NICE National Institute for Health and Care Excellence

Medical technologies advisory committee (MTAC)

27 September 2024

Information pack for draft guidance considerations on Robot assisted surgery for soft tissue procedures: early value assessment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 3 December and 17 December 2024.

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Papers included in pack:

1. Front sheet
2. Scope
3. Patient organisation submissions x5

3a. Bowel Cancer UK

3b. Fight Bladder Cancer

3c. Lobular Breast Cancer UK

3d. Ovacome patient submission

3e. Prostate Cancer UK patient submission

4. EAG assessment report (EAR)

5. EAG assessment report overview (ARO)

6. EAG assessment report addendum (Additional document not in original committee pack on 27 September 2024, supplied by EAG in November 2024)

7. EAR Stakeholder comments and EAG responses

8. Register of interest

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

HTE40 Robot-assisted surgery for soft tissue procedures (provisional title)

Scope

July 2024

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 that they could be used while evidence is generated. The process will 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 soft-tissue surgery as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP).

2 Description of the technologies

2.1 Purpose of the medical technology

Approximately 1 in 10 people have a surgical procedure in the UK, each year. Surgical techniques can be broadly categorised into open and minimally invasive surgery (MIS). In open surgery, large cuts are made to open the body so that the area for the procedure can be seen and accessed directly. The aim of MIS is to do the procedure with less damage to the body than open surgery. MIS includes conventional laparoscopic surgery, natural orifice surgery with existing equipment and robot-assisted surgery (RAS). In conventional laparoscopic surgery, a tiny camera (laparoscope) and specially designed tools are put into the body through small cuts and the tools are operated from outside the body. Conventional laparoscopic surgery has been used in the UK since the 1980's and NICE recommends its use with standard arrangements for many soft-tissue procedures in the NHS (see appendix A). Natural orifice surgery is used in some specialties like head and neck surgery and for some upper-gastrointestinal, colorectal and gynaecological procedures. The area that needs to be operated on is accessed by existing openings in the body, like the mouth, anus or vagina. Specially designed

cameras and tools are passed through these openings, meaning that no cuts on the outside of the body are needed to do the procedure.

RAS for soft-tissue procedures is an enhanced form of minimally invasive surgical techniques because a camera is used to visualise inside the body and tools are operated from outside the body. But, in RAS, the tools are usually attached to one or more robotic arms that are controlled by the surgeon from a console, near the operating table.

Robotic platforms for soft-tissue procedures are expensive and require specific training, but they may have several benefits to patients, surgeons and the wider NHS system. Many potential benefits are the same as for other minimally invasive surgical techniques if compared with open surgery. Benefits may include reduced pain, bleeding, length of hospital stay and recovery time. When RAS is compared with other minimally invasive surgical techniques, there may be technical and ergonomic benefits which could increase precision and control. These could lead to less surgical complications meaning the procedure is less likely to be converted to open surgery. There may be less scarring, shorter length of stay and faster recovery time for people having soft-tissue procedures. There may be benefits to the surgeon, including reduced strain and technical demand when doing the procedure. This may also mean that MIS could be offered to people or for procedures that were too technically challenging to do with other minimally invasive surgical techniques, or could be offered by surgeons that previously could not do MIS for some procedures. Both prospects could increase access to MIS across many surgical specialties and procedures. There may also be benefits for the wider NHS system; reduced length of stay, fewer readmissions and less recurrence of disease could reduce cancer and elective surgery waiting lists.

RAS is already recommended in some cases in the NICE Guideline for Prostate cancer: diagnosis and management (2021). RAS for prostate cancer is routinely commissioned in the NHS (NHSE Clinical Commissioning Policy: Robotic-assisted surgical procedures for prostate cancer, 2015). In other specialties and procedures, RAS is at different stages of maturity in terms of evidence and usage. In 2019, a Royal College of Surgeons (RCS) report on the future of surgery predicted major expansion of RAS over the next 10 years, and in 2023, they published a guide to good practice for RAS. This has been echoed by 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 robot assisted surgery 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.

In 2022, the RCS estimated that over 1.8 million RAS procedures were done internationally and it was available in more than 100 UK hospitals (RCS, 2023).

Robotic systems for soft-tissue procedures are used in operating theatres. They include one or more robotic arms that hold a tiny camera (endoscope) and other surgical tools, and a console with video feed from the endoscope. The tools are designed to be compatible with the specific robotic system they attach to. The surgeon typically operates the robotic arm or arms from the console, inside the operating theatre, whilst other operating theatre staff are present. 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.

Compared with conventional laparoscopic procedures, there is less national guidance on the use of RAS for soft-tissue procedures. Several NHS commissioning policies have considered RAS for soft-tissue procedures. Aside from the prostate cancer policy published in 2015, RAS is also routinely commissioned for use in the Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery (2016).

At a similar time, RAS was not routinely commissioned for lung resection for primary lung cancer, oesophago-gastric cancers, bladder cancer or trans-oral surgery for throat and voice box cancers.

Aside from the NICE Guideline for prostate cancer, the NICE Guideline for colorectal cancer (2020) recommends that robotic surgery should only be considered within established programmes that have appropriate audited outcomes. The following NICE guidance explicitly evaluates RAS for soft-tissue procedures:

- Robot assisted kidney transplant NICE Interventional procedures guidance 609. Use with special arrangements was recommended for people with obesity who would not otherwise be able to have a kidney transplant without significant risk of morbidity. When open surgery is suitable for people, the committee recommended RAS should be used only in research.

- Totally endoscopic robotically assisted coronary artery bypass grafting NICE Interventional procedures guidance 128, recommended with special arrangements.

Often, NICE's Interventional Procedures programme has considered RAS to be a minor variation of laparoscopic procedures in terms of safety and efficacy. RAS is acknowledged as a variation of other minimally invasive approaches in the following NICE Guidance: minimally invasive radical hysterectomy for early-stage cervical cancer, bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse, laparoscopic ventral mesh rectopexy for internal rectal prolapse, sacrocolpopexy using mesh to repair vaginal vault prolapse, sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse, endoscopic radical inguinal lymphadenectomy, transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy, laparoscopic cystectomy, laparoscopic prostatectomy for benign prostatic obstruction, and laparoscopic radical prostatectomy.

Consideration of RAS in this EVA will assess whether it shows clinical and cost-effectiveness in soft-tissue procedures. The EVA will assess what gaps there are in the evidence base to enable full clinical and cost-effectiveness evaluation. The evidence gap analysis will identify key outcomes that should be used for future evidence generation, and may inform the development of the RAS outcomes registry (MedTech strategy: One year on (2024).

Robotic platforms are here defined as a technology that enables minimally invasive surgery to be done across multiple interventional surgical procedures. They have one or more mechanical arms to which an endoscope and surgical instruments are attached. The operator controls the apparatus from a remote console.

For this EVA, NICE will consider robotic platforms that are used for soft-tissue procedures, that meet the following criteria:

1. Are intended for use for:
    - adult or paediatric populations
    - procedures for cancer or benign disease in at least one of the following specialties:
        - urology (excluding prostatectomy)
        - gynaecology
        - colorectal
        - head and neck
        - thoracic

- upper gastrointestinal (including bariatric and oesophago-gastric surgery)
- general (including hernia repair)
- hepato-pancreato-biliary
- transplant
- breast
- reconstructive and plastic surgery

2. have a CE or UKCA mark and, if applicable, meet the standards within the digital technology assessment criteria (DTAC).

3. are being used in the NHS or will be available for use in the NHS within the next 12 months.

Further detail on the included technologies is summarised in table 1.

Versius Surgical System (CMR Surgical)

The Versius Surgical System includes a bedside unit with an endoscope (visualisation unit), 2 or 3 other bedside units with attachment ports for surgical instruments and a surgeon console with 3-dimensional video feed from the endoscope. The surgical instruments are specially designed for use with the Versius system. They are wristed, meaning they mimic the movement of the human arm. The video feed on the surgeon console is open, so other people in the operating theatre can see the screen, as well as the surgeon. The units are designed to be smaller than other soft-tissue robotic systems, meaning the whole system is portable between theatres and can be used in standard operating rooms. The range of basic and advanced instruments that attach to bedside units is under continuous development. They enable endoscopic manipulation of tissue including grasping, cutting, blunt dissection, approximation, ligation, electrosurgery and suturing. During the procedure, the surgeon controls the robotic arms from the console, with the theatre nursing team present in the operating theatre.

It is designed for use across a range of soft-tissue procedures in adults aged 18 and over (see Table 1). The system has data collection capabilities for robot telemetry data, and with patient consent, surgical video and clinical data can be collected. There is an existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app. This can be used by surgical teams to review performance on past surgeries and interact with registry data.

Da Vinci Surgical System (X and Xi)

The Da Vinci (X and Xi) Surgical Systems include a surgeon console, a patient cart and a vision cart. The patient cart is positioned next to the patient in the operating theatre. It has 4 arms which hold the endoscope and up to 3 surgical instruments that are specially designed for use with the system. The wristed instruments are designed to move like the human hand, but with more range of motion. Each instrument does different tasks such as grasping, suturing, or tissue manipulation. During a procedure, the surgeon controls the robotic arms and instruments using hand and foot controls on the console. The console has a 3-dimensional, high-definition closed viewer which feeds the video from the endoscope. The vision cart duplicates the image seen in the surgeon console closed viewer, so the rest of the surgical team can see the procedure. The vision cart also has functionality to control parts of the system. The instruments attached to each arm on the patient cart can be changed during the procedure.

The 2 Da Vinci systems in mainstream UK use are Da Vinci X and Xi (respectively models IS4200 / IS4000). The Da Vinci Xi system has additional functionality but both systems are built on the same arm, use the same vision cart, console and core instruments and are indicated for the same procedures. The systems collect data on usage metrics such as time, date, kinetmatic and procedure information.

The Da Vinci (X and Xi) systems are designed to be used for a range of soft-tissue procedures in adults and children (see Table 1). The number and type of staff needed to use the Da Vinci platform varies by procedure, but includes a surgeon and operating room and nursing staff.

Da Vinci SP Surgical System

The Da Vinci SP system is designed for single port or natural orifice surgery. This may enable procedures in narrow surgical spaces to be done. Rather than being attached to a patient cart with 4 individual arms as in the Da Vinci X and Xi systems, up to 3 instruments and the endoscope are attached to a patient cart with 1 arm. Specially designed surgical instruments can be used, but not all instruments that can be used on the X and Xi models can be used on the SP, and not all instruments used on the SP can be used on the X and Xi models.

The Da Vinci SP model is CE marked for UK use but is a newer system than the X and Xi (CE mark was given in January 2024). It is indicated for use in adults for endoscopic abdominopelvic, thoracoscopic, transoral otolaryngology, and breast surgical procedures, with exclusions (see Table 1). This technology may have more pronounced and additional benefits to other technologies in the evaluation because of the single-port access, such as cosmetic outcomes and quality of life. It may also be quicker and simpler to do

the surgery and MIS may be offered for a broader range of procedures because there is only 1 arm, meaning alternative access routes might be possible to use.

Hugo RAS (Medtronic)

The Hugo RAS system has 3 key components: the system tower, the surgeon console and the arm carts. The system tower includes computers, systems and generators attached to a touchscreen interactive display for the operating room team. It enables communication between the surgeon console and the arm cart or carts, but can also be used without the surgeon console for manual control of 1 arm cart at the bedside, or alone for visualisation during conventional laparoscopic surgery. The surgeon console has an open, high-definition, 3-dimensional display, and an interactive touchscreen display. Up to 4 arm carts can be used at once. Each arm cart can host 1 surgical instrument or endoscope. They are designed to be portable. A range of compatible wristed articulating surgical instruments can be used for grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing. During a typical procedure, the surgeon controls the robotic arms using hand and foot pedals from the console, with the theatre nursing team present in the operating theatre. If only 1 arm is being used, it can be controlled directly from the bedside using the system tower.

The Hugo RAS system is indicated for use in specified urological, gynaecological and general surgery procedures, and in adults that MIS is suitable for. The system collects technical and usage data.

Table 1. Included technologies.

Technology name	Company / developer	Main components	Intended population and procedures	Delivery mode	Data collection functionality	Regulatory approval
Versius	CMR surgical	• bedside unit with an endoscope (visualisation unit), • 2 or 3 bedside units • wristed instruments that attach to bedside units. • surgeon console with open 3D video feed from the endoscope	• People aged 18 and over • Procedures in thoracic, upper gastrointestinal, colorectal, gynaecology, hepatobiliary, hernia and urology specialties. • Use for transoral robotic surgery is under investigation.	• Used in an operating theatre. • Once positioned in the room, the bedside units are remotely operated from the surgeon console. • Designed to be portable between operating theatres.	• Robot telemetry data, and with patient consent, surgical video and clinical data. • There is an existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app.	Certified to market in the UK under MDR 757173 R000
da Vinci X and Xi Surgical Systems (respectively models IS4200 / IS4000)	Intuitive	• Patient cart with 4 arms that host surgical instruments • Wristed instruments that attach to the arms, including the endoscope • Surgeon console with closed viewer • vision cart that duplicates the endoscope video and	• Indicated for use across urological surgical procedures and laparoscopic general, gynecologic, general thoracoscopic, nipple sparing mastectomy with reconstruction, and transoral otolaryngology surgical procedures restricted to benign tumors	• The system is used in an operating theatre. • Once positioned in the room, the patient cart is remotely operated from the surgeon console.	Usage metrics such as time, date, kinematic and procedure information.	Certified to market in the UK (complies with MDR 2017/745)

		has arm cart control functionality	and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. • Adults, across the full range of indications for use • Children across indications for use except for otolaryngeal procedures.			
da Vinci SP Surgical System (SP1098)	Intuitive	• Patient cart with 1 arm hosting endoscope and 3 instruments • Surgeon console with closed viewer • Wristed instruments that attach to the arm, including the endoscope • vision cart that duplicates the endoscope video and has arm cart control functionality	• Indicated for use in minimally invasive endoscopic abdominopelvic, thoracoscopic, transoral otolaryngology, and breast surgical procedures. • Indicated for use in adults • A list of procedures that are not suitable for use of the Da Vinci SP system that fall under these umbrella categories is given in the supplement to the user guide.	• The system is used in an operating theatre. • Once positioned in the room, the patient cart is remotely operated from the surgeon console.	Usage metrics such as time, date, kinematic and procedure information.	Certified to market in the UK (complies with MDR 2017/745)
Hugo Robotically Assisted Surgery System.	Medtronic	• System tower with operating room interactive display	• Procedures in urology, gynaecology and general surgery	• The system is used in an operating theatre.	Technical and usage data.	Certified to market in the UK under MDR 738197 R000

		• Arm cart hosting instruments. Up to 4 arm carts can be connected to the system tower. • Surgeon console with open display, interactive display and hand and foot controls. • Wristed instruments that attach to the arm carts, including the endoscope.	• Adults for whom MIS is suitable.	• Once positioned in the room, the arm carts are remotely operated from the surgeon console. If one arm cart is being used, it can be operated using the system tower. • The arm carts are portable.		

3 Target surgical procedures

Up to 8 million people are estimated to have surgery in the UK every year. Many of these procedures can be done with either open or minimally invasive surgical techniques. For this EVA, the target population is adults or children having a surgical procedure on soft tissues in the following specialties:

- Urology, excluding prostatectomy and including but not limited to the following procedures:
    - Cystectomy (radical, partial and simple)
    - Nephrectomy (radical, partial and simple)
    - Bladder substitution/ urinary diversion
    - Cyst removal
    - Adhesiolysis
    - Pyeloplasty
    - Ureterectomy
    - Ureteral reimplantation/reconstruction
    - Adrenalectomy
    - Lymphadenectomy
    - Mitrofanoff procedure
    - Bladder diverticulum removal
    - Bladder stone removal
    - Vasovasectomy
    - Ureterectomy

- Gynaecology, including but not limited to the following procedures:
    - Benign, simple, partial, supracervical and total hysterectomy
    - Salpingectomy
    - Oophorectomy
    - Sacrocolpopexy
    - Abdominal/pelvic lymphadenectomy
    - Tubal anastomosis
    - Ovarian cystectomy
    - Renal cystectomy
    - Resection of endometriosis
    - Omentectomy
    - Parametrectomy
    - Lysis of Adhesions
    - Myomectomy
    - Orthotopic or heterotopic human ovarian tissue transplantation

- Colorectal including but not limited to the following procedures:
    - Colectomy (including hemi-colectomy)
    - Polypectomy
    - Rectopexy
    - Hernia repair
    - Rectal resection
    - Total mesorectal excision

- Head and neck, including but not limited to the following procedures:

    - Lateral oropharyngectomy (radical tonsillectomy)
    - Tongue base resection
    - Tongue base mucosectomy
    - Supraglottic laryngectomy
    - Thyroidectomy

- Thoracic, including but not limited to the following procedures:
    - Lung resection (including lobectomy and segmentectomy)
    - Resection of mediastinal tumours
    - Thymic surgery
    - Transaxillary decompression
    - Pneumonectomy

- Upper gastrointestinal including bariatric and oesophago-gastric surgery

- General surgery including hernia repair

- Hepato-pancreato-biliary including but not limited to:
    - Whipple procedure
    - Pancreatectomy
    - Appendicectomy
    - Heller-myotomy

- Transplant, including but not limited to the following procedures:
    - Lung transplant
    - Kidney transplant
    - Liver transplant

- Breast surgery, including but not limited to the following procedures:
    - Nipple sparing mastectomy with reconstruction

- Plastic and reconstructive surgery

Procedures in these specialties include surgery for cancer and procedures for benign disease. Between 2013 and 2021, approximately 56% of all independent cancer treatments were surgical resections (National Disease Registration Service, accessed May 2024).

3.1 Care pathway

The care pathway varies between different specialties and indications for the procedures in scope for this assessment. The intended place of RAS in the pathway is to:

- replace the standard of care surgical technique for the soft tissue surgical procedure

- give an alternative option for the soft-tissue surgical procedure.

Prostatectomy for cancer is the only procedure for which RAS is established in the NHS care pathway (NHS Clinical Commissioning Policy for prostate cancer, 2015).

Conventional laparoscopic surgery is recommended in NICE guidelines for the diagnosis and management of Colorectal cancer, Prostate cancer, Diverticular disease, Ectopic pregnancy, Pancreatitis, Endometriosis, Gallstone disease, and the clinical guideline for Fertility problems: assessment and treatment (see Appendix A).

The Rapid cancer diagnostic and assessment pathways include information on the Faster Diagnosis Standard, which aims to ensure diagnosis within 28 days of an urgent suspected cancer referral or following a screening referral. This includes optimal timed pathways for suspected prostate, colorectal, lung, oesophago-gastric, gynaecology and head and neck cancer. New optimal pathways have been published for some faster progressing cancers like pancreatic cancer, which aim to deliver a diagnosis even more quickly.

The NHS England cancer programme Spring update 2024 aims to get NHS patients prompt access to innovative treatments; minimally invasive surgical techniques including RAS are considered to be a core part of this because of the potential to reduce recovery times.

