comparator:* Conventional (n=77) **GREEN** *Implants:* All patient received fixed-bearing posterior stabilised implant (Legion PS Total Knee System, Smith & Nephew)	*Inclusion:* Patients with primary knee osteoarthritis whose symptoms could not be treated with conservative measures, aged between 40 and 80 years. *Exclusion:* deformity from previous fracture or osteotomy of the tibia or femur, less than 90° range of motion, more than 30° of flexion contracture, BMI more than 40 kg/m2, previous hip arthroplasty, severe instability that could not be treated by posterior stabilised TKA, neurological problem. **GREEN** *Recruitment period:* March 2020 to January 2021.	Radiographical alignment, operative time, learning curve (CUSUM) **GREEN**	Short-term follow-up. Authors acknowledge difficulty in blinding patients (due to evidence of additional markers used during robotic surgery), alignment was not assessed using CT imaging.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
		without patellar resurfacing.	*Setting:* Thailand (N=1; single surgeon) *Follow-up:* Procedural		
25.	Vanlommel (J Exp Orthop, 2021; 119) *Funding:* Zimmer Biomet *Declaration of interest*: Multiple authors with Zimmer Biomet.	*Study design:* Retrospective cohort *Procedure:* TKA (primary), *Intervention:* ROSA Knee (n=30 consecutive patients for each surgeon, total n=90) **GREEN** *Comparator:* Conventional (n=90 consecutive patients) **GREEN** *Implants:* All patient received Persona Posterior Stabilised; Zimmer Biomet, Warsaw)	*Inclusion:* Between ages of 18 and 80 years, had indication for primary TKA due to osteoarthritis, had surgery by one of three surgeons. *Exclusion:* Patients with congenital deformity, underlying neurological dysfunction, severe deformity (>15° of preoperative varus/valgus alignment or a non-correctable deformity), a prior infection or osteotomy around the knee, prior unicompartmental procedure or osteotomy or fracture as the primary indication. **GREEN** *Recruitment period:* Between December 2019 and September 2020 (same recruitment period for both arms) *Setting:* Belgium (N=1, 3 surgeons) *Follow-up:* 90 days	Learning curve on operating time (patients split into consecutive groups of 10), complications, alignment (radiographic outliers). **GREEN**	EAG have included the study for the learning curve outcome only. Procedures conducted by 3 high-volume surgeons (>200 procedures each year), each received cadaveric training on the ROSA Knee system, 2 had prior experience with other robotic systems. Allocation based on availability of robotic system on the date of surgery.

#	Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
26.	Vermue (Int Orthop, 2023; 503-509) *Funding:* FWO Flanders (research grant 11F5919N). *Declaration of interest*: Authors declared no competing interests.	*Study design:* Prospective cohort (With retrospective comparator) *Procedure:* TKA *Intervention:* OMNIBot (n=30) **GREEN** *Comparator:* Conventional (n=30); conducted by same surgeon using same implant **GREEN** *Implants:* All patients received Unity Posterior Stabilised implant (Corin, Massachusetts, US).	*Inclusion:* Patients with end-stage primary osteoarthritis. *Exclusion:* Post-traumatic arthritis, inflammatory arthritis, neurologic disorder limiting knee mobility, history of femur or tibia fracture and history of ligamentous knee injury. **GREEN** *Recruitment period:* NR *Setting:* Belgium (N=1, single surgeon) *Follow-up:* Procedural	Learning curve based on operating times, alignment. **GREEN**	Included surgeon received two hours of training on the specific robotic system.

Key: **GREEN** aspect of study In scope; **AMBER** aspect of study not in scope; **RED** aspect of study in scope, or elements of this are not in scope. Abbreviations:; BMI, body mass index; bi-UKA, bi-unicompartmental knee arthroplasty; COVID, Coronavirus disease; CRP, C-reactive protein; DVT, deep vein thrombosis; ERAS, Enhanced Recovery After Surgery; FJS, Forgotten Joint Score; KOOS-JR, Knee injury and Osteoarthritis Outcome Score for Joint Replacement; KSFS, Knee Society Function Score; KSS, Knee Society Score; LoS, length of stay; MCID, minimally clinically important difference; NR, not reported; OHS, Oxford Hip Score; OKS, Oxford Knee Score; PACU, Post-Anaesthesia Care Unit; PROM, Patient Reported Outcome Measure; RAS, Robotic Assisted Surgery; ROM, range of motion; THA, total hip arthroplasty; TKA, total knee

arthroplasty; UCLA, University of California Los Angeles activity-level, UKA, unicompartmental knee arthroplasty; VAS, Visual Analogue Scale; WOMAC, Western Ontario & McMaster Universities Score.

Appendix B2 – Studies identified within scope but not prioritised by the EAG (N=101)

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
1.	Cochrane (J Arthroplasty, 2024; 1-5); US (N=3)	Retrospective cohort review (Single arm)	Revision TKA	CORI (n=115)	n/a	Up to 51 months
2.	Itou (J Exp Orthop, 2023; 65)	Retrospective cohort	TKA	CORI (n=60)	Conventional (n=81)	7 days
3.	Batailler (Knee Surg Sports Traumatol Arthrosc, 2019; 1232-1240) France (N=1)	Case-control	Primary UKA	NAVIO (n=81 patients)	Conventional (n=NR)	Mean follow-up of 19.7 months in robotic arm, and 24.2 months in comparator arm.
4.	Bell (J Robot Surg, 2022; 495-499)	Prospective (Single arm)	TKA	NAVIO (n=60)	n/a	Procedural
5.	Bensa (Bone & Joint, 2024; 374-384);	Systematic review and meta-analysis	UKA	NAVIO (n=258)	Conventional (n=215)	NR
6.	Bollars (Eur J Orthop Surg Traumatol, 2020; 723-729); Belgium (N=1)	Retrospective case controlled	TKA	NAVIO (n=77)	Conventional (n=77)	Procedural
7.	Collins (J Knee Surgery, 2022; 1295-1300); Australia (N=1)	Retrospective cohort (Single arm)	TKA	NAVIO (n=72)	n/a	Procedural
8.	Crizer (Adv Orthop, 2021; 4770960); US (N=2)	Retrospective cohort with propensity matching	UKA	NAVIO (n=50)	Conventional (n=39)	Up to 2 years
9.	Deroche (Arch Orthop Trauma Surg, 2022; 1645-1651); France (N=1)	Prospective cohort (Single arm)	Medial UKA	NAVIO (n=20)	n/a	Procedural
10.	Di Benedetto (Acta Biomed, 2019; 104-108); Italy (N=1)	NR	Medial UKA	NAVIO (n=29)	Conventional (n=30)	4 months
11.	Eerens (Acta Orthop Belg, 2022; 47-52); Belgium (N=1)	Retrospective case control	TKA	NAVIO (n=73)	Conventional (n=74)	2 years
12.	Foissey (Int Orthop, 2023; 533-541); NR (N=1)	Retrospective cohort	Medial UKA	NAVIO (n=197)	Conventional (n=159)	2-11 years
13.	Hasegawa (Scientific Reports, 2024; 3192); Japan (N=2)	Retrospective cohort	TKA	NAVIO (n=40)	ROSA (n=48)	1 year
14.	Hasegawa (Int J Med Robot, 2024; e2564); Japan (N=2)	Prospective	TKA	NAVIO (n=40)	Conventional (n=40)	1 year
15.	Held (Arthro Today, 2021; 130-134); US (N=1)	Retrospective cohort review	Primary TKA	NAVIO (n=37)	Conventional (n=49)	12 months
16.	Khuangsirikul (J Southeast Asian Med Res, 2020; 16-23)); Thailand (N=1)	RCT [EAG note: larger RCT included, Thiengwittayaporn et al. 2021]	Primary TKA	NAVIO (n=20)	Conventional (n=20)	NR

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
17.	Lau (Arthroplasty, 2024; 33); China (N=1)	Retrospective	UKA	NAVIO (n=58)	Conventional (n=82)	2 years
18.	Leelasestaporn (Knee Surg Relat Res, 2020: 13); Thailand (N=1)	Prospective cohort	UKA	NAVIO (n=17)	Mako (n=16)	1 year
19.	Masarwa (Int J Surg Open, 2022; 100557); Israel (N=1)	Retrospective cohort	Primary TKA	NAVIO (n=150)	Conventional (n=150)	NR
20.	Matsumoto (Int Orthop, 2023; 1473-1480); Japan (N=1)	Retrospective cohort	Bi-cruciate stabilized TKA unilateral & primary	NAVIO (n=35)	Conventional (n=35)	1 year (KSS)
21.	Mergenthaler (Knee Surg Traumatol Arthroscopy, 2021; 931-938); France (N=1)	Retrospective case control	UKA	NAVIO (n=175)	Conventional (n=1179)	Mean years 22.5 in robotics, mean 30.2 in conventional
22.	Negrín (Knee Surg Rel Res, 2021;5); Chile (N=1)	Prospective cohort	UKA	NAVIO (n=18)	Conventional (n=16)	6 months
23.	Negrín (J Exp Ortho, 2020; 94) NR	Retrospective cohort	UKA	NAVIO (n=40)	Conventional (n=22)	NR
24.	Popat (PLoS One, 2022; e0272722); Belgium, Republic of South Africa, Dubai, Germany, UK (N=6)	Retrospective cohort matched for BMI and age	Primary TKA	NAVIO (n=60)	Conventional (n=60)	NR
25.	Scaturro (BMC Musculoskelet Disord, 2023;140); Italy (N=1)	Prospective case-control	TKA	NAVIO (n=30)	Conventional (n=30)	3 months
26.	Sicat (Arch Orthop Trauma Surg, 2021; 2059-2067); US (N=NR)	Retrospective cohort	TKA	NAVIO (n=365)	CORI (n=70)	Procedural
27.	Vaidya (Knee Surg Sports Traumatol Arthrosc, 2022; 621-626); India (N=1)	RCT [EAG note: this study only described secondary outcomes: alignment]	Primary unilateral TKA	NAVIO (n=32)	Conventional (n=28)	NR
28.	Vaidya (J Robot Surg, 2023; 393-403); India (N=1)	Prospective cohort	TKA	NAVIO (n=75)	Conventional (n=25)	Procedural
29.	Vandenberk (Knee Surg Traumatol, 2023; 4798-4808) Belgium (N=1)	Retrospective case-control	TKA	NAVIO (n=230 or 231; unclear reporting)	Conventional (n=489)	30 months
30.	Alessio-Mazzola (Orthop & Trauma, 2024; 9) Italy (N=1)	Retrospective	THA	Mako (n=50)	Conventional (n=50)	1 year
31.	An (J Bone Joint Surg Am, 2023; 1338-1343)	Retrospective	TKA	Mako (n=60 CT scans, 54 patients)	Conventional (N=NR)	Procedural

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
	China (N=1)					
32.	Avram (Int Orthop, 2023; 2265-2273); NR	Retrospective	THA	Mako (n=32)	Conventional (n=32)	Procedural
33.	Bendich (J Arthroplasty, 2022; 1124-1129); NR	Retrospective cohort	Primary, unilateral, staged bilateral, posterior approach THA	Mako (n=1770)	Conventional (n=887) [Computer navigated (n=3155)]	Up to 2.5 years
34.	Caldora (J Biol Regul Homeost Agents, 2020; 37-49); Italy (N=NR)	Retrospective cohort	THA	Mako (n=395)	Conventional (n=1,142)	Average 33 months (6-60 months)
35.	Coulomb (Orthop Traumatol Surg Res, 2023; 103477); France (N=1)	Retrospective, case matched, propensity scored	THA	Mako (n=98)	Conventional (n=98)	1 year
36.	Deckey (Bone and Joint J, 2021; 74-80); US (N=1)	Retrospective cohort	Primary TKA	Mako (n=96)	Conventional (n=103)	Procedural
37.	Deckey (J Arthroplasty, 2022; S201-S206); US (N=1)	Retrospective cohort	Primary TKA	Mako (n=110)	Conventional (n=110)	Procedural
38.	Domb (J Am Acad Orthop Surg, 2020; 847-856); US (N=NR)	Retrospective (with propensity matching)	Primary THA	Mako (n=66)	Conventional (n=66)	5 years
39.	Glowalla (Knee Surg Sports Traumatol Arthrosc, 2023; 3912-3918); Germany (N=NR)	Prospective (Single arm)	TKA	Mako (n=36)	n/a	6 weeks
40.	Goffin (Arc Orthop Sug Trauma, 2024; 2413-2420); UK (N=1)	Prospective (Single arm)	TKA (n=19) THA (n=11)	Mako (n=30)	n/a	Intraoperative noise levels
41.	Hadley (Surg Technol Int, 2020; 685-690); US (N=1)	Retrospective cohort	THA	Mako (n=94)	Conventional (n=95)	16 months
42.	Hampp (J Knee Surg, 2023; 1386-1390); US (N=1)	Retrospective cluster analysis of two cohorts	TKA	Mako (n=758)	Conventional (n=95)	1 year
43.	Heckmann (J Arthroplasty, 2022; 831-836); US (N=1)	Retrospective case series (Single arm)	Lateral UKA	Mako (n=84 knees, 75 patients)	n/a	4.0 ± 1.4 years (range 2.0-7.0 years)
44.	Hönecke (Arch Orthop Trauma Surg, 2023; 2813-2819); NR	Prospective	TKA	Mako (n=8)	NAVIO (n=7) CORI (n=6)	N/A noise level study
45.	Incesoy (Tech Health Care, 2023); Turkey	Retrospective matched cohort	THA	Mako (n=82)	Conventional (n=82)	1 year
46.	Jin (BMC Musculoskelet	Retrospective cohort	TLA	Mako (n=36)	Conventional (n=72)	Procedural

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
	Disord, 2023; 492); China (N=1)					
47.	Jung (BMC Musculoskelet Disord, 2023; 332) Korea (N=1)	Prospective cohort	TKA	Mako (n=18 initial phase, n=32 proficiency phase)	Conventional (n=50)	Procedural
48.	Kang (Curr Orthop Pract, 2024; 63-70); US (N=NR)	Retrospective	TKA	Mako (n=79)	Conventional (n=61)	2 years
49.	Kara (Cureus, 2023; e42335); Turkey (N=1)	Retrospective cohort comparison	THA	Mako (n=55)	Conventional (n=58)	Post operative
50.	Khlopas (J Knee Surg, 2020; 685-690); US (N=NR, multicentre)	Prospective cohort	Primary TKA	Mako (n=150)	Conventional (n=102)	3 months
51.	King (J Knee Surg, 2022; 78-82); US (N=1)	Retrospective cohort comparison	Primary TKA	Mako (n=202)	Non-robotic (n=290)	Mako: mean 1.3 years Non-robotic: mean 3 years
52.	Kolodychuk (Bone Jt Open, 2021; 365-370); US (N=2)	Prospective cohort	THA	Shared by Stryker; assumed Mako, new surgeon (n=60)	Shared by Stryker; assumed Mako, experienced surgeon (n=60)	NR
53.	Lachance (Arthroplast Today, 2023; 101269); US (N=1)	Retrospective	Conversion from UKA to TKA	Mako	n=49 divided into 4 groups based on primary and conversion surgery: manual-to-manual (n=11), manual-to-robot (n=11), robot-to-manual (n=11), robot-to-robot (n=17)	1 year
54.	Lee (J Clin Med, 2023; 4570)	Retrospective propensity score matched	Staged bilateral TKA	Mako (n=53)	Conventional (n=107, matched=53)	1 week
55.	Ma (Int Orthop, 2024)	Retrospective cohort	TKA	Mako (n=22)	Conventional (n=26)	3 months
56.	Marchand (J Knee Surg, 2022; 409-415); US (N=1)	Retrospective cohort	TKA	Mako (n=140)	Conventional (n=60)	Procedural
57.	Masilamani, (J Robot Surg, 2024; 188); India (N=1)	Prospective cohort	Bilateral TKA	Mako (n=50 early RAS, n=50 last RAS)	Conventional (n=50)	Procedural
58.	Murphy (J ISAKOS 8, 2023; S61) Abstract; Australia	Retrospective cohort	TKA	Mako (n=207)	OMNIBot (n=298)	1 year
59.	Murphy (Int Orthop, 2023; 1221-1232); full paper of abstract	Retrospective cohort	TKA	Mako (n=207)	OMNIBot (n=298)	1 year
60.	Nam (J Exp Orthop, 2022; 108); Republic of Korea	Retrospective cohort (with propensity score matching)	TKA	Mako (n=110)	Conventional (n=110)	1 year
61.	Park (PLoS ONE, 2019; e0225941); Korea (N=1)	Retrospective cohort	Medial UKA	Mako (n=55)	Conventional (n=57)	2 years
62.	Peng (Int Orthop, 2024; 2047-	Retrospective (single arm)	TKA	Mako (n=97)	n/a	Procedural

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
	2054); China (N=1)					
63.	Perets (Orthopedics, 2021; e236-e242)	Prospective, matched	THA	Mako (n=85)	Conventional (n=85)	2 years
64.	Porcelli (J Biol Regul Homeost Agents, 2020; 393-404); Italy (N=1)	Prospective	UKA	Mako (n=18)	NAVIO (n=10)	2 years
65.	Rajgor (J Robot Surg, 2024; 33); UK (N=1)	Retrospective cohort	Primary TKA	Mako (n=50)	ROSA (n=50)	NR
66.	Sato (Arch Othop Trauma Surg, 2023; 2755-2761); Japan (N=1)	Retrospective propensity score matched	THA	Mako (n=84)	Conventional (n=84)	Postoperative
67.	Savov (Arch Orthop Trauma Surg, 2021; 2139-2146); Germany (N=NR)	Retrospective case-control	UKA	Mako (n=40)	NAVIO (n=63)	2 years
68.	Shatrov (Int Orthop, 2023; 437-446); France (N=1)	Prospective cohort (single arm)	TKA	Mako (n=50)	Subgroups of 10 consecutive cases	Procedural
69.	Shaw (J Arthroplasty, 2022; S881-S889); US (N=1)	Retrospective cohort	Primary THA	Mako (n=523)	Conventional (n=1724)	6 months
70.	Smith (J Knee Surg, 2021; 730-738); US (N=NR)	Retrospective cohort	Primary TKA	Mako (n=120)	Conventional (n=103)	1 year minimum Mako: average 17 months Conventional: 19 months
71.	Stimson (Arthroplast Today, 2022; 224-228); US (N=1)	Retrospective cohort	Primary TKA	Mako (n=299)	Conventional (n=187)	3 days postoperative
72.	Torre (JBJS Case Connect, 2023; e22.00733); US (N=1)	Case report	UKA	Mako (n=2) Safety issue of early tibial baseplate fracture after UKA	n/a	2.5 years
73.	Vermue (Knee Surg, Sports Traumatol, Arthrosc, 2022; 593-602) Belgium (N=1)	Retrospective cohort (Single arm)	TKA	Mako (n=386)	n/a	Procedural
74.	Winnock de Grave (Arc Ortho Trauma, 2023; 3391-3399) Belgium (N=NR)	Retrospective cohort	TKA	Mako (n=40)	Conventional (n=40), inverse kinematic alignment iKA (n=40)	1 year
75.	Xu (Surg Technol Int, 2020; 347-352) Singapore (N=1)	Prospective propensity matched	THA	Mako (n=25)	Conventional (n=25)	Post operative
76.	Yang (BMC Musculoskelet Disord, 2024; 92) China (N=1)	Prospective cohort	Primary unilateral TKA	Mako (n=40)	Conventional (n=46)	6 months

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
77.	Yee (Int J Med Robot, 2024; e2574) Hong Kong	Retrospective cohort	Primary TKA	Mako (n=95)	NAVIO/CORI (n=71)	12 months
78.	Zambianchi (Knee Surg Sports Traumatol Arthro, 2023; 5477-5484) Italy (N=1)	Retrospective cohort (Single arm)	Primary UKA	Mako (n=188)	n/a	10 years
79.	Zhang (Bone Joint J, 2022; 541-548) UK (N=NR)	Systematic review & meta-analysis (N=14)	UKA	Mako (n=NR)	Conventional (n=NR)	1.71 (0.93) years
80.	Zhang (J Arthroplasty, 2023; 129-134) China (N=NR)	Retrospective cohort comparison	THA	Mako (n=44 hips, 36 patients)	Conventional (n=40 hips, 31 patients)	1 year
81.	Zhou (Orthop Surg, 2024; 1168-1174); China (N=1)	Retrospective cohort	Primary TKA	Mako (n=20)	ROSA (n=20)	1 year
82.	Zhuang (BMC Musculoskeletal Disord, 2023; 756)	Retrospective comparative analysis	THA	Mako (n=31)	Arthrobot (n=31)	Post operative
83.	Durán-Serrano (Int J Med Robot, 2023; e2504); Spain (N=NR)	Retrospective	TKA	OMNIBot (n=47)	Conventional (n=36) Navigated (n=41)	Discharge
84.	Batailler (Arch Orthop Trauma Surg, 2023; 1599-1609); France (N=1)	Retrospective case-control	Primary TKA	ROSA (n=20)	Conventional (n=20)	Up to 6 months
85.	Bolam (J Exp Orthop, 2022; 86); New Zealand (N=1)	Prospective	Primary TKA	ROSA (n=52)	Conventional (n=80)	12 months (revision)
86.	Byrne (Arthroplasty Today, 2024; 101303); US (N=1)	Retrospective comparative cohort	Primary TKA	ROSA (n=19)	Conventional (n=41)	2 years
87.	Eason (Orthop Clin North Am, 2023; 153-159); US (N=1)	Retrospective	TKA	ROSA (n=86)	Conventional (n=86)	12 weeks
88.	Gamie (Eur J Orthop Surg Traumatol, 2024; online ahead of print); Greece (N=1)	Retrospective case control	TKA	ROSA (n=144)	Conventional (n=182)	Procedural
89.	Haffar (J Arthroplasty, 2022; S193-S200); US (N=1)	Prospective comparative cohort	TKA	ROSA (n=20)	Conventional (n=20)	Procedural
90.	Hax (Knee Surg, Sports Traumatol, 2024); Switzerland (N=1)	Retrospective cohort with propensity matching	TKA	ROSA (n=55)	Conventional (n=55)	12 months
91.	Kenanidis (Eur J Orthop Surg Traumatol, 2023; 3357-3363);	Retrospective comparative cohort	Primary TKA	ROSA (n=100)	Conventional (n=100)	Procedural

#	Author (journal, year); country, N centres	Study design	Procedure	Intervention (n patients)	Comparator (n patients)	Follow-up
	Greece (N=NR)					
92.	Khan (J Arthroplasty, 2023; S232-S237); US (N=NR)	Retrospective cohort with propensity matching	TKA	ROSA (n=254)	Conventional (n=762)	1 year
93.	Nogalo (J Exp Orthop, 2024; e12019); Austria (N=1)	Prospective cohort	TKA	ROSA (n=30)	Conventional (n=67)	6 months
94.	Shin (J Exp Orthop, 2022; 82); US (N=1)	Unclear Single cohort	TKA	ROSA (n=37)	n/a	Pos-operative
95.	Wininger (Arthroplasty Today, 2023: 101196) US (N=1)	Retrospective comparative cohort	Primary TKA	ROSA (n=103)	Conventional (n=103 different surgeon, and secondary analysis including an additional 44 conventional procedures conducted by the same surgeon conducting the robotic procedures)	6 months
96.	Ping (Int Ortho, 2024; 761-772); China (N=1)	Retrospective	TKA	SkyWalker (n=30)	Mako (n=45)	1 year
97.	Xia (J Orthop Translation, 2021; 143-151) China (N=1)	Prospective cohort (Single arm)	TKA	SkyWalker (n=31)	n/a	Procedural
98.	Huang et al. 2024 [paper provided AiC]; US (N=NR)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
99.	Huang (J Knee Surg, 2024; 2343-2444); US (N=NR)	Retrospective cohort with stratification and generalised linear models	Primary TKA	VELYS (n=866)	Conventional (n=128,643)	90 days
100.	Rajasekaran (J Robotic Surgy, 2024; 151); India (N=1)	Retrospective cohort	Primary TKA	VELYS (n=77; 100 knees)	Conventional (n=81; 100 knees)	6-18 months
101.	Severson et al. (2024) [AiC]; [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: KSS, Knee Society Score; NR, not reported; RCT, randomised control trial; THA, Total Hip Arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental Arthroplasty.

