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