3.2 Patient issues and preferences

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

One of the intended benefits of RAS is to provide an alternative approach to minimally invasive soft-tissue surgical procedures. As well as the potential to increase options for patient preference and choice, RAS may have several benefits to patients (see patient-level outcomes in table 2).

Robotic surgery comes with the same potential risks as other minimally invasive surgical options. As with other surgical techniques that involve a medical device, there are considerations for the patient about the risk of technical malfunction, and specialist training for the surgical team is needed. Equipoise when explaining options to the patient, joint decision making and full informed consent are key.

4 Comparator

RAS will be compared with surgical standard of care. For most surgeries this will be laparoscopic or thorascopic surgery. For some procedures, like the Whipple procedure or bladder removal, the only current option is open surgery. For head and neck surgery, the main comparator is radical radiotherapy.

5 Scope of the assessment

Table 2 Scope of the assessment

Populations	People (adults or children) having a soft-tissue surgical procedure. Soft-tissue surgery includes those done in the following specialties: • Urology (excluding prostatectomy) • gynaecology • colorectal • head and neck • thoracic • upper gastrointestinal including bariatric and oesophago-gastric surgery • general (including hernia repair) • hepato-pancreato-biliary • transplant • breast • plastic and reconstruction surgery The following subgroups have been identified: • Children and young people under the age of 18 • Procedures for cancer • Procedures for benign disease
Interventions (proposed technologies)	• RAS with Da Vinci X and Xi (Intuitive) • RAS with Da Vinci SP (Intuitive) • RAS with Versius (CMR Surgical) • RAS with Hugo RAS system (Medtronic)
Comparator	RAS will be compared with standard surgical care.
Healthcare setting	Admitted patient services including emergency and elective surgery.
Outcomes	**Primary outcomes** Patient level:

	• Conversion to open surgery (for RAS compared with other minimally invasive surgical techniques only) • Rate of MIS (other minimally invasive surgical techniques and RAS) compared with open surgery after RAS was introduced • Intraoperative and post-operative complications (e.g. Clavien-Dindo score) • Health-related quality of life Surgeon level: • Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Organisation level: • Volume of procedures • Length of hospital stay • Capacity and wait list reduction **<u>Secondary outcomes</u>** Patient level: • Days alive and out of hospital at 30 days • Length of hospital stay (for RAS compared with open surgery only) • Post-operative pain • Satisfaction • Intraoperative blood loss (for RAS compared with open surgery only) • Revision surgery for the same indication Condition/specialty specific outcomes: • Survival rate (cancer) • Need for adjuvant treatment (cancer) • Feeding tube dependency (head and neck) Surgeon level: • Career longevity and musculoskeletal injury • Human factors • Learning curve Organisation level: • Readmission at 30 days • Operating time • Staffing requirements

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.

6 Other issues for consideration

Characteristics of the technologies

- Some technologies can be used for some but not all procedures in the scope (see table 1).
- Different specialties may share the same robotic system, within the same hospital.
- Some technologies are designed to be portable between operating theatres (can go in lifts and through standard sized doors) whilst others are very large and may need purpose built operating theatres to host them. The impact of these adjustments for installation on capital cost or theatre downtime may be considered. How much robots are moved between theatres to enable sharing between specialties in practice and its impact on patient, surgeon and organisation level outcomes may be explored. The floorspace and practicalities of working with the robot in theatre may also be considered.

Evidence

- Different technologies have different levels of evidence and usage, across the NHS and within different specialties.
- Many of the patient level outcomes can be affected by factors unrelated to the use of RAS, for example unanticipated pathology. But, this applies to the comparators as well as RAS.
- If evidence is available, it may be necessary to examine the effect of the learning curve on outcomes.

Care pathway

- Different procedures have different care pathways, and the volume of procedures and indications means it is infeasible to map all of them. There are commonalities among cancer pathways.
- National policies and pathways may change over the coming months in response to national programmes running independently from the evaluation.

Safety

- Safety issues may fall into 2 categories: device failures and user errors.
- Device failures may include electrical and system faults or failures and elements of the hardware breaking.
- Due to their complexity, there is a learning curve associated with the use of RAS systems. Without adequate training there may be an increased risk of surgeon errors. In systems with multiple arms, there may be issues with arm collision if not positioned correctly.

Costs

- Various procurement options are available for each technology, including outright purchase, leasing, consumable-based and usage-based agreements.
- These technologies have high capital cost and come with associated costs for installation, instruments, additional sterilisation, consumables, energy utilisation, maintenance (like repairs, servicing and software upgrades), additional staff and training.
- Device sharing schemes may be considered between different specialties.
- Depending on whether a hospital is newly purchasing and setting up a robotic platform and service, or expanding the service of an existing platform, there may be different associated costs.
- The HTAi best practice considerations for the assessment of RAS recommend that the time horizon should consider the clinical outcome and the level of decision maker (i.e., national vs local). They recommend that malignant disease may require time horizons of over 5 years, while benign disease may only require 2–4 years.

Training

- Typically, training is included as part of the capital cost when a robot is first introduced to a hospital. But, if new teams or individuals need to be trained by the company later on, this will usually incur an extra cost. It isn't always necessary for the company to train new users of the platform.
- It might be easier to train surgeons to do RAS than other types of surgical techniques because of the characteristics of the technologies. For example, the trainer can easily see what the trainee is doing on a screen and platforms can have virtual environments to do training

exercises. Some systems collect data to give summary metrics on surgical performance.

- Gynaecological surgical training is the only specialty in which RAS is part of the curriculum. This is device agnostic training, and device-specific training is needed in addition to this. When logging training, general surgery trainees can select if a procedure is done open, laparoscopic or robotic. Other curriculums will not change for 5 years so training to use robotic platforms will remain a post-fellowship training role in the meantime.

- RAS may increase access for surgeons to train to do minimally invasive surgery. Because surgery is physically demanding it may mean that surgeons who were not physically able, can now do it.

7 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.

There may be some inequalities in access to MIS that may be worsened by RAS. A UK analysis of routinely collected data, linked to hospital episode statistics, found access to MIS for colorectal surgery is related to socioeconomic and geographical factors. Robotic platforms are expensive and if the placement of robotic systems is limited to larger, urban hospitals with more resources to procure and maintain the system and staff needed to use the system, access to RAS may exacerbate existing regional inequalities.

One of the proposed benefits of RAS is increased access to MIS because some procedures may not have been offered as MIS before RAS. This could be because the indication, or characteristics of the patient, or both meant that the procedure was high-risk. It could also be because of surgeon experience or physical constraints of the anatomy and laparoscopic tools. Some indications, procedures and patient characteristics that may mean that other minimally invasive surgical techniques would not be a suitable approach to do the surgery include:

- Tumours requiring multiple organ resection
- People with high BMI or obesity
- People with frailties or older adults (aged 65 and over)
- Procedures deep within the pelvic region
- Transoral procedures

- Indication or patient-specific anatomical characteristics (e.g. large uterus)

Age is a protected characteristic, and many people may be covered by the Equality Act 2010 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. In the absence of RAS, open surgery would be used for people that meet one or more of these criteria. RAS may enable MIS to be done in these groups.

RAS can be used to treat many types of cancer. All people with cancer are covered by the disability provision of the Equality Act 2010 from the point of diagnosis.

8 Potential implementation issues

National level support is anticipated as a requirement for the roll-out of RAS because of the capital costs and requirements for staff training and physical characteristics of the theatres needed to host some robotic platforms. The Royal College of Surgeons have published a good practice guide for RAS training. Some technologies have already been purchased and are already in use in many hospitals across the UK, whilst others are newer and used in fewer hospitals.

It may be possible to calculate how a robotic system could be shared between specialties with information about length of procedure. But, sharing a robotic system between specialties may be complex to implement in practice.

9 Authors

Louisa Robinson- Lead technical analyst

Kim Carter- Technical adviser

Ivan Maslyankov- Technical analyst

Harriet Wilson- Project manager

Date- 17 June 2024

Appendix A Related NICE Guidance: Laparoscopic procedures

Interventional procedures guidance

- Standard arrangements recommendations for urological cancers include:
    - Laparoscopic cryotherapy for renal cancer (2011) NICE interventional procedures guidance 405
    - Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE interventional procedures guidance 326
    - Laparoscopic cystectomy (2009) NICE interventional procedures 287
    - Laparoscopic deroofing of simple renal cysts (2007) NICE interventional procedures guidance 226
    - Laparoscopic nephrolithotomy and pyelolithotomy (2007) NICE interventional procedures guidance 212
    - Laparoscopic insertion of peritoneal dialysis catheter (2007) NICE interventional procedures guidance 208
    - Laparoscopic radical prostatectomy (2006) NICE interventional procedures guidance 193
    - Laparoscopic partial nephrectomy (2006) NICE interventional procedures guidance 151
    - Laparoscopic nephrectomy (including nephroureterectomy) (2005) NICE interventional procedures guidance 136
    - Laparoscopic live donor simple nephrectomy (2004) NICE interventional procedures guidance 57
    - Laparoscopic pyeloplasty (2004) NICE interventional procedures guidance 46

- Standard arrangements recommendations for gynaecology include:
    - Minimally invasive radical hysterectomy for early-stage cervical cancer (2021) NICE interventional procedures guidance 639
    - Laparoscopic techniques for hysterectomy (2007) NICE interventional procedures guidance 239

- Standard arrangements recommendations for breast surgery include:
    - Laparoscopic mobilisation of the greater omentum for breast reconstruction (2008) NICE interventional procedures guidance 253

- Standard arrangements recommendations for general surgery including the upper and lower gastrointestinal system include:
    - Single-incision laparoscopic cholecystectomy (2014) NICE interventional procedures guidance 508
    - Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedures guidance 503
    - Laparoscopic gastrectomy for cancer (2008) NICE interventional procedures guidance 269
    - Laparoscopic distal pancreatectomy (2007) NICE interventional procedures guidance 204
    - Laparoscopic liver resection (2005) NICE interventional procedures guidance 135

NICE Guidelines

- Colorectal cancer (2020) NICE guideline NG151
- Prostate cancer: diagnosis and management (2019) NICE guideline NG131
- Diverticular disease: diagnosis and management (2019) NICE guideline NG147
- Ectopic pregnancy and miscarriage: diagnosis and initial management (2019) NICE guideline NG126
- Pancreatitis (2018) NICE guideline NG104
- Endometriosis: diagnosis and management (2017) NICE guideline NG73
- Gallstone disease: diagnosis and management (2014) Clinical guideline CG188
- Fertility problems: assessment and treatment (2013) Clinical guideline CG156

Other NICE guidance

- Laparoscopic surgery for colorectal cancer (2006) Technology appraisal guidance TA105
- Laparoscopic surgery for inguinal hernia repair (2004) Technology appraisal guidance TA83

Commissioning policies

- Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery (2016) - commissioned
- Clinical Commissioning Policy: Robotic assisted lung resection for primary lung cancer (2016) - not commissioned
- Clinical Commissioning Policy: Robotic assisted surgery for oesophago-gastric cancers (2016) - not commissioned
- Commissioning Policy: Robotic Assisted Surgery for bladder cancer (2016) - not commissioned
- Clinical Commissioning Policy: Robotic assisted trans-oral surgery for throat and voice box cancers (2016) - not commissioned

RAS acknowledged as a variation of MIS in the following:

- Minimally invasive radical hysterectomy for early-stage cervical cancer NICE Interventional procedures guidance 686
- Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse NICE Interventional procedures guidance 669
- Laparoscopic ventral mesh rectopexy for internal rectal prolapse NICE Interventional procedures guidance 618
- Sacrocolpopexy using mesh to repair vaginal vault prolapse NICE Interventional procedures guidance 583
- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse NICE Interventional procedures guidance 577
- Endoscopic radical inguinal lymphadenectomy NICE Interventional procedures guidance 398
- Transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy NICE Interventional procedures guidance 484
- Laparoscopic cystectomy NICE Interventional procedures guidance 287
- Laparoscopic prostatectomy for benign prostatic obstruction NICE Interventional procedures guidance 275
- Laparoscopic radical prostatectomy NICE Interventional procedures guidance 193

Questions for the scoping workshop

Population

1. Is the term soft-tissue procedures meaningful and informative in the context of this evaluation?

2. Is the list of procedures outlined in the draft scope appropriate?

    a. Which specialties should we prioritise?

    b. Is it appropriate to exclude prostatectomy, given it RAS is established in the care pathway?

    c. Should any other subgroups be assessed?

Intervention

3. Is the definition of robotic platform appropriate and complete?

4. Are there any other technologies that should be included in this assessment?

Comparators

5. Is this the most appropriate comparator for this evaluation?

Outcomes

6. Are all of the listed outcomes suitable for inclusion in the assessment?

    a. Are the listed primary outcomes the most important?

Other considerations

7. Have all of the costs associated with the purchase and ongoing use of RAS systems been identified?

8. Are there any other potential equalities issues that should be considered?

9. Are there any other barriers to implementation that are relevant to the scope of the EVA?

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

NICE Medical Technologies Advisory Committee

Please read the guide to completing a submission fully before completing this template.

Information about your organisation	
Organisation name	Bowel Cancer UK
Contact person's name	Sarah Milne
Role or job title	Policy Officer
Email	
Telephone	
Organisation type	Patient/carer organisation (e.g. a registered charity) ☒ Informal self-help group ☐ Unincorporated organisation ☐ Other, please state:
Organisation purpose (tick all that apply)	Advocacy ☒ Education ☒ Campaigning ☒ Service provider ☒ Research ☒ Other, please specify:

What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)?

We are the UK's leading bowel cancer charity. We are determined to save lives and improve the quality of life of everyone affected by bowel cancer by championing early diagnosis and access to best treatment and care. We support and fund targeted research, provide expert information and support to patients and their families, educate the public and professionals about the disease and campaign for early diagnosis and access to best treatment and care. The majority of our income is generated from individual, corporate and trust fundraisers. A small proportion is given by pharmaceutical and medical device

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Patient Organisation Submissions for Medical Technologies - Submission Template

companies in support of patient and healthcare professional education days and award-winning information sources.

Registered Charity Number 1071038 (England and Wales) and SC040914 (Scotland) and a company limited by guarantee number 3409832.

Registered office: Bowel Cancer UK, Unit 301, Edinburgh House, 170 Kennington Lane, London SE11 5DP.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

If you haven't already, please register as a stakeholder by completing the stakeholder registration form and returning it to medtech@nice.org.uk

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Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

The information gathered on bowel cancer patient experience with robot-assisted surgery (RAS) has been sourced via an anonymous survey which was created using Microsoft Forms and posted on our Bowel Cancer UK patient forum for 3.5 weeks. 8 detailed responses were collected from patients.

Commented [JB1]: Just checking in case you meant microsoft forms

Commented [JB2]: The numbered bullets need sorting out

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

Impact of the symptoms, condition or disease

1. How do symptoms and/or the condition or disease affect people's lives or experiences?

A bowel cancer diagnosis is life-changing and can affect almost every aspect of daily life, not only for the individual diagnosed but also for their family and loved ones. This is even more acute for those diagnosed at the later stages of the disease, when it is harder to treat, and the chance of survival is lower. Patients experience numerous difficulties and challenges across the pathway, from getting an initial diagnosis to timely treatment and care. These challenges relate to the impact and reality of an advanced bowel cancer diagnosis, the difficulty and complexity in navigating treatment and care pathways and the impact treatment can have on quality of life.

Our community told us:

- *" … came as a shock … I have had to work hard on regaining my physical health but I am fortunate to have been through therapy in the past for my mental health which has helped massively in coming to terms with the diagnosis and helped me to keep a positive outlook on my condition"*
- *"… on diagnosis it was utter shock"*
- *"… limited pain after op, but on return home had back problems for 3 months. In some ways I am finding emotionally harder now, with the fear especially around blood tests etc. I also find it difficult with bowel problems and flatulence which gets me down"*
- *"… was like my life had ended when diagnosed. Bad side-effects on chemo post op, op was a dream though, felt better very soon"*
- *"The diagnosis is terrifying – the treatments are hard and I now live with a stoma"*
- *"Traumatising, it's taken so much from me. Heightened anxiety. Fear for my children. I don't think words can even describe it"*
- *"huge shock"*
- *"Worrying, tiredness"*

2. How do symptoms and/or the condition or disease affect carers and family?

Shock and/or fear at their bowel cancer diagnosis emerged as the main theme from patients and their family, telling us:

- *"… came as a shock to my wife and myself"*
- *"… the hardest bit was telling my son, he was 19 when I was diagnosed and he cried. I had made him cry. I was devastated, but I couldn't show it"*
- *"… Fear for my children"*
- *"… huge shock to me, my husband and family"*

This shows how a bowel cancer diagnosis affects family and loved ones as well as the patient themselves.

3. Are there groups of people that have particular issues in managing their condition?

N/A

Experiences with currently available technologies

4. How well do currently available technologies work?

N/A since the survey focused on patient experience with RAS.

5. Are there groups of people that have particular issues using the currently available technologies?

N/A since the survey focused on patient experience with RAS.

About the medical technology being assessed

6. For those <u>with</u> experience of this technology, what difference did it make to their lives?

The patient responses around this question were overwhelmingly positive. They largely praised the speed of the procedure and the recovery time, as well as the ease at which recovery took place, with minimal side-effects and discomfort. Lack of scarring was also highlighted as a key advantage of the procedure. Patients shared that the length of the procedure and the recovery time meant that they were able to return to their usual activities more quickly, such as work and family life, suggesting broader quality of life as well as productivity benefits. One patient expressed that this procedure likely has a positive impact on hospital capacity and bed availability.

Our community told us:

- *"very fast"*
- *"… the pain relief was fantastic"*

- *"incredible (but painful)"*
- *"treatment was quick (and fantastic!)"*
- *"RAS is definitely a great advancement in treatment. I was able to leave hospital after 5 days which obviously has a positive impact on hospital bed availability and so helps the hospital to meet the growing demand for bed space. I also found that my recovery was quicker than I had anticipated and was able to return to as near normal as possible much sooner than I had expected"*
- *"Robotic operation was so much easier to recover from, it was easier to get back some sort of fitness"*
- *"… utterly fantastic, no side-effects, up and back to normal activity in a few weeks"*
- *"… very few side-effects"*
- *"I felt I healed much quicker following the robotic surgery, I have much less scarring and the operation was much quicker"*
- *"I healed so quick with the robotic surgery for my resection, barely any scars"*
- *"… I will return to work and normal family life much quicker than I would have done [with other surgery]. I am 7 weeks post-surgery and doing amazing with very little discomfort"*

7. For those without experience of the technology being assessed, what are the expectations of using it?

N/A since the survey focused on patient experience with RAS.

8. Which groups of people might benefit most from this technology?

The majority of patients from our community shared that they believe that most people should have access to RAS, telling us:

- *"I think any operation that can benefit from robotic would be beneficial, especially if the patient has other medical issues"*
- *"Everyone"*
- *"All should have this option"*
- *"I feel that most patients would benefit from this type of surgery"*
- *"If possible, it should be available to everyone"*
- *"All deserve a chance with the robot"*
- *"… the more it can be used the better"*

Additional information

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9. Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)

With the patient responses from the previous question in mind (**8.**), the vast majority of survey respondents expressed gratitude and luck to have been treated with RAS. This may be indicative of the fact that not all patients will have access to RAS, which is something to consider with health inequalities and 'postcode lotteries' in mind.