Appendix B3 – Additional identified economic evidence (N=22)

#	Study	Time horizon	Model structure	Perspective	Country	Population	Intervention	Comparator	Summary of results
1.	(Alexander et al., 2024);	28 days after discharge	Cost analysis	Healthcare	Australia	TKA, UKA	Mako	Comparison between total and partial	Surgical time, time in operating room and length of stay were significantly shorted in robotic UKA than robotic UKA. Robotic TKA patients were older and more likely discharged to inpatient rehabilitation. Total in hospital costs greater for robotic TKA (AU$18,580 versus AU$13,275), robot and maintenance less for TKA (AU$3,867 versus AU$ 5,008). Total cost significantly higher for TKA than UKA. Lower volume surgeons associated with higher total cost of UKA. Increased age and male sex associated with higher total cost of TKA.
2.	(Barsoum et al., 2023);	90 days	Cost analysis (propensity matched analysis)	Payer	US	THA	Robot-assisted (Mako, Stryker)	Conventional	In-hospital costs ($31,507 compared with $32,804, p<0.0001), length of stay (1.51 compared with 1.71 days, p<0.0001), post-index hospital utilisation (inpatient: 2.31% compared with 3.38%, p=0.02; outpatient: 44.98% compared with 48.81%, p=0.0002) and total costs ($35,436 compared with $37,009; p<0.0001) were statistically lower for robot-assisted.
3.	(Burn et al., 2020);	Lifetime	Markov	Healthcare (NHS)	England	Hip and knee replacement	Computer- and robot-assisted (System N/A – results of threshold analysis can be applied to any robotic system)	Current practice	Robot-assisted knee replacement associated with lifetime QALYs of 10.3 (95%CI 9.9 to 10.7) and cost of £6060 (£5947 to £6203), robot-assisted hip replacement lifetime QALYs of 11.0 (10.6 to 11.4) and £6506 (£6335 to £6710). Reduction in proportion requiring revision alone does not justify additional cost, additional gains in quality of life needed.
4.	(Christen et al., 2022);	Procedure only	Cost analysis	Healthcare	Switzerland	TKA	Mako, NAVIO	Conventional surgery, computer navigation (out of scope), patient specific instruments (out of scope)	All assistive technologies used increased total cost compared with conventional TKA. Mako created additional cost of USD 2,600, resulting from technical support, disposals, CT scanning, and extra 14 minutes of operating room time. NAVIO was associated with greatest increase in operating room time, with an extra 25 minutes on average, and incurred additional costs of USD 1,530.
5.	(Clement et al., 2022);	10 years, lifetime	Cost utility analysis (using data from 2 centres)	Healthcare (NHS and private)	UK	THA	Robot-assisted (Mako, Stryker)	Conventional	Robot-assisted was associated with £2,349 per QALY after discounting at 10-years. This was sensitive to hospital volume, and duration of follow-up. The lifetime cost per QALY was £1,432 adjusted (5% disutility) compared to conventional surgery.
6.	(Clement et al., 2019)	Lifetime	Markov	Healthcare (NHS)	UK	UKA and TKA	Robot-assisted (Mako, Stryker): unicompartmental only	Conventional: unicompartmental and total knee arthroplasty	Robot-assisted UKA associated with an overall cost per QALY of £1395 when compared to conventional TKA, and £1170 when compared to conventional UKA. Cost per QALY was influenced by case volume (due to annual cost of robot) and length of stay.
7.	(Clement et al., 2023);	5 years	Incremental cost utility analysis	Healthcare (NHS)	UK	UKA	Mako	Conventional	Robotic UKA associated with relative QALY gain of 0.012 at five years, and incremental cost per QALY of £13,078 if unit undertakes 400 cases per year. More than 300 cases per year was threshold for cost per QALY less than £20,000. Cost per QALY > £38,000 when a septic revision was excluded from conventional TKA group. Cost per QALY < £20,000 when absolute cost difference was less than £240, and robotic surgery cost neutral with more than 900 cases per year, and also with zero consumable costs.

#	Study	Time horizon	Model structure	Perspective	Country	Population	Intervention	Comparator	Summary of results
8.	(Cool et al., 2019);	90 days	Cost analysis	Payer (Medicare)	US	TKA	Mako	Conventional	Overall 90 day costs were US$2,391 less for robotic surgery than conventional surgery. Over 90% of patients in both cohorts used post-acute services, with the robotic surgery cohort accruing fewer costs. Savings were driven by fewer readmissions and less costly discharge destinations.,
9.	(Cotter et al., 2022);	90 days	Cost analysis	Payer	US	TKA	Robot-assisted (Mako RIO, Stryker)	Conventional	Higher intraoperative costs for robot-assisted ($10,295 compared with $9998, p<0.001) due to longer operating room time, higher anaesthesia costs, operating room supplies, robot specific costs, and implant costs higher in robotic arm. Lower post-operative costs for robot-assisted ($3893 compared with $5587, p<0.001) due to reduced length of stay, fewer prescribed opioids, and lower post-discharge healthcare resource utilisation.
10.	(Ezeokoli et al., 2023);	90 days	Cost analysis	Healthcare	US	TKA	Mako	Conventional	Robotic surgery associated with higher index surgery costs, no difference in 90 day reoperation costs. Cost not associated with age, BMI, time in operating room, or length of stay. Main driving factor is supply cost.
11.	(Fang et al., 2022);	In-hospital	Cost analysis	NR (Healthcare?)	US	TKA	Robot-assisted (Mako, Stryker)	Conventional	Total hospital costs were 10% higher for robot-assisted than conventional (p<0.0001), which based on a hospital volume of 4000 annually would equate to an additional 370 conventional total knee arthroplasty procedures.
12.	(Goh et al., 2022);	In-hospital	Cost analysis (time driven activity based)	Healthcare	US	UKA	Robot-assisted (NAVIO, Smith & Nephew)	Conventional	Overall reduction in total facility costs with robot-assisted (-$236 [-$431 to -$41],p<0.001) per case. Robot-assisted associated with higher operation time costs, higher personnel costs, but lower total supply costs.
13.	(Huang et al., 2024);	90 days	Cost analysis	Healthcare	US	TKA	VELYS	Conventional	Total costs were similar without accounting for the cost of the robot.
14.	(Kolessar et al., 2022);	90 days	Cost analysis	Healthcare	US	UKA and TKA	Robot-assisted (Mako, Stryker)	Conventional	Total peri-operative costs were statistically higher for robot-assisted unicompartmental ($4025 (SD $489) compared with $3287 (SD $271); p=0.0001) and total knee arthroplasty ($4668 (SD $644) compared with $4087 (SD $1085); p<0.0001). No statistical difference in length of stay, or total post-operative costs were observed.
15.	(Maldonado et al., 2021);	5 years	Markov	Payer	US	THA	Robot-assisted (Mako RAA, Stryker)	Conventional	Robot-assisted was less costly for Medicare and private insurance by $945 and $1,810 respectively. ICER for Medicare was $23,625 per QALY (robot-assisted was both less costly and more effective). PSA indicated robot-assisted was cost effective in 99.4% of cases. The dominant treatment was sensitive to changes in utilities of successful treatment.
16.	(Nherera et al., 2020);	5 years	Markov	Healthcare	UK	UKA	Non-CT robot-assisted (NAVIO, Smith & Nephew)	Conventional	Robot-assisted surgery associated with £2,831 per QALY, more favourable outcomes in patients aged less than 55 years and was sensitive to case volume and follow-up period.
17.	(Tompkins et al., 2022a);	10 years	Cost analysis	Healthcare (and Home Healthcare and Skilled Nursing	US (but uses UK National Joint	TKA	Mako	Conventional	Total episode cost for the cohort was $5.7 million higher for robotic surgery than conventional surgery. 131 revision TKAs would need to be prevented in the robotic cohort to make it cost neutral. Not possible to demonstrate cost parity through reduction in revision rate alone.

#	Study	Time horizon	Model structure	Perspective	Country	Population	Intervention	Comparator	Summary of results
				Facility costs estimated)	Registry data)				
18.	(Tompkins et al., 2022b)	30 days	Cost analysis (of electronic health records with propensity matching)	NR (healthcare?)	US	TKA	Robot-assisted (Mako, Stryker)	Conventional	Total median [Q1,Q3] costs were statistically higher for robot-assisted ($11,615 [$9,975, £13,025]) than conventional surgery ($8,674 [$7,880, $9,543]). Median operative time was statistically longer in robot-assisted (139 [124,155] compared with 107 [82,130] minutes, p<0.0001), with no statistical difference in median length of stay (33 [28,54] compared with 33 [30,52], p=0.0118) or 90-day complications (0.7 % compared with 0.9%, p=0.15). 30-day readmissions were statistically lower for robot-assisted (1.2% compared with 4.9%, p<0.000). Note cost of pre-operative CT scan for robotic cases was not included.
19.	(Varughese et al., 2024)	In-hospital	Cost analysis	Healthcare	Australia	TKA	Robot-assisted	Conventional	Average cost saving of AU$7,179 per case with robot-assisted compared with conventional. Operating times were statistically higher for robot-assisted (86.0 compared with 75.9 mins, p=0.004) however length of stay (1.8 compared with 4.8 days, p<0.001) and use of opioids (125.0 compared with 522.1 morphine equivalent, p<0.001) were statistically lower.
20.	(Vermue et al., 2021);	20 years	Markov	Payer	Belgium	TKA	Robot-assisted (Mako, Stryker)	Conventional	Robot-assisted surgery was not cost effective at 70 cases annually (£376,145/QALY), with only 2.18% of PSA observations being considered cost-effective using a WTP of $50,000. Robot-assisted surgery became cost-effective at 253 cases (assuming maintenance costs are fixed and independent of surgical volume).
21.	(Yeroushalmi et al., 2022);	5 years	Markov	Payer	US (but uses UK National Joint Registry data)	UKA	NAVIO	Conventional	Robotic surgery was beneficial from the payer's perspective, compared with conventional surgery. Estimated ICER was $14,737 per revision avoided in unit treating 100 patients per year. Case volume was primary variable affecting cost-effectiveness. Robotic surgery remained cost effective, even after investigating several different assumptions.
22.	(Zhang et al., 2023)	Lifetime	Markov	NR	Singapore	TKA	Robot-assisted (Mako, Stryker)	Conventional	Robot-assisted surgery led to an incremental cost of $128,526 Singapore dollars per QALY.

Abbreviations: ICER. Incremental cost-effectiveness ratio; NR, not reported; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty; WTP, willingness to pay.

Appendix C – Patient Reported Outcome Measures

#	PROM	Range (polarity)
1.	American Knee Society Score (AKSS) AKSS Clinical (pain, stability, range of motion) AKSS Functional (walking distance, and climbing + descending stairs)	0 to 100 (scored worst to best health)
2.	Euro QoL 5 Dimensional (EQ-5D)	0 to 100 (scored worst to best health)
3.	EQ-VAS	0 to 100 (scored worst to best health)
4.	Forgotten Joint Score (FJS)	0 to 100 (scored most to least awareness of joint)
5.	Knee Injury and Osteoarthritis Outcome Score (KOOS)	0 to 100 (scored worst to best knee health)
6.	Knee Society Function Score (KSFS)	0 to 100 (scored worst to best function)
7.	Knee Society Knee Score (KSKS)	0 to 100 (scored worst to best knee conditions)
8.	Numerical Rating Scale	0 to 10 (score from no pain at all, to worst pain ever possible)
9.	Oxford Knee Score (OKS)	0 to 48 (scored worst to best knee function)
10.	Oxford Hip Score (OHS)	0 to 48 (scored worst to best hip function)
11.	Physical Component Score (PCS) and Mental Component Score (MCS) of the Short-Form survey	0 to 100 (scored worst to best)
12.	University of California, Los Angeles (UCLA) Activity Scale	1 to 10 (scored low to high physical activity)
13.	Visual Analogue Scale (VAS) (as reported in (Adamska et al., 2023), (Kenanidis et al., 2023))	0 to 10 (scored best to worst)
14.	Visual Analogue Scale (VAS) – pain (as reported in (Clement et al., 2020), (Banger et al., 2021), (Clement et al., 2021))	0 to 100 (scored best to worst)
15.	Visual Analogue Scale (VAS) – stiffness (as reported in (Banger et al., 2021))	0 to 100 (scored best to worst)

16.	Western Ontario & McMaster Universities Score (WOMAC)	Subsections (scored best to worst): pain 0 to 20 stiffness 0 to 8 functional limitation 0 to 68

Appendix D – Ongoing studies identified by the EAG conducted in a UK setting (N=6)

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
A Real-World, In-Situ, Evaluation Of The Introduction And Scale-Up Of Robot-Assisted Surgical Services In The NHS: Evaluating Its Impact On Clinical And Service Delivery, Effectiveness And Cost (REINFORCE) [ISRCTN18320267] UK (N=16 sites)	Study design: Observational cohort, multi-centre (stepped-wedge: with NHS hospitals planning to introduce robotic-assisted surgery, switched from non-robotic to robotic surgery in a random order). Intervention: Robotic-assisted surgery (RAS) [Note: specific devices not reported] **AMBER** Comparator: Non-robotic assisted surgery **GREEN** Status: Recruiting (n=1,943 as of Feb 2024) Estimated completion date: April 2025	Target/actual enrolment: n=2,560 Inclusion criteria: All patients undergoing the index procedure (robot-assisted surgery or otherwise) at each site across all time periods. Will include orthopaedic and soft-tissue procedures. Exclusion criteria: None listed. **AMBER**	Patient-level: Disease-specific quality of life [baseline, 3 months] Overall quality of life, EQ5D [baseline, 3 months] Overall measure of treatment effectiveness or benefit using patient questionnaire [baseline, 3 months] Complication including Clavien-Dindo score [3 months] Surgeon/team level: Precision/accuracy using Surgeon Task Load Index [day of surgery] Visualisation using Surgeon Task Load Index [day of surgery] Organisation level: Equipment failure using Surgery Form [day of surgery] Standardisation of operative quality using process	None

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	Sponsor: University of Oxford Funder: NIHR Health and Social Care Delivery Research (NIHR131537)		evaluation interventions [pre, peri, post RAS implementation] Overall economic/cost-effectiveness [throughout study] Population-level: Equity of access using Health Economics review [throughout study] **GREEN**	
Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial (RACER) [ISRCTN27624068] UK (N=8 sites)	Study design: RCT, multi-centre Intervention: Total knee replacement using Mako robotic system and Triathlon implant (the only implant compatible with Mako robotic system) cemented. **GREEN** Comparator: Non-robotic total knee replacement with Triathlon cemented implant. **GREEN**	Target enrolment: n=332 (actual n=339) Inclusion criteria: Osteoarthritis of the knee with pain, disability and changes on standard of care clinical images (x-rays or MRI according to normal clinical practice) that, in the opinion of the treating clinician, warrants total knee replacement (TKR) Conservative therapy has been unsuccessful, as judged by the treating clinician Exclusion criteria:	Patient awareness of their joint measured using the Forgotten Joint Score questionnaire [12 months] **GREEN**	In-hospital outcomes: Mean pain intensity using NRS [day 1,2,3 after surgery] Estimate blood loss using Brecher's formula [in-hospital] Opioid use [in-hospital, to end of day 3] Hours from surgery to hospital discharge [discharge] Pain [day 1,2,3 after surgery] Post-operative:

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	Status: No longer recruiting (recruitment ended 05 Feb 2024) Estimated completion date: 31 March 2032 Sponsor: University Hospitals Coventry and Warwickshire NHS Trust Funder: NIHR (NIHR128768)	Osteoarthritis secondary to inflammatory arthropathy or intra-articular fracture as determined by the treating clinician Revision surgery or need for complex implants, or any other implant than a standard Triathlon total knee replacement (TKR), as determined by the treating clinician. This includes nickel-free implants as well as those that require a long stem, augments, or custom made devices Age <18 years Unfit for TKR, or surgery is otherwise contraindicated (for example, concurrent infection) Previous randomisation in the present trial (i.e. other knee) Unable to take part in trial processes, including prisoners or people unable to communicate or complete questionnaires in English, or people unable to give informed consent **GREEN**		Overall knee function using FJS [baseline, 3,6,12 months, 2,5,10 years] Outcomes of knee osteoarthritis surgery using Oxford Knee Score [baseline, 3,6,12 months, 2,5,10 years] Level of activity using Oxford Knee Score Activity and Participation Questionnaire [baseline, 3,6, 12 months, 2, 5, 10 years] Generic health status using EQ5D5L [baseline, 3, 6, 12 months, 2, 5, 10 years] Pain over last week using PROMIS pain intensity questionnaire [baseline, 3, 6, 12 months, 2, 5, 10 years] Satisfaction using Likert scale [3, 6, 12 months, 2, 5, 10 years] Activity limitation, symptoms, emotions an overall quality of life assessed using Participant Global Impression of Change questionnaire [3, 6, 12 months, 2, 5, 10 years]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
				Number of re-operations [3, 6, 12 months, 2, 5, 10 years] Number of episodes and type of NHS services used via questionnaire [3, 6, 12 months, 2, 5, 10 years]
An Evaluation of Health Outcomes for Mako Hip Replacement (HELLO) [NCT03846791] UK [N=1 site]	Study design: Observational cohort Intervention: Hip replacement using Mako robot **GREEN** Comparator: N/A **GREEN** Status: Recruiting Estimated completion date: June 2024 (final data collection date for primary outcome measure) Sponsor: Bournemouth University	Target enrolment: 200 Inclusion criteria: 18 years and older Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, suitable for unilateral primary hip replacement; Rheumatoid arthritis; Correction of functional deformity; Voluntary written Informed Consent obtained. Participant able to complete study follow-up. Exclusion criteria: Prospect for recovery to independent mobility compromised by known coexistent medical problems; Requiring revision hip replacement;	Surgical complications post-surgery [1 year] Readmission post surgery [1 year] **GREEN**	Accuracy of component positioning [1 year] Functional assessment: chair stand [1 year] Functional assessment: fast paced walk [1 year] Functional assessment: stair climb [1 year] Gait analysis [1 year] Muscle testing [1 year] Measurement of PSOAS muscle mass [pre-operative] PROMs: EQ5D [6 months] PROMs: Pain Catastrophizing Score [pre-operative] PROMs: Hip disability and osteoarthritis outcome score [pre-operation, 3, 6-8 weeks, 3,6,12 months] Length of stay in-hospital [1 year]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	Collaborators: Nuffield Health Bournemouth Orthopaedic Research Institute Stryker Orthopaedics	Previous hip replacement (resurfacing or THR) on the contralateral side, with outcome achieving an Oxford Hip score <18 points; Likely post-operative leg length inequality >5cm; Neuromuscular disease affecting hip (Parkinson's, cerebral palsy, other spasticity); Primary or metastatic tumour involving this hip; Loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint; Previous arthrodesis or excision arthroplasty Acetabular deficiency - >2cm superior loss acetabular dome or >1.5cm protrusion acetabular or wall deficiency> half a wall; Dysplasia (DDH) with >2.5cm subluxation or complete dislocation; Body mass index > 40kg/m2; Active or previous or suspected infection in this hip; Sepsis or osteomyelitis; Known sensitivity to device materials;		Time in theatre [1 year] Unplanned hospital visits [1 year] Non-routine medication [1 year] Outpatient appointments [1 year] Physiotherapy appointments [1 year] Physical activity [6-8 weeks] Oedema [6-8 weeks]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
		Not physically able to use Grail gait lab and Primus muscle testing equipment; Women judged by the Investigator to be of childbearing potential who are pregnant, nursing, or planning to become pregnant, and those who do not agree to remain on an acceptable method of birth control throughout the entire study period; Unable to provide informed consent (insufficient English, cognitive disorder such as dementia, psychiatric illness); Unable to complete follow-ups (life expectancy <5 years, insufficient English, lives overseas, unable to return easily). **GREEN**		
A Prospective Randomised Control Trial of Mako Medial Unicondylar Knee Arthroplasty Versus Jig-based Oxford Unicompartmental Knee Arthroplasty With Navigation Control [NCT04095637]	Study design: RCT (single blind) Intervention: Mako medial unicondylar knee arthroplasty (UKA) **GREEN** Comparator: Jig-based Oxford UKA with navigation control medial	Target enrolment: 140 Inclusion criteria: Patient has medial unicompartmental knee osteoarthritis requiring primary UKA Patient and Surgeon are in agreement that UKA is the most appropriate treatment	Accuracy of component positioning [6 weeks] **GREEN**	Lower limb alignment [pre-op, 6 weeks, 6, 12, 24 months] Femoral implant alignment [pre-op, 6 weeks, 6,12, 24 months] Tibial implant alignment [pre-op, 6 weeks, 6, 12, 24 months] Operating time [intra-operative]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
Study protocol: Kayani et al. (2020) UK	unicondylar knee arthroplasty (UKA) **RED** Status: Recruiting Estimated completion date: 31 December 2024 (final data collection date for primary outcome measure) Sponsor: University College London Collaborator: Stryker Instruments	Patient is fit for surgical intervention following review by surgeon and anaesthetist Patient is between 40-80 years of age at time of surgery Patient must be capable of giving informed consent and agree to comply with the postoperative review program Patient must be a permanent resident in an area accessible to the study site Patient must have sufficient postoperative mobility to attend follow-up clinics and allow for radiographs to be taken Exclusion criteria: Patient is not suitable for primary UKA for example, multi-compartmental knee osteoarthritis, anterior cruciate ligament rupture Patient is not medically fit for surgical intervention Patient requires revision surgery following previously failed correctional osteotomy or ipsilateral UKA Patient is immobile or has another neurological condition affecting musculoskeletal function		Length of hospital stay [6 weeks] Oxford Knee score [pre-op, 6 weeks, 6, 12, 24 months] SF-12 [pre-op, 6 weeks, 6, 12, 24 months] WOMAC [pre-op, 6 weeks, 6, 12, 24 months] KOOS [pre-op, 6 weeks, 6, 12, 24 months] EQ5D [pre-op, 6 weeks, 6, 12, 24 months] Mobilisation distance, metres [pre-op, 6 weeks, 6, 12, 24 months] Use of mobility aids [pre-op, 6 weeks, 6, 12, 24 months] Range of movement [pre-op, 6 weeks, 6, 12, 24 months] Complications [During inpatient admission, post-op 6 weeks, 6, 12 months]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
		Patient is less than 40 years of age or greater than 80 years of age Patient is already enrolled on another concurrent clinical trial Patient is unable or unwilling to sign the informed consent form specific to this study Patient is unable to attend the follow-up programme Patient is non-resident in local area or expected to leave the catchment area postoperatively **GREEN**		
A Prospective Randomised Control Trial Comparing Mako Robotic-arm Assisted Functionally Aligned Total Knee Arthroplasty Versus Mako Robotic-arm Assisted Mechanically Aligned Total Knee Arthroplasty [NCT04092153]	Study design: RCT (double blind) Intervention: TKA with mechanical alignment using Mako robotic system **GREEN** Comparator: TKA with functional alignment using Mako robotic system **AMBER**	Target enrolment: 100 Inclusion criteria: Patient has symptomatic knee osteoarthritis requiring primary TKA. Patient and surgeon are in agreement that TKA is the most appropriate treatment Patient is fit for surgical intervention following review by surgeon and anaesthetist Patient is between 18-80 years of age at time of surgery	WOMAC [2 years] **GREEN**	Lower limb alignment [pre-op, 6 weeks] Operating time [Interoperative] Time to discharge [discharge] FJS [pre-op, 6 weeks, 6, 12, 24 months] OKS [pre-op, 6 weeks, 6, 12, 24 months] SF-12 [pre-op, 6 weeks, 6, 12, 24 months] KOOS [pre-op, 6 weeks, 6, 12, 24 months]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
UK [N=1 site]	Status: Recruiting Estimated completion date: 31 December 2024 Sponsor: University College London Collaborator: Stryker Orthopaedics	Patient must be capable of giving informed consent and agree to comply with the postoperative review program Patient must be a permanent resident in an area accessible to the study site Patient must have sufficient postoperative mobility to attend follow-up clinics and allow for radiographs to be taken Exclusion criteria: Patient is not suitable for routine primary TKA for example, patient has ligament deficiency that requires a constrained prosthesis Patient has bone loss that requires augmentation Patient is not medically fit for surgical intervention Patient requires revision surgery following previously failed correctional osteotomy or ipsilateral TKA Patient is immobile or has another neurological condition affecting musculoskeletal function Patient is less than 18 years of age or greater than 80 years of age		University of California at Los Angeles knee score [pre-op, 6 weeks, 6, 12, 24 months] EQ5D [pre-op, 6 weeks, 6, 12, 24 months] Use of mobility aids [during inpatient admission, 6 weeks, 6, 12, 24 months] Mobilisation distance [during inpatient admission, 6 weeks, 6, 12, 24 months] Range of movement [during inpatient admission, 6 weeks, 6, 12, 24 months] Radiosteriometric analysis [2,6 weeks, 6, 12, 24 months] Gait analysis [6, 12 months] Complications [during inpatient admission, 6 weeks, 6, 12, 24 months]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
		Patient is already enrolled on another concurrent clinical trial Patient is unable or unwilling to sign the informed consent form specific to this study Patient is unable to attend the follow-up programme Patient is non-resident in local area or expected to leave the catchment area postoperatively **GREEN**		
A Comparison of Impingement Free Range of Motion With CT Scan After Manual and Robotic Total Hip Replacement [NCT05507073] UK (N=1 site]	Study design: RCT (single-blind). Stratification for age and sex by minimisation technique. Intervention: Robotic total hip replacement [Note: specific devices not reported] AMBER Comparator: Conventional total hip replacement **GREEN**	Target enrolment: 50 Inclusion criteria: Participant is willing and able to give informed consent for participation in the trial Male or Female, aged 18 to 85 years at recruitment into trial Diagnosed with hip OA, post-traumatic OA, inflammatory arthropathy, , or congenital or developmental hip disease, avascular necrosis of the hip Listed for total hip replacement Suitable for Accolade 2 stem and Trident cup prostheses Female participants of child bearing potential must be willing to ensure that	Impingement [6 weeks] **GREEN**	Forgotten Joint Score [12 months] Oxford Hip score [12 months] EQ5D [12 months] Leg length [12 months] Duration of surgery [surgery] Length of hospital stay [hospital stay]

Study title, reference	Status, estimated completion	Population (n)	Primary outcome measure(s)	Secondary outcome measure(s)
	Status: Recruiting Estimated completion date: 30 December 2024 (final data collection date for primary outcome measure) Sponsor: The Royal Orthopaedic Hospital NHS Trust Collaborator: Stryker Nordic	they use effective contraception during the trial In the Investigator's opinion, is able and willing to comply with all trial requirements Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial. Exclusion criteria: Inability to provide informed consent Previous surgery to the ipsilateral hip and implantation of metalwork. Significant co-morbidities that would make follow up difficult or uncomfortable Scheduled elective surgery or other procedures requiring general anaesthesia during the trial. Pregnancy or intention to become pregnant within the trial period. **GREEN**		

Key: **GREEN** aspect of study in scope; **AMBER** aspect of study partially in scope, or elements of this are not in scope. **RED** aspect of study not in scope. Abbreviations: FJS, Forgotten Joint Score; KOOS, Knee injury and Osteoarthritis Outcome Score; NRS, Numerical Rating Score; OKS, Oxford Knee Score; PROM, Patient Reported Outcome Measure; PROMIS, Patient Reported Outcome Measures Information System; RAS, Robotic Assisted Surgery; RCT, randomised controlled trial. THR, total hip replacement; TKA, Total Knee Arthroplasty, TKR, Total Knee Replacement; UKA, unicompartmental Arthroplasty; WOMAC, Western Ontario & McMaster Universities Score.