One patient also shared that they were part of an Enhanced Recovery Programme, suggesting that this could be something to consider in combination with RAS.

Our community told us:

- *"I feel so sorry to hear others in different areas are not so lucky"*
- *"I was also part of an Enhanced Recovery Programme … was amazing … This is maybe something that could work very well in tandem with robot-assisted surgery*

Key messages

10. In up to five statements, please list the most important points of your submission.

1. **Quick recovery time** emerged as a main theme from patient responses to the survey, with patients emphasising how quickly they could resume to their usual activities following RAS.
2. **Ease of recovery** was another important theme that surfaced from the survey, with patients repeatedly highlighting the lack of side-effects and discomfort as well as pain-relief following RAS.
3. **Minimal scarring** was also frequently mentioned by participants, indicating this as another benefit of RAS.
4. Broader positive implications of RAS were also raised in the survey, relating to **family life**, **work life**, **physical health**, as well as **hospital capacity** issues.

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

NICE Medical Technologies Advisory Committee

Please read the guide to completing a submission fully before completing this template.

Information about your organisation	
Organisation name	Fight Bladder Cancer
Contact person's name	Lydia Makaroff
Role or job title	Chief Executive
Email	[redacted]
Telephone	[redacted]
Organisation type	Patient/carer organisation (e.g. a registered charity) ☒ Informal self-help group ☐ Unincorporated organisation ☐ Other, please state:
Organisation purpose (tick all that apply)	Advocacy ☒ Education ☒ Campaigning ☒ Service provider ☒ Research ☒ Other, please specify:
What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)? Fight Bladder Cancer represents a broad community of people diagnosed with bladder cancer and caregivers across the UK. Our membership includes thousands of individuals affected by bladder cancer, spanning a diverse range of demographics but united by a common condition.	

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

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Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

Direct feedback, surveys, and personal stories collected through our support networks, patient forums, and surveys conducted in collaboration with medical researchers.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

Impact of the symptoms, condition or disease

1. How do symptoms and/or the condition or disease affect people's lives or experiences?

Bladder cancer severely affects the emotional well-being of people, with younger people experiencing the most substantial impacts across multiple aspects of life. Emotional support is notably lacking, as many people were not offered help to cope with the psychological burden of their diagnosis. Financial challenges are also prominent, especially among younger and advanced-stage patients.

Makaroff, L. E., Filicevas, A., Boldon, S., Hensley, P., Black, P. C., Chisolm, S., ... & Kamat, A. M. (2023). Patient and carer experiences with bladder cancer: results from a global survey in 45 countries. Eur Urol, 84, 248-51.

2. How do symptoms and/or the condition or disease affect carers and family?

Carers face substantial challenges, with many expressing emotional distress and a lack of sufficient information to effectively support their loved ones.

Makaroff, L. E., Filicevas, A., Boldon, S., Hensley, P., Black, P. C., Chisolm, S., ... & Kamat, A. M. (2023). Patient and carer experiences with bladder cancer: results from a global survey in 45 countries. Eur Urol, 84, 248-51.

3. Are there groups of people that have particular issues in managing their condition?

Groups particularly affected include: (1) older adults, who are most commonly diagnosed with bladder cancer and may have other co-morbidities that complicate management and treatment; (2) women, who are more commonly diagnosed later and have worse outcomes; (3) younger people, who are more likely to suffer later diagnosis and financial distress due to the condition.

Makaroff, L. E., Filicevas, A., Boldon, S., Hensley, P., Black, P. C., Chisolm, S., ... & Kamat, A. M. (2023). Patient and carer experiences with bladder cancer: results from a global survey in 45 countries. Eur Urol, 84, 248-51.

Experiences with currently available technologies

4. How well do currently available technologies work?

The iROC study compared recovery times and health outcomes between robot-assisted and traditional open surgery for people diagnosed with bladder cancer. Conducted across 9 UK sites from 2017 to 2020, the trial involved 338 participants who were randomly assigned either to undergo robot-assisted surgery or the conventional open method. Those

who had robotic surgery spent slightly more days at home (rather than at the hospital) in the first 90 days after surgery compared to those who had open surgery. Robotic surgery resulted in fewer complications like blood clots and wound issues, and people reported better quality of life shortly after surgery. However, there was no significant difference in cancer recurrence or overall mortality between the two groups after about 18 months of follow-up.

In this study, neoadjuvant chemotherapy, which is chemotherapy given before surgery to shrink tumours, was used for 34% of the participants. Generally, in the UK, neoadjuvant chemotherapy is quite common, with about 48% of suitable people receiving it, typically involving 3 to 4 cycles of specific chemotherapy drugs. After the chemotherapy, 24% of these people showed no remaining cancer during surgery, and 12% had significant reduction in tumour size.

Catto, J. W., Khetrapal, P., Ricciardi, F., Ambler, G., Williams, N. R., Al-Hammouri, T., ... & iROC Study Team. (2022). Effect of robot-assisted radical cystectomy with intracorporeal urinary diversion vs open radical cystectomy on 90-day morbidity and mortality among patients with bladder cancer: a randomized clinical trial. JAMA, 327(21), 2092-2103.

Catto, J. W., Khetrapal, P., Ambler, G., & iROC Study Team. (2022). Effect of Robot-Assisted Radical Cystectomy vs Open Radical Cystectomy on 90-Day Morbidity and Mortality Among Patients With Bladder Cancer—Reply. JAMA, 328(12), 1258-1259.

5. Are there groups of people that have particular issues using the currently available technologies?

Rural people face particular challenges with the currently available healthcare technologies and services. Rural people experience longer wait times for diagnosis, less clear communication from doctors regarding testing, and more difficulties related to traveling for treatment compared to their urban counterparts. Rural residents may benefit from targeted improvements in healthcare access and communication, as well as enhanced support for travel to treatment facilities.

Makaroff, L., Filicevas, A., Hensley, P. J., & Kamat, A. M. (2024). Experiences of patients with bladder cancer: A comparison of urban and rural areas. JCO 42, 568-568(2024). DOI:10.1200/JCO.2024.42.4_suppl.568

About the medical technology being assessed

6. For those <u>with</u> experience of this technology, what difference did it make to their lives?

The varied responses to robotic-assisted surgeries for bladder cancer, shared by members of the Fight Bladder Cancer community, illustrate a range of outcomes.

Most reported rapid recoveries, minimal scarring, and quick returns to daily activities, a few experienced severe complications. Most participants praised the benefits of faster recovery times compared to traditional surgeries, with activities resuming within weeks and minimal pain management required post-surgery.

"I had robotic surgery to remove my bladder. I was out of bed the following day and walked the length of the ward. I did this every day for the 9 days I remained in hospital. Recovery was non-eventful, and I would recommend this type of surgery." Wendie, bladder cancer patient

However, a small minority of people had multiple complications and severe outcomes.

"My bladder surgery was done robotic. First of all it cut through my bowel and left it open, they opened me back up again to fix it and twisted my tubes so then I got sepsis. This is three operations in less than two weeks. My wife was told twice that the next 24 hours were crucial as I might die in that time." Tony, bladder cancer patient

7. For those without experience of the technology being assessed, what are the expectations of using it?

Many anticipate that robotic surgery could lead to shorter hospital stays, less postoperative pain, and faster recovery times compared to traditional surgeries. There's also an expectation of smaller incisions, which could result in less scarring. People often hope for a high degree of precision from the robotic technology, which might lead to better surgical outcomes and fewer complications. Patients expect a quicker return to normal activities and less overall impact on their quality of life.

“With only a few small incisions I would expect that the recovery time with Robotic Assisted to be far faster than the traditional method." Ian, bladder cancer patient

8. Which groups of people might benefit most from this technology?

Robotic surgery might be particularly beneficial for people with physical limitations, obesity, or fatigue from chemotherapy.

Catto JWF, Khetrapal P, Ambler G, iROC Study Team. Effect of Robot-Assisted Radical Cystectomy vs Open Radical Cystectomy on 90-Day Morbidity and Mortality Among Patients With Bladder Cancer—Reply. JAMA. 2022;328(12):1258–1259. doi:10.1001/jama.2022.13600

Additional information

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

9. Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)

Ensuring that both urban and rural people have equal access to treatments without burdensome travel. Technologies such as telemedicine can improve communication and understanding, especially in underserved areas.

Ethical considerations must guide the deployment of medical technologies to prevent widening health disparities, ensuring all demographic groups benefit equally and contribute to overall better health outcomes.

Key messages

10. In up to five statements, please list the most important points of your submission.

- Bladder cancer significantly affects people' emotional well-being, particularly among younger individuals, with a notable lack of emotional support. Financial challenges are also prevalent, especially for younger and advanced-stage patients.
- Carers of people diagnosed with bladder cancer experience considerable emotional distress and often lack adequate information to effectively support their loved ones.
- Women, and younger people face specific challenges in managing bladder cancer, including late diagnoses and greater financial burdens.
- People who have undergone robotic-assisted surgeries report varied outcomes; many experience rapid recoveries and minimal scarring, while a minority face severe complications. Those without experience have high expectations for the technology, anticipating shorter recovery times and less pain.
- Robotic surgery is seen as particularly beneficial for people with physical limitations, those who are overweight, or those experiencing fatigue from chemotherapy, offering potential for less invasive procedures and quicker recovery.

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

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Patient Organisation Submissions for Medical Technologies - Submission Template
NICE Medical Technologies Advisory Committee

Please read the guide to completing a submission fully before completing this template.

Information about your organisation	
Organisation name	Lobular Breast Cancer U.K.
Contact person's name	Lorna McHattie
Role or job title	Research Group member
Email	[redacted]
Telephone	[redacted]
Organisation type	Patient/carer organisation (e.g. a registered charity) ✔ Informal self-help group Unincorporated organisation Other, please state:
Organisation purpose (tick all that apply)	Advocacy ✔ Education ✔ Campaigning ✔ Service provider Research ✔ Other, please specify:
What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)? **We cover the United Kingdom. We are run by a small group of patients (<20) who have had a diagnosis of Lobular Breast Cancer. Clinicians, healthcare professionals and researchers are on our Board and Scientific Advisory Group.**	

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Patient Organisation Submissions for Medical Technologies - Submission Template

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Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

We meet as a group of patients every 2 months or so. Patient experiences are also gathered through social media:
Facebook (Linking Lobular Ladies, closed group), which has a membership of over 1000. Membership is for those living and being treated in the U.K.
Instagram which has 850 followers
X which has 1000 followers
We also collaborate with DMU for patient-led research, which we are in the process of writing up.

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Patient Organisation Submissions for Medical Technologies - Submission Template

Impact of the symptoms, condition or disease

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

1. **How do symptoms and/or the condition or disease affect people's lives or experiences?**

2. Lobular BC accounts for 10-15% of all breast cancers and is under-researched. In addition, due to the nature of Lobular BC, it is especially difficult to identify in dense breasts.

3. The pathophysiology is different from the better known Ductal BC. Diagnosis, treatment and monitoring has been developed mainly considering Ductal BC, which more commonly forms a lump. Lobular BC patients lack e-cahedrin which results in cancer cells presenting as discohesive single celled strings, which are very difficult to identify by mammogram. 40% of Lobular BC tumours are not found by mammogram. Lobular BC tumours tend to found later than Ductal BC tumours and are commonly larger which necessitates mastectomy more frequently.

4. Lobular BC also has a different recurrence profile, more commonly being 5-15 years post-diagnosis. Current breast cancer protocols for post-treatment monitoring is 5-10 years of mammogram, which is more appropriate for identifying Ductal BC.

5. Overall

Lobular BC is difficult to diagnose

Patients are often unaware of the difference of Lobular and Ductal BCs in terms of treatment and monitoring, there is a significant need for education. There is also a need for clinical and healthcare education.

Lobular BC carries a significant psychological burden due to: the unpredictability of the recurrence pattern and timescale. 25% of Lobular patients will have a recurrence, perhaps as late as 15 years after initial diagnosis. Patients are told to vigilant and also to be aware of different metastases sites.

Lobular BC metastases can present as single line cells in the peritoneum, meninges, bones, ovaries, bowel, as well as the liver and lungs. The challenge is to identify early symptoms, as there is often to lump.

Patients report:

Repeated failure to be diagnosed (often repeated mammograms)

Lack of awareness of clinicians and healthcare staff in taking into account count the challenges of Lobular BC, especially in terms of the over reliance of protocols designed for Ductal BC

High levels of anxiety

Having to advocate for themselves in terms of Lobular appropriate protocols. LBCUK has been instrumental in developing a referenced letter to clinicians to campaign for MRI followup, rather than mammogram. The latter providing no psychological comfort and is often ineffective at identifying tumours.

2.**How do symptoms and/or the condition or disease affect carers and family?**

As recurrence is hard to identify and occurs over a long timescale, patients can be anxious, and/or try not to worry family members with the constant worry, so may become distant/ have mood changes, which affects relationships.

The main long term treatment, to prevent recurrence is hormone therapy. This medication very commonly causes stiffness and joint pain, cognitive issues, tissue dryness. Vaginal atrophy is common with significant loss of libido, due to oestrogen-stripping nature of the medication. This commonly affects couples' relationships.

3.Are there groups of people that have particular issues in managing their condition?

A significant proportion of patients with Lobular BC would have issues managing their condition, as hormone therapy causes joint pain, causing difficulty in exercising. The medication and lack of exercising often results in weight gain.

Due to the nature of Lobular BC, the constant vigilance for new pain or bodily changes is very wearing

Experiences with currently available technologies

4. How well do currently available technologies work?

The first and most important issue for patients with LobularBC is that many will not be diagnosed by the technology which most women rely upon - mammograms will fail 40% of tumour identification.

Ultrasound is more effective, but usually quantifies the tumour size as significantly smaller than the reality.

MRI with contrast identifies most Lobular BC tumours. Many patients want MRI monitoring rather than mammograms, but this carries the risk of side effects due to the contrast chemicals.

Many patients with LobularBC have mastectomies, many of them have reconstruction surgery and many of these will require additional surgery to rectify a failed or inadequate reconstruction. Would robotic surgery help to reduce these costly extra surgeries?

5. Are there groups of people that have particular issues using the currently available technologies?

Some women find mammogram too painful.

Around 10% of all patients offered a MRI will refuse it due to claustrophobic or excessive noise.

About the medical technology being assessed

6. For those <u>with</u> experience of this technology, what difference did it make to their lives?

7. Robotic-assisted surgery is not something which is being discussed by patients on the LBCUK social media platforms

7. For those <u>without</u> experience of the technology being assessed, what are the expectations of using it?

Robotic-assisted surgery is not something which is being discussed by patients on the LBCUK social media platforms

8. Which groups of people might benefit most from this technology?

All patients with Lobular BC could benefit from robot-assisted surgery.

Additional information

9. Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)

There is a shortage of surgeons, so this could help the NHS provide a better service.

It could reduce surgery times, freeing the operating rooms for more patients.

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Patient Organisation Submissions for Medical Technologies - Submission Template

Key messages

10. In up to five statements, please list the most important points of your submission.

- **Lobular BC patients are often diagnosed later than Ductal BC patients due to the nature of the disease. They are commonly missed by mammograms in the public health screening programme.**
- **Lobular BC patients may need more mastectomies than lumpectomies than Ductal BC patients, so more extensive surgeries, taking up more operating theatre time.**
- **Lobular patients with secondary cancer may have tumours in unusual areas such as peritoneum, meninges, bones, which would benefit from robot-assisted surgery.**
- **The NHS is experiencing difficulties in recruiting surgeons in certain geographical areas eg Aberdeen and robot-assisted surgery could help improve access to timely treatment by speeding up surgeries**
-
-
-
-

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

NICE Medical Technologies Advisory Committee

Please read the guide to completing a submission fully before completing this template.

Information about your organisation		
Organisation name	Ovacome ovarian cancer charity	
Contact person's name	Cathryn Gort	
Role or job title	Support Services Officer	
Email	[redacted]	
Telephone	[redacted]	
Organisation type	Patient/carer organisation (e.g. a registered charity)	☒
	Informal self-help group	☐
	Unincorporated organisation	☐
	Other, please state:	
Organisation purpose (tick all that apply)	Advocacy	☒
	Education	☒
	Campaigning	☒
	Service provider	☒
	Research	☐
	Other, please specify:	Support and information

What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)?

Ovacome is the national UK ovarian cancer charity focused on providing support and information to anyone affected by ovarian cancer. This includes people who have either been diagnosed with the disease or think that they might be at risk, as well as their friends and family and healthcare professionals.

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Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

We currently have 5316 members and we have 17 members of staff.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

If you haven't already, please register as a stakeholder by completing the stakeholder registration form and returning it to medtech@nice.org.uk

Further information about registering as a stakeholder is available on the NICE website.

Did you know NICE meetings are held in public? You can register on the NICE website to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place. Up to 20 places will be available, depending on the size of the venue. Where meetings are oversubscribed NICE may need to limit the number of places we can offer.

Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

We used our knowledge and experience from providing support to those affected by ovarian cancer and those who have had surgery as a treatment for ovarian cancer.

We requested feedback from our members via our 'My Ovacome online community. Two people responded to this request and we spoke to them both individually.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

Impact of the symptoms, condition or disease

Ovarian cancer has a significant impact on quality of life. The majority are diagnosed at Stage III when it has already spread outside of the pelvis. This means they can experience symptoms impacting their health and quality of life, such as ascites. Treatment is therefore aimed at minimising the burden of the disease and maximising periods of wellness between treatments. As treatment lines are exhausted, those diagnosed fear being told there is no more treatment available to manage their ovarian cancer.

Cytoreductive surgery is commonly used as a treatment of ovarian cancer. The procedure undertaken in the first line setting is most usually a laparotomy for total abdominal hysterectomy, bilateral salpingo-oophorectomy (TAHBSO) and omentectomy. This operation can have long term effects on abdominal organs and particularly the bowel with associated continence issues. In some cases, surgery results in the formation of a stoma. This means having to manage a stoma, either short or long term. TAHBSO will also result in immediate surgical menopause.

Associated issues include fatigue, possible chronic pain and changes to body image and function affecting sexuality. Despite these long-term side effects our members report being very motivated to undergo surgery both at initial diagnosis and at recurrence. They are aware that surgery resulting in no residual macroscopic disease is associated with better prognosis. In some circumstances, secondary surgery is considered to treat a recurrence of ovarian cancer.

Long-term effects of chemotherapy treatment can include peripheral neuropathy which can limit both walking mobility and ability to drive.

These physically and psychologically debilitating side effects can impact relationships, work and caring roles permanently.

Those diagnosed live with the anxiety of possible recurrence. The time after treatment whereby patients are under routine surveillance can be psychologically very hard to cope with. Our members report feeling adrift and as if they are waiting for their disease to return.

Having a diagnosis of ovarian cancer can have a significant impact on finances, not just on the individual with a diagnosis, but also on the wider family. This is due to a number of reasons including loss of earnings, the cost of travel to and from hospital appointments and the costs involved due to side effects of ovarian cancer such as wigs, scarfs and clothing.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

8. How do symptoms and/or the condition or disease affect carers and family?

For both those living with ovarian cancer and their friends, family and carers, ovarian cancer can be very isolating. Due to its comparative rarity they may not meet anyone else with the same condition or facing the same issues of living with ovarian cancer.

Having a diagnosis of ovarian cancer can have a significant impact on relationships with partners, friends and family members and on day-to-day life. Those closest to the person diagnosed can find themselves taking on a caring role or no longer being cared for by those closest to them; being the primary seeker of information and treatment options; being the primary income earner and taking on other roles to which they are unaccustomed.

We support anyone affected by ovarian cancer and this includes friends and family members. Having someone close to you diagnosed with ovarian cancer can have a significant emotional impact and people may find they need ongoing emotional and psychological support.

9. Are there groups of people that have particular issues in managing their condition?

We know that some people with ovarian cancer can struggle to access treatments if they don't fully understand treatment options and choices. This may include people with learning disabilities, people who have English as a second language or who have low levels of literacy.

It is important that all patients have equal access to this treatment option where clinically appropriate, and that includes detailed understanding of risk-benefits. It is essential that all patients' information and support needs are assessed on an individual basis and that risk-benefit conversations take place in an appropriate and accessible manner. These should take into consideration patient preferences such as preferred language and preference for face to face, or over the phone appointments.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

Experiences with currently available technologies

10. How well do currently available technologies work?

11. Are there groups of people that have particular issues using the currently available technologies?

One of our members who has a diagnosis of congenital Ehlers Danlos Syndrome shared:

"I have Ehlers Danlos syndrome and if I had not had robotic surgery, I would have triggered my Ehlers Danlos and in my experience, I mean, I don't think I would have recovered physically at all, I don't think I would be walking. I think it would have been catastrophic to have surgery any other way other than by robotic surgery because Ehler Danlos affects the whole of my body, and when I have had any episodes, of which I have had four in my life in the space of 20 years, each time, and that was not from an operation, it was from simply moving the wrong way, it has taken me two years to recover and I have been not walking for a year or so and then it has taken me another year to walk again. So, to do open would surgery from my ribcage to my pubis, I would never have recovered."

About the medical technology being assessed

6. For those <u>with</u> experience of this technology, what difference did it make to their lives?

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

Robot-assisted surgery is not commonly used as a treatment for ovarian cancer, but it is an area of research (MIRRORS trial). Two of our online community members shared their experiences of having this treatment.

One of our members shared: “I am grateful beyond words that I had robotic surgery and I had no ED [Ehlers Danlos] problems at all in any part of my body after the robotic surgery which took around 10 hours and that is miraculous that they could do that. There is only one word that sums up that surgery and which is miraculous for me. Every day I bless those two surgeons for what they did for me. It obviously makes me quite emotional, it was a difference between what would be catastrophic and what meant that I was fine. As well as the removal of the cancers, it was the method of surgery that was miraculous”.

Our member shared details of her surgery as she felt that it was important to capture: “They did a massive operation on me and they took out organs. On the discharge letter is says ‘Da Vinchi Robot assisted radical hysterectomy, laparoscopic bilateral salphingo oophrectomy, excision of R pelvic node, appendicectomy, bilateral ureterolysis, supracolic omentectomy and partical gastrectomy. I think it’s important as it shows how extensive that operation was”

In terms of recovery after the procedure our member shared: “I was five days in intensive care after the operation. But I think that the length of that stay was partly because they didn’t have a bed to move me to. I never had any pain at any time after the operation, which I can’t understand why, but I never did. It was miraculous. I had five,1cm cuts on my stomach”.

Our member also shared how she was able to joke with her consultant the next day after her operation: “So, that will give you an idea of what my mood was immediately after I’d come round from the surgery, that I was able to laugh and joke with him”.

Our member continued: “After the five days in intensive care, I was five days in the general cancer ward so all in all I was in hospital for 10 days which I believe is longer than the usual sort of time spent for women recovering from robotic surgery, but I don’t really know why I was kept for 10 days. Maybe it was because it wasn’t just a radical hysterectomy, it was everything else that they did. I don’t know, I never asked the question anyway. So, I came home and I didn’t have any pain whatsoever but for the next six weeks I was extremely tired. Because I’ve got EDS, I wouldn’t lie in bed because I knew that would weaken my muscles so I used to get up every day out of bed and sit around. I had to have help in the home, I couldn’t have made myself even a ready meal or anything, I was completely fatigued. I couldn’t even, and I’m a person who puts a great deal of emphasis on my physical appearance and I’m always smart, even if it’s just for me, it’s just my way and it has always been my way, I couldn’t get dressed because I was so tired I just didn’t have the energy to get dressed”.

“They did warn me I think beforehand I remember they said the operation would be like running 10 marathons, so the fact that I was so fatigued I think fitted into that picture and

would probably not be exceptional. But my stamina came back and my stamina is what I would regard as normal for a 77 year old woman or 76, whatever I was. Even though I was on olaparib and everything after, I didn't, once I'd actually recovered my fatigue from the surgery, then my stamina levels returned to normal for a woman of my age. It's just miraculous, absolutely".

The second person we spoke to has had robot-assisted surgery twice as a treatment for ovarian cancer. When asked "What difference did it make to you having this surgery?", they replied:

"So it meant I didn't, robotic surgery compared to open surgery… it means that I didn't have a foot long incision line through open surgery and I had five port sites instead. If you added them together it would be a smaller incision so ultimately a quicker recovery time and shorter inpatient stays as well, which meant as a self-employed person who wouldn't get paid sick pay also financially I had a lot less downtime. So, for my first robot-assisted operation I had two days off of work in total, including recovery, I am predominately home-based so that did make a difference, but I had two days off as I was mid-contract and wasn't expecting to get cancer. And then my second operation I had one day off, surgery tends to happen on a Thursday or Friday or Thursday and then a day off, and then the weekend and then back at work on the Monday. So, I basically could have downtime.
I think also having less scarring or less visible scarring because the port sites are sort of in line with the navel are less visible, so, not that I go on beaches in bikinis, but in underwear you don't see them and that makes it easier I think for family and stuff like that. My partner finds any operation stuff really difficult, you know you can't even talk about 'cause he finds it really challenging, so for me personally, not to have visible scars all of the time, was quite helpful in not causing them difficulties as well. I mean ultimately quicker recovery time, back to work which lessens financial impact on the household 'cause I am the main earner as well".

Referring to the second surgery that they had: "…I had one day in hospital, like overnight so went on the Thursday, pretty much worked up until the operation, and then had the operation, stayed overnight and was discharged the next about just after lunchtime the next day. And then 'cause it's, the hospital's around a four hour round trip pretty much for me, both operations were done, they weren't in my local area, as I couldn't get them done in London 'cause they wouldn't take me or accept it, and then so it's round trip. So I then booked myself into a hotel for week down there, and just like self-cared basically for myself and I got a lot of Deliveroo to reception, and so for me again I know that's slightly unusual, but for me that works…It is difficult because I still have pain now. I still, I don't know, like post-surgery I had some, I healed up fine and stuff like that and within like three weeks I was out roller skating with friends and I've gone back, …, so I was back on the limited basis doing that three weeks after my second surgery so it shows it shows how quickly you can go back to normality.

You have to be a bit a bit safe I wasn't you know, I was safe as well didn't really you know require like pain relief and stuff … I was fine pain-wise and mobilising and stuff like that so

I had sort of fairly quickish recovery and going back to work on the Monday, you know as usual working fine, but then also get going in a bit, so for that for that part it's been quite successful around surgery".

Our member went on to share her thoughts on transparency during surgery:

"One of the important things if you're offering robotic surgery, the transparency so that professionals can raise concerns if they see anything untoward, that there needs to be visibility in the surgery to other professionals" They continued: "…robot assisted surgery I would say will be beneficial to patients but with safeguards put in and may be videoing and I did approach to hospital about video of the operations as they probably do video it, I don't know, but I would say that would be an important thing to do for either for training purposes or for reassurances 'cause it's not the same as open surgery as you can't quite see what people are doing, open there is a better view I suppose".

When asked about the advantages of the procedure this member shared the following points:

- Smaller incision sites which will heal quicker so you can be discharged sooner with more chance of avoiding hospital acquired infections
- For the NHS, less nights in hospital, better patient flow which will be cheaper
- People with caring responsibilities can get back to those sooner which will have an impact on health and social care costs
- Quicker recovery having an impact on quality of life
- People may be able to have chemotherapy sooner after surgery as they potentially have healed more quickly
- It's easier to travel with smaller wounds

When asked about the disadvantages this member shared:

- It's an emerging field do less research, less evidence available for patients to make a decision
- Less information about the impact of robot-assisted surgery such as recovery of pain
- Not many people who specialise in this so there may not be an available workforce at the moment
- Cost of the technology
- Transparency "again I'm unclear if there's a screen people can see but transparency about the process and also for people to raise concerns but people understanding the process so they know, the wider staffing team understanding what's right and what's wrong so it's not all dependent on a single surgeon to do what they want to do without challenge…I would like operations recorded and made available to patients should, not everyone will, wish to like you know look at them later on to see what happens inside their own bodies as well"
- Having access to a stock of drapes "there was delays for the lady before me because they had to get in from somewhere else like another hospital or something"

Our member also added: “And also cons might be if you've got, so when I went in for my second surgery because of the potential involvement of bowel they had to have two machines in the same room in case a second bowel surgeon had to come in. Again it depends if the local economies or hospitals can afford, you know what happens if you, you know 'cause you could convert open surgery because you don't have trained staff to do robot- assisted surgery for bowel which is quite common in ovarian cancer for that involvement and things like that.”

When asked if there was anything else that they thought we should capture or share, our member replied:
“Just so yeah, so just for the patient journey, just having like literature available. Obviously I had, well I thought I had a slightly different surgery to other people and a lot of it was just all the same surgery not taking on people's individual needs so it's important to have accurate patient information depending on the stuff you know the needs of the patient rather just generalising for some people will have thought different surgeries and often it's focused around, rather than about retaining hormones, it's focused on younger people retaining fertility which I don't think as a whole, is the whole story”.

“I think with robotic surgery they don't. I don't think they cover information about equipment malfunction, and you know you the whole range of stuff plus longer term health implications”.

7. For those <u>without</u> experience of the technology being assessed, what are the expectations of using it?

8. Which groups of people might benefit most from this technology?

Our members have highlighted the following groups who might benefit:

Those with other chronic conditions which would impact recovery

Those who may find recovery from laparotomy more challenging

Those with working responsibilities

Those with caring responsibilities

National Institute for Health and Care Excellence
Patient Organisation Submissions for Health Technologies- Robot assisted surgery for soft tissue procedures

Additional information
9. Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)

Key messages
10. In up to five statements, please list the most important points of your submission.

- Robot - assisted surgery is not commonly used in the treatment of ovarian cancer, but it is an area of research. As such our points are dependent on the clinical trial results supporting our statements from a wider experience. Our points are based on the two members we interviewed.
- Both our members who had the procedure felt it was vital they were offered the choice of robotic surgery and they strongly self-advocated and pursued this option with their clinical teams.
- Robot assisted surgery offers patients who may find recovery from a laparotomy more challenging, the choice of potentially better recovery times.
- The faster recovery time enables people to return to work and caring roles sooner and therefore has less disruptive impact on their wider lives.
- Robotic surgery can potentially improve the quality of life for patients both in terms of immediate physical recovery and longer-term continued fulfilment of life roles.

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

Sent by email from Lizzie Ellis to Helen Crosbie – Public Involvement Adviser, NICE on 11 June 2024.

Response from Prostate Cancer UK below:

Are you able to comment on what benefits to patients there have been following the introduction of RAS as compared to treatment before RAS?

Yes I believe initially there was some reticence in uptake by patients due to it being new and not the “norm” in terms of surgery but once it had been around for a while we certainly only heard positives with regards to patients having had RAS. Specifically we heard about patients being pleased with healing time, and shorter length of stay in general after their surgery. We hear that men generally want RAS due to its perceived precision and therefore it’s higher potential to preserve sexual function and continence over regular surgery.

Do patients have any concerns around the use of RAS? Do you have any comments of the feasibility of a surgery robot being used for multiple indications with a 'timeshare' arrangement?

I think a main concern on feasibility would be potentially longer waiting times for access, however if more indications were approved for access then presumably more robots should be made available? That and/or training up of more clinical staff to use them.

Lizzie Ellis
Senior Policy Officer

Prostate Cancer UK
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Document cover sheet

Assessment report: Robot-assisted Surgery for Soft-tissue Procedures

EAG team: Rachael McCool, Hayden Holmes, Robert Malcolm, Chris Bartlett, Anne Littlewood, Alice Sanderson, Luc Curtis-Gretton, Emma Bishop, Benjamin Hyde

Project lead(s): Hayden Holmes, Rachael McCool

Information specialist: Anne Littlewood

Clinical evidence reviewer: Rachael McCool, Anne Littlewood, Alice Sanderson, Emma Bishop, Benjamin Hyde

Economic evidence reviewer: Hayden Holmes, Robert Malcolm, Chris Bartlett, Luc Curtis-Gretton

EAG sign-off: Hayden Holmes

Version number	Brief description of changes	Author/reviewer (e.g. J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
1.0	Draft report submitted to NICE	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	22/08/24	22/08/24
1.0	Comments on draft report	Louisa Robinson Ivan Maslyankov Kim Carter Jason Fleming Declan Dunne Prasanna Sooriakumaran Neil Hawkins Liviu Titu	29/8/2024	-

2.0	Final report submitted to NICE	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	06/09/24	06/09/24
3.0	Updates prior to company responses	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	18/09/2024	18/09/2024
4.0	Updates post consultation comments	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	24/09/2024	24/09/2024

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

[GID-HTE10040] - Robot-assisted Surgery for Soft-tissue Procedures

External Assessment Group report

Produced by: York Health Economics Consortium (YHEC)

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Date completed: 24/09/2024

Contains confidential information: Yes

Number of attached appendices: 5

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 and/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.

Acknowledgements

Clinical experts and company representatives for the scoped technologies provided input into this EVA. These are noted within the correspondence log submitted to NICE.

Responsibly 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.

Contents

Abbreviations

Term	Definition
CDSR	Cochrane Database of Systematic Reviews
CENTRAL	Cochrane Central Register of Controlled Trials
CI	Confidence interval
CPCI-S	Conference Proceedings Citation Index - Science
CPRD	Clinical Practice Research Datalink
D_2	Group 2
DHSC	Department of Health and Social Care
DSA	Deterministic sensitivity analysis
EAG	External assessment group
EJP	Economically justifiable price
EUR	Euros
EuraHS QoL	European Registry for Abdominal Wall Hernias quality of life
EVA	Early Value Assessment
GI	Gastrointestinal
HES	Hospital episodes statistics
HPB	Hepato-pancreato-biliary
HRQoL	Health related quality of life
HTA	Health Technology Assessment
IQR	Interquartile range
ICER	Incremental cost-effectiveness ratio
ICTRP	International Clinical Trials Registry Platform
ITT	Intention to treat
LoS	Length of stay
LRC-EA	laparoscopic operation with extracorporeal anastomosis
MDR	Medical Device Regulation
MIS	Minimally invasive surgery
NA	Not applicable
NASA-TLX	NASA Task Load Index
NHS	National Health Service

NHS EED	NHS Economic Evaluation Database
NHSSC	National Health Service supply chain
NICE	National Institute for Health and Care Excellence
NOTECHS	Oxford Non-Technical Skills Scale
NR	Not reported
NS	Not significant
NSAID	Non-steroidal anti-inflammatory drug
OR	Odds ratio
PSA	Probabilistic sensitivity analysis
PSM	Propensity score-based matching
PSSRU	Personal Social Services Research Unit
QALY	Quality adjusted life year
RAS	Robot-assisted surgery
RCT	Randomised controlled trial
REBA	Rapid Entire Body Assessment
RRC-EA	Robotic operations with extracorporeal anastomosis
RRC-IA	Robotic operation with intracorporal anastomosis
SD	Standard deviation
SoC	Standard of care
SP	Single port
SURG-TLX	Surgery task load index
TORS	Trans-oral robotic surgery
VAS	Visual analogue scale
VAT	Value added tax
Vs	Versus

Executive summary

Background

Soft-tissue surgical procedures encompass a range of procedures involving internal organs, the body wall, masses or tumors, and hernias or defects. The target population for this assessment are adults and children having a soft-tissue surgical procedure. This early value assessment summarises the clinical and economic evidence for robotic platforms to support standard surgical care, while also outlining the current evidence gaps for these technologies.

Quality and relevance of the clinical evidence

The EAG considered evidence for all 5 of the scoped technologies identified in a pragmatic review. The objectives and scope of the Early Value Assessment (EVA) process does not include exhaustive assessment of all identified evidence. The included studies were prioritised for synthesis on the basis of relevance to the decision problem, study quality and geographic location. The EAG notes that the pragmatic approach means some relevant, lower quality data may have been deprioritised.

20 comparative studies were prioritised and included, involving patients undergoing a variety of different procedures in different specialties. Six of the studies assessed patients with cancer, and one reported on a paediatric population. The evidence suggests that RAS is generally comparable with current standard of care for primary patient level outcomes. For some of the outcomes there was either no or limited evidence, but where there was evidence available, the results for each technology were aligned. Primary outcomes at a surgeon level (procedure-related discomfort and ergonomics) were only measured by one study. None of the studies reported the organisation-level primary outcomes. It was difficult to compare the results across studies due to unclear definitions or differences in the scales used to measure some of the primary outcomes. Nineteen of the 20 studies were either cohort or non-randomised

studies, and the EAG had concerns over exaggerated treatment effects due to selection bias and an increased risk of confounding. Even where prospective, comparative evidence was available, studies were small and had limited evidence on the primary and secondary outcomes. It is also unclear whether the results from one type of soft-tissue surgery are comparable with other types of surgery. The EAG noted that results could differ for outcomes such as learning curve and operating time depending on surgeon experience and other factors such as the complexity of surgery. Only 3 of the prioritised studies took place in the UK, so it is uncertain how generalisable the results are to a UK population.

Quality and relevance of the economic evidence

A total of 3 economic costing studies were identified by the EAG, with 1 of those costing studies set within an NHS context. The NHS-based study reported potential cost-savings, but omitted key costs from the analysis, including the robotic platform itself. Overall, the quality of the economic evidence was low. The economic analysis conducted by the EAG was a cost-comparison model designed to capture the potential benefit that could be provided from the robotic platforms over a 1-year time horizon. The analysis, capturing a range of different scenarios to reflect heterogeneity across soft-tissue procedures, found that the incorporation of robotic platforms to support standard surgical care in the NHS was likely to be cost incurring. The results of RAS replacing open surgeries would incur less costs than RAS replacing conventional MIS, £177-£396 per procedure compared with £675-£971 per procedure respectively. The analysis found that it is likely that long-term benefit is required from the use of robotic platforms to be cost-effective at a £20,000 per quality-adjusted life year (QALY) threshold. The likely long-term benefit required is an increase of at least 0.10 QALYs per procedure due to robotic platforms (36.5 additional days in perfect health or 10% of one year). Current evidence on the long-term benefits of robot-assisted surgery (RAS) is unknown and so has not been captured. The model results are based on limited data, mixed across a range of different soft-tissue procedures, with a high level of

uncertainty. Therefore, the model results provide a general overview of the average impact of embedding robotic platforms within the NHS, accounting for the cost-benefit of sharing across specialties. However, the results may not represent the expected outcomes within every specific clinical area. Model inputs were sourced through company-provided evidence, published literature, and clinical advice.