Appendix E – Device costs as provided by manufacturer

Cost parameter	ApolloKnee	CORI	Mako	ROSA	VELYS
OPTION 1: Capital purchase					
System Capital Purchase Cost (£)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
What is included?	[redacted]	[redacted]	[redacted]	-	[redacted]
Service contract (£, annually)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Software	-	[redacted]	[redacted]	[redacted]	-
Optional Additional Instruments Tray (£)	-	[redacted]	[redacted]	-	[redacted]
Consumables (THA) (£ per procedure)	Not applicable	[redacted]	[redacted]	Not applicable	Not applicable
Consumables (TKA) (£ per procedure)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Consumables (UKA) (£ per procedure)	Not applicable	[redacted]	[redacted]	Not applicable	Not applicable
Implant (£ Average per procedure)	[redacted]	-	-	[redacted]	[redacted]
Implant (THA) (£ Average per procedure)	-	[redacted]	[redacted]	-	-
Implant (TKA) (£ Average per procedure)	-	[redacted]	[redacted]	-	-
Implant (UKA) (£ Average per procedure)	-	[redacted]	[redacted]	-	-
OPTION 2: Monthly lease					
Long term rental (£ per month)	Not applicable	[redacted]	[redacted]	[redacted]	[redacted]
What is included?	-	[redacted]	[redacted]	-	[redacted]
Surgical service plan (£ Annually)	-	[redacted]	[redacted]	[redacted]	[redacted]
Consumables (£ per procedure)	-	[redacted]	[redacted]	[redacted]	[redacted]
Additional Robotics Instruments (Optional £ per month)	-	[redacted]	[redacted]	-	Not applicable
OPTION 3: Volume based agreement					

Cost parameter	ApolloKnee	CORI	Mako	ROSA	VELYS
Placement option(subject to a volume-based commitment agreement)	-	[redacted]	[redacted]	[redacted]	-
What is included?	-	[redacted]	[redacted]	[redacted]	-
Surgical service plan (£ Annually)	-	[redacted]	[redacted]	[redacted]	-
Software subscription (£ Annually)	-	[redacted]	[redacted]	[redacted]	-
Consumables (£ per procedure)	-	[redacted]	[redacted]	[redacted]	-
Optional Additional Robotics Instruments (£ per month)	-	[redacted]	[redacted]	-	-
OPTION 4: Pay-per-use Model					
Payment per use of the robot (minimal usage contracted)	-	-	-	[redacted]	-
What is included?	-	-	-	-	-
Cases per month (£ per month)	-	-	-	[redacted]	-
Surgical service plan (£ Annually)	-	-	-	[redacted]	-
Software subscription (£ Annually)	-	-	-	[redacted]	-
Consumables (£ per procedure)	-	-	-	[redacted]	-
Optional Additional Robotics Instruments (£ per month)	-	-	-	-	-

Abbreviations: EMEA, Europe, Middle East and Africa; SEA, Supplier equipment agreement; THA, total hip arthroplasty; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

Appendix F – Output of Markov model: base case state occupancy

Appendix F1 - TKA (conventional and RAS arms)

Year	Primary Surgery	Well After Primary	Revision Surgery and Post-revision	Well After Revision	Dead
0	1000	0	0	0	0
1	0	988.42	3.12	0.76	7.7
2	0	971.46	5.95	3.5	19.09
3	0	952.7	6.31	7.29	33.7
4	0	931.8	5.65	10.95	51.6
5	0	908.36	4.78	14.01	72.85
6	0	881.96	4.06	16.43	97.55
7	0	852.31	3.49	18.29	125.91
8	0	819.12	3.06	19.66	158.16
9	0	782.13	2.72	20.62	194.53
10	0	741.09	2.49	21.19	235.23
11	0	695.92	2.33	21.42	280.33
12	0	647.11	2.2	21.35	329.34
13	0	595.29	2.08	20.99	381.64
14	0	541.09	1.97	20.36	436.58
15	0	485.13	1.86	19.45	493.56
16	0	428	1.73	18.28	551.99
17	0	370.19	1.59	16.83	611.39
18	0	312.14	1.43	15.12	671.31
19	0	254.32	1.25	13.13	731.3
20	0	214.02	1.03	11.74	773.21
21	0	176.73	0.84	10.26	812.17
22	0	142.74	0.68	8.74	847.84
23	0	113.19	0.54	7.29	878.98
24	0	87.66	0.41	5.92	906.01
25	0	66.48	0.32	4.7	928.5
26	0	49.19	0.22	3.64	946.95
27	0	35.52	0.17	2.74	961.57
28	0	24.99	0.12	2.01	972.88

Appendix F2 - UKA (conventional and RAS arms)

Year	Primary Surgery	Well After Primary	Revision Surgery and Post-revision	Well After Revision	Dead
0	1000	0	0	0	0
1	0	989.01	7.14	1.74	2.11
2	0	971.25	14.24	8.22	6.29
3	0	955.51	15.84	17.65	11
4	0	940.92	15.24	27.43	16.41
5	0	926.32	14.35	36.67	22.66
6	0	910.65	14.04	45.4	29.91
7	0	893.72	14.11	53.92	38.25
8	0	875.55	14.29	62.36	47.8
9	0	856.16	14.45	70.72	58.67
10	0	835.57	14.53	78.95	70.95
11	0	813.76	14.51	86.94	84.79
12	0	790.49	14.45	94.57	100.49
13	0	765.5	14.36	101.75	118.39
14	0	738.55	14.25	108.38	138.82
15	0	709.43	14.12	114.34	162.11
16	0	677.94	13.98	119.52	188.56
17	0	643.99	13.79	123.77	218.45
18	0	607.49	13.53	126.94	252.04
19	0	568.38	13.19	128.85	289.58
20	0	529.5	12.09	129.54	328.87
21	0	490.05	11.08	128.71	370.16
22	0	450.36	10.13	126.47	413.04
23	0	410.23	9.21	122.73	457.83
24	0	369.99	8.31	117.57	504.13
25	0	329.87	7.39	111.04	551.7
26	0	290.23	6.52	103.24	600.01
27	0	251.75	5.65	94.43	648.17
28	0	215.03	4.83	84.89	695.25
29	0	180.51	4.06	74.86	740.57
30	0	148.77	3.34	64.71	783.18
31	0	120.21	2.71	54.75	822.33
32	0	94.92	2.15	45.21	857.72
33	0	73.52	1.66	36.57	888.25
34	0	55.55	1.25	28.83	914.37
35	0	41.1	0.93	22.22	935.75
36	0	29.64	0.67	16.68	953.01
37	0	20.86	0.47	12.21	966.46
38	0	14.27	0.33	8.68	976.72

Appendix F3 - THA (conventional and RAS arms)

Year	Primary Surgery	Well After Primary	Revision Surgery and Post-revision	Well After Revision	Dead
0	1000	0	0	0	0
1	0	984.57	5.79	1.41	8.23
2	0	971.34	5.43	4.95	18.28
3	0	957.28	5.04	8.21	29.47
4	0	942.08	4.73	11.2	41.99
5	0	925.43	4.56	13.98	56.03
6	0	907	4.59	16.63	71.78
7	0	886.55	4.71	19.24	89.5
8	0	863.87	4.88	21.83	109.42
9	0	838.75	5.07	24.39	131.79
10	0	810.99	5.24	26.9	156.87
11	0	780.46	5.36	29.32	184.86
12	0	747.25	5.45	31.57	215.73
13	0	711.53	5.43	33.59	249.45
14	0	673.45	5.32	35.29	285.94
15	0	633.14	5.13	36.57	325.16
16	0	590.74	4.85	37.37	367.04
17	0	546.33	4.5	37.61	411.56
18	0	499.98	4.09	37.21	458.72
19	0	451.73	3.64	36.13	508.5
20	0	408.43	3.3	34.93	553.34
21	0	364.68	2.95	33.23	599.14
22	0	321.13	2.61	31.07	645.19
23	0	278.59	2.26	28.54	690.61
24	0	237.71	1.93	25.71	734.65
25	0	199.2	1.62	22.69	776.49
26	0	163.75	1.34	19.59	815.32
27	0	131.63	1.08	16.51	850.78
28	0	103.87	0.84	13.64	881.65
29	0	80.02	0.65	10.98	908.35
30	0	60.34	0.49	8.64	930.53
31	0	44.38	0.36	6.61	948.65
32	0	31.84	0.26	4.94	962.96
33	0	22.26	0.18	3.59	973.97

HTE10043: Robot-Assisted Surgery for Orthopaedic Procedures

Medical technologies advisory committee:

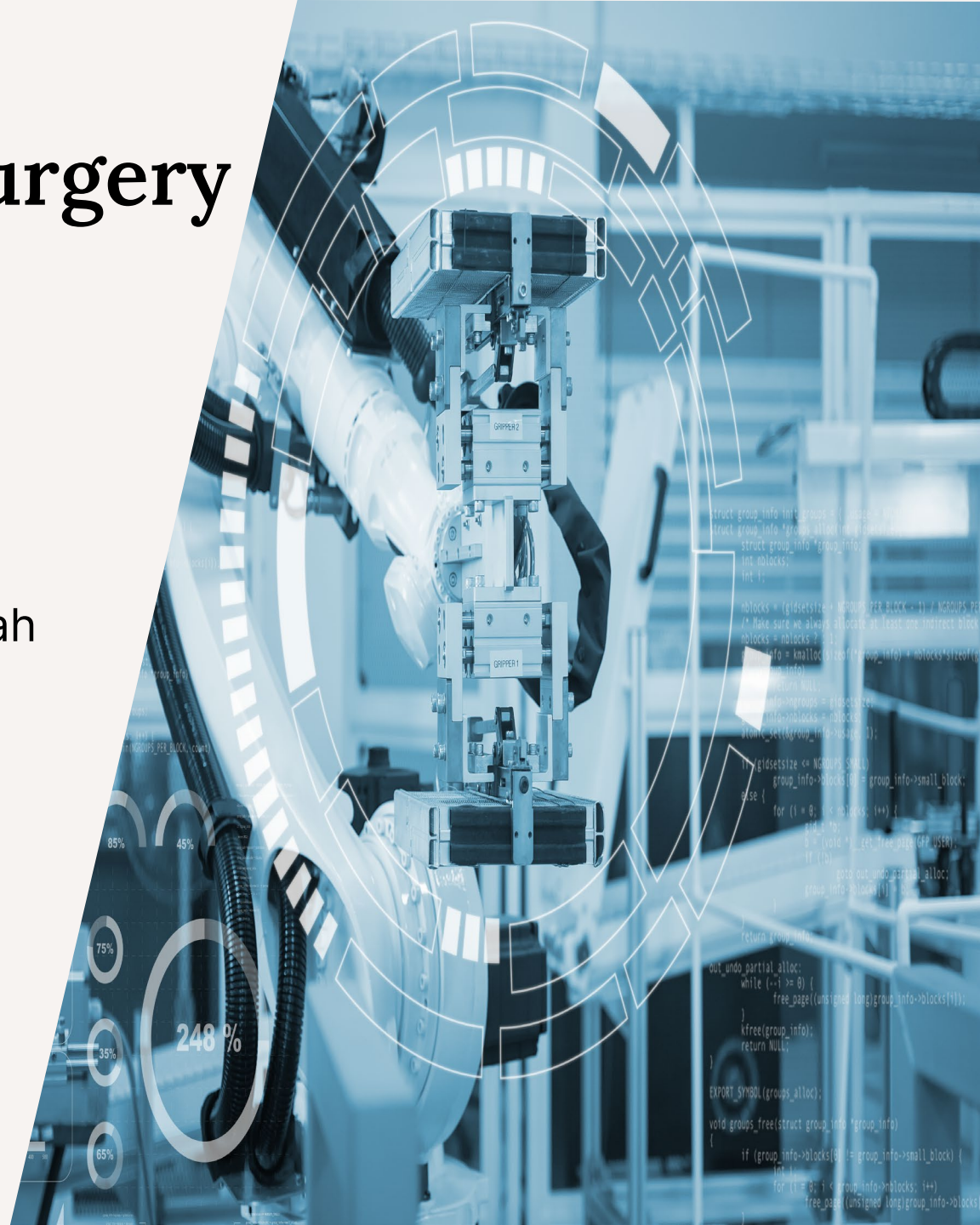
31 October 2024

Introducers: David Deehan, Rebecca Dickens, Abdullah Pandor

External Assessment Group (EAG): Kim Keltie, Rachel O'Leary and Luke Vale (NuTH)

Technical team: Toby Sands, Bernice Dillon, Ivan Maslyankov

NICE National Institute for Health and Care Excellence



Robotic-assisted surgery for orthopaedic procedures

The following slides provide an overview of the external assessment group (EAG) report for this topic. Not all these slides will be presented at the committee meeting but the main information in this set of slides will be summarised. We have tried not to repeat information found in the other documents and references can be found in the slide notes.

Key documents in this assessment include:

- The final scope contains the decision problem for the assessment
- The external assessment report (EAR)* - evidence assessment of the included technologies by the EAG. The report has a more detailed executive summary which provides an overview of the EAG's work and links to the relevant sections of the report

* These documents are in the Committee pack and will be published at consultation

Terminology

- **Conventional surgery:** surgery conducted without robotic assistance or computer navigation
  - Otherwise known as manual or mechanical surgery
- **Total knee arthroplasty (TKA):** replacement of both tibial and femoral condyles (with or without resurfacing of the patella) with or without cement
- **Unicondylar knee arthroplasty (UKA):** replacement of one tibial condyle and one femoral condyle in the knee, with or without resurfacing of the patella
- **Partial knee arthroplasty (PKA):** replacement of more than 1, but not all tibial or femoral condyles in the knee, with or without resurfacing of the patella – **All UKAs are PKAs, but not all PKAs are UKAs**
- **Total hip arthroplasty (THA):** replacement of the femoral head with a stemmed femoral prosthesis and insertion of an acetabular cup, with or without cement

Population, Condition and Diseases

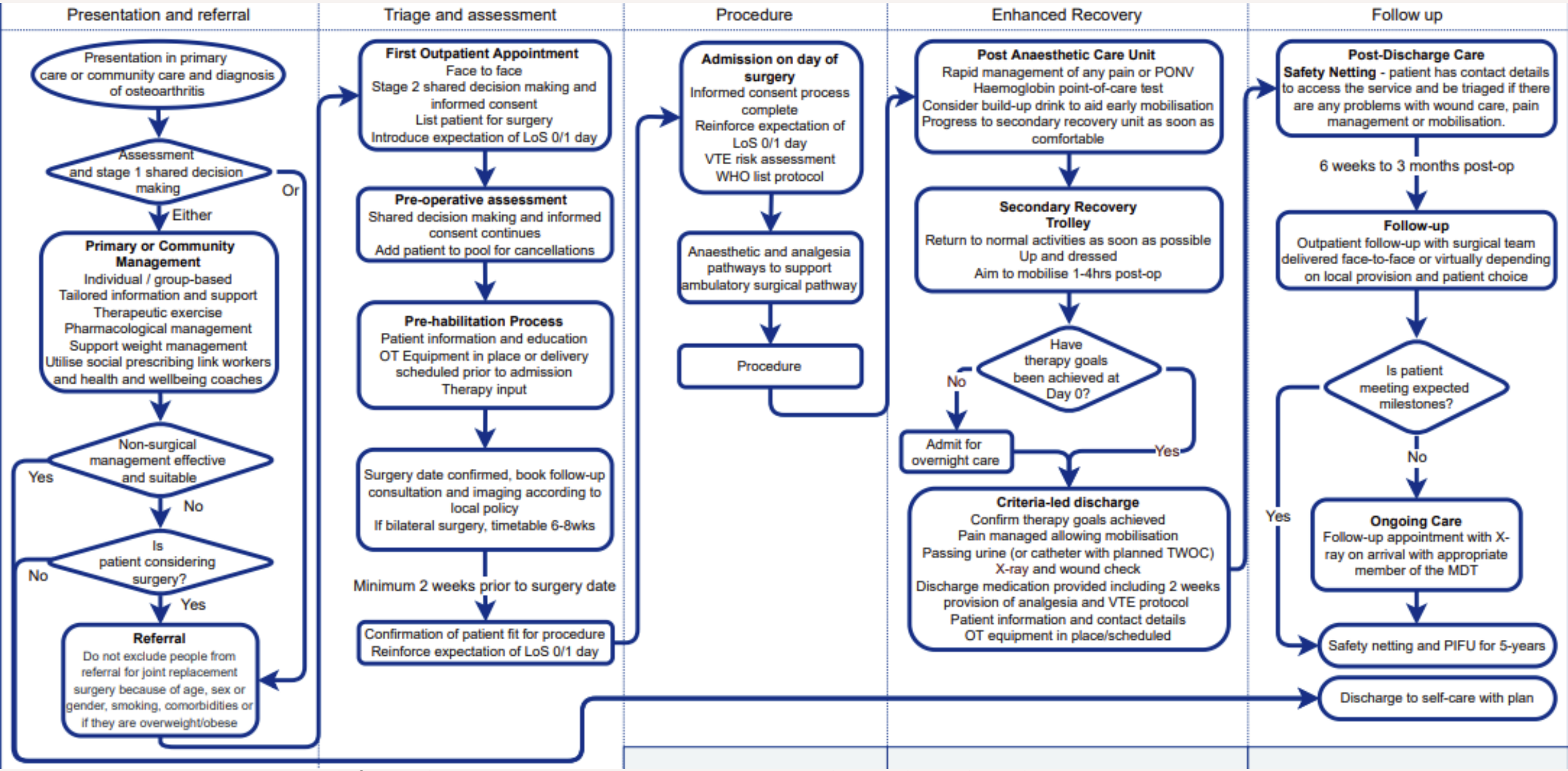
- Knee and hip replacement surgery involves replacing damaged parts of the knee or hip joint, that are causing pain or stiffness, with metal or plastic implants
- It can be used to replace the whole knee joint (total knee replacement) or some of it (partial knee replacement); total hip replacement is the only option for the hip joint.
- The reason for knee replacements is most often osteoarthritis, and less commonly rheumatoid arthritis, gout or injuries. It may be recommended if other treatments or lifestyle changes have not worked, and knee pain is affecting daily activities
- It can take several months or more to fully recover afterwards, but knee implants can last for 20 years or more, and hip implants for 15 or more, and can significantly improve daily life
- Last year there were ~125,000 knee procedures, and >100,000 hip replacements (NJR 20th Annual Report)

For more information, see NHS Health A to Z hip replacement and knee replacement

Current Care Pathway

- NICE guideline (NG157) Joint replacement (primary): hip, knee and shoulder (2020) describes the current care pathway
- Conventional surgery relies on 2-dimensional X-ray images that allow surgeons to map the target site for the implant and what it will look like after implantation
- In conventional surgery, extra or intra medullary jigs (guides) are used to achieve cuts at a pre-determined angle. The cut is made, implant aligned and placed manually, using guides and tools to achieve the best fit
- The process is reliant on a surgeon's skill and judgement, and this may result in variability in precision and alignment
- NHS Getting It Right First Time has published 2 reports on orthopaedic surgery in the NHS (2015 and 2020)

Getting It Right First Time flow chart of the current care pathway for orthopaedic procedures

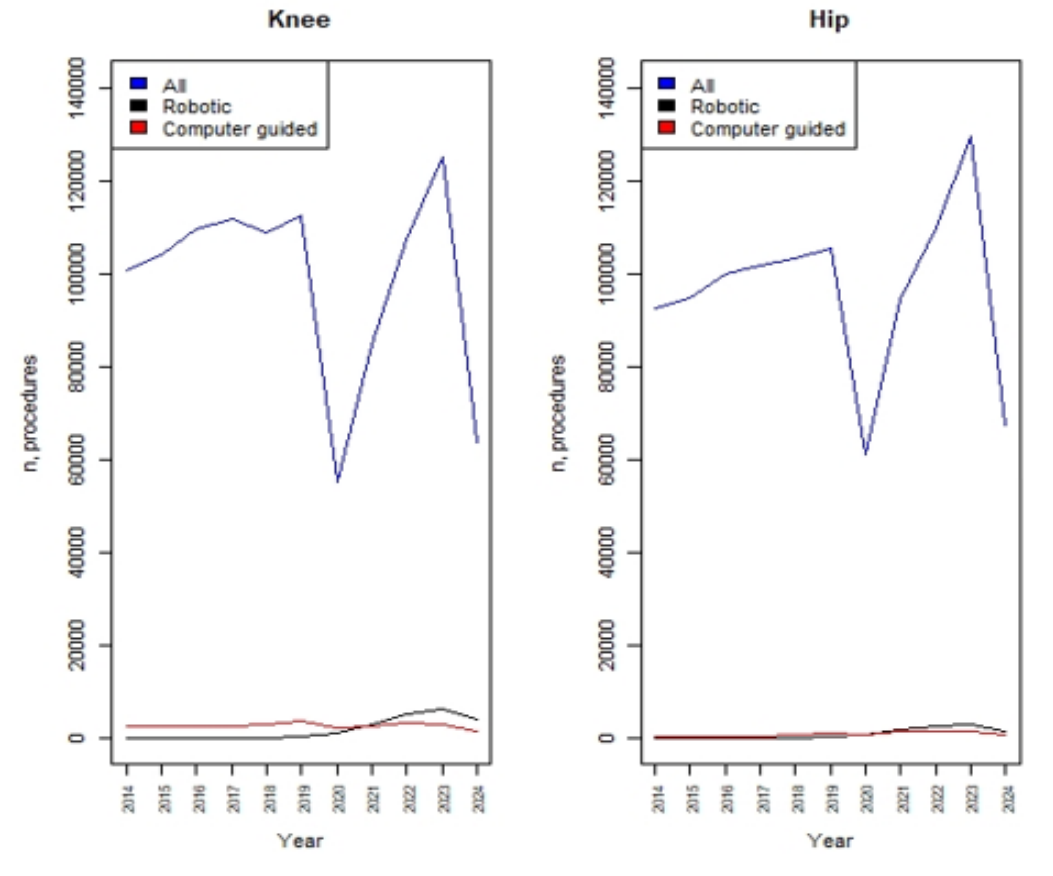


For more information on current care pathway see Getting It Right First Time THA and TKA and PKA, https://gettingitrightfirsttime.co.uk/surgical_specialties/orthopaedic-surgery/

National Joint Registry

The National joint registry (NJR) collects and reports on data from joint replacement procedures across the NHS and the independent sector. It has been running for more than 20 years and is the largest database of this type in the world.