Evidence gap analysis

Future evidence should be generated from large, multi-centre prospective studies across a range of surgeries. The EAG recommends at least a twelve month follow up to understand the effect of the learning curve. It would be beneficial to undertake studies in settings where robotic surgery is already established and where it is in the process of being introduced. Studies in this review have all considered one surgery type and there may be indication specific outcomes that are clinically relevant that have not been considered as part of this evaluation. Given that studies which attempt to capture all soft-tissue procedures would most likely focus on high-level, generalisable outcomes, it is recommended that a hybrid approach to evidence generation is taken, where similar surgeries are grouped by outcomes or specialty. This would require qualitative research with clinical experts to establish the most appropriate groupings. There is also a need for mixed-methods studies to investigate patient acceptability of RAS, and to establish surgeon preferences and the benefits of the various features of the robotic systems.

1 Decision problem

The decision problem is described in the Scope.

Table 1.1: Summary of decision problem

Decision problem	Scope	EAG comment
Population	People (adults or children) having a soft-tissue surgical procedure. Soft-tissue surgery includes those done in the following specialties: • Urology (excluding prostatectomy) • Gynaecology • Colorectal • Head and neck • Thoracic • Upper GI including bariatric and oesophago-gastric surgery • General (including hernia repair) • Hepato-pancreato-biliary • Transplant • Breast • Plastic and reconstruction surgery	No change.
Intervention	• RAS with Da Vinci X and Xi (Intuitive) • RAS with Da Vinci SP (Intuitive) • RAS with Versius (CMR Surgical) • RAS with Hugo RAS system (Medtronic)	Senhance (Asensus Surgical) was added to the EVA after publication of the final scope.
Comparator(s)	RAS will be compared with standard surgical care	No change.
Outcomes	**Primary outcomes** Patient level: • Conversion to open surgery (for RAS compared with other minimally invasive surgical techniques only) • Rate of conversion to conventional MIS (other minimally invasive surgical techniques) from RAS • Length of hospital stay	Rate of conversion to conventional MIS was clarified as a primary patient level outcome. Length of hospital stay was changed from a secondary organisational level outcome to a primary patient level outcome. Rate of MIS compared with open surgery after RAS was

	• Intraoperative and post-operative complications (e.g. Clavien-Dindo score) • Health-related quality of life Surgeon level: • Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Organisation level: • Rate of MIS compared with open surgery after RAS was introduced • Volume of procedures • Hospital capacity and wait list reduction **<u>Secondary outcomes</u>** Patient level: • Days alive and out of hospital at 30 days • Post-operative pain • Satisfaction • Intraoperative blood loss (for RAS compared with open surgery only) • Revision surgery for the same indication Condition/specialty specific outcomes: • Survival rate (cancer) • Need for adjuvant treatment (cancer) • Feeding tube dependency (head and neck) Surgeon level: • Career longevity and musculoskeletal injury • Human factors • Learning curve Organisation level: • Readmission at 30 days • Operating time • Staffing requirements	introduced was clarified and changed to an organisation level outcome from a patient level outcome.
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.	Given the wide scope of procedures, and the purposes of an early value assessment, only a 1-year time horizon is considered for the economic evaluation. Long-term outcomes are very heterogenous across procedures, and these should be

		explored further as part of future evidence generation and assessment.
Subgroups	The following subgroups have been identified: • Children and young people under the age of 18 • Procedures for cancer • Procedures for benign disease	No change.

Key: GI – Gastrointestinal, RAS – Robot-assisted surgery, SP – Single port, SURG-TLX – Surgery task load index.

2 Overview of the technology

Included in this early value assessment (EVA) are robotic platforms for soft-tissue procedures. The population includes people (adults or children) who are having a soft-tissue procedure. Soft-tissue procedures, the clinical specialities this entails, and placement in the pathway are described further in Section 3.

Robotic platforms for soft-tissue procedures are used in operating theatres. Robotic platforms are here defined as a technology that enables minimally invasive surgery (MIS) to be conducted across multiple interventional surgical procedures. They have one or more mechanical arms to which an endoscope and surgical instruments are attached. The operator controls the apparatus from a remote console. Robot-assisted surgery (RAS) is complex and requires 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.

Many potential benefits associated with robotic platforms are the same as for other conventional MIS techniques when compared with open surgery. Benefits of RAS, compared with open or conventional MIS, may include reductions in:

- pain
- complications
- length of hospital stay
- recovery time
- conversions to open surgery.

There may also be benefits to the surgeon, including reduced strain and technical demand when doing the procedure. If surgeons consider there will be a reduction in surgical risk because of RAS, there may be an increase in MIS.

RAS is already recommended in the NICE guidelines for prostate cancer, while the Department for Health and Social Care has also predicted that RAS will expand over the next decade (Department of Health and Social Care 2024, NHS 2019).

2.1 Included technologies

In total, 5 robotic systems were identified as relevant to the assessment, of which 3 companies covering 4 technologies provided information to NICE. Senhance (Asensus Surgical) were identified after the NICE Scope was published. Asensus was recently acquired by Karl Storz but did not respond to an invitation to participate. Da Vinci robotic platforms, including previous iterations, have been available longer than other technologies. Previous literature, which is deprioritised, is likely to refer to earlier versions of da Vinci robotic platforms.

Details relevant to this EVA are summarised in Table 2.1, summarised from the company submitted documents. Features listed should be considered by clinical experts to determine if they are reflective of their experiences in clinical practice.

Advanced instrumentation is also available for each platform, which may be specific to individual procedures. Further details on the original 4 technologies are provided in the NICE Scope. RAS for orthopaedic procedures is another EVA in development alongside RAS for soft-tissue procedures. The focus of this EVA is only on RAS for soft-tissue procedures. Therefore, evidence and features related to RAS outside of soft-tissue procedures is out of scope. All 5 technologies are certified with appropriate regulatory approval for the UK, which has been confirmed with NICE. Further detail on regulatory approval for the UK is provided in the NICE Scope, and in Table 2.1.

Table 2.1: Included technologies

Technology (Company)	Regulatory Status	Indications for use	Main components	Can be used to support open surgeries	Data collection	Current use in NHS
Versius (CMR Surgical)	Certified to market in the UK under MDR 757173 R000 Not currently licensed for people under the age of 18 (paediatrics) or for TORS	• Thoracic • Upper GI • Colorectal • Gynaecology • Hepatobiliary • Hernia • Urology	Bedside unit with an endoscope (visualisation unit) 2 or 3 bedside units Wristed instruments that attach to bedside units Surgeon console with open 3D video feed from the endoscope	Not supported for open surgery [redacted]	Robot telemetry data, and with patient consent, surgical video and clinical data Existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app	[redacted] Procedures undertaken cover: [redacted]colorectal[redacted] [redacted]general and upper GI[redacted] • gynaecology[redacted] • urology[redacted] • thoracic[redacted] • head and neck[redacted] • HPB[redacted]

da Vinci X / Xi Surgical System* (Intuitive)	Certified to market in the UK under MDR 2017/745 Not currently licensed for trans-oral otolaryngology robotic surgery in paediatrics	• Urology • General surgery • Gynaecology • Thoracoscopic • Nipple sparing mastectomy with reconstruction • Transoral otolaryngology (restricted to adults, and benign tumours or malignant tumours classified as T1 and T2)	Patient cart with 4 arms that host surgical instruments Wristed instruments that attach to the arms, including the endoscope Surgeon console with closed viewer and open 3D video feed from the endoscope Vision cart that duplicates the endoscope video and has arm cart	Not supported for open surgery	Usage metrics such as time, date, kinematic and procedure information	[redacted] Procedures undertaken cover: • urology [redacted] • general surgery [redacted] • gynaecology [redacted] • thoracic [redacted] [redacted]Other [redacted] • commonly used in prostatectomy, but this is outside of the NICE scope [redacted]

			control functionality			
da Vinci SP Surgical System**	Certified to market in the UK under MDR 2017/745 Not currently licensed for people under the age of 18 (paediatrics) Further exclusions are listed in Appendix E	• Endoscopic Abdominopelvic • Thoracoscopic • Transoral otolaryngology • Breast	Patient cart with 1 arm hosting endoscope and 3 instruments Surgeon console with closed viewer and open 3D video feed from the endoscope Wristed instruments that attach to the arm, including the endoscope Vision cart that	Not supported for open surgery	Usage metrics such as time, date, kinematic and procedure information	At time of this report, used in [redacted] for Urology and Head & Neck procedures.

			duplicates the endoscope video and has arm cart control functionality			
Hugo Robotically Assisted Surgery System (Medtronic)	Certified to market in the UK under MDR 738197 R000 Not currently licensed for people under the age of 18 (paediatrics)	• Urology • Gynaecology • General surgery	System tower with operating room interactive display Arm cart hosting instruments. Up to 4 arm carts can be connected to the system tower Surgeon console with open display interactive display, hand and foot	Not supported for open surgery	Storage of technical and usage data	[redacted] Used in urology in the NHS. Procedures include prostatectomy, radical or partial nephrectomy, pyeloplasty, cyst removal, ureteral re-implant. [redacted]

			control, and open 3D video feed from the endoscope Wristed instruments that attach to the arm carts, including the endoscope			
Senhance (Asensus Surgical)	The company did not provide information to NICE. However, from the literature and clinical experts, a brief description of the technology is provided below (Coussons et al. 2021). The technology is comprised of an open‐platform, modular architecture with four mobile arms that allow for use of existing laparoscopic vision systems. Senhance system's instruments are reusable. The system incorporates eye‐tracking camera control, haptic sensing, 3DHD visualisation and joy-sticks during the procedure. Case set-up for Senhance procedures generally includes raising the patient so the camera port is aligned with the front of then arms' collar; setting the patient in Trendelenburg; setting the scope to 0° to provide clearance for anaesthesiology; and using the xyphoid process as the point for arm placement. Both arms use instruments that are 310 mm in length. The platform uses eye and head movements and tracking to control the robotic camera arm					

*Respectively models IS4200 / IS4000
** model SP1908
*** Information used to populate Table 2.1 has been extracted directly from company RFIs
Key: EVA – Early Value Assessment, GI – gastrointestinal, HPB – Hepato-pancreato-biliary, MDR – Medical Device Regulation, NICE – National Institute for Health and Care Excellence, NHS – National Health Service, TORS – Trans-oral robotic surgery.

3 Clinical context

Within the healthcare system, there are a range of reasons why people may need surgery to treat or manage a health condition. Soft-tissue surgical procedures encompass a range of procedures involving internal organs, the body wall, masses or tumors, and hernias or defects. Soft-tissue procedures do not cover procedures conducted on bones, or wider musculoskeletal conditions (NHS 2021). Soft-tissue surgical procedures may be carried out through open surgery, or through MIS techniques. Open surgery involves the surgeon making a single or multiple, often large, incision(s). MIS is a method of carrying out an operation without having to make a large incision, which may involve using a natural body orifice or a smaller incision. Examples of MIS used often in soft tissue include laparoscopy, endoscopy and hysteroscopy, as outlined in the NICE Scope.

MIS is likely to provide benefits for people when compared with open surgery, which may include (Randell et al. 2019, Varela et al. 2010, Sheng et al. 2018):

- less pain after surgery
- reduced length of hospital stay
- quicker return to normal function
- improved cosmetic effect
- reduction in infection and complication rates
- reduction in mortality risk.

Furthermore, evidence across a range of conditions suggests that long term outcomes with MIS are at least comparable with open surgeries, with studies reporting no statistically significant differences (Huang et al. 2020, Tschann et al. 2022, Wang et al. 2020).

However, it can be technically challenging to perform MIS, due to the two-dimensional image of the surgical site and instruments that have limited freedom of movement and require awkward and unnatural handling. Not all surgeons in a hospital may be trained on more complex MIS procedures, with constrained capacity to uptake training (Cole A et al. 2018). In addition, for groups of people with higher risk characteristics, such as people with comorbidities, a surgeon may be less willing to conduct a procedure through MIS, when balancing the risks and benefits to the patient. As a result, uptake of MIS for specific procedure, such as lower anterior resection, and hernia repair, has been slow (Cole A et al. 2018). However, evidence suggests that RAS (a form of MIS) may provide solutions to overcome barriers to conducting MIS and may lead to greater accuracy than when conducting MIS without the support of a robot (Cole A et al. 2018).

The target population for this assessment is adults or children who require a soft-tissue surgical procedure. In the UK, it is estimated that approximately 1 in 10 people require a surgical procedure, which includes soft-tissue, orthopaedic and neurological procedures. As people begin to live longer, it is likely that the demand for soft-tissue procedures will increase, as the prevalence of noncommunicable diseases, such as cancers, also increase.

Previous NICE guidelines and the NHS long-term plan both highlight the importance of RAS, in supporting the workforce through innovation as well as the effectiveness in specific interventions, such as prostatectomy (National Institute for Health and Care Excellence 2019).The introduction of robotic platforms may have led to improvements for patients, surgeons and the wider NHS system. However, these platforms tend to be expensive and require specific training for the surgeons to operate. Potential benefits of RAS are likely to be similar to those of MIS, where MIS is currently possible without a robotic platform, but may also be amplified with RAS. The introduction of RAS could also potentially facilitate a higher proportion of MIS relative to open surgeries, as well

as reducing conversion rates from MIS to open surgery. Conversions to open surgery during the MIS are likely to increase the risk of complications, increase the length of stay (LoS) for the patient, increase pain after surgery and increase the risk of mortality, when compared with an initial decision to do open surgery or if MIS was possible (Masoomi et al. 2015). The additional benefits of robotic platforms, beyond increasing the rates of MIS, are likely to stem from the increased precision and reduction in technical demand required for MIS, which may lead to improved outcomes. Further details of the value propositions of RAS are provided in the NICE Scope and throughout this report.

Special considerations including issues related to equality

No further equality issues have been identified since the publishing of the Scope.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

Searches were conducted by the EAG to identify studies of the 4 technologies (Da Vinci X/Xi, Da Vinci SP, Hugo and Versius) named in the Scope. The searches were designed to identify both clinical and economic evidence. They were conducted on 5 July 2024, in a range of resources. The Senhance robotic system was added to the Scope at a later date and additional searches were undertaken by NICE on this technology on 25 July 2024.

Full details of the search methods are provided in Appendix A.

The initial EAG searches retrieved a total of 3,874 records after elimination of 1,029 duplicates. The additional searches for the Senhance robotic system retrieved 156

records after the removal of 63 duplicates. Titles and abstracts were screened by 1 reviewer (the first 10% assessed by 2 reviewers independently) based on the intervention and populations. Due to the volume of literature identified, studies which did not name one of the 5 technologies in the title or abstract were excluded. 676 records were initially identified from the trial registry searches and a further 7 were identified from the additional Senhance searches. These were not assessed due to the high numbers of records retrieved. Ongoing studies were identified from company submissions instead. A total of 492 full texts were retrieved and examined by one reviewer (first 10% assessed by 2 reviewers) to select those meeting the scope.

Company submissions were received from 4 of the companies. We did not receive a company submission from Asensus Surgical for the Senhance system. 79 documents were examined from the company evidence and 62 relevant studies not identified by the EAG searches were added to full text screening.

4.2 Included and excluded studies

A total of 110 studies were considered to meet the scope because they evaluated a named technology in the relevant population. Of these studies, 20 comparative studies were prioritised for further data extraction and are summarised in Table 4.1. Prioritisation was conducted per technology, with some higher-level evidence de-prioritised if there was a high volume of literature for a particular technology. A further 17 studies were identified to be relevant systematic reviews of which the references were checked. The remaining 73 studies were deprioritised and are reported in Appendix B. These studies were deprioritised for a number of reasons, including the comparator being out of scope (n= 28) or the evidence being single arm (n=39). Due to the volume of literature identified, studies of Da Vinci X/Xi in a non-EU setting were also deprioritized (n=6).

A list of the 426 studies excluded at full text is provided in Appendix B.

Table 4.1: Studies selected by the EAG as the evidence base

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Da Vinci Xi				
Aktas et al 2020 (Aktas et al. 2020) **Location:** Turkey **Setting:** Two hospital centres	**Design:** Retrospective cohort study GREEN **Intervention:** Da Vinci Xi **Comparator:** MIS GREEN	**Indication:** Gastro adenocarcinoma, radical gastrectomy Patients underwent robotic (n=30) or laparoscopic (n=64) gastrectomy and D_2 lymph node dissection with a curative intent for gastric adenocarcinoma. GREEN **Median (range) age:** **MIS:** 59 (32 to 74) **Da Vinci Xi**: 55 (37 to 69) **Male gender n (%):** **MIS:** 41 (64.1) **Da Vinci Xi**: 18 (60)	• Conversion to open surgery • Operative time • Clavien-Dindo score • Length of hospital stay • Mortality • Neoadjuvant chemotherapy/radiotherapy	Retrospective study from a prospectively maintained database. Also presents analysis based on gastrectomy type (distal or total).

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location:** Spain **Setting:** Mutua de Terrassa University Hospital and Germans Trias i Pujol University hospital	**Design:** Prospective, non-randomised study GREEN **Intervention:** Da Vinci Xi **Comparator:** MIS GREEN	**Indication**: Pancreatic disease, pancreatectomy Patients who had a pancreatectomy and were treated by MIS (n=35) or robotic (n=22) surgery. GREEN Mean (SD) age: **Da Vinci Xi:** 64.73 (3.8) **MIS**: 65.9 (4.7) Male gender (n) **Da Vinci Xi**: 8 (36.4*) **MIS**: 19 (54.3*)	• Operative time • Hospital stay • Conversion rate • Severe morbidity (Dindo-Clavien ≥III) • Post-operative bleeding • 30/90-day readmission • Reoperation	

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location:** Sweden **Setting:** Sahlgrenska University Hospital	**Design:** Prospective, non-randomised study GREEN **Intervention:** Da Vinci Xi **Comparator:** Open surgery GREEN	**Indication**: Metastatic germ cell cancer, retroperitoneal lymph node dissection Patients with metastatic germ cell cancer (testicular) who are candidates for robot lymph node dissection were referred and 29 received robotic surgery whilst 58 had open surgery. GREEN **Mean age (range):** **Da Vinci Xi:** 35 (18-62) **Open surgery:** 37 (17-74) **Male gender:** NR	• Conversion to open surgery • Operative time • Estimated blood loss • Length of stay • Clavien-Dindo surgical complications • Adjuvant chemotherapy rates • Reoperation • Clavien-Dindo complications	Patients chose whether they received open or robotic surgery. Patients received either a unilateral (n=23) or bilateral (n=4) resection.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting**: Tertiary care centre	**Design:** Retrospective cohort study **GREEN** **Intervention:** Da Vinci Xi **Comparator:** MIS **GREEN**	**Indication:** left sided colonic diverticulitis, colectomy Patients undergoing MIS (n=22) or robotic (n=20) colectomy for left-sided colonic diverticulitis **GREEN** **Mean age (±SD)** **Da Vinci Xi:** 55.25 (12.4) **MIS:** 56.1 (11.6) **Male gender (%):** **Da Vinci Xi**:11 (55) **MIS**: 12 (55)	• Operating time • Conversion to open surgery • Postoperative complications • Length of hospital stay • Readmission	Retrospective study from a prospectively maintained database. Presents analysis based on morbidity.
Butnari et al 2024 (Butnari et al. 2024) **Location:** UK **Setting:** District general hospital	**Design:** Retrospective cohort study **GREEN** **Intervention:** Da Vinci Xi	**Indication**: Colorectal cancer, colorectal resection Patients who underwent robotic (n=100) or MIS (n=112) colorectal procedures between	• Total operative time • Conversion rates • 30-day post-operative complications (Clavien-Dindo classification)	This is a retrospective study and so may be open to bias. Morbidity, mortality and indication specific surgical complications were also reported.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
	Comparator: MIS GREEN	February 2020 and October 2022 GREEN **Median age (IQR):** **Da Vinci Xi:** 68 (57-74.6) **MIS**: 71 (62-75.6) **Male gender** **Da Vinci Xi:** 56% **MIS:** 53%	• Length of in-patient stay • 90-day mortality • Re-admission rates • Reoperation • Neoadjuvant chemoradiotherapy	
Di Franco et al 2022 (Di Franco et al. 2022) **Location:** Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery)	**Design:** Retrospective cohort study GREEN **Intervention:** Da Vinci Xi **Comparator:** Open surgery GREEN	**Indication**: Pancreatic disease, pancreatoduodenectomy Patients who had pancreatic surgery and were treated by robotic pancreatoduodenectomy (n=20) or open surgery (n=40). Patients were matched 1:2 (robotic:open)	• Operative time • Conversion to open or MIS • Overall peri-operative complications • Postoperative complications • Clavien-Dindo score ≥3 • Reoperation • Length of hospital stay	Data were retrospectively reviewed and analysed, from a prospectively collected database

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		GREEN **Mean age (SD)**: **Open surgery**: 71.6 (9.2) **Da Vinci Xi:** 68.4 (7.7) **Male gender:** **Open surgery**: 23 (57.5) **Da Vinci Xi:** 8 (40)		
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital	**Design:** Retrospective cohort study **GREEN** **Intervention:** Da Vinci Xi **Comparator:** MIS **GREEN**	**Indication:** Colorectal cancer, hemicolectomy Patients with colorectal cancer who had hemicolectomies conducted laparoscopically (n=15) or robotically (n=7) **GREEN** **Mean age (SD):** **MIS:** 75 (3.0)	• Operative time • Length of hospital stay • Perioperative complications • Conversion to open or MIS(in case of robotic) surgery • Learning curve • Mortality	One patient in the MIS arm had surgery for caecum angiodysplasia and not colorectal cancer Data prospectively collected, retrospectively analysed

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Da Vinci Xi: 75.7 (2.56) **Male gender n (%):** **MIS:** 7 (46.7*) **Da Vinci Xi**: 3 (42.9*)		
Galata et al 2019 (Galata et al. 2019) **Location:** Germany **Setting:** University hospital	**Design:** Prospective cohort study **GREEN** **Intervention:** Da Vinci Xi **Comparator:** MIS **GREEN**	**Indication:** Rectal adenocarcinoma, anterior resection Patients with high- to low-lying histologically proven rectal adenocarcinoma scheduled to undergo elective minimally invasive curative treatment for rectal cancer in the form of (low) anterior resection laparoscopically (n=33) or robotically (n=18) **GREEN**	• Surgical morbidity (according to the Clavien-Dindo classification) • Perioperative complications • Conversion to open surgery • Rate of reoperation • Readmission 30 days after surgery • Operative time • Postoperative LoS • Postoperative pain • Patients needing neoadjuvant therapy	

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Mean age (SD): **MIS:** 62.3 (13.7) **Da Vinci Xi:** 60.0 (11.8) **Male gender n (%):** **MIS:** 21 (63.6*) **Da Vinci Xi**: 10 (55.6*)		

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Gitas et al 2022 (Gitas et al. 2022) **Location:** Germany **Setting:** University Hospital	**Design:** Retrospective cohort study GREEN **Intervention:** Da Vinci Xi **Comparator:** MIS GREEN	**Indication**: Gynaecological indications, hysterectomy Women who had undergone robot-assisted hysterectomy with Da Vinci Xi for benign indication (bleeding disorders, growth of uterus myomas, dyspareunia or abdominal pain) or early endometrial cancer (n=42) or hysterectomy by conventional MIS(n=97) GREEN **Mean age (SD):** **MIS:** 54.874 (13.196) **Da Vinci Xi:** 56.450 (13.185) All patients were female	• Postoperative pain • Intraoperative complications • Postoperative complications • Clavien-Dindo Grade IIIa • Need for reoperation • Satisfaction with cosmetic outcome • Positive experiences after robotic surgery • Satisfaction with surgeon's preoperative explanation • Reasons for dissatisfaction • Positive/negative experiences • Surgeon learning curve • Operating time	Included subgroup analysis of endometrial cancer, benign disease, and obesity All patients were female
Muysoms et al 2018 (Muysoms et al. 2018)	**Design:** Historically controlled cohort study GREEN	**Indication:** Groin hernia, transabdominal preperitoneal groin hernia repair	• Skin-to-skin operating time • Total OR time • Learning curve	The text reports that there are 45 total patients in the bilateral group but the patient characteristics

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Location: Belgium **Setting:** Maria Middelares Hospital	**Intervention:** Da Vinci Xi **Comparator:** MIS GREEN	Patients schedules for MIS groin hernia treatment who were eligible for a robotic-assisted unilateral (n=34) or bilateral (n=16) approach and patients who had the same surgery performed laparoscopically by the same surgeon unilaterally (n=22) or bilaterally (n=42) GREEN **Mean age (SD)** **Da Vinci Xi unilateral**: 60.4 (16.5) **Da Vinci Xi bilateral:** 55.3 (12.5) **MIS unilateral:** 59 (11.8) MIS bilateral: **Tertile 1:** 55 (17.4) **Tertile 2:** 58.6 (9.6)	• Intraoperative complications • Postoperative complications • HRQoL • Postoperative pain • Conversions to open or MIS	table reports 42. It's also reported that were are 50 RAS patients but the patient characteristics table reports 49. The missing patients are not accounted for.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Tertile 3: 57.4 (12.0) Gender (% female) **Da Vinci Xi unilateral:** 3% (1/34) **Da Vinci Xi bilateral**: 0% (0/15) **MIS unilateral**: 9% (2/22) MIS bilateral: **Tertile 1:** 0% (0/13) **Tertile 2**: 0% (0/13) **Tertile 3:** 0% (0/15)		
Ozben et al 2019 (Ozben et al. 2019) **Location:** Turkey **Setting:** Two specialised centres	**Design:** Retrospective cohort study GREEN **Intervention:** Da Vinci Xi **Comparator:** MIS GREEN	**Indication:** Colorectal indications, Colectomy Patients with a diagnosis of either synchronous colonic cancer, obstructive cancer, multiple dysplasia, inflammatory bowel disease, familial adenomatous polyposis or	• Operative time • Complications • Conversions (from robotic to MIS or open OR from MIS to open) • Length of hospital stay • Reoperation	A subgroup analysis of histopathological results was conducted in patients with cancer. Data prospectively collected, retrospectively analysed.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		colonic inertia who had robotic (n=26) or MIS (n=56) total or subtotal colectomy **GREEN** **Mean age (SD):** **MIS:** 56.2 (18.1) **Da Vinci Xi:** 51.3 (15.4) **Male gender n (%):** **MIS:** 36 (64.3) **Da Vinci Xi:** 18 (69.2)	• Readmission •	
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting:** NR	**Design:** Historically controlled cohort study **GREEN** **Intervention:** Da Vinci Xi **Comparator:** MIS **GREEN**	**Indication:** Colon cancer, right hemicolectomy Patients undergoing robotic assisted right hemicolectomy for colon cancer compared with historical MIS right hemicolectomy from the same institution.	• Conversion to open surgery • Length of stay • In hospital complications • Complications (Clavien-Dindo) • Readmission • Pain scores • Operative time	The paper does not report where the study was carried out or how the controls were selected other than they were recent hemicolectomy surgical cases.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		GREEN **RRC-IA** (n=35) **LRC-EA** (n=40) **RRC-EA** (n=22) **Median age (range):** **RRC-IA:** 74 (53-92) **LRC-EA:** 73 (47-89) **RRC-EA:** 71 (49-93) **Female gender (%):** **RRC-IA:** 19 (54) **LRC-EA:** 25 (63) **RRC-EA:** 13 (59)		
Schmelzle et al 2022 (Schmelzle et al. 2022) **Location:** Germany	**Design:** Historically controlled cohort study **GREEN** **Intervention:** Da Vinci Xi	**Indication:** Liver indications, liver resection Patients underwent robotic (n=129) or laparoscopic	• Postoperative complications (Clavien-Dindo) • Duration of surgery • Length of hospital stay	PSM was performed to control for selection bias.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Setting: University hospital	**Comparator:** MIS GREEN	(n=471) liver resection. Most patients (81%) had malignant primary or secondary liver tumours. The most common tumour entity was colorectal liver metastasis (28%), followed by hepatocellular carcinoma (23%) and intrahepatic cholangiocarcinoma (12%). GREEN **Age, median (range):** **MIS (matched population):** 62 (19 to 86) **MIS (unmatched population):** 62 (19 to 88) **Da Vinci Xi**: 64 (22 to 85) **Male gender n (%):** **MIS (matched population):** 70* (54*)	• Conversion to open or MIS (in case of robotic) surgery	

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		MIS (unmatched population): 260* (55*) **Da Vinci Xi:** 66* (51*)		
Da Vinci SP				
Lee et al 2023 (Lee and Hong 2023) **Location**: Korea **Setting**: Kyungpook National University Chilgok Hospital	**Design**: Prospective cohort study **GREEN** **Intervention**: Da Vinci SP **Comparator**: MIS **GREEN**	**Indication**: Uterine fibroids, hysterectomy Patients requiring a hysterectomy for uterine fibroid were given a chose between MIS (n=48) or robotic surgery (n=31). **GREEN** **Age mean (SD):** Da Vinci SP: 45.45 (3.89) **MIS:** 46.69 (6.00)	• Operative time • Inoperative complications • Postoperative complications • Length of hospital stay	27 patient were excluded from the Da Vinci SP group and 33 from the MIS group prior to analyses. All patients were female
Hugo				
Prata et al 2024 (Prata et al. 2024)	**Design:** Retrospective cohort study	**Indication:** Renal tumours, partial nephrectomy	• Perioperative complications • Operative time	Study claims to have collected data for postoperative

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Location: Italy **Setting:** University hospital	GREEN **Intervention:** Hugo **Comparator:** MIS GREEN	Patients with renal tumours (benign or malignant) who underwent robotic (n=27) or laparoscopic (n=62) partial nephrectomy. GREEN **Age, median (IQR):** **MIS:** 65.5 (54 to 72) **Hugo:** 68 (57 to 73) Male gender n (%): **MIS**: 37 (59.7) **Hugo**: 22 (81.5)	• Length of stay • Readmission • Conversions	complications (that were classified by Clavien-Dindo) but only reports perioperative complications. Postoperative complications were part of a composite outcome and not reported separately
Senhance				
Aggarwal 2020 (Aggarwal et al. 2020)	**Design:** Retrospective cohort study GREEN	**Indication:** Cholelithiasis, cholecystectomy	• Surgery duration (operative and console time) • Learning curve	A prospectively updated database was retrospectively analysed

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Location: UK **Setting:** St Mary's Hospital, Imperial Collage, London	**Intervention:** Senhance **Comparator:** MIS GREEN	Patients receiving a robotic (n=20) or laparoscopic (n=20) cholecystectomy GREEN **Age, mean ± SD** **Senhance:** 45.9 ± 13.0 **MIS:** 48.4 ± 12.2 **Male gender, % (n):** **Senhance:** 15 (3) **MIS:** 15 (3)	• Adverse events (Clavien-Dino score) • Conversion to open surgery • Complications • Length of hospital stay • Pain	
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital	**Design:** Historically controlled cohort study GREEN **Intervention:** Senhance	**Indication:** Gastroesophageal reflux disease, nissen fundoplication Children from 0 to 17 years with a diagnosis of gastroesophageal reflux disease. Patients treated with robotic nissen fundoplication (n=20) were matched with a	• Conversion to open surgery • Conversion to MIS • Operative time • Perioperative complications • Hospital LoS • Postoperative complications • Readmission • Reintervention	Prospective robotic surgery cohort matched with retrospective cohort of MIS Study is in a paediatric population

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
	Comparator: MIS GREEN	retrospective cohort of laparoscopic nissen fundoplication (n=20). **Age, mean (SD):** **Senhance:** 7.9 (6.0) **MIS:** 8.3 (6.1) **Male gender n (%):** **Senhance:** 11 (55) **MIS:** 11 (55)	• Clavien-Dindo score • Learning curve	
Samalavicius et al 2022 (Samalavicius et al. 2022) **Location:** Lithuania **Setting:** University hospital	**Design:** Retrospective cohort study GREEN **Intervention:** Senhance **Comparator:** MIS GREEN	**Indication:** cholelithiasis, Cholecystectomy Patients requiring cholecystectomy due to cholelithiasis. Patients who had robotic surgery (n=20) were matched to patients who had MIS (n=20) GREEN	• Operative time • Length of hospital stay • Postoperative complications • Intraoperative complications • Conversion to open surgery	Robotic surgery cases were matched to MIS patients Data was prospectively collected Unclear whether this study is a retrospective

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Age, mean (SD): Senhance: 49.5 (18.6) **MIS:** 55.1 (13.3) **Male gender n (%):** **Senhance:** 8 (40) **MIS:** 6 (30)		cohort study or whether it was historically matched
Versius				
Dixon et al 2024 (Dixon et al. 2024) **Location:** UK **Setting:** NR	**Design:** RCT **GREEN** **Intervention:** Versius **Comparator:** MIS **GREEN**	**Indication:** Colorectal indications, Major colorectal resection Patients requiring minimally invasive colorectal resection were randomly allocated to receive robotic (n=40) or MIS (n=20) .	• Surgeon ergonomic risk (REBA tool) • Surgeon cognitive strain • Operative time • Pain score • Length of hospital stay • Team communication • Conversions • Complications during primary admission • Complications post-discharge (<30 days)	All patients randomised were allocated and included in analysis.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		GREEN **Age mean (SD):** **Versius:** 65.8 (11.2) **MIS:** 64.2 (14.5) **Male gender n (%)** **Versius**: 23 (58) **MIS:** 12 (60)	• Clavien-Dindo complications • Readmission	
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location**: India **Setting:** Hospital and research centre	**Design:** Prospective non-randomised study GREEN **Intervention:** Versius **Comparator:** MIS GREEN	**Indication:** Inguinal hernia, totally extraperitoneal hernia repair Patients with inguinal hernia who underwent inguinal hernia repair robotically (n=44) or laparoscopically (n=44) GREEN **Age, mean (range):** **MIS:** 47.40 (26 to 71)	• Operative time • Postoperative pain • Complications • Conversions to open or MIS (in case of robotic) surgery • Day of discharge from hospital • Learning curve (docking time only)	All patients were male

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Versius: 45.9 (27 to 79) **Male gender n (%):** **MIS:** 44 (100*) **Versius:** 44 (100*)		

Key: D[2] - Group 2,IQR – Interquartile range, LRC-EA - laparoscopic operation with extracorporeal anastomosis, MIS – Minimally invasive surgery, NR – Not reported, OR – Operating room, PSM – Propensity score-based matching , REBA - Rapid Entire Body Assessment, RRC-EA - robotic operations with extracorporeal anastomosis, RRC-IA - robotic operation with intracorporal anastomosis, SD – Standard deviation, SP – Single port.

GREEN: Study characteristic aligns with the scope**; AMBER:** Study characteristic does not fully align with the scope**; RED:** Study characteristic does not align with the scope.

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

All 20 prioritised studies were comparative and included 1 randomised controlled trial (RCT) (Dixon et al. 2024), 3 prospective non-randomised studies (Grenabo Bergdahl et al. 2022, Kakkilaya et al. 2023, Espin Alvarez et al. 2023), 2 prospective cohort studies (Galata et al. 2019, Lee and Hong 2023), 10 retrospective cohort studies (Aktas et al. 2020, Bilgin et al. 2020, Butnari et al. 2024, Di Franco et al. 2022, Di Lascia et al. 2020, Gitas et al. 2022, Ozben et al. 2019, Prata et al. 2024, Aggarwal et al. 2020, Samalavicius et al. 2022) and 4 historically controlled cohort studies (Schmelzle et al. 2022, Rattenborg et al. 2021, Muysoms et al. 2018, Killaars et al. 2024).

Patients

The EAG considered all studies to fully meet this component of the decision scope. The evidence base evaluated the use of technologies in patients undergoing a variety of surgical procedures in different specialties.

The most commonly reported indication was colorectal surgeries (n=7) (Bilgin et al. 2020, Butnari et al. 2024, Di Lascia et al. 2020, Galata et al. 2019, Ozben et al. 2019, Rattenborg et al. 2021, Dixon et al. 2024), followed by pancreatic (n=3) (Schmelzle et al. 2022, Di Franco et al. 2022, Espin Alvarez et al. 2023), hernial repair (n=2) (Muysoms et al. 2018, Kakkilaya et al. 2023), gynecological (n=2) (Gitas et al. 2022, Lee and Hong 2023), gastrointestinal (n=2) (Aktas et al. 2020, Killaars et al. 2024) and cholelithiasis (n=2) (Aggarwal et al. 2020, Samalavicius et al. 2022). Other indications evaluated were testicular cancer (n=1) (Grenabo Bergdahl et al. 2022), urology (n=1) (Prata et al. 2024).

6 studies assessed patients with cancer (Aktas et al. 2020, Grenabo Bergdahl et al. 2022, Butnari et al. 2024, Di Lascia et al. 2020, Galata et al. 2019, Rattenborg et al. 2021), 7 reported on patients with benign disease (Bilgin et al. 2020, Muysoms et al. 2018, Lee and Hong 2023, Kakkilaya et al. 2023, Killaars et al. 2024, Aggarwal et al. 2020, Samalavicius et al. 2022) and 7 reported on mixed benign and malignant patient groups (Di Franco et al. 2022, Schmelzle et al. 2022, Espin Alvarez et al. 2023, Gitas et al. 2022, Ozben et al. 2019, Prata et al. 2024, Dixon et al. 2024).

One study (Killaars et al. 2024) reported on a paediatric population.

Interventions

Included studies assessed the 4 technologies identified in the NICE Scope including Da Vinci X and Xi (Intuitive), Da Vinci SP (Intuitive), Hugo (Medtronic) and Versius (CMR surgical). A fifth technology, Senhance (Asensus Surgical) was added to the EVA at a later date.