Knee and hip surgeries in the NJR 2014-2024



- Since 2014 it has been collecting data on robots used in hip and knee surgeries.
- 95% of procedures between 2014 and 2024 were completed without robot assistance or navigation.
- The NJR collects information on orthopaedic procedures, advising that the registry contained (01/08/2024):
  - 14,682 RAS TKA procedures
  - 9,462 RAS PKA procedures
  - 9,429 RAS THA procedures.

Potential benefits of RAS and unmet need

NHS Long Term plan (2019), identified musculoskeletal (MSK) conditions as one of the key long-term conditions responsible for a substantial amount of poor health in the population. Since 2019, 'MSK problems' have continued to be among the top three reasons for sickness absence in the UK, and in 2022 this equated to 19.5 million workdays (ONS 2022). Potential benefits of RAS include:

Patients
- May enable quicker return to normal daily activity
- May increase access to surgery for high-risk patients

Surgeons
- Reduced physical strain and cognitive demand
- Improved precision and alignment with use of robotics

Wider NHS
- Potential reduced length of stay, fewer readmissions, fewer revisions, fewer complications
- Reduced need for secondary interventions such as physiotherapy and pain management
- Increase the ratio of partial to total knee replacements by reducing the learning curve associated with manual surgery

The technologies

- 6 robotic technologies available in the NHS were included in this assessment
- 5 companies covering 5 technologies provided information to NICE
    - ApolloKnee (preceded by OMNIBotics) (Corin)
    - CORI Surgical System (preceded by NAVIO) (Smith+Nephew)
    - MAKO SmartRobotics System (Stryker)
    - ROSA Knee System (Zimmer Biomet)
    - VELYS Robotic-Assisted Solution (Johnson & Johnson)
- 1 company did not provide information on their technology to NICE and the EAG used publicly available information
    - SkyWalker (MicroPort MedBot)

RAS: robot-assisted surgery

Robotic-assisted surgery platforms

- For orthopaedic procedures, RAS platforms usually incorporate a robotic arm controlled by the surgeon that holds and aligns cutting tools, computer-assisted navigation and registration systems. RAS platforms may also have data collection features that can be used to verify and score the accuracy of bone resections and placement of implants.

- RAS platforms for orthopaedic systems include a range of different characteristics and features:
  - Direct or indirect cutting: In direct cutting systems the robot cuts the bone into the preplanned desired shape, in indirect cutting systems the robot places or holds a cutting jig with cuts made by a surgeon.
  - Pre-operative imaging: Some systems use pre-operative imaging to aid preoperative planning and provisional implant alignment. Other systems are “image-free” and rely on surface mapping technologies with intraoperative identification of landmarks.
  - Open or closed platforms: Closed platforms limit the surgeon to specific proprietary implants and, potentially, tools and other peripherals such as scanners. Open systems allow the surgeon to use implants or tools from different companies. **All technologies in this EVA are closed platforms.**
- Use of RAS is complex and requires dedicated training programmes for the operating team.
  - Learning curve is reported to be in the range of 10-30 cases by companies
  - Training requirements vary by RAS platform.

Device	Indication			Robotic arm or handheld	Cutting	Imaging requirements	Current UK use
	TKA	PKA	THA				
ApolloKnee (Corin)	✓			Arm	Indirect	Imageless	In preparation for use in 1 NHS hospital
CORI/NAVIO Surgical System (Smith+Nephew)	✓ (+ revision)	✓	✓	Handheld	Direct	Imageless	Used in 12 NHS hospitals in the past year
MAKO SmartRobotics System (Stryker)	✓	✓	✓	Arm	Direct	CT	[redacted]
ROSA Knee System (Zimmer Biomet)	✓			Arm	Indirect	Optional	[redacted]
SkyWalker (MicroPort MedBot)	✓		✓	Arm	Direct	CT	No information provided
VELYS Robotic-Assisted Solution (Johnson & Johnson)	✓			Arm	Direct	Imageless	Available in 1 private hospital

Decision problem (PICO)

Population	People having a joint replacement or revision procedure in an area with a robotic-assisted surgery (RAS) option available: • Stratified by procedure: Total knee replacement, Partial knee replacement, Total hip replacement, Shoulder replacement • Revision surgeries considered separately
Intervention	ApolloKnee, CORI Surgical System, Mako SmartRobotics System, ROSA Knee, SkyWalker, VELYS Robotic-Assisted Solution
Comparator	Conventional manual surgery
Outcomes	Primary outcomes **Patient level:** Patient Reported Outcome Measures, frequency and grade of complication **Surgeon level:** Learning curve **Organisation level:** Revision surgery, cost of additional equipment including the device and single use instrumentation, maintenance and servicing costs, training costs, volume of procedures / operating time, case mix for example proportion of partial knee replacements rather than total knee replacements

The final scope contains the decision problem with all secondary outcomes

Equality and diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

- The EAG noted the following equality and diversity considerations in addition to those outlined in the scope:
- People at higher risk, such as, but not limited to people who are elderly, have a high BMI or multimorbidity, may benefit from increased access to surgery
- Potential for greater benefit in Asian population
  - Unique anatomy can result in poor alignment and implant positioning, which may be eliminated by RAS
- Mental or neuromuscular conditions affecting control of the knee joint or insufficient bone quality may prevent fixation of sensors
- Any condition preventing full articulation of the hip joint could exclude patients due to the need for systems to complete bone registration
- Systems requiring CT scans may exclude some patients e.g., pregnant, allergies, kidney disorders

Clinical Evidence

The following slides summarise evidence for key outcomes outlined in the scope. Full evidence summaries, including secondary outcomes, are available in the external assessment report.

Prioritised Evidence

- Search designed to find full publications that specified the robotic system used within 5 years, and conference abstracts within 2 years
  - Full publications that did not name the robotic system used were searched for with a 2-year time limit
  - 750 papers identified, 170 reviewed as full texts
- Ovid Embase, Ovid Medicine and Cochrane Library CENTRAL, Clinicaltrials.gov via Scanmedicine, NIHR Library, EngRxiv, MedRxiv, CEA Registry, RePEC IDEAs and INAHTA searched in July 2024

- 26 studies prioritised, as described in EAG's protocol
- 15 conducted in a UK setting
- 15 studies in TKA
  - 5 RCTS and 3 prospective cohort studies with matched comparator arms
- 5 studies in PKA
  - 3 RCTs and 1 retrospective UK cohort study
  - 2 studies reported data from the same RCT, comparing TKA to PKA
- 1 study reported TKA and PKA as separate subgroups
- 5 studies in THA
  - 5 observational studies

Summary of Clinical Evidence

- Mako had the highest quality evidence base with 3 RCTs in TKA, 3 RCTs in UKA, and was the only system with any evidence for THA
- CORI/NAVIO had the next best evidence base, with 2 RCTs in TKA, but limited retrospective evidence in UKA and no evidence for THA, followed by ROSA Knee which had non-randomised evidence for TKA but no evidence for THA
- Evidence broadly reported non-inferiority of RAS compared with conventional surgery across a range of outcomes
- Alignment was consistently superior with Mako for TKA and THA (UKA not reported) and was demonstrated to be superior with CORI/NAVIO for TKA in randomised evidence
- No published evidence was adequately powered to detect differences in revisions
- No UK, randomised or prospective comparative studies with cohort matching for ApolloKnee, SkyWalker or VELYS

Prioritised evidence landscape across procedures

Technology	TKA	PKA	THA
ApolloKnee or OMNIBot	Limited evidence: 1 non-UK prospective cohort (n=60, reporting intraoperative outcomes)	Not indicated	
ROSA Knee	Limited evidence: 2 non-UK prospective cohorts (with matched comparator); longest FU 6 months, and 1 non-UK retrospective cohort (learning curve outcome only)		
SkyWalker	Limited evidence: 1 non-UK retrospective cohort (n=60, FU 3 months)		
VELYS	Limited evidence: 1 non-UK prospective comparator cohort. 1 non-UK retrospective cohort (included for learning curve outcome only)		
CORI or NAVIO	2 non-UK RCTs (longest follow up 1-year, largest n=215 patients) and 1 UK retrospective cohort	Limited evidence: 1 UK retrospective cohort (procedural outcomes only, n=200 patients)	Lack of evidence
Mako	5 UK RCTs (longest follow up 5 years with n=120 patients), 2 UK prospective cohorts, 1 non-UK prospective (with matched comparator)	1 UK RCT (longest FU 5 years with n=139 patients), 2 UK prospective cohorts (1 with matched comparator)	Limited evidence: 3 UK prospective cohort (1 with matched comparator), 1 UK retrospective cohort; longest FU 1 year, 1 non-UK retrospective cohort

FU; follow-up, colours indicate: green; evidence available, orange; limited evidence available, red; lack of evidence available

OMNIBot / ApolloKnee - TKA

Author Country	Study design [duration of follow-up]	Interven-tions (number of participants)	Outcomes extracted	Findings
Vermue 2023 Belgium	Prospective cohort with historical comparator [procedural]	OMNIBot (n=30) Vs Conventional (n=30)	Learning curve (first 10 vs last 10 RAS procedures) Operating time (last 10 RAS cases vs 30 conventional cases)	**Learning Curve:** Significant difference in time for positioning femoral resection guide combined with femoral resection Significant reduction in total surgical time **Operating time:** Significantly increased total operative time with RAS

ROSA - TKA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Fary 2023 International	Prospective propensity matched [up to 1 year]	ROSA (n=216) Vs Conventional (n=216)	PROMs Complications Revision surgery	No statistically significant difference in PROMs Significantly lower opioid use at 1-month with RAS, no difference at 3 months No difference in septic or aseptic revisions
Kenanidis 2023 Greece	Prospective matched comparative cohort (age, sex, BMI) [6 months]	ROSA (n=30) Vs Conventional (n=30)	PROMs Complications	Significantly better Oxford Knee Score, Forgotten joint Score and visual analogue scale with ROSA at 6 months 100% satisfaction with ROSA vs 86.7% with conventional surgery at 6 months (statistically significant difference) No complications in either arm
Vanlommel 2021 Belgium	Retrospective cohort [90 days]	ROSA (n=90) Vs Conventional (n=90)	Learning curve	Learning curve of between 6 and 11 cases in 3 high volume surgeons ~16-minute reduction in total surgical time once mastered compared to during learning phase

SkyWalker - TKA

Author Country	Study design [duration of follow-up]	Interventions (number of pariticipants)	Outcomes extracted	Findings
He 2022 China	Retrospective cohort [3 months]	SkyWalker (n=30) Vs Conventional (n=30)	PROMs Complications Operating time	No difference in PROMs Statistically significant reduction in blood loss with RAS No difference in time from skin incision to suturing Significantly shorter total torniquet time with conventional surgery

VELYS - TKA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Leslie 2024 US	Prospective cohort [1 year; Online abstract reporting outcomes to 3 months]	VELYS (n=100) Vs Conventional (n=100)	PROMs Complications Learning curve Operating time	[redacted]
Morrisey 2023 US	Retrospective cohort [Up to 6 months]	VELYS; kinematically aligned (n=66) Vs Traditional mechanically aligned (n=99)	Learning curve	No statistically significant difference in tourniquet time, range of motion, pain and operative time between first 20 and subsequent 46 conventional cases No difference in operative time compared with conventional surgery when dismissing the initial 2 cases that were deemed to be the learning phase

CORI/NAVIO

Author Country	Study design [duration of follow-up]	Procedure	Interventions (number of participants)	Outcomes extracted	Findings
Adamska 2023 Poland	RCT (3-arm) [1 year]	TKA	CORI (n=71) and NAVIO (n=76) Vs Conventional (n=68)	PROMs Complications Operating time Revision surgery	Statistically significant better KOOS with conventional vs CORI or NAVIO No difference in VAS pain No complications in either arm Statistically significant reduction in blood loss with RAS Statistically signicantly longer surgical time with RAS No revisions in any arms
Thiengwittayaporn 2021 Thailand	RCT [procedural]	TKA (primary)	NAVIO (n=75) Vs Conventional (n=77)	Learning curve Operating time	Proficiency achieved after 7 cases Statistically significant reduction in total operative time in proficiency phase compared to learning phase Statistically significantly longer surgical time with RAS when comparing all cases
Khan 2021 UK	Retrospective cohort [procedural]	TKA (primary) or UKA (primary)	NAVIO (n=50 TKA, n=50 UKA) Vs Conventional (n=50 TKA and n=50 UKA)	Complications	Statistically significant reduction in blood loss with RAS (TKA) No statistically significant difference in blood loss (UKA) Statistically significant reduction in people needing transfusions (TKA) No transfusions required in either arm (UKA)

Mako - TKA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Clement 2024 UK	RCT [up to 1 year]	Mako (n=50) Vs Conventional jig based (n=50)	PROMs Complications	Statistically significant improvement in EQ-5D with RAS, no difference in other reported PROMs No difference in complications
Ng 2024 Singapore	Prospective cohort with propensity score matching [6 months]	Mako (n=42) with ERAS protocol Vs Conventional with ERAS protocol (n=42)	PROMs Complications Revision surgery Operating time	No difference in any reported PROMs No difference in complications No revisions in either arm Statistically significantly longer surgical duration with RAS
Kayani 2023 UK	Prospective cohort [up to 5 years]	Mako (n=60) Vs Conventional jig based (n=60)	PROMs	Statistically significant improvement in FJS with RAS, no difference in any other reported PROMs
Kayani 2019 UK	Prospective cohort [up to 30 days]	Undefined; shared by Stryker, assumed Mako (n=60) Vs Conventional jig based (n=60)	Learning curve	Proficiency achieved after 7 cases Operative times were statistically significantly longer in the learning phase vs the proficiency phase

Mako – Bi-UKA vs TKA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Banger (Bone Joint J, 2022; 433-443); UK	RCT [1 year]	Bi-UKA with Mako (n=42) Vs TKA with conventional (n=34)	Only secondary outcomes reported: Gait and sway analysis	No difference in gait analysis Statistically significant difference in sway analysis favouring UKA with RAS Statistically significant worsening in proprioception after 1-year in TKA conventional arm, but not in UKA with RAS arm
Banger (Bone Joint J, 2020; 1511-1518); UK	RCT [post-procedure]	Bi-UKA with Mako (n=32) Vs TKA with conventional (n=38)	Only secondary outcomes reported: Alignment	Statistically significant difference in 3 femoral and 3 tibial markers of alignment favouring UKA with RAS, and changes in hip-knee-ankle angle were statistically significantly lower in UKA with RAS

Mako – UKA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Banger 2021 UK	RCT [up to 5 years]	Mako (n=69) Vs Conventional (n=70)	PROMs Complications Revision surgery	No difference in any PROMs No difference in post-operative complications or hospital outpatient department visits Zero revisions with RAS, 2 revisions with conventional surgery
Clement 2020 UK	Prospective cohort with propensity matching [up to 6 months]	Mako (n=30) Vs Conventional (n=90)	PROMs	Statistically significant improvement in EQ-5D, FJS, OKS with RAS Statistically significantly lower VAS-pain with conventional No difference in satisfaction
Kayani 2019 UK	Prospective cohort [up to 90 days]	Mako (n=73) Vs Conventional jig based (n=73)	PROMs Pain	Statistically significantly higher NRS on days 0, 1 and 2 following discharge Statistically significant opiate analgesia consumption on days 0, 1 and 2

Mako – THA

Author Country	Study design [duration of follow-up]	Interventions (number of participants)	Outcomes extracted	Findings
Ammori 2024 UK [*Abstract only*]	Prospective database [1 year]	Mako (n=NR) Vs Conventional (n=NR)	PROMs	Statistically significantly higher EQ-5D-3L with conventional Statistically significantly higher EQ-VAS and OHS with RAS
Kong 2020 Location NR	Retrospective cohort [3 months]	Mako (n=100) Vs conventional (n=100)	Learning curve	Proficiency achieved after 14 cases, alignment data suggests proficiency was achieved after 8 cases Statistically significantly reduced total operating time, acetabular registration and cup implantation times between learning and proficiency phases
Clement 2021 UK	Prospective cohort with propensity matching [up to 12 months]	Mako (n=40) Vs Conventional (n=80)	PROMs	Statistically significantly higher FJS and OKS with RAS No difference in any other reported PROMs

Data from the National Joint Registry

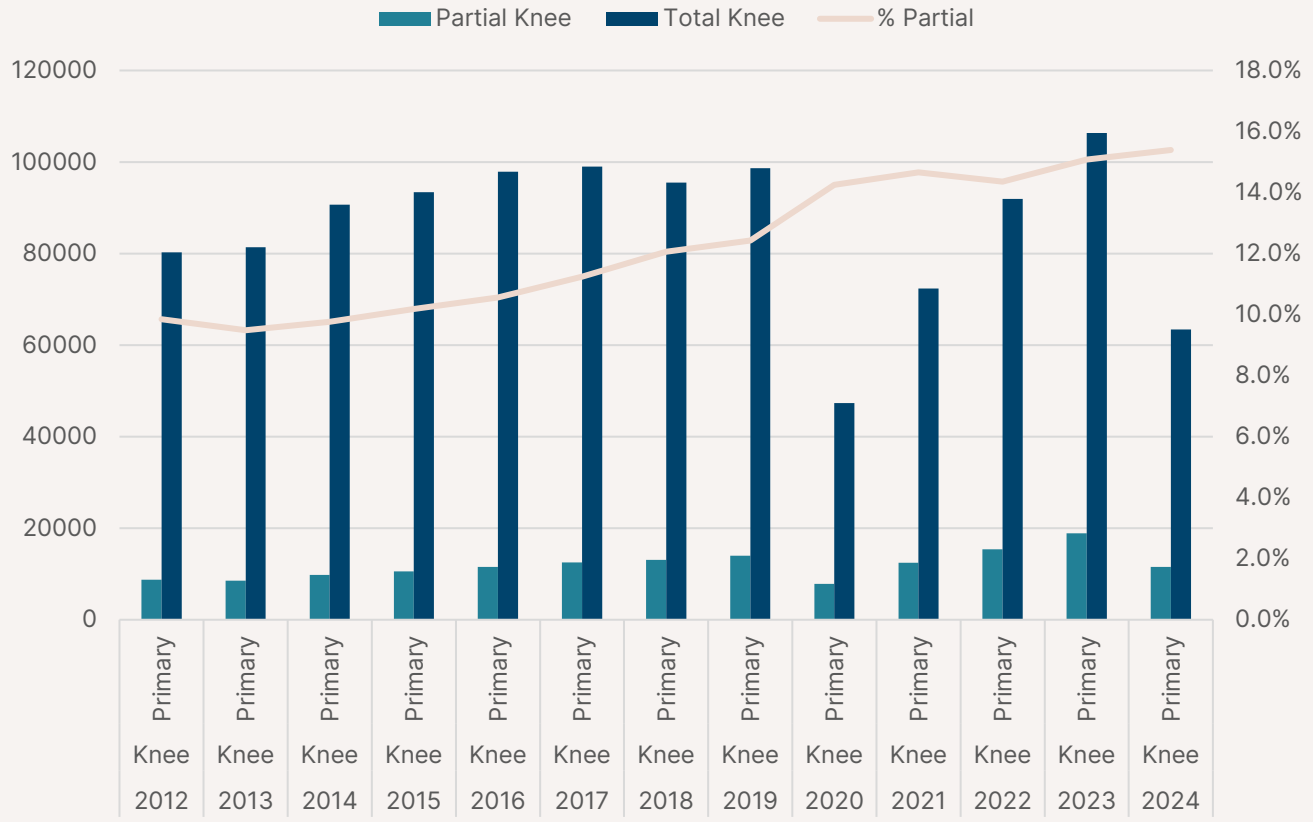
Revisions after robotic-assisted procedures (within 3 years):

- 8,903 TKAs [redacted] 59 revisions (0.7%) recorded
- 2,674 UKAs [redacted] 27 revisions (1.0%) recorded
- 5,771 THAs [redacted] 31 revisions (0.5%) recorded
- The NJR 20th Annual Report reported that 1.45% of primary TKA procedures, 3.49% of primary UKA procedures, and 1.44% of primary THA procedures had been revised at 3 years
    - Note that these figures are for conventional surgery and RAS combined – data per surgical method was not reported

Proportion of partial knee replacements

- Steady increase in partial knee replacement from 9.8% (in 2014) to 15.4% (in the partial year of 2024)

Number and proportion of total and partial primary knee replacement procedures in the National Joint Registry, 2012-2024 (20th Annual Report, provided to the EAG upon request)



The Australian Orthopaedic Association National Joint Replacement Registry

- Revision rates reported within the 2024 annual report
- 71,906 RAS TKA procedures recorded since 2016, representing 35.7% of primary TKA procedures conducted in 2023
    - Lower revisions within 6 years in RAS procedures (1.2% - 886/71,505) when compared with conventional surgery (2.3% - 4,058/174,394), however when adjusted for confounding factors there was no difference between arms (hazard ratio 1.04, 95%CI 0.96-1.13, p-value= 0.332)
- 9,760 robotic assisted UKA procedures recorded since 2015, representing 48.1% of UKA conducted in 2023
    - Lower revisions within 8 years in RAS procedures (3.4% - 331/9,760) when compared with conventional surgery (4.7% - 789/16,799), however when adjusted for confounding factors there was no difference between arms (hazard ratio 0.90, 95%CI 0.77-1.05, p-value= 0.171)

Differences in age and pre-operative risk (determined by ASA class) of people undergoing joint replacement surgery in Australia compared to the UK means caution should be exercised when considering if this data is generalisable to the UK.