Of the 20 included studies, 13 reported on the Da Vinci Xi (Aktas et al. 2020, Espin Alvarez et al. 2023, Grenabo Bergdahl et al. 2022, Bilgin et al. 2020, Butnari et al. 2024, Di Franco et al. 2022, Di Lascia et al. 2020, Galata et al. 2019, Gitas et al. 2022, Muysoms et al. 2018, Ozben et al. 2019, Rattenborg et al. 2021, Schmelzle et al. 2022), 1 on Da Vinci SP (Lee and Hong 2023), 1 on Hugo (Prata et al. 2024), 3 on Senhance (Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022) and 2 on Versius (Dixon et al. 2024, Kakkilaya et al. 2023).

5.2 Critical appraisal of studies

As specified by the NICE early value assessment interim guidance no formal risk of bias assessment was conducted.

Study design

There was one RCT prioritised in the review (Dixon et al. 2024). This study was unblinded due to there being no patient-reported outcomes in the trial. The trial conducted an intention to treat (ITT) analysis and is considered to be of low risk of bias.

Three studies were non-randomised, prospective studies (Grenabo Bergdahl et al. 2022, Kakkilaya et al. 2023, Espin Alvarez et al. 2023). As the allocation method is not randomised, there is an increased likelihood of confounding and a risk of exaggerated treatment effects due to selection bias. For example, RAS could be used for patients who would not have otherwise been eligible for MIS, which could lead to a systemic difference in the populations. Additionally, surgeon preference for one type of surgery over the other, availability of the robot or other factors such as patient disease severity, complexity of surgery and body type could influence the choice of surgery and could contribute to a potential selection bias in the studies.

Sixteen of the 20 studies were cohort studies (Aktas et al. 2020, Bilgin et al. 2020, Butnari et al. 2024, Di Franco et al. 2022, Di Lascia et al. 2020, Galata et al. 2019, Gitas et al. 2022, Muysoms et al. 2018, Ozben et al. 2019, Rattenborg et al. 2021, Schmelzle et al. 2022, Lee and Hong 2023, Prata et al. 2024, Samalavicius et al. 2022, Killaars et al. 2024, Aggarwal et al. 2020), of which ten were retrospective (Aktas et al. 2020, Bilgin et al. 2020, Butnari et al. 2024, Di Franco et al. 2022, Di Lascia et al. 2020, Gitas et al. 2022, Ozben et al. 2019, Prata et al. 2024, Aggarwal et al. 2020, Samalavicius et al. 2022). The study design of one of these studies was unclear

(Samalavicius et al. 2022). Similarly to non-randomised designs, these studies are at risk of selection bias and confounding.

Blinding was not possible for the surgeons due to the nature of the interventions and there was no information given on blinding of patients or outcome assessors in the non-randomised or cohort studies. There is a particular risk of bias in the collection of subjective patient or surgeon-reported outcomes in unblinded studies, more so than objective outcomes such as operative time.

Statistical analysis

There were some concerns related to the statistical analyses presented in the studies:

- Only two cohort studies reported results for a matched population in the comparator arm (Di Franco et al. 2022, Samalavicius et al. 2022) and four studies used historically matched controls (Schmelzle et al. 2022, Muysoms et al. 2018, Rattenborg et al. 2021, Killaars et al. 2024).
- Some studies presented results for each intervention, but no comparative estimate or p-value.

Generalisability

There were some concerns over the generalisability of the 20 studies:

- Only three were conducted in a UK population: one RCT evaluating Versius (Dixon et al. 2024) and two retrospective cohort studies evaluating Da Vinci Xi (Butnari et al. 2024) and Senhance (Aggarwal et al. 2020). All three studies compared robotic surgery to MIS. No UK evidence was available for Da Vinci SP or Hugo. It is possible that the results of the remaining studies may not be generalisable to the UK setting.
- There was a wide range of conditions, both malignant and benign, assessed across the studies due to the variety of different indications robotic surgery can be

used for. However, all studies assessed one specific type of surgery. The most common indication was colorectal surgery which was evaluated in seven studies (Bilgin et al. 2020, Butnari et al. 2024, Di Lascia et al. 2020, Galata et al. 2019, Ozben et al. 2019, Rattenborg et al. 2021, Dixon et al. 2024). Patient populations also varied across the studies. It is possible that the results for one type of surgery may not be generalisable to other types of surgery for certain outcomes.

- The EAG noted that results could differ for outcomes such as learning curve and operating time depending on surgeon experience and other factors such as the complexity of surgery. Therefore, the generalisability of these results is unclear.

5.3 Results from the evidence base

Full outcome data are presented in Appendix C .

Clinical outcomes – primary outcomes (patient level)

Conversion rates

Six studies evaluating the Da Vinci Xi robot reported conversion to open surgery (Aktas et al. 2020, Grenabo Bergdahl et al. 2022, Bilgin et al. 2020, Butnari et al. 2024, Galata et al. 2019, Rattenborg et al. 2021) and six studies also included conversion to MIS in the robotic arm (either separately or included as part of a amalgamated outcome) (Di Franco et al. 2022, Di Lascia et al. 2020, Espin Alvarez et al. 2023, Ozben et al. 2019, Muysoms et al. 2018, Schmelzle et al. 2022). Conversion rates to open for Da Vinci Xi ranged from 0% to 22.2%, and for MIS they ranged from 0% to 14.3%. Nine studies reported comparisons between treatment arms of which eight reported no significant difference in the rates of conversion across a range of indications (Aktas et al. 2020, Espin Alvarez et al. 2023, Bilgin et al. 2020, Butnari et al. 2024, Di Lascia et al. 2020, Ozben et al. 2019, Muysoms et al. 2018, Schmelzle et al. 2022). One prospective cohort study evaluating anterior resection for rectal adenocarcinoma in 51 patients

found a statistically significant difference in the rate of conversion to open surgery which was in favour of MIS (p=0.012) (Galata et al. 2019).

Three studies comparing Senhance to laparoscopy reported conversion rates (Aggarwal et al. 2020, Samalavicius et al. 2022, Killaars et al. 2024). Two studies reported no conversions to open surgery (n=20 patients in each arm of both studies) (Samalavicius et al. 2022, Aggarwal et al. 2020), and one reported one conversion to MIS from Senhance (5%) (Aggarwal et al. 2020). The third study reported two conversions to open surgery (10%) in the MIS arm and 0 in the Senhance arm but found no statistically significant difference between the two (p=0.5) (Killaars et al. 2024). The same study also reported two conversions from Senhance to MIS (10%)

One study evaluating Hugo vs. MIS reported no conversions in either arm (Prata et al. 2024).

Two studies assessing Versius (Dixon et al. 2024, Kakkilaya et al. 2023) vs. MIS reported no conversions in either arm.

Conversion rates were not reported for Da Vinci SP (Lee and Hong 2023).

Only one study in patients with cancer (rectal adenocarcinoma) found a statistically significant difference in conversion to open surgery which was in favour of MIS (p=0.012) (Galata et al. 2019). Where reported, none of the studies in benign disease (Bilgin et al. 2020, Muysoms et al. 2018, Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022), a mixed population (benign or malignant) (Espin Alvarez et al. 2023, Ozben et al. 2019, Prata et al. 2024, Dixon et al. 2024, Schmelzle et al. 2022) or in a pediatric population (Killaars et al. 2024) reported a statistically significant difference in conversion rates.

Conversion to conventional MIS from RAS

Five studies evaluating Da Vinci Xi reported the rate of conversion from RAS to conventional MIS separately to conversion to open surgery In all five studies there were

no conversions to MIS in the Da Vinci Xi arm (Espin Alvarez et al. 2023, Di Franco et al. 2022, Di Lascia et al. 2020, Ozben et al. 2019, Muysoms et al. 2018).

Three studies assessing the Senhance robot reported the rates of conversion to MIS from RAS (Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022). In one study, there were no conversions to MIS in the Senhance arm (n=20) (Samalavicius et al. 2022). In the remaining two studies, conversion to MIS from RAS was slightly higher at 5% (1/20 patients) in one (Aggarwal et al. 2020) and 10% (2/20 patients) in the other (Killaars et al. 2024). One of these studies was also conducted in a pediatric population (Killaars et al. 2024).

In one study assessing Hugo (Prata et al. 2024) and two assessing Versius (Dixon et al. 2024, Kakkilaya et al. 2023), no conversions were reported.

Length of hospital stay

Nine studies assessing Da Vinci Xi reported the median length of hospital stay (Aktas et al. 2020, Espin Alvarez et al. 2023, Grenabo Bergdahl et al. 2022, Bilgin et al. 2020, Butnari et al. 2024, Di Franco et al. 2022, Di Lascia et al. 2020, Rattenborg et al. 2021, Schmelzle et al. 2022) and two reported the mean LoS (Galata et al. 2019, Ozben et al. 2019). The median LoS ranged from 3 to 10 days in the robotic arm. In studies comparing Da Vinci Xi with MIS, the MIS arm had a similar median LoS that ranged from 4 to 8 days (Aktas et al. 2020, Espin Alvarez et al. 2023, Bilgin et al. 2020, Butnari et al. 2024, Di Lascia et al. 2020, Rattenborg et al. 2021, Schmelzle et al. 2022). Where mean was reported, the LoS was slightly longer in the MIS arm than in the Da Vinci Xi arm (Galata et al. 2019, Ozben et al. 2019). However, none of the studies reporting median or mean LoS found a significant difference between robotic surgery and MIS. Conversely, in studies where Da Vinci Xi was compared with open surgery, the median

LoS in the open surgery arm was significantly longer (range 7 to 16 days) (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022).

Two of the three studies comparing Senhance to MIS reported the mean length of hospital stay (Killaars et al. 2024, Samalavicius et al. 2022). Neither study found a significant difference in the LoS between robotic surgery and MIS. The third study only reported that all but one of the patients (in the Senhance arm) were discharged on the day of surgery (Aggarwal et al. 2020).

In the three studies comparing Da Vinci SP or Versius with MIS, there was no significant difference between the arms in length of hospital stay (Lee and Hong 2023, Kakkilaya et al. 2023, Dixon et al. 2021). However, in the study comparing Hugo with MIS, LoS was significantly shorter in the robotic surgery arm (median [IQR] Hugo: 3 [3 to 4] days; MIS: 5 [4 to 5] days; p=0.002).

Of the three studies that found a significant difference in the length of hospital stay,one was in patients with cancer (Grenabo Bergdahl et al. 2022) and two were in a mixed population of patients with benign and malignant disease (Di Franco et al. 2022, Prata et al. 2024). All three favoured robotic surgery over open surgery (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022) or MIS (Prata et al. 2024).

Intraoperative complications

Six studies evaluating Da Vinci Xi reported either overall, intraoperative or perioperative complications. Five studies compared Da Vinci Xi with MIS (Di Lascia et al. 2020, Galata et al. 2019, Gitas et al. 2022, Ozben et al. 2019, Muysoms et al. 2018) and one with open surgery (Di Franco et al. 2022). The proportion of patients experiencing complications varied widely from 0% to 62.5%, with the highest number reported by the study of pancreaticoduodenectomy which compared Da Vinci Xi (50%) to open surgery

(62.5%) (Di Franco et al. 2022). The lowest number of complications (0%) for Da Vinci Xi were reported in a study of colectomies (0/26 patients) (Ozben et al. 2019) and a study of groin hernia repair (0/49 patients) (Muysoms et al. 2018). However, where p-values were reported, none of the studies found a statistically significant difference in intraoperative or perioperative complications between robotic surgery and MIS or open surgery (Di Franco et al. 2022, Galata et al. 2019, Gitas et al. 2022, Ozben et al. 2019).

In the two studies comparing Da Vinci SP and Hugo to MIS, intraoperative and perioperative complication rates were low (Lee and Hong 2023, Prata et al. 2024) ranging from 2.1% in one MIS arm (Lee and Hong 2023) to 11.1% in the Hugo arm (Prata et al. 2024). Neither study reported a significant difference in intraoperative or perioperative complications (Lee and Hong 2023, Prata et al. 2024).

Intraoperative or perioperative complications were reported in all three studies evaluating Senhance (Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022). These ranged from 0% to 10% in the robotic arm and 0% to 15% in the MIS arm. None of the studies reported a significant difference between the arms.

One study evaluating Versius compared with MIS reported complications during primary admission. There were 6 (15%) reported in the Versius arm and 2 (10%) reported in the MIS arm. No significant difference was found between the two arms (p=0.59) (Dixon et al. 2024).

Where reported, none of the studies in any of the subgroups of interest found a significant difference in intraoperative or perioperative complications between the arms.

Postoperative complications

Four studies reported overall postoperative complications for Da Vinci Xi compared with MIS (Bilgin et al. 2020, Gitas et al. 2022, Muysoms et al. 2018) or open surgery (Di

Franco et al. 2022). In the studies of MIS, the proportion of postoperative complications varied and ranged from 2.4% to 30% in the Da Vinci Xi arms and 3.1% to 27.3% in the MIS arms (Bilgin et al. 2020, Gitas et al. 2022, Muysoms et al. 2018). For both MIS and Da Vinci Xi, the lowest rates of postoperative complications were found following hysterectomy for gynaecological indications (Gitas et al. 2022), whereas the highest rates were found following colectomy for left sided colonic diverticulitis (Bilgin et al. 2020). Postoperative complication rates were higher in the study comparing Da Vinci Xi to open surgery to conduct pancreatoduodenectomies (37.5% for Da Vinci Xi; 50% for open surgery) (Di Franco et al. 2022). None of the studies found a significant difference in postoperative complications between the modalities. One study (Ozben et al. 2019) reported cardiac and pulmonary complications, finding no significant difference between Da Vinci Xi and MIS ($p>0.99$ for both). Another study (Rattenborg et al. 2021) reported several surgical “in-hospital complications”: bleeding (2.9%), bowel paralysis/ileus (16.8%), wound abscess (2.5%) and anastomotic leakage (5.4%) but did not report p-values.

Postoperative complications were reported in all three studies evaluating Senhance (Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022). These ranged from 5% to 25% in the Senhance arm and 0% to 25% in the MIS arm. There was no significant differences found between the arms in any study.

Three studies comparing Da Vinci SP and Versius to MIS also reported postoperative complications (Lee and Hong 2023, Kakkilaya et al. 2023, Dixon et al. 2024). Two studies reported low proportions of complications (up to 3.2% across all arms), and there was no difference between the treatment arms in either study (Lee and Hong 2023, Kakkilaya et al. 2023). The third study reported post-discharge complications (<30 days) and found higher rates of complications (17.5% in the Versius arm and 30% in the MIS arm), but there was no significant difference reported ($p=0.27$).

Where reported, none of the studies in any of the subgroups of interest found a significant difference in postoperative complications between the arms.

Clavien-Dindo score

For Da Vinci Xi, where reported, under 25% patients experienced ≥ grade III Clavien-Dindo complications (Aktas et al. 2020, Espin Alvarez et al. 2023, Grenabo Bergdahl et al. 2022, Butnari et al. 2024, Di Franco et al. 2022, Galata et al. 2019, Gitas et al. 2022, Ozben et al. 2019, Rattenborg et al. 2021, Schmelzle et al. 2022). There was no significant difference in Clavien-Dindo score vs. MIS (Aktas et al. 2020, Espin Alvarez et al. 2023, Butnari et al. 2024, Galata et al. 2019, Ozben et al. 2019, Gitas et al. 2022, Schmelzle et al. 2022) or open surgery (Di Franco et al. 2022)

Two studies reported Clavien-Dindo grades for the Senhance robot (Aggarwal et al. 2020, Killaars et al. 2024). For Senhance, between 0% and 10% patients experienced ≥ grade III Clavien-Dindo complications, whereas for MIS this ranged from 5% and 15%. There was no statistically significant difference in Clavien-Dindo score vs. MIS reported (Aggarwal et al. 2020).

Of the other robots, only one study comparing Versius to MIS reported Clavien-Dindo grades (Dixon et al. 2024). One patient (5%) in the MIS arm experienced a ≥ grade III Clavien-Dindo complication (small bowel perforation secondary to ileus) during primary admission, which was graded as IVa. Additionally, one patient (2.5%) in the robotic arm experienced a post-discharge complication that was ≥ Clavien-Dindo grade III (graded at IIIa), for which they required a radiologically-guided drain insertion into a perineal wound collection.

Where reported, none of the studies in any of the subgroups of interest found a significant difference in Clavien-Dindo graded complications between the arms.

Health related quality of life (HRQoL)

One study comparing Da Vinci Xi with MIS reported information on HRQoL which was measured using the EuraHS QoL score (Muysoms et al. 2018). This study reported on patients with benign disease (groin hernia repair). There was no significant difference in the postoperative one-month scores (p=0.344), with a median (interquartile range (IQR)) of 4 (1 to 2) in the robotic arm and 6 (3 to 14) in the MIS arm.

Clinical outcomes – primary outcomes (surgeon level)

Procedure-related discomfort and ergonomics

One study of major colorectal resection for colorectal indications in a mixed malignant and benign population reported information on procedure-related discomfort and ergonomics (Dixon et al. 2024). The study used the Rapid Entire Body Assessment (REBA) posture analysis scale and the NASA Task Load Index (NASA-TLX) to assess ergonomic risk and cognitive strain in surgeons performing robotic (using Versius) or MIS. The study found that there was a significant difference in both scales in favour of Versius ($p<0.001$), suggesting both a lower ergonomic risk and lower overall cognitive strain when conducting robotic surgery with this technology.

Clinical outcomes – primary outcomes (organisation level)

Rate of MIS compared with open surgery after RAS was introduced

None of the prioritised studies reported the rate of MIS compared with open surgery after RAS was introduced

Volume of procedures

None of the prioritised studies reported the volume of procedures.

Hospital capacity and wait-list reduction

None of the prioritised studies reported hospital capacity and wait-list reduction.

Clinical outcomes – secondary outcomes (patient level)

Days alive and out of hospital at 30 days

None of the prioritised studies reported days alive and out of hospital at 30 days.

Post-operative pain

Four studies comparing Da Vinci Xi with MIS evaluated postoperative pain. One reported a pain score on a numbered scale from 1 to 10 (Gitas et al. 2022), one the pain domain of the EuraHS QoL score (Muysoms et al. 2018) two reported a VAS (score (Galata et al. 2019, Rattenborg et al. 2021) and one also reported the use of additional painkillers (Rattenborg et al. 2021). There was no significant difference in the pain score at either postoperative time point or on the pain domain of the EuraHS QoL score at one month (Gitas et al. 2022, Muysoms et al. 2018). One study also reported that there was no significant difference in pain in subgroups of patients with benign or malignant disease (Gitas et al. 2022). In the studies that measured pain using the VAS very similar scores were reported (Galata et al. 2019, Rattenborg et al. 2021), with a mean of 1.1 across the arms of one study (p=0.657) (Galata et al. 2019) and a median of 2 across the arms of the other (Rattenborg et al. 2021). In terms of additional painkillers, there was only a significant difference in the number of patients who received additional gabapentin (p=0.0006), with more patients receiving it in the Da Vinci Xi arm (88%) for intracorporeal anastomosis than the other two arms (56% in the MIS arm and 52% in the Da Vinci Xi arm for extracorporeal anastomosis) (Rattenborg et al. 2021). There was no difference in the amount of additional paracetamol, NSAIDS or opioids given in this study.