Adverse events

Noise

- 2 studies evaluated noise exposure in RAS → surgeon and assistant had statistically significantly greater noise exposure than other staff and continuous sound pressure exposure exceeded lower exposure values in the Control of Noise at Work Regulations 2005 – although this wasn't compared to conventional surgery
- 3 clinical experts reported RAS being noisier than conventional surgery, 3 reported no difference
  - Noise in orthopaedic surgery is associated with saw and laminar flow that is not specific to RAS

Fractures

- 1-study reported 2 case studies of early fractures of the tibial baseplate following UKA, both requiring revision to TKA – the number of cases before these two occurred was not reported, making this event difficult to contextualise – again, this wasn't compared to conventional surgery

Ergonomics

- 3 studies addressed ergonomics of operating staff – one reported TKA surgery time being ~16 minutes longer than conventional, but that the time spent in a demanding flexion position, calorie expenditure, heart rate and minute ventilation of staff was lower

MHRA Safety Notices

- 3 notices identified, 2 for Mako, 1 of which referred to programming errors of the saw blade, potentially leading to discrepancies between the planned and performed cuts, 1 advised loss of function when switching between surgical applications, 1 identified for CORI referring to marker registration error, causing flickering of tracker arrays on the screen – all of which can increase surgical time and increase risk of complications

EAG summary of Clinical Evidence

- The EAG prioritised 26 studies, 15 of which were UK-based and included 8 RCTs
- Mako had the highest quality evidence base with 3 RCTs in TKA, 3 RCTs in UKA, and was the only system with any evidence for THA
- CORI/NAVIO had the next best evidence base, with 2 RCTs in TKA, but limited retrospective evidence in UKA and no evidence for THA, followed by ROSA Knee which had non-randomised evidence for TKA
- Evidence broadly reported non-inferiority of RAS compared with conventional surgery across a range of outcomes
- Alignment was consistently superior with Mako for TKA and THA (UKA not reported) and was demonstrated to be superior with CORI/NAVIO for TKA in randomised evidence
- No published evidence was adequately powered to detect differences in revisions. The EAG considered the NJR the most robust evidence available for this outcome
- No UK, randomised or prospective comparative studies with cohort matching for ApolloKnee, SkyWalker or VELYS

Key Clinical Issues

Technologies

- Some technologies have a more mature evidence base: No UK, randomised or prospective comparative studies with cohort matching for ApolloKnee, SkyWalker or VELYS
- No randomised evidence for THA, and evidence only identified for Mako system

Primary Outcomes

- Limited data for revisions in published literature. The NJR is collecting this data.
- Unclear if RAS is associated with better quality of life (utilities) compared with conventional surgery – lack of comparative studies with large sample sizes means large variances around point estimates.

Secondary Outcomes

- Most consistent benefit is in alignment, however it is unclear if this results in better patient outcomes
- Effect of RAS on surgeon and organisation level outcomes largely unknown

Economic evidence, model and findings

Robot-assisted surgery for orthopaedic procedures

NICE National Institute for Health and Care Excellence

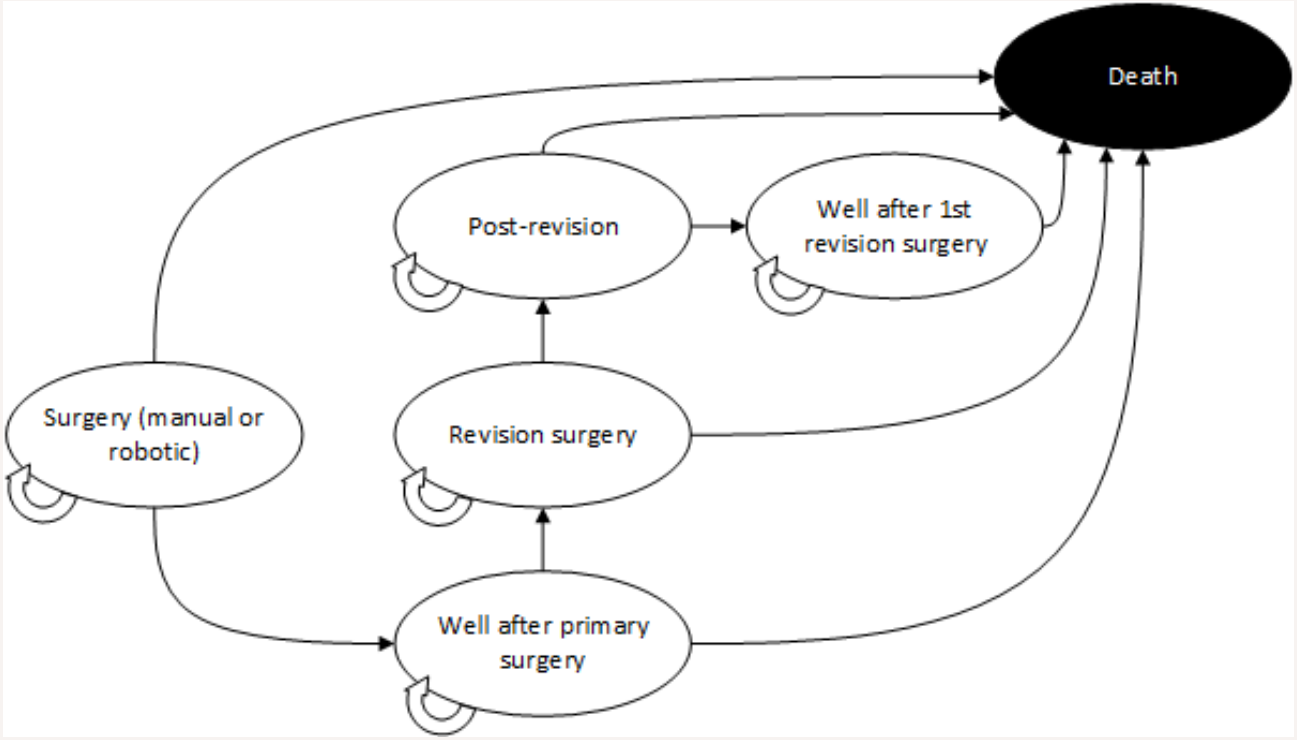
Searches and Study Selection

- 196 records identified through independent literature search
- Only included records that explicitly stated the technology name or predecessor from the scope, or reported threshold analysis such that the device name was not specified
- 22 studies considered relevant to the decision problem, 7 of which contained a Markov model, with the other 15 containing cost or cost utility analyses. They studies related to a range of technologies:
    - 15 with Mako and 1 with Mako RIO (predecessor)
    - 3 with NAVIO
    - 1 with Mako and NAVIO
    - 1 with VELYS
    - 1 with no technology reported (UK threshold analysis applicable to any technology)

Author (year)	Procedure	Starting age in model, years	Purchasing option	Procedural volume (annually)	Robotic cost per patient (in addition to procedure costs)	Cost of procedure	Cost of revision	Incremental utility gain for robotic surgery	Incremental cost per QALY: discounted (undiscounted)
(Clement et al., 2022)	THA with Mako	69	Monthly rental: £9,600 Annually: £115,200, consumables £278 per patient	100	£1,516 (robotic system, consumables, CT scan)	£6,207	Aseptic (87%): £11,897 Septic (13%): £21,937	0.091 compared to conventional THA	£2,349 (£1,910) at 10-year horizon, and £1,432 (£980) at lifetime horizon compared to conventional THA.
(Clement et al., 2019)	UKA with Mako	65	Monthly rental: £9,600 Annually: £115,200, consumables £626 per patient	100	£1,866 (robotic system, consumables, CT scan)	£5,010	Aseptic: £9,655 Septic: £30,011	1.39 compared to conventional UKA and 1.80 compared to conventional TKA	£1,170 compared to conventional UKA and £1,395 compared to conventional TKA from lifetime model.
(Clement et al., 2023)	UKA with Mako	66	Annual rental £115,200, consumables £626 per patient	400	£1,070 (robotic system, consumables, CT scan)	£5,721	Aseptic: £9,655 Septic: £30,011	0.012 [95%CI -0.413, 0.437]	£13,078 compared to conventional UKA at 5 years.
(Nherera et al., 2020)	UKA with NAVIO	65	Capital purchase £358,000 with 5-year lifespan, with service contract (2-5 years) of £21,500 per year, consumables £260 per patient	100	£1,225 (robotic system, service contract consumables)	£6,267 (additional £289 rehabilitation)	£10,390	9.47 compared to mUKA	£2,831 compared to conventional UKA at 5 years

EAG's conceptual model

- Markov model developed to include contemporary evidence and costs, based on single revision models previously applied in 3 UK studies
- Hypothetical starting point is 1000 people entering the model at the time of primary surgery, with separate models for TKA, UKA and THA, all using the same structure depicted below
- 1-month cycle length applied



Model states:

Surgery

Enter the model and remain here until discharged well from hospital, or death

Well after primary surgery
May remain here after surgery until requiring revision or death occurs

Revision surgery
State entered when first revision surgery occurs

Post revision

Enter from revision surgery (included to account for utility decrement in year following revision surgery)

Well after first revision surgery
Remain here after revision surgery until death

Death
Absorbing state; can be transitioned into from any other state

Key Model Considerations

Events considered by the EAG, but not included in the model:

- Adverse events - no evidence that they are different between RAS and conventional surgery
- Conversion to manual surgery - not reported in the included studies and was considered a rare event by experts
- Experts raised dislocation as a specific adverse event in THA, although no evidence to suggest a difference between RAS and conventional surgery was identified
- Lifetime time horizon applied in the model base case to reflect the life expectancy of people undergoing orthopaedic procedures
- Minor complications experienced in hospital after surgery not considered as separate Markov states as these were considered to be incorporated into the HRG procedure cost
- Assumed that all revision surgery is with conventional surgery, and revision surgery modelled with a weighted average of septic and non-septic revisions, assuming same rates in RAS and conventional surgery
- Model only allowed for one revision procedure, and assumed all revisions were single stage (according to NJR report, 78.5% are single stage), noting that two-stage revisions would incur additional cost
- System costs were calculated using a lease agreement of 250 procedures per year
- Due to the range of implants available, average costs were taken across the range offered per robotic system

Model Parameters

Variable	Value		
	TKA	PKA	THA
Median age (years)	72	62	67
Sex (% male)	43	51	40
Median procedure volume (cases per year)	250	250	250
Median length of stay (days)	2	1	2.5

Revision and mortality rates were assumed to be the same across both model arms based on published literature and information obtained from the NJR, see Table 33 of the EAR

Note that median procedure volume is based on historic data across the UK (2020-2022), indicating a median procedure volume of 140 TKA and 18 UKA procedures per provider per year and this figure varies by centre. The EAG acknowledges that the increasing availability of RAS over time may cause these procedure volumes to rise in the future, hence the higher input of knee surgeries per centre per year (combining both TKA and UKA)

Health State Utilities

- Note that the utility values used for TKA were converted to final values by the EAG (baseline plus 12-month change value), resulting in model inputs of:
  - 0.752 (95%CI 0.646-0.857) in the conventional surgery arm
  - 0.750 (95%CI 0.661-0.838) in the RAS arm
- Revision utilities sourced from Clement (2019) economic model applied to TKA and PKA. For THA, utilities were assumed to be the same as after primary surgery as no other evidence was available.

Parameter	Procedure	Time point	Literature reported values (mean (SD))		Favours
			Conventional	RAS	
EQ-5D-3L	TKA	Pre-operative (baseline)	0.476 (0.275)	0.458 (0.296)	Conventional
		12 months (change from baseline)	0.276 (0.331)	0.292 (0.331)	RAS
Utility tool not reported		Post-revision	0.565	0.565	Assumed same
EQ-5D (final values)	PKA	Pre-operative	0.427 (0.295)	0.466 (0.297)	RAS
		1-year	0.728 (0.250)	0.744 (0.266)	RAS
		2 years	0.746 (0.228)	0.749 (0.279)	RAS
		5 years	0.729 (0.273)	0.704 (0.315)	Conventional
Utility tool not reported		Post-revision	0.565	0.565	Assumed same
EQ-5D (final values)	THA	Pre-operative	0.384 (0.320)	0.384 (0.320)	Neither
		Post-operative (6-12 months)	0.754 (0.263)	0.845 (95%CI 0.740-0.949)	RAS
		Post-revision	0.754	0.845	RAS
Utility tool not reported	All	First 12 months post-septic revision	-0.2	-0.2	Assumed same
		First 12 months post-aseptic revision	-0.1	-0.1	Assumed same

Device Cost per Patient - 12-month contract (used in base case)

Parameter	CORI	Mako	ROSA	VELYS
Rental cost, per patient	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for THA, per patient	[redacted]	[redacted]	-	-
Consumable costs for TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for UKA, per patient	[redacted]	[redacted]	-	-
Implant costs for THA, per patient	[redacted]	[redacted]	[redacted]	[redacted]
Implant costs for TKA, per patient	[redacted]	[redacted]	-	-
Implant costs for UKA, per patient	[redacted]	[redacted]	-	-
CT imaging costs (pre-procedure), per patient	-	[redacted]	-	-
Service plan, per patient	[redacted]	[redacted]	[redacted]	-
Total costs (THA)	[redacted]	[redacted]	-	-
Total costs (TKA)	[redacted]	[redacted]	[redacted]	[redacted]
Total costs (UKA)	[redacted]	[redacted]	-	-

Costs are assuming an annual procedure volume of 250 cases, optional extras per patient for [redacted]

Device Cost per Patient - Capital Purchase (explored in sensitivity analysis)

Parameter	ApolloKnee	CORI	Mako	ROSA	VELYS
Lifetime of system, years	10	5	[redacted]	10	7
Device costs (assuming procedural volume and lifetime of robot above), per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for THA, per patient	-	[redacted]	[redacted]	-	-
Consumable costs for TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Consumable costs for UKA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for THA, per patient	-	[redacted]	[redacted]	-	-
Implant costs for TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Implant costs for UKA, per patient	-	[redacted]	[redacted]	-	-
CT imaging costs (pre-procedure), per patient	-	-	[redacted]	-	-
Service plan, per patient (assuming not applied in first year and included in 12-month warranty and that costs of 4 years spread across 5 years)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total costs (THA)	-	[redacted]	[redacted]	-	-
Total costs (TKA)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total costs (UKA)	-	[redacted]	[redacted]	-	-

Costs are assuming an annual procedure volume of 250 cases, optional extras per patient for [redacted]

Breakdown of Cost Components (TKA)

Cost component	CORI	Mako	ROSA	VELYS
Rental	[redacted]	[redacted]	[redacted]	[redacted]
Consumables	[redacted]	[redacted]	[redacted]	[redacted]
Implant	[redacted]	[redacted]	[redacted]	[redacted]
CT imaging (pre-procedure)	-	[redacted]	-	-
Service plan	[redacted]	[redacted]	[redacted]	[redacted]
Total cost TKA, per patient	[redacted]	[redacted]	[redacted]	[redacted]

Based on a 12-month contract with no optional extras assuming a volume of 250 procedures per year

Other Cost Parameters

Parameter	Value	Source
Procedural cost, primary total knee and primary partial knee	[redacted]	National Schedule of NHS Costs (2021-2022)
Procedural cost, primary total hip	[redacted]	National Schedule of NHS Costs (2021-2022)
Procedural cost, revision knee or hip (no diagnosis of infection)	[redacted]	National Schedule of NHS Costs (2021-2022)
Procedural cost, revision knee or hip (infection)	[redacted]	National Schedule of NHS Costs (2021-2022)
Length of stay, bed day cost (per day)	[redacted]	NHS Reference Costs 2017-2018, inflated to 2021-2022 costs
Pre-operative CT scan knee or hip (robotic surgery only)	[redacted]	National Schedule of NHS Costs (2021-2022)

Base Case Results – TKA

	Total costs, per patient	Total QALY, per patient	Difference in cost (compared with conventional)	Difference in QALY (compared with conventional) [difference when using the lower and upper confidence interval of utilities]	ICER [difference when using the lower and upper limit of utilities]
Conventional	[redacted]	8.406 [7.243, 9.559]			
Robotic: CORI	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	Dominated [Dominated, [redacted]*]
Robotic: Mako	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	Dominated [Dominated, [redacted]*]
Robotic: ROSA	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	Dominated [Dominated, [redacted]*]
Robotic: VELYS	[redacted]	8.385 [7.408, 9.35]	[redacted]	-0.022 [-0.999, 0.944]	Dominated [Dominated, [redacted]*]

Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *

Base Case Results - PKA

	Total costs, per patient	Total QALY, per patient	Difference in cost (compared with conventional)	Difference in QALY (compared with conventional) [difference when using the lower and upper confidence interval of utilities]	ICER [difference when using the lower and upper limit of utilities]
Conventional	[redacted]	10.998 [9.982, 12.001]			
Robotic: CORI	[redacted]	10.769 [9.654, 11.869]	[redacted]	-0.229 [-1.343, 0.872]	Dominated [Dominated, [redacted]*]
Robotic: Mako	[redacted]	10.769 [9.654, 11.869]	[redacted]	-0.229 [-1.343, 0.872]	Dominated [Dominated, [redacted]*]

Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *

Base Case Results - THA

	Total costs, per patient	Total QALY, per patient	Difference in cost (compared with conventional)	Difference in QALY (compared with conventional) [difference when using the lower and upper confidence interval of utilities]	ICER [difference when using the lower and upper limit of utilities]
Conventional	[redacted]	9.871 [9.569, 10.159]			
Robotic: CORI	[redacted]	11.063 [9.687, 12.426]	[redacted]	1.192 [-0.183, 2.555]	[redacted]* [Dominated, [redacted]*]
Robotic: Mako	[redacted]	11.063 [9.687, 12.426]	[redacted]	1.192 [-0.183, 2.555]	[redacted]* [Dominated, [redacted]*]

Note: Incremental cost effectiveness ratios less than the willingness to pay threshold of £20,000 are marked with a *

Sensitivity Analyses Results

- Sensitivity analysis showed that the only scenario where RAS was not dominated, for TKA and UKA, was when zero revisions were assumed in the RAS arm only.
    - When zero revisions in the RAS arm were assumed for UKA, RAS was dominant, and TKA ICER= [redacted]
    - In all other scenarios, including best case combination, conventional surgery was dominant
- Best case combination of 20% reduction of revisions, 20% reduction in length of stay and lower limit of implant costs
    - Incremental costs of [redacted] and incremental QALYs of -0.010 for TKA – RAS dominated
    - Incremental costs of [redacted] and incremental QALYs of -0.180 for UKA – RAS dominated
    - Incremental costs of [redacted] and incremental QALYs of 1.194 for THA – ICER= [redacted]

Dominant refers to an outcome when an option is both cheaper and more effective, dominated refers to an outcome when an option is both more expensive and less effective

For full sensitivity analysis explanation, see section 9.2.4 of the EAR, and for full results, see Table 40, Table 41 and Table 42 of the EAR

Key Model Limitations

- Revision and mortality aggregated across technologies and assumed to be the same in RAS and conventional surgery
  - No available evidence that compared RAS with conventional surgery – the EAG did not exclude the possibility that rates do not vary. The NJR contains too few RAS revisions to be able to carry out a RAS versus conventional surgery analysis.
- Utilities only available for the Mako system, limiting the applicability of the model to other technologies
  - RCT data for TKA and UKA, propensity score matched prospective cohort for THA, but from small samples (less than 50 participants per arm) with large confidence intervals, representing uncertainty in the effect estimate
- No utility data available for post-THA revision – assumed to be the same as post primary procedure
- Does not account for differences in range of motion, gait analysis, or time to return to normal function
  - However, all would contribute to EQ-5D score, which is factored in
- Does not account for potential improvements in quality of life of operating staff through ergonomic benefits
- Does not account for impact of RAS on expanding joint replacement capacity and the subsequent effect on waiting lists
- Does not consider additional staff time costs associated with training and managing competencies

EAG conclusions for economic modelling

- RAS dominated by conventional surgery for TKA and UKA, however, when applying upper estimates of utilities RAS almost becomes dominant, reflecting the high degree of uncertainty in the effect estimate used
- RAS appears to be cost-effective at a willingness to pay threshold of £20,000 per QALY for THA, however, this is not the case when the lower estimate on utilities is applied, again reflecting uncertainty in the effect estimate, especially considering the lower quality study design of the study the utilities were sourced from

The EAG notes that the point estimates lie in a region of the cost effectiveness plane close to the y axis (small differences in QALYs) and not far from the x axis (relatively small differences in costs), where being "dominated" or "dominant" is strongly influenced by uncertainties in model parameters

The EAG concluded that the model simply demonstrates the sensitivity of the model to changes in utilities, suggesting that larger, controlled comparative trials would reduce uncertainties in this area

Key Economic Issues

- Utilities were reported for Mako only, and were assumed to be applicable to all other robot systems
- Post-revision utilities were not reported for THA and had to be assumed to be the same as post-primary surgery
- High degree of uncertainty in the QALYs used in the model
    - When applying the upper and lower confidence intervals of utilities, the ICER changed direction from dominated to almost being dominant
- Many potential benefits of RAS not captured in the model due to a lack of data:
    - Assumed to be no difference in revisions – but means that the only differences between conventional surgery and RAS in the model are costs and utilities.
        - This may explain why published evidence found RAS to be cost-effective, but the EAG did not
    - Effect on surgeons and operating teams – clinical experts suggested that RAS could prolong the career of surgeons
    - Effect on waiting lists, expanding capacity and variation between centres and surgeons
    - Differences in accuracy of implants, range of motion, gait analysis and time to return of normal function
        - The EAG considered it plausible that improvements in these factors may lead to increased activity levels and reduced revision rates

Evidence Gap Analysis

- Define main areas of focus for evidence generation
- Proportionate, pragmatic real-world evidence approaches
- Identify implementation considerations

NICE National Institute for Health and Care Excellence

Committee support to plan development

Evidence gaps

- Clear definition of evidence gaps and reduce the potential for misinterpretation
- Prioritisation of evidence gaps

Rationale

- Clear justification for why particular evidence gap needs to be addressed
- Real-world evidence has potential to address key evidence gaps

Safety considerations

- Specific safety concerns to inform approaches to evidence generation and implementation

Availability of evidence for primary outcomes across 26 included studies

Device: procedure	PROMs	Complications	Learning curve	Revision Surgery	Operating time
ApolloKnee: TKA	RED	RED	GREEN	RED	AMBER
CORI: TKA	GREEN	GREEN	GREEN	GREEN	GREEN
Mako: TKA	GREEN	GREEN	GREEN	GREEN	GREEN
ROSA Knee: TKA	GREEN	GREEN	GREEN	GREEN	RED
SkyWalker: TKA	AMBER	AMBER	RED	RED	AMBER
VELYS: TKA	AMBER	AMBER	GREEN	RED	AMBER
CORI: UKA	RED	GREEN	RED	RED	RED
Mako: UKA	GREEN	GREEN	RED	GREEN	RED
CORI: THA	RED	RED	RED	RED	RED
Mako: THA	GREEN	RED	GREEN	RED	RED

Key: **GREEN** RCT or comparative observational study with matched baseline characteristics (or single-arm study for learning curve outcome only); **AMBER** comparative observational study with unmatched baseline characteristics. **RED** single-arm only or no evidence.

Identified Gaps

Population

- Lack of randomised evidence for total hip replacement
- Lack of evidence in revision procedures

Intervention

- No UK evidence for ApolloKnee, ROSA Knee, SkyWalker or VELYS robotic systems
- No randomised evidence or prospective cohorts with matched comparator arm to account for differences in patient characteristics (within the last 5 years) for ApolloKnee, SkyWalker or VELYS robotic systems
- No evidence on shoulder replacement using robotics systems in scope

Outcome

- Lack of utilities for ApolloKnee, CORI, ROSA knee, SkyWalker and VELYS technologies, and uncertain effect estimate for Mako
- Lack of reported adverse events in UK setting
  - May be rare events and difficult to capture in randomised studies
- Lack of UK data on long-term outcomes, namely revisions and mortality
- Lack of reporting of procedure duration; not captured in NJR or HES
- Lack of reporting of length of stay; not captured in NJR, but is captured in HES
- Lack of randomised evidence to determine whether there are differences in subsequent healthcare costs (other than revision) between arms,
  - E.g., physiotherapy appointments, readmission within 30 days

Conclusions of the Gap Analysis

The EAG highlighted the following as key considerations in future evidence:

- Further data to understand the variation in procedural and technology costs associated with robotics, including the procedural volume per hospital, use of consumables and implants across the NHS
- Consideration of higher and lower volume centres, further consideration of consumables, and more options of implant price to reflect costs incurred in practice
- Reducing uncertainties in the clinical effectiveness data
- Robust effectiveness evidence is missing for some technologies, and additional real-world analysis of the National Joint Registry linked to Hospital Episode Statistics and PROMs, as collected by NHS Digital, may assist with filling these gaps
- In addition, a more thorough assessment of impacts on health-related quality of life and estimation of health state utilities to inform the model is needed. Ideally this should come from larger studies to minimise imprecision and maximise generalisability to the NHS population and may also consider quality of life of theatre staff

NHS Integration considerations

- All systems in this EVA are ‘closed’ and must be used with manufacturer specific implants
  - Volume-based contracts reduce the immediate cost to hospitals and may benefit implant variation, increasing access to RAS and introducing fair competition between manufacturers
- Minimum number of cases per year likely necessary to maintain skill with RAS
- Impact of RAS on conventional surgery skills is unknown
  - Surgeons need to maintain conventional skills as conversion to conventional surgery is a possibility
- Plausible, and some evidence to suggest, that RAS reduces physical burden on surgeons, potentially resulting in career prolongation
- Impact of RAS on procedure volume and waiting lists is unknown, but could plausibly increase capacity by improving theatre slot efficiency through improved planning with systems
- Size of robotic system relative to theatre space must be considered
- British Orthopaedic Association, Royal College Surgeons (RCS) and RCS Edinburgh have produced guidance documents: Robotics in orthopaedics including a practical tool kit for hospitals setting up a new MSK robotic surgical service.

Possible recommendations

Conditionally recommended for use while further evidence is generated

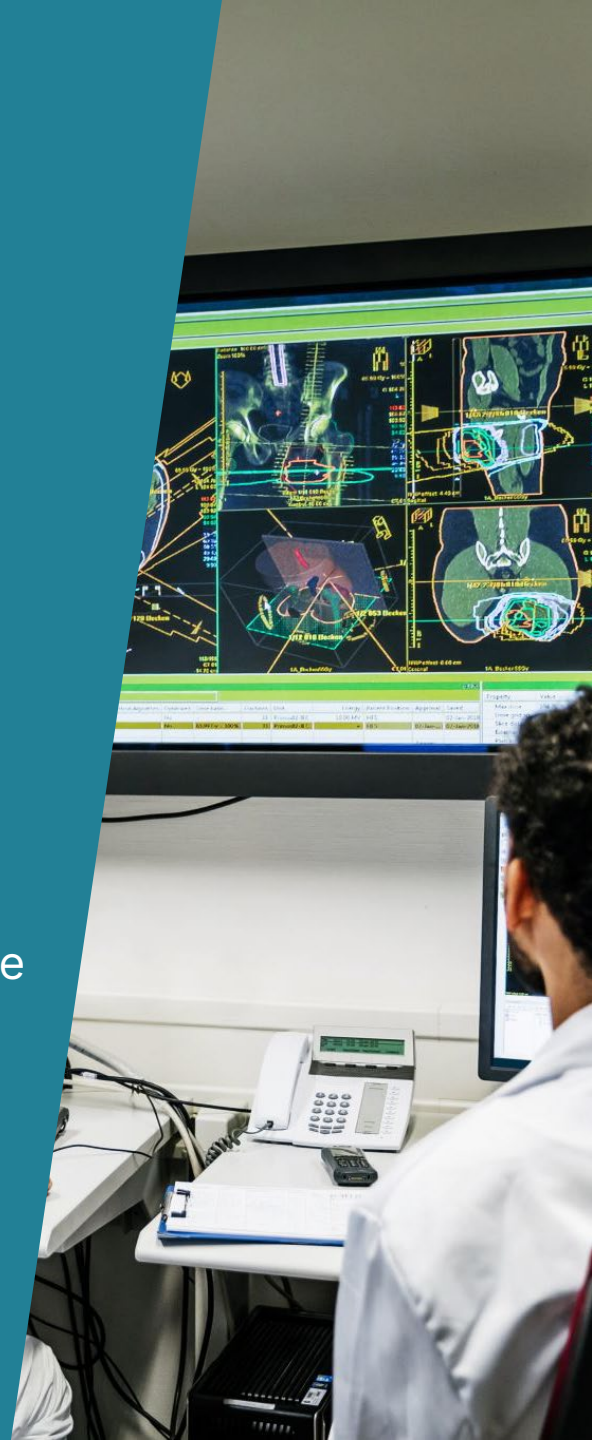
- Likely that the technology will solve the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated

Recommended only in a research context

- Uncertain if the technology has the potential to solve the unmet need, or it is not acceptable to be widely used in practice while further evidence is generated

Not recommended for use

- Unlikely that a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context



Clinical Issues

General

- Some technologies have a more mature evidence base: No UK, randomised or prospective comparative studies with cohort matching for ApolloKnee, SkyWalker or VELYS
- No randomised evidence for THA, and evidence only identified for Mako system
- Benefits of RAS are not consistently demonstrated across robotic systems or outcomes, with high degrees of uncertainty stemming from randomised trials containing small sample sizes or lower quality study designs that have reduced power to detect differences between surgical methods

Primary Outcomes

- Limited data for revisions in published literature. The NJR is collecting this data but has small numbers for RAS revisions.
- Unclear if RAS is associated with better quality of life (utilities) compared with conventional surgery – lack of comparative studies with large sample sizes means large variances around point estimates.

Secondary Outcomes

- Most consistent benefit is in alignment, however it is unclear if this results in better patient outcomes
- Effect of RAS on surgeon and organisation level outcomes largely unknown

1. Is there sufficient evidence to suggest any RAS technologies have a potential benefit within the NHS?
2. Are there any other outcomes that need to be considered?

Economic Issues

- RAS appears to not be cost-effective for TKA and UKA, but this is based on utilities with high degrees of uncertainty as reflected in the ICER changes when applying upper and lower utility estimates
- All utilities are for the Mako system and have been applied to other systems – limits the applicability of the model results for other systems
- Many potential benefits of RAS not captured in the model because of a lack of data:
    - Assumed to be no difference in revisions – but means that the only differences between conventional surgery and RAS in the model are costs and utilities.
    - Effect on surgeons and operating teams – clinical experts suggested that RAS could prolong the career of surgeons
    - Effect on waiting lists, expanding capacity and variation between centres and surgeons
    - Differences in accuracy of implants, range of motion, gait analysis and time to return of normal function
        - The EAG considered it plausible that improvements in these factors may lead to increased activity levels and reduced revision rates
- Flexible pricing structures may become available, for example, volume-based contracts which may improve patient access and reduce consumable costs

1. How generalisable are the utilities from Mako to other robotic systems?
2. Is it likely that RAS would be cost-effective if all the potential benefits not captured in the EAG's economic model were included?

NICE National Institute for Health and Care Excellence

Thank you.

NICE National Institute for Health and Care Excellence

Health Tech Programme

GID-HTE10043 Robot-assisted surgery for orthopaedic procedures: Early Value Assessment

Section A: External Assessment Report – Collated comments table:

Comment number	Page number	Section number	Comment	EAG response
Factual inaccuracies and typos				
3		Table 20	I think the final column should say ‘intervention’ and not ‘comparator’	Thank you for raising this. It has been corrected, along with an error in the direction of the Knee injury and Osteoarthritis Outcome score in Appendix C.
7	18,19	Executive Summary	Despite evidence for shoulder robotic surgery is not available, the DiNovo model applies to shoulder replacement as well as the conclusion that cost differences in the economic model between the robotic and conventional arms were broadly attributable to lower implant costs associated with volume-based contracts with manufacturers. ???	Thank you for your comment. The wording has been updated to better reflect that the structure of the model could be applicable to total shoulder replacement if evidence for that procedure becomes available in the future. Unfortunately, it is not possible to further clarify the statement relating to implant costs. To prevent backwards calculation, this detail relating to how implant costs have been applied across conventional and robotic arms appears in the redacted sections of the “Comment” column in Table 37.
26	162	Appendix A4	*#1 Intervention: Evidence focused on Zimmer implants not specific to ROSA Knee system.* *All robotic procedures on Zimmer Biomet implants in Australia can only be performed by the ROSA robotic platform.*	These papers would still be considered by the EAG to be out of scope, as the focus is on the implants themselves and not the use of the ROSA platform. The reason for exclusion in Appendix A4 has been updated for clarity.
27	206	Appendix B2	#91 The study is a 6 month follow up study and NOT as stated follow up at procedure only.	The EAG can find no reference to this extended follow up in paper 91 listed in Appendix B2 (Kenanidis; Eur J Orthop Surg Traumatol, 2023; 3357-3363), so the table has not been updated.

				The EAG would like to highlight that another paper by Kenanidis was published in the same journal in the same year (Kenanidis (Eur J Orthop Surg Traumtol, 2023; 1231-1236). This does report 6 month outcomes, and has been considered by the EAG as key evidence in the EAG report (see Table 5).
32	17	Executive Summary	"None of the technologies are currently indicated for shoulder replacement or revision surgery, no comparative evidence was identified for these indications." CORI is indicated for revision knee arthroplasty. We request that this is amended to state that CORI is indicated for revision knee arthroplasty.	Thank you for sharing this update. Indication for revision TKA was noted as due soon, and highlighted as CiC, in company RFI "Smith and Nephew HTE40 HTE43 RAS- Company request for information FINAL [CIC]]", therefore was redacted in the EAG report correctly at the time of writing. The Company has since confirmed that that this information is no longer CiC (see email to Toby Sands 24/10/2024), therefore the EAG has updated the text throughout the report to state that CORI is indicated for revision TKA and removed the redaction accordingly.
34	20	Summary of decision problem. Table 1	Intervention "The EAG note that currently none of the technologies are explicitly indicated for use in revision". We request this is amended to state that CORI is indicated for Revision Knee Arthroplasty	Please see the EAG response to comment 17.
35	25	2.1 Included technologies	"The EAG notes that none of the devices within the scope of this assessment are indicated for revision surgery". We request this is amended to state that CORI is indicated for Revision Knee Arthroplasty	Please see the EAG response to comment 17.

36	26	2.1. Table 2 Summary of technology	**Device indication** requires addition of Revision Knee Arthroplasty RKA **Open Closed** “Closed - Recommended use of Smith + Nephew implant systems JOURNEY II, JOURNEY UNI” **Please amend to** Closed - Recommended use of Smith + Nephew implant systems JOURNEY II, JOURNEY UNI, JOURNEY II UK UNI, LEGION™ Revision Knee (RK) Femur and Tibia components and LEGION™ TKS	Please see the EAG response to comment 17. The EAG has also amended the text within “Open/Closed” to reflect this newly provided information unredacted.
37	27	2.1. Table 3 Summary of technology components	**Tracking reference arrays and fixation method** “Two-pin bicortical fixation system, comprised of: 2 bone pins, Tissue protector, tracking array clamps that allow the attachment of the bone tracking arrays to be attached to both femur and tibia” We request amendment following amendment: Two-pin 4.0mm and 3.2mm bicortical fixation for engagement but not penetration of the second cortex, with intra-incisional options available, comprised of: 2 bone pins, Tissue protector, tracking array clamps that allow the attachment of the bone tracking arrays to be attached to both femur and tibia	Thank you for sharing this update, which has been made to table 3.
38	31	Table 4. Overview of training requirements as reported by companies.	Sterile Services “None explicitly stated” Sterile services training provided in UK by Robotics technical field specialists upon installation of system and upon additional request with no additional cost	Thank you for sharing this update, which has been made to table 4.

39	41	4.1	The EAG note that none of the robotic systems in scope of this assessment are currently indicated for revision surgery; this may change in future. CORI is indicated for Revision Knee Arthroplasty, please amend sentence above accordingly.	Please see the EAG response to comment 17.
42	129	11.1	Lack of evidence in revision procedures, however none of the devices in scope are currently indicated for revision procedures and ROSA Knee is explicitly contraindicated." CORI is indicated for revision knee arthroplasty. Please amend he sentence above accordingly.	Please see the EAG response to comment 17.
45	26	2.1	FACTUAL INACCURACY: Table 2. VELYS is stored and moved on the satellite station, not the base station.	Thank you for raising this, this has now been updated.
50	89	9.1	FACTUAL INACCURACY: Table 32. Clement et al 2023 is a study of unicompartmental knee replacement, not total knee replacement. Please confirm that all other studies have been correctly interpreted since this is fundamental to the outcome of the analysis.	Thank you for raising this, it has now been corrected.
75	79	5.9 The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)	The EAG states that the Australian Registry shows no difference in arms. This is incorrect there has been further analysis on Mako that shows there is a reduction.	The EAG has reviewed the latest annual report of the AOANJRR 2024, and it states much the same as the previous report cited in the EAG's report: "Similarly, with the same adjustments for potential confounding factors, there is no difference in the rate of revision when procedures using robotic assistance are compared to procedures with no technology assistance." The EAG acknowledges the later comment (#82) and thanks the company for highlighting the exact location of evidence to support this statement. Please see EAG response to comment 82.

76	85	6.5 Other Considerations	The level of radiation exposure from a CT Scan is 2 mSv, which is significantly under a year of natural radiation exposure which is 2.7 mSv (Ionising radiation: dose comparisons - GOV.UK (www.gov.uk)	Thank you for raising this, this was taken directly from wording provided by a Head of Imaging Physics & Radiation Safety within an NHS Trust. We have updated the report to remove the word "just". It is important to note that the 2 mSV stated in the report is approximate; some people may receive higher doses, and some may receive lower. The EAG would therefore be cautious about stating that it is significantly under a year of natural background radiation, especially when the radiation dose received from the CT scan will be additional to a person's exposure to background radiation.
Evidence selection				
5	17	Executive Summary	It is listed in Table 6 the 8 RCTs which are limited to total and partial knee replacements. Hence the sentence Across 8 RCTs, none reported a statistical difference in patient reported outcome measures at 1 year between robotic surgery and conventional surgery is not generalizable to include total hip replacement and accordingly requires further detail/accuracy. The findings come from selected RCTs with failure to capture real world evidence retrospective comparative studies.	Thank you for your comment. The EAG has added a sentence to the report to further clarify the procedures for which the RCT evidence applies, and to note again the limited evidence for THA. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence and that of greatest relevance to the decision problem for each technology.
8	20	1 Table 1	There are significantly more studies reporting on the learning curve and adverse event outcomes than what has been reported in this document and considered for the assessment. More explicit inclusion criteria could be listed but prioritising UK studies limits findings.	Thank you for your comment. Evidence for ZimmerBiomet's technology for learning curve and adverse events is not from the UK (Greece, Belgium, location not reported). Although the EAG prioritised comparative UK evidence if available, they did consider other lower quality evidence if needed for specific technologies or outcomes, as per section 4.1, and the published Final Protocol.
13	32	3	Section heading 'Clinical Context' first section is misleading as this paragraph appears to be on surgeon ergonomics, yet fails to incorporate the study by Haffar demonstrating less surgeon stress and strain with robotics. Haffar A, Krueger CA, Goh GS, Lonner	Thank you for commenting. The study by Haffar was identified in the EAG's literature search, and was included by the EAG in section 6.4, as it provides comparative evidence relevant to the

			JH. Total Knee Arthroplasty With Robotic Surgical Assistance Results in Less Physician Stress and Strain Than Conventional Methods. The Journal of Arthroplasty 2022. doi:https://doi.org/10.1016/j.arth.2021.11.021	decision problem. The opening paragraph of the clinical context section is a general introduction to orthopaedic surgery, which the EAG has stated as applicable to both conventional and robotic surgery.
16	41	4.1	The document states The EAG only considered single arm studies for the learning curve outcome. Ideally, learning curve studies would have a comparison as a true learning curve study must evaluate both a surgical component as well as a clinical component (i.e. surgical times and complications) see: Hopper AN, Jamison MH, Lewis WG. Learning curves in surgical practice. Postgrad Med J 2007;83(986):777-9. doi:10.1136/pgmj.2007.057190	Thank you for your comment and for sharing an interesting paper describing learning curves. The EAG would like to clarify that they did not exclude comparative evidence for learning curve where it existed, but that this outcome (and device related adverse events) were the only outcomes for which single arm studies were also considered.
17	43	Table 5	The criteria for selecting studies, has resulted in a significant number of retrospective comparative studies not included, which may have limited the assessment findings.	The EAG has followed the steps outlined within the Final Protocol. Retrospective comparative studies were considered less robust than those included.
18	43	Table 5	Vanlommel (J Exp Orthop, 2021; 119); This paper also reported complications and not just learning curve as stated in the table. "There were no intraoperative or postoperative complications associated with the robotic system. Postoperative complications were minimal and included arthrofibrosis (learning raTKA = 1, mastered raTKA = 1, and mTKA = 1), surgical site infections (SSI, mastered raTKA = 1, mTKA = 3), deep vein thrombosis (DVT, mastered raTKA = 1, mTKA = 0), and periprosthetic joint infection (PJI, raTKA = 0, mTKA = 1). Only one of the SSIs (mTKA) required intervention consisting of wound revision. For the three arthrofibrosis cases, one (mastered raTKA) was diagnosed at 12 weeks and had manipulation under anesthesia (MUA), with good results. The other two (one each mTKA and learning raTKA) were diagnosed at 6 weeks and received oral steroids for 4 weeks with improvement of their function, avoiding MUA. The one PJI case underwent polyethylene exchange 3.5 months after the index procedure associated with severe erysipelas."	Thank you for raising this. As stated in section 5.1 and 5.3 of the EAG report, Vamlommel et al. 2021 was a retrospective cohort study, included only for the learning curve outcome. The wording has now been made clearer in section 5.1. The EAG note that studies were considered for ROSA higher in the hierarchy based on their study design (2 prospective propensity matched studies; Fary et al. 2023, and Kenanidis et al. 2023).

19	50	Table 6	Only 2 prospective cohort studies were included here for the final quality assessment although Appendix B clearly included more comparative studies for the ROSA platform. What was the criteria for including theses only two studies?	Thank you for commenting. The two prospective cohort studies featured prospective matching of participants between study arms, and included priority outcomes, as detailed in the Final Protocol, and therefore were considered the highest quality and most relevant evidence for inclusion by the EAG. Of the remaining prospective studies in Appendix B2, none met the same criteria, although the EAG notes that Haffar et al. 2022 was included in section 6.4 to address outcomes relating to ergonomics for those carrying out the surgery.
31	16	Executive Summary/Quality and relevance of clinical evidence	The EAG prioritised 26 comparative studies,15 of which were conducted in a UK setting. The EAG noted that the quantity and quality of clinical evidence varied by joint replacement procedure and by technology:" We request that a bullet point be added which states: • We acknowledge there is a body of evidence for CORI that fell outside the SLR search inclusion criteria which demonstrated additional benefits relating to early recovery not mentioned within this report. For UKA, faster return to sport (Canetti et al.), and faster walking speed (Batailler et al.) compared to conventional surgery. For TKA significantly faster muscle strength recovery has been observed compared with conventional TKA (Matsumoto et al.).	Thank you for this suggestion. The EAG has not reported on outcomes not included in the Final Scope, therefore no change made to the report.
33	18	Quality and relevance of economic evidence	The EAG assumed the same length of stay, revision and mortality outcomes between robotic and conventional surgery" There is a body of evidence which exists to support reduced length of stay in total knee indication. We request that the assumption be amended to reflect this and or comment be made to recognise this evidence exists and explain why it has not been considered appropriate to use.	Thank you for your comment. The EAG used data from NHS for the length of stay supplemented by Clinical Expert opinion (see section 9.2.1). The EAG also varied the length of stay between robotic and conventional surgery in the sensitivity analysis due to the uncertainty. The EAG note that the economic model could be updated in the future to incorporate further UK data should it become available.

			TKA papers: Masarwa R, Yonai Y, Ben Natan M, Steinfeld Y, Berkovich Y. Short-term outcomes of an imageless robot-assisted total knee arthroplasty compared with a conventional method: A retrospective cohort study. International Journal of Surgery Open. 2022;47. Bhimani SJ, Bhimani R, Smith A, Eccles C, Smith L, Malkani A. Robotic-assisted total knee arthroplasty demonstrates decreased postoperative pain and opioid usage compared to conventional total knee arthroplasty. Bone & Joint Open. 2020;1(2):8-12. Pelkowski JN, Wilke BK, Crowe MM, Sherman CE, Ortiguera CJ, Ledford CK. Robotic-Assisted versus Manual Total Knee Arthroplasty in a Crossover Cohort: What Did Patients Prefer? Surgical technology international. 2020;37:336-340. Austin Smith M, Christian Eccles M, Samrath Bhimani M, Kevin Denehy M, Rohat Bhimani B, Langan Smith B. Improved Patient Satisfaction Following TKA Using Intraoperative Computer Technology to Obtain Accurate Gap Balancing. CAOS. 2019;3:344-350. Kayani B, Konan S, Pietrzak JRT, Tahmassebi J, Haddad FS. Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty. Bone and Joint Journal. 2018;100B(7):930-937. Naziri Q, Cusson BC, Chaudhri M, Shah NV, Sastry A. Making the transition from traditional to robotic-arm assisted TKA: What to expect? A single-surgeon comparative-analysis of the first-40 consecutive cases. Journal of Orthopaedics. 2019;16(4):364-368	Length of stay was extracted from prioritised RCTs for CORI/NAVIO in Table 25 in the EAG, as this was considered the highest quality and most relevant evidence available. The RCT by Adamska et al. 2023 reported no statistical difference in length of stay between CORI, NAVIO and conventional surgery. Of the 6 papers referenced: • Masarwa et al. 2022 was reviewed by the EAG but not prioritised (listed in Appendix B2) due to its retrospective design and that the intervention and comparator arms had different recruitment periods (conventional July 2018 to July 2019, robotic August 2019 to August 2020). Only statistical comparisons of age, gender and place of birth were reported (other clinical factors may have differed; no analytical adjustment to account for differences in population between arms was reported). Study used NAVIO for TKA and was set in Israel and hence was not prioritised. • The other 5 papers were not captured in the EAG literature search because of the date restriction applied, as detailed in section 4.1 of the EAG report. The EAG has since reviewed these additional papers; • Bhimani 2020: is a retrospective cohort. No statistical differences in age, gender or ASA were reported between arms. Same recruitment period in both arms, same surgeon, same institution, same implant in both arms. Mako system was used for TKA

				and set in US. This study would not be prioritised over evidence already included in the EAG report for Mako. • Pelkowski 2020 is a retrospective chart review of TKA (Mako and conventional surgery). The study was set in the US. This study would not be prioritised over evidence already included in the EAG report for Mako. • Smith 2019 is a prospective cohort of TKA performed using Mako. Same surgeon and same implant in both arms. No differences in age, gender or BMI were noted; but no other clinical factors reported (no demographics table was reported, for example). Setting not reported, but assumed as US from author affiliations. This study would not be prioritised over evidence already included in the EAG report for Mako. • Kayani 2018 was reviewed by the EAG and excluded (see Appendix A4). • Naziri 2019 was a retrospective cohort of TKA using Mako, 1:1 matching was based on age, gender, BMI, comorbidities (undefined) and range of motion. Study was set in US. This study would not be prioritised over evidence already included in the EAG report for Mako.
40	62	5.6	An additional 28 studies were identified as relevant to the scope but not prioritised by the EAG” We request that it is acknowledged that these studies and those which fell outside the SLR search inclusion criteria demonstrated additional benefits relating to early recovery not mentioned within this report. For UKA, faster return to sport (Canetti et al.), and	Thank you for this suggestion. The EAG has not reported on outcomes not included in the Final Scope,

			faster walking speed (Batailler et al.) compared to conventional surgery. For TKA significantly faster muscle strength recovery has been observed compared with conventional TKA (Matsumoto et al.).	
44	20	1	"Due to the size of the evidence base and time/resource constraints the EAG focused on highest quality evidence (prioritising UK, prospective designs with the largest sample size) and primary outcomes." We are not in alignment with this approach as we do not believe it is fit for purpose for an EVA. As stated on the NICE website an "EVA is for promising medical technologies that meet a national unmet need. Technologies suitable for EVA are: in need of further data collection or evidence generation before they can be recommended for use in the NHS". With this in mind, the evidence included in the review of these medical technologies should not be restricted to only the highest quality of evidence, namely, RCTs. The purpose of the EVA is to provide an early evaluation on promising technologies that may address an unmet need, but are acknowledged to need more evidence, as such, criteria for the inclusion of evidence should be broad, and diverse study designs and sources of evidence should be considered. It should also be noted that the EAG has not accepted retrospective evidence for the clinical evidence section but has decided to use and accept NJR data, which is retrospective in nature, for use within the economic model. Further, there are 101 studies that were defined as in-scope by the EAG, but have been disregarded; we feel that in order to complete a comprehensive assessment of these novel medical technologies, these studies should have been evaluated more thoroughly. We also believe that time and resource constraints should not be prioritized over quality when it comes to NICE assessments.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, but also that of greatest relevance to the decision problem, hence the acceptance of NJR data.

49	80	5.1	EAG note that it's plausible that improvements in alignment may lead to improvements in activity levels and lower revision rates. We ask that our evidence on revision rates are taken into consideration. [redacted] We are awaiting permission from AOANJRR to share the report and are happy to do so when that is confirmed.	Thank you for sharing this. The EAG note that there is still no statistically significant difference reported for revision between robotic and conventional surgery as a whole, in the AOANJRR 2024 annual report. The EAG acknowledge that the results shared suggest an improvement in revision outcomes specifically when using the VELYS robotic technology with the ATTUNE knee system. However, the EAG notes that these are non-UK results. Furthermore, the comparator is all other knee replacement procedures (assumed to include other robotic systems and conventional surgery) should be interpreted with caution, due to heterogeneity between approaches used in the comparator group and potential influence of factors not applicable in the UK. Indeed, the EAG has compared the age, sex, and ASA classes of those having UKA and TKA between the Australian and UK registries, and found that differences exist to suggest the cohorts having each procedure may not be comparable between countries, and the results may therefore not be generalisable.
58	129	11.1	While we acknowledge there is a paucity of RCT evidence for RAS, there are studies conducted in other countries, with similar populations, that could fill these evidence gaps. The purpose of an EVA is to evaluate technologies with a limited degree of evidence, so we ask that NICE consider a wider range of evidence in this EVA.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, and that of greatest relevance to the decision problem.
59	130	11.1	Similarly, we ask that NICE accepts reports of adverse events from other countries where populations are similar and RAS has been in use for longer than the UK.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has

				prioritised the highest quality evidence, and that of greatest relevance to the decision problem and also considering generalisability to the UK. The EAG also asked Clinical Experts to comment on adverse events (see Correspondence Log), so that in the absence of published reports, this could be reflected in the report.
60	135	12.1	We contend that it is incorrect to consider differences in surgical technique between robotic/conventional surgery as a confounder, and therefore discounting studies where this is included. One of the proposed benefits of robotic surgery is that it enables the performance of alternative surgical techniques that would otherwise not be consistently achievable without the precision afforded by robotics.	Thank you for your comment. The EAG did not discount any studies on the basis of perceived confounding between the techniques used in intervention and comparator arms. The EAG prioritised UK, RCT and prospective comparative study designs. The feature of this evidence is that a patient could be treated by either technique and that outcomes may differ due to the relative advantages and disadvantages of either technique. Thus, if an approach allows something not as readily possible with another approach then that would be reflected in the outcomes.
62	16 & 17	Exec summary	Quality and relevance of clinical evidence: • Study selection is limited to UK setting mainly with RCT evidence being prioritized: this perspective is too narrow and ignores the breadth of evidence available on robotics, especially Mako, from across the globe • For Mako TKA application, the EAR mentions that RCT evidence from UK broadly shows clinical non-inferiority between Mako and conventional surgery. For the partial knee application, the EAR comments that generalizability of the clinical results is unclear. And for total hip application, the EAG reads out that no statistical differences were found in VAS, utility, and satisfaction between treatment arms. Multiple studies published which show there is a (significant) difference between Mako and conventional surgery: - Banger M, Doonan J, Rowe P, Jones B, MacLean A, Blyth MJB.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence. We have reviewed the references provided and summarise them below: • Banger et al. 2021 is an RCT of UKA conducted in the UK (already included as key evidence in the EAG report). This study reported no statistical difference in median AKSS, OKS, pain VAS, FJS, EQ5D3L, EQ5D

			Robotic arm-assisted versus conventional medial unicompartmental knee arthroplasty: five-year clinical outcomes of a randomized controlled trial. Bone Joint J. 2021;103-B(6):1088-1095. doi:10.1302/0301-620X.103B6.BJJ-2020-1355.R2 - Fontalis, Andreas MD, MSc, MRCS; Kayani, Babar BSc, MBBS, MRCS, PhD; Asokan, Ajay MBBS, BSc, MRCS; Haddad, Isabella Catrina; Tahmassebi, Jenni BSc, MCSP; Konan, Sujith MBBS, MD, MRCS, FRCS; Oussedik, Sam BSc, MBBS, MRCS, FRCS; Haddad, Fares S. BSc, 2 of 6 MD, MCh, FRCS, FFSEM. Inflammatory Response in Robotic-Arm-Assisted Versus Conventional Jig-Based TKA and the Correlation with Early Functional Outcomes: Results of a Prospective Randomized Controlled Trial. The Journal of Bone and Joint Surgery 104(21):p 1905-1914, November 2, 2022. | DOI: 10.2106/JBJS.22.00167 - Bendich, I., Vigdorchik, J. M., Sharma, A. K., Mayman, D. J., Sculco, P. K., Anderson, C., Della Valle, A. G., Su, E. P., & Jerabek, S. A. (2022). Robotic Assistance for Posterior Approach Total Hip Arthroplasty Is Associated With Lower Risk of Revision for Dislocation When Compared to Manual Techniques. Journal of Arthroplasty, 37(6), 1124-1129. Https://doi.org/10.1016/j.arth.2022.01.085	VAS, pain catastrophizing scale, or ROM between arms at 5 years. This study also reported no statistical difference in ceiling effects measured in OKS (3 months or 1,2,5 years) AKSS Knee score (at 1,2 years), AKSS function score (3 months or 1,2,5 years), total AKSS (at 1 year) between arms. • Fontalis et al. 2022 reports additional outcomes from an UK RCT (same population as Kayani et al. 2021 study, same trial registration NCT04192006; with n=15 patients in each arm). Outcomes focus on inflammatory markers (not listed as outcome in Final Scope). Additional outcomes include length of stay (no statistical difference between arms), PROMs (including WOMAC, KOOS, OKS, EQ5D, EQ5D VAS, SF-12 MCS, SF-12 PCS – where no statistical difference between arms was found at 2 years), short term pain (up to 7 days) and opiate consumption (up to 3 days), significant reduction in pain at 1, 2 and 7 days but no indication that this influences longer term outcomes. • Bendich et al. 2022 is a retrospective cohort using Mako (already in EAG report, not considered key evidence, Appendix B2). This study compared robotic, to computer-navigated and manual THA. IPTW adjustment was conducted accounting for differences in age, sex, BMI, femoral cementation, history of spine function and Charlson Comorbidity Index. This study does not report on utility or PROMs; therefore

				cannot comment on these outcomes. Study was set in the US. The EAG note that they recommended that adverse events (including dislocation) should be recorded prospectively in the UK in the key evidence generation section (see Table 44 of EAG report).
65	18	Exec summary	There are RWE propensity matched analyses showing reductions in LOS. LOS assumption can be well supported. We do not support the EAG's approach of prioritising RCT data for things such as LOS. The below publication show clear reductions in LOS when using robotics: Fontalis A, Raj RD, Haddad IC, et al. Length of stay and discharge dispositions following robotic armassisted total knee arthroplasty and unicompartmental knee arthroplasty versus conventional technique 3 of 6 and predictors of delayed discharge. Bone Jt Open. 2023;4(10):791-800. doi:10.1302/2633-1462.410.BJO2023-0126.R1 Fontalis A, Wignadasan W, Mancino F, et al. Factors associated with decreased length of stay following robotic arm-assisted and conventional total hip arthroplasty. Bone Joint J. 2024;106-B(3 Supple A):24-30. doi:10.1302/0301-620X.106B3.BJJ-2023-0569.R2 Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS. Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty. Bone Joint J. 2018;100-B(7):930-937. doi:10.1302/0301-620X.100B7.BJJ-2017-1449.R1	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, and that of greatest relevance to the decision problem. The EAG has reviewed all 3 references provided, all are observational. The authors of 2/3 call for prospective randomised trials to corroborate findings: • Fontalis (Bone Jt Open, 2023; 791-800) is a retrospective cohort in UKA and TKA using Mako, set in UK. The study reported reduced length of stay for both procedures with robotics on univariate analysis. However, when reporting results from binary logistic regression they found age, PACU admission, use of conventional technique, ASA grade > II, and use of general anaesthesia were all predictors in a multivariate model of prolonged length of stay (>3 days) in TKA. Whereas sex, PACU admission and ASA grade > II were predictors of prolonged stay in UKA. Therefore, use of robotic surgery did not predict differences in length of stay.

				• Fontalis (Bone Joint J, 2024; 24-30) was included as key evidence in the EAG report. This was a retrospective cohort in THA using Mako. • Kayani (Bone Joint J, 2018; 930-937) was identified by the EAG and excluded due to date of publication (more than 5 years from time of search). This was a prospective cohort study, TKA, conducted in the UK. The EAG notes that length of stay is a difficult outcome to ensure the quality of, especially in observational studies where other unknown factors may have had an influence.
69	20	Decision problem	The scope of evidence was too limited as a result of time constraints. More time should be given to assess the wider evidence base.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, and that of greatest relevance to the decision problem.
72	40	4.1 Evidence Search strategy and Study selection	Evidence selection process criteria appear have been applied inconsistently. The overall scope was too narrow and excluded a wide range of evidence that would support more informed decision making.	Thank you for your comment. The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has consistently prioritised the highest quality evidence, and that of greatest relevance to the decision problem.
Clinical evidence				
2		Table 17	The number of adverse events is alarmingly high! Was there a reason for this?	Thank you for your comment. The authors did not provide any reasoning for high number of adverse events, and only provided a breakdown of those considered serious.

4		Table 25	I worry about the alignment data from this Thai study. I struggle to believe a difference of 0.6 degrees (88.5 versus 87.9) is statistically significant (and also question its clinical relevance). Quite a lot of this data raises questions about how the surgeon has used the system and I think it looks like they don't know what they are doing!	Thank you for your comment. The EAG has added a sentence preceding Table 25 to note that whilst statistical differences were noted in the RCTs in alignment outcomes, that the clinical significance of each is unclear.
6	17	Executive Summary	Document states The learning curve associated with robotic surgery was considered short, between 7 and 30 cases, but requires training of staff involved in the procedure to achieve competency Sentence slightly misleading as the achievement of competency is required for all surgical procedures independent of the utilisation of the robot or not. For example, conventional direct anterior approach in total hip arthroplasty has a significant learning curve	Thank you for your comment. The report has been changed slightly to address this.
11	30	2.2	Lurning Curve The learning curve is the initial learning process and cannot be quantified per year. It might be required to do at least 10 cases per year to maintain the learned skill. For ROSA the initial learning curve can be achieved in less than 10 cases and up to 30+ cases, with no mentioning of time frame in any of the studies. Documents states completing at least 10 cases per year would be considered sensible to stay current with the system. We are not aware of any study that supports this statement.	Thank you for clarifying this. The EAG had misinterpreted the response sent to our questions on 19 July 2024, and have now updated the report to reflect this.
15	38	3.4	Evidence on improved accuracy and precision is not limited to the Asian population. There are multiple studies for most systems that demonstrate this.	Thank you for your comment. By including this equality consideration, the EAG does not suggest that improved accuracy and precision is not possible in other populations. As defined in the Final Scope, accuracy was a secondary outcome and therefore extracted data for these outcomes from RCTs and comparative UK studies only,

				where this information was available (see section 5.6.6 and .5.7.6 of the EAG report)
20	65	Table 11	Statistical difference is for TOTAL OPERATIVE TIME which is not clearly stated.	Thank you for providing this clarification, it has been updated it in the report.
21	81	5.1	For ROSA Knee nothing was mentioned regarding alignment although it was summarised for other robots.	Thank you for raising this. Alignment was a secondary outcome. The EAG extracted secondary outcomes from RCTs and comparative UK studies only (as stated in Section 4.1 in EAG report). No RCTs or UK studies were identified for ROSA Knee.
22	81	5.1	*No significant difference in revision or opioid use were reported, but fewer wound complications were identified. But Fary et al (Table 10) clearly stated that opioid use at 1 month was significantly different between robotic and conventional surgery arms; 31.2% compared with 42.6%, p=0.017. No difference was observed at 3 months (p=0.703).*	Thank you. The EAG has edited the wording to reflect the short term reduction in opioid use in the robotic arm at 1 month, but no statistical difference at 3 months.
47	59	5.5.1	We are unable to comment on the accuracy or completeness of the data presented in Table 16 for our own system because it has all been redacted.	All 'in confidence' data is redacted, to allow the same version of the report to be sent to all stakeholders.
48	77	5.8	Despite the low number of revisions and limited duration of follow-up it would seem pertinent to consider all the available evidence to make every effort to differentiate revision rates by robotic system or in comparison with conventional surgery, given the impact this is likely to have on subsequent analysis and is likely to be at least in part dependent on the implants used, which differ by robotic system.	Thank you for your comment. The EAG has acknowledged this limitation in section 9.3.3 and identified it as an evidence gap to be filled in table 44.
71	32	3. Clinical context	The cognitive burden and the impact of vibration are greatly reduced by RAS, this is not acknowledged.	Thank you for your comment. The EAG sought insight from Clinical Experts which was incorporated in the EAG report. See section 3: "Joint surgery involves exposure to noise, vibration, and the cognitive burden associated with a complex procedure. These

				challenges apply to both conventional surgery and RAS." Please also see section 10: "the ability for robotic systems to decrease physical and cognitive burden for operators, with ergonomic and career longevity outcomes which cannot be easily captured in the literature. It is plausible that a reduction in physical burden for operating staff, and increased planning with systems using pre-operative imaging could provide theatre slot efficiencies and enable additional procedures over time"
73	49	Clinical evidence review	It would require a significant amount of additional set up time for the use of RAS to result in the reduction of the number of procedures being reduced across a whole day. This is not the real world experience.	Thank you for sharing this insight. However, it remains plausible that the number of procedures performed per day could be affected by longer set up times for RAS, and the statement in the report reflects the experience of a Clinical Expert using RAS, so no change made to the report.
93	52	5.2.5	I agree with the clarified definition of operative time. It should encompass the total theatre time, including setup, which tends to be longer with RAS. This extended duration may affect the number of procedures that can be performed on a theatre list per day. The scheduling is a key to optimal utilisation to achieve a certain annual surgical volume.	Thank you for this insight, unfortunately different studies report operative time / surgical time in different ways, so standardisation is an issue.
Economic evidence and model				
28	97	9.2	Was there a reason why EAG did not separate septic and aseptic revisions? Could give different results because of assumed higher costs of septic.	In Table 37, the EAG has stated separate costs for septic and aseptic revisions, and a weighted average of these was used in the model, based on NHS activity. Unfortunately, to prevent backwards calculation, this detail appears in the redacted sections of the "Comment" column. The EAG did not consider it necessary to split the two types of revision into separate health states in the model, because there was no relevant evidence available to differentiate the different robotic

				systems for this outcome, and it was in line with other published economic models (although the EAG do acknowledge that some published models split revisions in this way). This could be updated in the future should new evidence become available.
51	94	9.1.3	We are unable to comment on the accuracy or completeness of the assessment for our own system because it has all been redacted.	All 'in confidence' data is redacted, to allow the same version of the report to be sent to all stakeholders.
52	98 and 112	9.2 and 9.2.3	While it is plausible that utilities may be similar for all robotic systems. We believe that due to the enhanced accuracy and precision associated with the use or robotics, all systems are likely to provide superior utility values when compared to conventional surgery. However, given that the different robotic systems are used with different implant systems, have different software which may facilitate different techniques, and use different imaging modalities, it is plausible that there would be some differentiation. Therefore, we question the validity of using Mako data to represent all of the other robotic systems within the analysis. We understand that given the paucity of evidence considered this may be a difficult task, but this limitation should be better captured and documented within the EAG report.	Thank you for this well balanced critique – the report has been updated to better reflect the limitation of applying utility data from one technology to the others.
53	105	9.2.2	In order to run a complete assessment on all robots within the scope of this evaluation, we believe that all technologies should have been included and assessed in the economic model, especially as the EAG note that minor cost differences may have been observed. The scenario of volume-based purchasing should also have been modelled, as this is one of the main procurement options available to the NHS, therefore replicating the real-world financial scenario. [redacted]	Thank you for this comment. NICE do not accept changes at this stage of the EVA development process. This can be submitted in response to the draft guidance consultation. When the EAG stated that minor cost differences may be observed if all technologies were formally modelled, this would not be significant enough to change the direction of the results. The base case presented for all technologies is intended to be illustrative, and analysis could be repeated in the future, when further evidence is available.

54	106	9.2.2	We believe that there are other important factors that should be taken into consideration and included in the economic model, such as length of stay, reduction in adverse events requiring intervention, reduction in revisit and readmissions, number of trays used and sterilisation costs. An English publication reported the cost of sterilisation per tray at £113 in 2019 (*Attard et al. Health costs and efficiencies of patient-specific and single-use instrumentation in total knee arthroplasty: a randomised controlled trial, BMJ Open Qual., 2019*). We also note that the use of the VELYS robotic-assisted system may be associated with a reduction of up to 4.5 trays, compared with a conventional procedure. Not including these data from manufacturers means that an incomplete assessment has been undertaken on the robots in scope and that the full cost-savings associated with the use of the robots has not been realised.	Thank you for this comment. The EAG did not find any evidence for differences in length of stay (although we did explore the effect of reducing this in sensitivity analysis), adverse events, or readmissions, either between conventional surgery and robotic surgery, or indeed, between robotic technologies. The EAG has also suggested a detailed micro-costing exercise to better understand the need for accessories (noting that this may differ between robotic systems), as this was not feasible within an EVA. The EAG notes that costs for sterilisation, for example, could be taken from the shared reference to Attard et al. 2019. The economic model could be updated to reflect such differences in the future, and this has been highlighted for future evidence generation in Table 44.
55	108-110	9.2.2	We are unable to comment on the accuracy or completeness of the data presented in Tables 34, 35, or 36 for our own system because it has all been redacted. [redacted]	All 'in confidence' data is redacted, to allow the same version of the report to be sent to all stakeholders. Please also see the EAG response to comment 53.

56	116	9.3.1	As the EAG notes, it is plausible that the improvements in alignment observed by many robotic systems may be associated with improved clinical and patient outcomes. As such, it is conceivable that the QALYs associated with the use of robotic surgery would be higher than with conventional surgery. In addition, there are several studies for VRAS that demonstrate a reduction in pain (Alton et al, 2023) a reduction in morphine use (Severson et al, 2023), improvement in functional scores (Alton et al, 2023), improvement in walking scores (Spitzer et al, 2024), reduction in adverse events requiring intervention (Alton et al, 2023), reduction in revisit and readmissions (Huang et al, 2024) and reduction in length of stay (Severson et al, 2024). Hence, we believe it is reasonable to expect an improvement in quality of life with VRAS compared to conventional surgery in the months following primary TKA.	Thank you for this – this has now been noted more clearly in the limitations of economic modelling in the EAG report. • Alton et al. 2023 was considered and excluded by the EAG (see Appendix A4, EAG report) • Unclear what the reference Severson et al. 2023 is (no additional information provided). However, Severson et al. 2024 was included in the EAG report as in scope but not prioritised [provided AiC] • Spitzer et al. 2024 was considered and excluded by the EAG (see Appendix A4, EAG report) • Two studies by Huang et al. 2024 were included in the EAG report as in scope but not prioritised [provided AiC] The EAG has outlined evidence generation recommendations for VELYS specifically due to lack of UK evidence for that robotic technology.
57	117	9.3.1	“The EAG note that the lack of cost-effectiveness demonstrated for TKA and UKA is likely because of the utility values used”. Due to the uncertain nature of the evidence source for utility values, combined with the EAG’s comment that it’s plausible that increased precision may result in improvements in activity levels and lower revision rates, we believe it would be practicable to use utility values that are deemed clinically plausible. As noted above, there are several studies for VRAS that demonstrate a reduction in pain (,Alton et al, 2023) a reduction in morphine use (Severson et al, 2023), improvement in functional scores (Alton et al, 2023), improvement in walking scores (Spitzer et al, 2024), reduction in adverse events requiring intervention (Alton et al, 2023), reduction in revisit and readmissions (Huang et al, 2024) and reduction in	Cost-effectiveness estimates were affected by the lack of evidence on differences in clinical effectiveness as well as on utilities. Please see the EAG response to comment 56.

			length of stay (Severson et al, 2024). Hence, we believe it is reasonable to expect an improvement in quality of life with VRAS compared to conventional surgery in the months following primary TKA.	
64	18	Exec summary	Quality and relevance of economic evidence: Given that the EAG mentions that there is non-inferiority and uncertainty about how robust the clinical evidence findings are comparing Mako to conventional surgery, we feel that at this EVA stage it is premature to perform a cost-effectiveness analysis as shown in section 9.3 of the report. It would be more appropriate for the EAR to report that a more robust evidence base is required prior to performing a cost-effectiveness analysis comparing Mako to conventional surgery. One could also argue that in case of non-inferiority results between two treatment arms, it may be methodologically incorrect to perform a cost-effectiveness analysis as the difference in relative effectiveness between the two treatments may not be confirmed (yet) based on any robust evidence.	Thank you for your comment. Because there are published economic studies, using a similar model structure, the EAG disagrees that it is premature to perform the analysis presented in the report and indeed would argue that an important part of the EVA process is to use the economic evaluation modelling to highlight key uncertainties. The limitations of the modelling have been well documented, and minor updates have been made to the report to more explicitly and clearly state that the base case is illustrative and subject to the stated limitations.
66	18	Exec summary	The clinical impact on patient quality of life and economic impact on healthcare resource usage remains uncertain. Data currently insufficient to perform economic analysis.	Please see the EAG response to comment 64.
74	67	5.7.1	The EAG note that it was only observational studies that reported significant differences in PROMs and utilities between robotic and conventional surgery arms. Two RCTs found no significant difference in utilities between robotic and conventional surgery at any timepoint. Another reason why it is premature to use different utilities and disutility values in the economic model in the EAR given that there is mixed evidence on this.	Please see the EAG response to comment 64.

77	85	7	As it was not feasible to undertake meta-analysis for evidence within any of the technologies in this EVA because of study heterogeneity (populations, interventions, comparator, and definition and timing of outcomes), performing an economic evaluation based on these heterogeneous studies is inappropriate.	Please see the EAG response to comment 64. Additionally, there is no requirement for parameters included in an economic model to have been derived from meta-analysis of published studies alone. The economic model developed uses UK relevant data and key limitations with the analyses presented are acknowledged and approaches to address these limitations (which primarily relate to deficiencies in the evidence base) have been described. Furthermore, the model can be updated as more evidence becomes available in the future.
79	97	9.2 Economic modelling	The below publications show reduced dislocation for Mako: Bendich I, Vigdorchik JM, Sharma AK, et al. Robotic Assistance for Posterior Approach Total Hip Arthroplasty Is Associated With Lower Risk of Revision for Dislocation When Compared to Manual Techniques. J Arthroplasty. 2022;37(6):1124-1129. doi:10.1016/j.arth.2022.01.085 5 of 6 Shaw JH, Rahman TM, Wesemann LD, Z Jiang C, G Lindsay-Rivera K, Davis JJ. Comparison of Postoperative Instability and Acetabular Cup Positioning in Robotic-Assisted Versus Traditional Total Hip Arthroplasty. J Arthroplasty. 2022;37(8S):S881-S889	Thank you for sharing these retrospective publications from the US. The EAG did identify these papers as in scope, but they were not prioritised for inclusion in the report because of the study design and relevance to the NHS – the wording around this has been clarified in section 9.2 to make clear that evidence was not identified in the studies prioritised for inclusion, and not that the evidence does not exist. Because all dislocations reported by Bendich et al. were revised, these would be captured in the revision rates used in the model, and although Shaw et al. reported some dislocations being treated conservatively, the cost difference for this between robotic and manual surgery is likely to have been captured by the range of sensitivity analysis carried out by the EAG.
80	98	9.2 Economic modelling	The model assumes that utilities will be similar for different platforms. We do not support this assumption. The various platforms are significantly different and therefore evidence gathered on one platform should not be applied to another. As this is an EVA this should be highlighted as an evidence gap and an area for further evidence generation.	Thank you for sharing this concern. This was already noted as an evidence gap, but the EAG has strengthened the limitations section of the report to acknowledge the possibility that utilities may differ because of differences between the technologies.

81	98	9.2 Economic modelling	NJR data shows the data in relation to specific implants, some of which are only used via RAS. It is therefore possible to undertake an analysis on revision rates.	Thank you for your comment. The EAG does not consider it appropriate to interpret the NJR report in this way. The comment states that some implants are only used via RAS, which implies that other implants may be used with both RAS and conventional surgery, which (as is currently the case) cannot be differentiated. The EAG would update revision rates for the two arms only when data is available to unequivocally and accurately distinguish between them.
82	102	Table 33: Main clinical parameters	Table 33 states that the 2023 AOANJRR found no difference between revision rates of robotic surgery and non-robotic assisted TKA when adjusting for age, gender, ASA, BMI, bearing surface, patella component usage and stability. The 2024 AOANJRR found significant improvements in Stryker's Triathlon implant when used for TKA implanted using Mako. • Triathlon CR (with and without patella) shows a significantly lower six-year CRR when implanted with Mako compared to manual: 2.1 vs 2.6. This is a 19% relative improvement. • Triathlon CR with patella shows a significantly lower six-year CRR when implanted with Mako compared to manual: 1.6 vs 2.3 . This is a 30% relative improvement).	Thank you for highlighting this. The 2024 report was unknown to the EAG at the time of writing the report, and the EAG note that there is still no difference reported between robotic and conventional surgery as a whole. The EAG has updated the report to reflect the updated results from the 2024 report. The EAG acknowledge that the results shared suggest an improvement in revision outcomes specifically when using the Mako robot and Triathlon implant, both with patella resurfacing and when resurfaced and unresurfaced are combined. However, the EAG notes that these are non-UK results and therefore differences between arms for specific subgroups should be interpreted with caution, as they may be influenced by factors not applicable in the UK. Indeed, the EAG has compared the age, sex, and ASA classes of those having UKA and TKA between the Australian and UK registries, and found that differences exist to suggest the cohorts having each procedure may not be comparable between countries, and the results may therefore not be generalisable.

				The EAG has updated the evidence generation recommendations in table 44 to state that the NJR reporting revisions in a similar way to the AOANJRR annual report would be useful.
83	106	9.2.2 Resource use and cost	Certain benefits are ignored as it is stated they could not be considered without a detailed micro-costing approach. We do not consider these costs to be 'micro-costs' and instead believe them to be of significant value and should therefore be included in any future modelling.	Thank you for this suggestion. Further costs could be incorporated in the model in future, if there was evidence to suggest differences between robotic and conventional arms, or indeed, between different robotic technologies. At present evidence is lacking that these costs differ.
84	116-125	9.3	The EAG assumed the same length of stay, revision rates, and utility between Mako and conventional surgery. This is a key assumption and significantly impacts the economic outcomes. The EAR reports that improvements in alignment were observed in the RCT evidence for Mako, and the EAG considered it plausible that this may lead to increased patient activity levels and lower revision rates. Therefore, 6 of 6 assuming the same length of stay, revision rates, and utility between Mako and conventional surgery may not hold true in reality. Also, one can argue that if these variables are considered to be the same for both treatment arms, it may not be appropriate to estimate an ICER due to lack of a difference in relative effect size between Mako and conventional surgery.	Thank you for your comment. The EAG have acknowledged the limitations of the model in their report, and have since added emphasis that the analysis is illustrative and should be interpreted in light of the stated limitations. If evidence of differences between arms is published in the future, then the model can be updated to reflect that.
85	116-125	9.3	The ICER estimated for Mako compared to conventional surgery seems to be low and to be sensitive to changes in the economic analysis (as shown in Tables 39-42) where the ICER moves from being dominated to being dominant. Probably, this is driven by the assumptions made in the model. This requires a careful consideration as this is based only on a univariate sensitivity	Please see the EAG response to comment 84.

			analysis, not a PSA. Estimating an ICER based on robust clinical evidence findings would be more appropriate to generate meaningful outcomes and inform decision-making around the use of robotic technology as standard practice in the NHS setting.	
86	116-125	9.3	QALYs: on the one side, the EAG reports that there is non-inferiority and uncertainty about how robust the clinical evidence findings are when comparing Mako to conventional surgery. Hence, it assumes the same length of stay, revision rates, and utility between Mako and conventional surgery. On the other hand, the EAG uses different utility and disutility values (Table 38) between different treatment arms, resulting in a higher estimate of QALYs gained with conventional surgery compared to robotic surgery. This is contradictory to the earlier findings and assumptions made by EAG and lacks consistency. We feel it is premat1ure to estimate QALYs and perform a cost-effectiveness analysis at this stage of the EVA process. It would be more appropriate for the EAR to report that a more robust evidence base is required prior to performing a cost-effectiveness analysis comparing Mako to conventional surgery.	Thank you for the comment. Whilst the EAG concluded in the clinical evidence section that Mako appeared to be non-inferior to conventional surgery in terms of utilities, this was a broad statement to highlight the lack of evidence of a statistically significant difference. There remains evidence of a numerical difference between arms, for which the limitations and uncertainty are well stated in the EAG report. If we assume equal utilities for both arms, the results would reflect only differences in costs, and RAS would still be dominated by conventional surgery. Please also see the EAG response to comment 84, regarding interpretation of results of the economic modelling.
87	117	9.3.1	The EAG considers the base case results of economic analysis as simply demonstrating the model sensitivity to changes in utility. They recommend that future larger, controlled comparative studies capturing utilities would reduce uncertainties in this area. Therefore, this economic evaluation in the current EAG report should not be used to inform decisions regarding the uptake of robotics in NHS as further (robust) evidence is required prior to estimating the ICERs for robotic technology.	Thank you for your comment. In line with the EVA Interim Process and Methods, the EAG has developed an illustrative base case to demonstrate the sensitivity of economic modelling of robotics versus conventional orthopaedic surgery in order to demonstrate the key drivers, and to inform future evidence collection. The EAG has listed the limitations of the economic modelling approach within the report.
Evidence generation				

24	130	11.1	Outcome Gaps Haffar refers to reduction in physical stress and strain on surgeons and theatre staff for RAS versus conventional surgery1. Although evidence is minimum it does exist. It is stated there is a lack of evidence which can mean no evidence at all.	Thank you for highlighting this. The report has been updated to state that evidence is limited, rather than lacking.
General				
1		General	Really interesting read	Thank you for your positive comment.
9	22	Terminology	*Conventional surgery is also referred to as manual or mechanical surgery in the literature.* *Statement requires further clarity as mechanical can mean use of mechanical instrumentation or mechanical alignment.*	Clarification has been added, thank you!
10	23	2	Document states In orthopaedic procedures, RAS systems usually integrate pre-operative planning with real-time intraoperative guidance "usually" suggests that system should have the capability to perform pre-operative planning, this term should be used with caution. We would recommend replacing with the term "may"	Thank you for this suggestion. We have made this change in the report.
12	31	2.2 Table 4	Table 4 states that ZimmerBiomet does not explicitly mentions training of nurses and theatre team but in the company request for information ZB provided, we have mentioned in section 8 that **200 nurses and ODP have been given customised training.**	Thank you for providing this clarification, table 4 has been updated to state that customised training is provided.
14	32	3.3	Document states *Some RAS systems are image free and do not require extra scans* Type of scans need to be explicitly mentioned as this has an economic implication and resource for Radiology department including waiting time. It can also be referred to as 'additional imaging from routine care.'	Thank you for your comment. The EAG has altered the sentence, however notes that the following sentences do highlight the type of imaging required (CT for one robotic system).
23	84	6.4	Given the workflow differences between the robots, the names of the platforms should specifically be mentioned here.	Thank you for this suggestion, technology names, where available, have been added alongside the results reported.
25	135	12.1	It states that broadly RAS seems clinically non inferior. Looking at the evidence the sentence may need to be more specific to TKA.	Thank you for this suggestion. We have added this to our report.

29		General	The assessment does not have a dedicated section to 'Benefit for Patients'	Thank you for pointing this out. The EAG considers that patient benefit is sufficiently captured throughout the report.
30	16	Executive Summary/Quality and relevance of clinical evidence	"The majority of evidence included total knee arthroplasty (TKA); N=16 studies of which the EAG considered 5 RCTs and 3 prospective cohorts with comparator arms with matched baseline characteristics to be the highest quality evidence. RCT evidence from the UK has broadly shown clinical non-inferiority of the Mako robotic system when compared with conventional TKA. Improvements in alignment were observed in the RCT evidence for Mako". This is also stated to be true for CORI in section 5.6.6, we would therefore request that it is acknowledged in this paragraph.	Thank you, we have clarified that the Mako evidence was from a UK setting (prioritised evidence). However the EAG note that they do already acknowledge the CORI system within the quoted paragraph: "Randomised non-UK evidence for CORI and its predecessor NAVIO, as well as prospective cohorts with matched comparator arm using ROSA Knee gave similar results."
41	78	5.8, National Joint Registry	"Case mix; for example, proportion of partial knee replacements rather than total knee replacements. The NJR provided on 01 August 2024 a breakdown of the total number total and partial knee replacements recorded in the Registry between 2014 and the partial year of 2024, Figure 2; which demonstrated a steady increase in partial knee replacement from 9.8% (in 2014) to 15.4% (in the partial year of 2024)." We request that the following be added to end of the sentence above; however this is still significantly below the possible number of patient suitable for partial knees replacement described in NICE NG157 estimated to be 40%.	The EAG was unable to find reference to 40% in the NG157 guidance other than a reference to resurfacing. NJR represents real-world evidence from the UK. The SCMs have reviewed this report and have not suggested that the figures provided by NJR are lower than expected, therefore no change made.
43		Overall	J&J has been unable to critically assess the work done by the EAG, as the document and model is fully redacted. The information and results pertaining to our own technology has not been made visible to us. This impedes our ability to participate in this consultation period, check for factual inaccuracies and/or fully respond to the EAG's assessment report.	All 'in confidence' data is redacted, to allow the same version of the report to be sent to all stakeholders.
46	33	3.2	While we accept that selection bias may be a consideration, it is unreasonable to assume that Royal College of Surgeons of England guidance is universally followed and therefore the selection criteria quoted are systematically present in non-	Thank you for your comment. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, and that of greatest relevance to the decision problem. In this we

			randomised studies. This is particularly relevant to studies conducted beyond the initial learning curve of the surgeon, and outside the UK. As stated above, we believe that inclusion of evidence should be broad, and diverse study designs considered, without deprioritisation of non-randomised or retrospective studies on the assumption that such selection bias exists.	prioritised data relevant to the NHS and data where attempts were made to adjust or account for possible selection biases. This does not presuppose that such biases do exist. Including studies that do not make such changes is tantamount to assuming that such assumptions do not exist, or that if they do, they are unimportant. The EAG considers the approach it has adopted to provide protection against possible biases.
61		General comment from email body	Please find attached the comments from Stryker on the Early Value Assessment, HTE10043 Robot-assisted surgery for orthopaedic procedures: External Assessment Group report. I have added these to the NICE Documents web page. I would like to take this opportunity to highlight elements of the feedback which we believe create fundamental issues for the ongoing Early Value Assessment process. We believe the evidence selection criteria was too narrow and has limited the ability to properly assess the potential benefits on offer. The prioritisation process, which appears to have been driven by time constraints, has led to a number of conclusions which we do not support. Given where we are in the EVA process and the approach to evidence taken, we do not believe it is appropriate to have created an economic model and drawn conclusions on the impact of the various RAS platforms. Second to this, Mako data on utility was applied across all platforms for the purposes of modelling. This approach was undertaken as sufficient evidence was not available for the other platforms. We do not support the assumption that utilities are similar and do not support the usage of Mako data in relation to other platforms. RAS platforms are significantly different in their	The NICE process and methods for early value assessment allow for a pragmatic approach to be taken. As indicated in the published Final Protocol, the EAG has prioritised the highest quality evidence, and that of greatest relevance to the decision problem. The EAG has since reviewed specific studies shared as part of this review, and note that their conclusions would not have been changed by the inclusion of this additional evidence. The EAG has noted that it is a limitation of the model that the clinical parameters and utilities for Mako were applied to the other technologies (and that only technology costs differed across arms), and highlighted this as an evidence generation recommendation in Table 44. Costs within Appendix E were checked individually with each company, and corrected if needed. However, all 'in confidence' data is redacted, to allow the same version of the report to be sent to all stakeholders. EAG has developed an illustrative base case to demonstrate the sensitivity of economic modelling of robotics versus conventional orthopaedic surgery in order

			operation and application, including a number of areas where we currently have patent protection. Applying Mako data to the other platforms is a fundamentally flawed approach. We were unable to gain full visibility of costings data owing to concerns around data protection, which we acknowledge. On this basis it is difficult for us to fully understand the approach to costings. Mako is a piece of capital equipment that supports three distinct and separate procedures. Where volume level thresholds have been used to assess costs, it is not clear how this has been done and whether the volumes are based on total procedures performed by the robot or the number of procedures performed within a specific application. The method used to undertake this analysis will have a significant impact on the individual procedure price calculated. We appreciate that Economic Assessment Report is part of the overall process of the Early Value Assessment and that the Committee is yet to assess the report and published its own report. We welcome the opportunity to continue engaging with you in this process and driving a successful outcome. We do, however, have concerns about the unintended consequences of the publication of this report in its current form.	to demonstrate the key drivers, and to inform future evidence collection. However, the EAG acknowledge that using the same robot for different procedures may affect the cost per procedure, however it is possible that the impact of this has been captured in the sensitivity analysis carried out considering 400 procedures per year and the upper and lower limits of implant costs. Frequency of use of individual robots and the impact this has on costs has been added to table 44 as a recommendation for evidence generation.
63	16	Exec summary	The purpose of this early value assessment is to identify evidence for 6 robotic systems used in joint replacement surgery when compared with conventional surgery, identify evidence gaps to help direct further research and data collection, and develop a model to inform future economic evaluations. However, in the current EAG Report, an early-HTA assessment is conducted on robotic technologies, especially Mako, with cost per QALY estimates (ICER) provided together with the sensitivity analysis. In our opinion, this EVA should focus on providing recommendations for additional evidence generation to inform future economic evaluations, instead of performing an early-HTA as it is premature to do this based on limited evidence available.	Please see the EAG response to comment 87.

67	19	Exec summary	There are multiple causes of revisions which are not properly explored in the EAR, which could limit the understanding and assessment of the benefits of robotics.	Thank you for this comment, the EAG agree and note that revision surgery is outlined in section 11.2 as a key area for evidence generation.
68	19	Exec summary	The potential to use Hospital Episodes Statistics, potentially linked to NJR, as a means to gain better information and understanding of outcomes is referenced several times, yet the analysis is not undertaken.	Thank you for raising this. It would not be possible to complete this work in the timeframe of an EVA. An outcome of the process is development the Evidence Generation Plan, and this further work is outlined in section 11.2 as a key area for evidence generation.
70	23	Overview of the technology	Image based technology offers significant benefits in pre-operative planning. This includes efficiencies in planning and set up, sustainability benefits in reprocessing and the reduced strain on the workforce. This is not given sufficient emphasis and is largely ignored	Thank you for your comment. The EAG has outlined key evidence generation recommendations in section 11.2 including quality of life of surgical staff, and better understanding of capacity constraints.
88	30	2.2 Training	Each robotic platform has distinct training requirements to overcome its learning curve, as specified by the manufacturers. It's important to highlight that operational proficiency with one robotic system is not transferable to other platforms. To maintain the necessary operative skills, the surgical team must perform a specified number of cases annually, as recommended by the respective manufacturers.	Thank you for raising this, it has been added to section 2.2.
89	33	3.2	RAS is not a direct replacement for all conventional joint replacement surgeries due to the complexity and variety of procedures involved. This suggests the need to consider a hybrid approach (mix-used scenarios), where both conventional and robotic-assisted techniques are utilised. In such cases, it’s important to assess the proportion of switching between methods and the potential benefits. Does increased utilisation of RAS lead to improved outcomes, such as higher QALYs? These factors warrant careful evaluation to optimise patient care and resource allocation.	Thank you for this insight, with which the EAG agrees. However in this EVA the focus has been on situations where either approach would be suitable for a patient. An analysis looking at scale of implementation within the NHS of the technologies and optimal mix of approaches was beyond the remit of this project. We do note however that there is ongoing work funded by NIHR looking at the implementation and adoption of RAS approaches within the NHS. An ambition for that project is to consider adoption at a system level.

90	33	3.2	The assertion that additional costs (such as imaging costs) associated with robotics may be offset by reduced inpatient stays, post-discharge care, or fewer costly complications, such as revision surgery, is a strong statement. Caution is needed when making such claims, as these potential benefits should be carefully evaluated and substantiated with robust evidence.	Thank you for this comment. We used the word 'may' as this is still unknown. The EAG has previously outlined in section 11 and Table 44 (key evidence generation) that detailed micro-costing to better understand the economic implications of adoption of robotics is required.
91	38	3.4	I appreciate that the issues related to equality was considered.	Thank you for your comment. No change required.
92	46	5.1	The varying implementation periods across institutions may lead to different training outcomes in terms of surgical proficiency. Early-stage adopters might experience lower clinical effectiveness due to the learning curve, which could impact the generalisability of these findings. As training protocols and prior experience vary widely, the outcomes observed in one institution may not be directly applicable to others.	Thank you for this comment, which flags several unknowns. Of these most would be more appropriately addressed in an implementation study. Other ongoing work may fully or partly address this. For example the NIHR funded REINFORCE study is explicitly considering impact of clustering on outcomes. Qualitative components of the same study are exploring experience of adoption, both to understand differences and to inform future adoption. Within section 5.1 the EAG has commented on the variability in prior training, and hospital volume in learning curve outcome and explicitly noted that the generalisability of these outcomes was unknown.
94		5.8	Real-world data is being collected, with median procedure volumes for primary joint replacements obtained from the NJR 20th Annual Report. To offset the high capital costs of robotic platforms, annual surgical volume at each centre is a key factor. However, this dataset includes a significant number of private centres, which may skew the median values, as these centres often target patients seeking high-end technology. In contrast, public centres may not achieve sufficient volumes during the early stages of implementation. The model is based on the scenario of	Thank you for this comment. The EAG agrees that impact on utilisation of the robotic system is important. Consequently the EAG has performed sensitivity analyses where the number of procedures per year is varied. These are reported in Table 40 of the EAG report.

			the volume-based contract. However, it can include the estimation of underutilised scenarios that what the ICER value is.	
95		general	For conventional arms, clinical outcomes assumed to be the same. But I can understand that was conservative assumption.	Thank you for your comment, this is a noted limitation of the work, and used for illustrative purposes only. Suggestions for further studies have been proposed by the EAG in table 44.

NICE National Institute for Health and Care Excellence

Medical Technologies Advisory Committee Interests Register

Topic: Robot-assisted surgery for orthopaedic procedures

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Paul Baker	Specialist Committee Member	Financial Interests	Private Practice	January 2024	May 2024	ongoing	No further action
		Non-financial professional and personal interests	Trial Steering Committee Member - NIHR RACER trial (robotic versus conventional Knee replacement trial)	June 2020	May 2024	ongoing	No further action
Andrew Port	Specialist Committee Member	n/a	NIL	n/a	May 2024	n/a	No Further action
Usman Bhatty	Specialist Committee Member	n/a	NIL	n/a	May 2024	n/a	No Further action
Rebecca Dickens	Lay Specialist Committee Member	n/a	NIL	n/a	May 2024	n/a	No Further action
David Deehan	Professional Expert	Financial Interests	I perform private practice	2001	July 2024	ongoing	No further action
		Financial Interests	full time NHS surgeon I am a full time NHS consultant in elective practice	2000	July 2024	ongoing	No further action
		Financial Interests	I receive no personal funding in any form from private industry	2000	June 2024	ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		Non-financial professional and personal interests	professor of surgery	2009	July 2024	ongoing	No further action
		Non-financial professional and personal interests	I have published extensively on many aspects of knee replacement and robotic surgery	2001	July 2024	not relevant	Prevents appointment as SCM – to participate as Professional Expert
		Non-financial professional and personal interests	Newcastle Hospitals receives institutional support for research from several orthopaedic companies	-	June 2024	-	No further action
		Non-financial professional and personal interests	Unpaid founder / director Newcastle surgical training centre www.nstcsurg.org	2007	June 2024	ongoing	No further action
		Non-financial professional and personal interests	Published the first RCT on robotic assisted knee replacement Robotic Arm-assisted versus Manual (ROAM) total knee arthroplasty: a randomized controlled trial | Bone & Joint (boneandjoint.org.uk)	2023/4	June 2024	-	Prevents appointment as SCM – to remain as Professional Expert
		Non-financial professional and personal interests	None of the above have I received any form of payment whether through salary or otherwise	-	June 2024	-	No further action
Jonathan Rees	Specialist Committee Member	Financial Interests	Non-Exec Director (unpaid) and share holder - University Spin out company called PROMAPP Ltd	2017	July 2024	ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		Non-financial professional and personal interests	Head of Dept, NDORMS, University of Oxford	2022	July 2024	ongoing	No further action
		Non-financial professional and personal interests	Trustee Pembroke College Oxford	2005	July 2024	ongoing	No further action
		Non-financial professional and personal interests	Trustee British Elbow and Shoulder Society CIO	2019	July 2024	ongoing	No further action
		Non-financial professional and personal interests	Trustee Lord Nuffield Orthopaedic Centre Trust	2021	July 2024	ongoing	No further action
		Non-financial professional and personal interests	Trustee Nuffield Orthopaedic Centre Charity	2022	July 2024	ongoing	No further action
Nicholas Carleton-Bland	Professional Expert	Non-financial professional and personal interests	NHS National Director of online neurosurgical training	Feb 2024	June 2024	-	No further action
		Non-financial professional and personal interests	Honorary Senior Clinical Lecturer University of Liverpool	Aug 2018	June 2024	-	No further action
		Non-financial professional and personal interests	SAC neurosurgery member	Aug 2022	June 2024	-	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
David Houlihan-Burne	Professional Expert	Financial Interests	Paid speaker / educationalist for Stryker	2020	June 2024	ongoing	No further action
		Financial Interests	Paid speaker / educationalist for Smith and Nephew	2017	June 2024	ongoing	No further action
		Non-financial professional and personal interests	Paid speaker / educationalist for Stryker	2020	June 2024	ongoing	No further action
		Non-financial professional and personal interests	Paid speaker / educationalist for Smith and Nephew	2017	June 2024	ongoing	No further action
Dinesh Nathwani	Professional Expert	Financial interests	Educational consultancy with Smith & Nephew on delivery of education to surgeons on the safe use of the CORI system. Also, KOL for the company for robotic knee surgery. Consultant advisor to Smith & Nephew for delivery of education and international lectures on the CORI system. Research support for studies.	2017	October 2024	present	Declare verbally and participate
Edward Davies	Professional Expert	Financial interests	Private practice	2008	May 2024	present	No further action
		Financial interests	Consultant for Smith and Nephew	2010 approx	May 2024	present	No further action
		Financial interests	Consultant for Stryker	2019 approx	May 2024	present	No further action
		Financial interests	Research funded by Smith and Nephew	2010 approx	May 2024	present	Declare verbally and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		Financial interests	Research funded by Stryker	2019 approx	May 2024	present	Declare verbally and participate
		Financial interests	Research funded by NIHR	2018	May 2024	present	No further action
		Non-financial professional and personal interests / Indirect interests	RCS MSK robotic surgery group member	2021	May 2024	present	No further action
		Non-financial professional and personal interests / Indirect interests	Co-Chief investigator of the RACER hip and Knee studies funded by the NIHR	2019	May 2024	present	No further action
		Non-financial professional and personal interests / Indirect interests	Published on computer aided and robotic surgery	2008	May 2024	present	No further action
Katherine Boylan	Committee Member	Non financial professional and person interests	I am leading on the negotiation of a research, development and innovation master agreement between my employing organisation (MFT) and Medtronic. It is currently close to sign off, but no projects have been initiated as a result yet. Robotic surgery is likely to be a topic which we explore for	Ongoing	October 2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			collaboration in the future. I will not have any personal financial benefit as a result, but the success of future collaboration could benefit my organisation, either through paid research contracts or joint adoption projects – this is ongoing				
Katherine Boylan	Committee Member	Non financial professional and personal interests	I have previously been paid by Medtronic for participating in an advisory panel around their remote monitoring technology. I did not benefit financially personally - the money went back into my employing organisation	April 2023	11/10/2024	April 2023	No further action
Michael Kolovetsios	Committee Member	Financial interests	I'm employed by Medtronic, which has a robotic-assisted surgery system in its portfolio. However, the Medtronic RAS system is not included in this evaluation.	Ongoing	Ongoing		No further action