One study comparing Senhance with MIS reported the proportion of patients who experienced pain (Aggarwal et al. 2020) and found no difference between the surgeries, with 5% reporting pain in each arm.

Two studies comparing Versius with MIS both reported post-operative pain (Dixon et al. 2024, Kakkilaya et al. 2023). One study reported a pain score at four different timepoints (postoperative day 1, 2, 3 and 28) (Dixon et al. 2024). Pain was low in both arms (a maximum median of 1 in the robotic arm and 0.5 in the MIS arm) and there was no significant difference between the surgeries at any time point. In the second study, MIS exhibited significantly higher pain at postoperative day 1 when measured by a VAS (a mean of 1.43 in the robotic arm and 2.06 in the MIS arm; p=0.023), but there was no significant difference between the arms by week one or month one (Kakkilaya et al. 2023).

Neither study evaluating Da Vinci SP or Hugo reported post-operative pain (Lee and Hong 2023, Prata et al. 2024).

Of the two studies that reported significant differences in post-operative pain-related outcomes, one was in patients with colon cancer (Rattenborg et al. 2021) and one in a benign condition (hernia repair) (Kakkilaya et al. 2023). The study of hernia repair (measuring pain on the VAS) found patients had significantly lower pain with robotic surgery compared with MIS (Kakkilaya et al. 2023). The study in colon cancer only reported a statistically significant difference in the proportion of patients prescribed one additional painkiller (garbapetin) but found no differences in VAS scores or other pain medication between the arms (Rattenborg et al. 2021).

Satisfaction with surgery

One study (Da Vinci Xi vs. MIS) evaluated postoperative satisfaction in patients who had a hysterectomy for either benign or malignant conditions (Gitas et al. 2022). The study measured patient satisfaction with the cosmetic outcome and preoperative explanation and found that over 85% patients for each arm were satisfied with both. There was no significant difference between the types of surgery (p=0.723 and p=0.208 for cosmetic outcome and preoperative explanation, respectively). The study also found that there was no significant difference in the subgroups of patients with benign or malignant disease for either outcome.

Revision surgery for the same indication

Seven studies, five comparing Da Vinci Xi with MIS (Espin Alvarez et al. 2023, Butnari et al. 2024, Galata et al. 2019, Gitas et al. 2022, Ozben et al. 2019) and two with open surgery (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022) reported the proportion of patients who were reoperated on for the same indication. One open surgery study only reported the proportion for the Da Vinci Xi group (6.9%) (Grenabo Bergdahl et al. 2022) and one MIS study did not report a p-value for the difference between treatments (Espin Alvarez et al. 2023). However, the proportion of reoperations were similar in each arm (4.3% and 3.2% in the Da Vinci Xi and MIS arm, respectively).

In the remaining four studies vs. MIS, up to 9% in the Da Vinci Xi arm and 12.5% in the MIS arm required reoperation (Butnari et al. 2024, Galata et al. 2019, Gitas et al. 2022, Ozben et al. 2019). Similarly, proportions were low in the study comparing Da Vinci Xi (0%) to open surgery (5%) (Di Franco et al. 2022). There was no significant difference in the number of reoperations between robotic surgery or MIS, or between robotic and open surgery, in any of these studies.

One study comparing Senhance with laparoscopic surgery found that 10% patients in the robotic arm and 15% patients in the MIS arm required reintervention following surgery (Killaars et al. 2024). The study found no significant difference between the two arms (p=1.000).

Where reported, none of the studies in any of the subgroups of interest found a significant difference in the proportion of patients needing reoperation.

Clinical outcomes – secondary outcomes (patient level- specific study designs)

Compared with open surgery – intraoperative blood loss

One study evaluating Da Vinci Xi vs. open surgery in patients with metastatic germ cell cancer reported the estimated blood loss which was significantly higher in the open surgery arm than in the robotic arm (p<0.01) (Grenabo Bergdahl et al. 2022).

Cancer studies – survival rate

None of the studies in cancer patients reported survival rates. However, two evaluating Da Vinci Xi vs. MIS reported mortality at 30 days (Aktas et al. 2020, Di Lascia et al. 2020) and one at 90 days (Butnari et al. 2024). One of the studies reported no mortality (Di Lascia et al. 2020), one reported 0% mortality in the Da Vinci Xi arm and 3.2% mortality (2 patients) in the MIS arm and the other 2% mortality in the Da Vinci Xi arm and 2.67% in the MIS arm. There was no significant differences reported in these studies (Aktas et al. 2020, Butnari et al. 2024).

Cancer studies – need for adjuvant treatment

One study comparing Da Vinci Xi with open surgery reported the need for adjuvant treatment, 2/29 patients received adjuvant chemotherapy in the Da Vinci Xi arm. The difference between this and the open surgery arm was not reported (Grenabo Bergdahl et al. 2022).

Head and neck studies – feeding tube dependency

None of the prioritised studies reported feeding tube dependency.

Clinical outcomes – secondary outcomes (surgeon level)

Career longevity and musculoskeletal injury

None of the prioritised studies reported information on career longevity and musculoskeletal injury.

Human factors

One study evaluating Versius vs. MIS in a mixed population with malignant and benign conditions assessed intraoperative team communication using the Oxford NOTECHS II score. The study reported a mean (standard deviation (SD)) score of 72.6 (3.7) in the robotic arm and 71.6 (3.9) in the MIS arm and found no significant difference in intraoperative communication between the two modalities (p=0.33) (Dixon et al. 2024).

Learning curve

Three studies evaluating Da Vinci Xi reported data on surgeon learning curve (Di Lascia et al. 2020, Gitas et al. 2022, Muysoms et al. 2018). The first study compared the duration of the first and last three robotic surgeries and found a significant reduction

in the duration of surgery in the last three compared with the first three (Di Lascia et al. 2020). The second study compared the duration of the first and last fifty robotic surgeries, finding that the last 50 surgeries were marginally quicker with a mean of 141.54 vs. 144.38 minutes (Gitas et al. 2022). However, the study found no significant difference (p=0.945). The third study divided surgery into halves or tertiles to compare skin-to-skin and overall operating times and found that the time taken to conduct robotic surgery decreased for both unilateral and bilateral hernias over time (significance not reported) (Muysoms et al. 2018). The same study also found a decrease in console time.

One study comparing Senhance to MIS found a significant difference in the time it took to conduct the first 10 of 20 robotic surgeries (mean (SD):164 (42) minutes) compared with the last 10 robotic surgeries (mean (SD): 120 (15) minutes; p=0.024) (Killaars et al. 2024). A second study evaluating Senhance found that operating time with the robot decreased over the series of 20 operations yet was consistently higher than MIS (Aggarwal et al. 2020). Docking and console time also decreased in this study, but there was no significant difference between the first and last ten surgeries.

One study evaluating the Versius robot reported a reduction in docking time for the first 16 cases (mean: 15.8 minutes) compared with the following 16 cases (mean: 12.31 minutes) and the final 12 cases (mean: 9.76 minutes), suggesting that overall operating time could also be reduced over time (Kakkilaya et al. 2023). No p-value was reported.

One of the two studies that reported significant reductions in the time it took to conduct the later robotic surgeries was conducted in cancer patients (Di Lascia et al. 2020), and the other was in a benign condition (gastroesophageal reflux disease) and a pediatric population (Killaars et al. 2024). The remaining studies (three in a benign population and one in a mixed population including patients with cancer) either were not significant

or did not report p-values (Aggarwal et al. 2020, Kakkilaya et al. 2023, Muysoms et al. 2018, Gitas et al. 2022).

Clinical outcomes – secondary outcomes (organisation level)

Readmission at 30 days

Six studies assessing Da Vinci Xi vs. MIS reported readmission rates. Five reported non-significant differences between the arms (Espin Alvarez et al. 2023, Bilgin et al. 2020, Butnari et al. 2024, Galata et al. 2019, Ozben et al. 2019). The sixth study reported three readmissions in one of the two robotic arms in the study (intracorporeal anastomosis vs extracorporeal anastomosis) but did not report a p-value for the difference between treatments (Rattenborg et al. 2021).

One study evaluating Senhance reported readmission rates (Killaars et al. 2024). In this study 2 (10%) patients were readmitted in the Senhance arm and 0 (0%) in the MIS arm. There was no significant difference between the two arms (p=0.500).

In two studies comparing Hugo and Versius with MIS, the proportion of patients readmitted within 30 days was 0% in both arms of the Hugo study and 5% in the Versius study, suggesting no difference between the robotic and MIS arms (Prata et al. 2024, Dixon et al. 2024).

Where reported, none of the studies in any of the subgroups found significant differences in readmission rates.

Operating time

All 20 studies reported information on operating time. Operating time was not clearly defined by all of the studies. However, the below narrative focuses on the outcome described closest by each study as the “overall” or “total” operative time. Where studies

have reported multiple durations for the different elements of surgery (e.g. docking and console time), these have been extracted and can be found in Table C:7.

For Da Vinci Xi, operating time was reported to be significantly longer than MIS in seven studies (Aktas et al. 2020, Espin Alvarez et al. 2023, Butnari et al. 2024, Di Lascia et al. 2020, Galata et al. 2019, Ozben et al. 2019, Rattenborg et al. 2021). In these seven studies, the median operating time ranged from 247.5 minutes to 400 minutes for Da Vinci Xi and 200 to 250 minutes for MIS. The mean operating time ranged from 138 to 394 minutes for Da Vinci Xi and 104 to 324 minutes for MIS. There was no significant difference in time when compared with MIS in a further two studies (Bilgin et al. 2020, Schmelzle et al. 2022).

In the two studies comparing Da Vinci Xi with open surgery, both reported longer operating times with Da Vinci Xi (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022). One reported a non-significant p-value (p=0.212) (Di Franco et al. 2022). In the remaining two Da Vinci Xi studies, one reported longer total operating times for Da Vinci Xi than MIS (but no p-value for the difference) (Muysoms et al. 2018) and the other did not report times for MIS, only Da Vinci Xi (Gitas et al. 2022).

In the three studies comparing Senhance with MIS, all three found that robotic surgery took significantly longer than MIS (Aggarwal et al. 2020, Killaars et al. 2024, Samalavicius et al. 2022). Two of the studies reported mean operating time, which was 88.5 and 142 minutes for Senhance, and 60.8 and 93 minutes for MIS. The third study reported the median total operating time, which was 86.5 minutes for Senhance and 31.5 minutes for MIS (Aggarwal et al. 2020).

For the three other technologies, results were mixed. In the study evaluating Da Vinci SP, mean overall operating time was significantly shorter in the MIS arm (76.38 minutes) compared with Da Vinci SP (111.26 minutes; p<0.01) (Lee and Hong 2023).

There was no significant difference in operating time when comparing Versius to MIS in one study (p=0.21) (Dixon et al. 2024), but there was a difference in favour of MIS for the other (mean: 38.45 minutes vs. 60.47 minutes;p=0.001) (Kakkilaya et al. 2023). For the Hugo robot, operating time was significantly shorter than MIS (median: 91 minutes vs 149.5 minutes; p=0.005) (Prata et al. 2024).

Where reported in the cancer subgroup and the benign subgroup, the majority of studies (5/6 in the cancer subgroup; 5/7 in the benign subgroup), found that robotic surgery took significantly longer than MIS (Aktas et al. 2020, Butnari et al. 2024, Di Lascia et al. 2020, Galata et al. 2019, Rattenborg et al. 2021, Lee and Hong 2023, Killaars et al. 2024, Kakkilaya et al. 2023, Aggarwal et al. 2020, Samalavicius et al. 2022). In the studies that evaluated a mixed benign and malignant population, results varied. Two studies reported a significant difference in operative time favouring MIS (Espin Alvarez et al. 2023, Ozben et al. 2019), one reported a significant difference favouring robotic surgery (Prata et al. 2024) and three reported no significant difference (two vs. MIS and one vs. open surgery) (Di Franco et al. 2022, Schmelzle et al. 2022, Dixon et al. 2024). In the study of a pediatric population, robotic surgery also took significantly longer than MIS (Killaars et al. 2024). The final study in a mixed population did not report operative time for MIS (Gitas et al. 2022).

Staffing requirements

None of the prioritised studies reported staffing requirements.

6 Adverse events and clinical risk

The adverse events reported by the studies were perioperative and postoperative complications, Clavien-Dindo scores and rates of conversion to either MIS or open surgery. The details are discussed in Section 5.3 and presented in Appendix C .

7 Evidence synthesis

The results of the studies are narratively discussed.

The EAG prioritised 20 studies. The evidence-base evaluated the use of robotic surgery in patients with a variety of both benign and malignant indications (including colorectal, hepato-pancreato-biliary and gynaecological). Therefore, a range of different surgeries were included such as colectomy, pancreatoduodenectomy and hysterectomy. Patient demographics, such as age, varied between studies and one study reported results for a pediatric population (Killaars et al. 2024). Some outcomes were reported using different descriptive statistics, and definitions were sometimes unclear or different (for example for intraoperative/perioperative complications and operative time)

For primary outcomes where evidence was available at a patient level (conversion rate, intraoperative complications, postoperative complications, Clavien-Dindo score, HRQoL and LoS), one prospective cohort study in patients undergoing anterior resection for rectal adenocarcinoma reported a significant difference in conversion rate in favour of MIS (Galata et al. 2019). Differences were found in hospital LoS when comparing robotic (Da Vinci Xi) to open surgery and suggested a shorter LoS for robotic surgery (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022). However, there was only a difference between robotic surgery and MIS reported in one study, where patients in the Hugo arm had a statistically significantly shorter LoS (Prata et al. 2024). None of the remaining studies reported a significant difference between robotic surgery and MIS or open surgery in any patient-level outcome. Primary outcomes at a surgeon level (procedure-related discomfort and ergonomics) were only measured by one study, which reported a significant difference in favour of the Versius robot (compared with

MIS) (Dixon et al. 2024). Finally, three retrospective, one prospective non-randomised study and two historically controlled cohort studies reported data on surgeon learning curve and found that operative or docking time for RAS decreased between the first and last surgeries conducted (Di Lascia et al. 2020, Gitas et al. 2022, Muysoms et al. 2018, Killaars et al. 2024, Kakkilaya et al. 2023, Aggarwal et al. 2020). Two studies reported that the difference in the time taken to conduct RAS was statistically significant (Di Lascia et al. 2020, Killaars et al. 2024). The number of surgeries assessed varied across the studies from 6 (first three vs. last three) to 100 (first 50 vs. last 50).

8 Economic evidence

8.1 Economic evidence

A single set of searches was conducted to identify both clinical and economic evidence for the scoped technologies (see Section 4.1). Search methods are reported in Appendix A and study selection criteria is summarised in Appendix D . Three costing studies were identified through the searches and company submitted evidence and are summarised below and in Table 8.1 One company submitted document from Intuitive was an unpublished cost analysis of potential savings from da Vinci Xi Surgical System in England. One published study assessed the comparative cost of da Vinci Xi and da Vinci Si Surgical Systems in Switzerland. The other identified study considered the Senhance robot, compared with laparoscopic surgery and an unspecified iteration of the da Vinci robot. Three other studies reporting costs for da Vinci systems set in Italy were de-prioritised, but are briefly summarised below. No economic evidence was identified for Hugo or Versius. Additional evidence was identified for other economic evaluations of RAS, although, these studies were not specific to the scoped interventions and were therefore deprioritised.

Intuitive submitted a cost-comparison analysis as part of their company submission documents (Chatterjee 2022). It was a 2022 analysis of potential cost savings for da Vinci Xi used in malignant hysterectomy, from an England perspective, intended for key stakeholders (potential payers). Total potential cost avoidance per case where RAS is used was reported as £3,433 (open surgery) and £1,610 (laparoscopic surgery). However, the results did not include the costs of the da Vinci system, annual service costs, and other robot-related surgery costs. Therefore, the results do not account for all costs' impacts to the healthcare system. The parameters were costed by Intuitive using nationally recognised sources representing national averages, which included NHS data. No single cost year was reported.

Niclauss et al. (2019) assessed the cost impact of da Vinci Xi and da Vinci Si Surgical System (both Intuitive Surgical) in Roux-En-Y gastric bypass procedures in Switzerland (Niclauss et al. 2019). The main cost difference was acquisition cost of a robot console: EUR 1,850,000 for da Vinci Xi versus EUR 1,590,000 for da Vinci Si. There was no significant difference in clinical outcomes such as complications (and therefore, the associated costs).

Coussons et al. (2021) evaluated the cost impact of Senhance compared with the da Vinci robot (unspecified model iteration) and laparoscopic surgery for vaginal hysterectomy procedures. The study used data from six surgeons' patients across four US and European hospitals. The study was prioritised as it was the only study that provided economic outcomes for Senhance. The study suggested that Senhance had a lower median instrument cost per surgery when compared with da Vinci ($559 vs $1393 respectively) and similar operative times (91.5 minutes vs 96 minutes, p=0.898). The study also suggested that Senhance and standard laparoscopic costs were similar, despite surgeons still being within their learning curve period. The study omitted key costs that should be considered within an economic evaluation, and used a multi-

country perspective, where outcomes are not likely to be generalisable. The results should therefore be interpreted with caution (Coussons et al. 2021).

Three studies (Di Franco et al. 2022, Morelli et al. 2019, Marra et al. 2023) assessed da Vinci Xi in Italian settings (Morelli et al compared da Vinci Xi to da Vinci Si) and so were de-prioritised as not providing UK evidence. These were costing studies that reported favourably for the da Vinci systems compared to non-RAS interventions in respect of safety and impact on lowering hospital stay costs. The deprioritised studies covered procedures for pancreatoduodenectomy, ventral mesh rectopexy and total mesorectal excision resection for rectal cancer. Other deprioritised UK studies which did not identify specific robotic platforms highlighted a range of cost-effectiveness results, ranging from dominant incremental cost-effectiveness ratios (ICERs) (cost-savings and positive health outcomes) to ICERs over £100,000 per quality adjusted life year (QALY), across a range of specific procedures. Previous published evidence only considered specific procedures, rather than soft-tissue procedures as a whole.

Table 8.1: Narrative summary of economic studies

Study ID and location	Title	Study type	Narrative summary
da Vinci Xi			
Intuitive company submission costing model for da Vinci Xi (2022) England	Quantify the impact - Malignant Hysterectomy	Cost-comparison analysis	• Intuitive submitted a costing model as part of their company submission documents. It was a 2022 analysis of potential cost savings for da Vinci Xi used in malignant hysterectomy, from an England perspective, intended for key stakeholders (potential payers). • It reported potential differences in clinical outcomes and associated cost savings when using RAS versus other surgical methods (open and laparoscopic surgery were calculated). The parameters were costed by Intuitive using nationally recognised sources representing national averages, which included NHS data sources. • Total potential cost avoidance per case where RAS is used was reported as £3,433 (open surgery) and £1,610 (laparoscopic surgery). Areas of savings were from reduced LoS, post-operative complications, readmissions and conversions. • These savings were applied to a single-surgeon experience (based in the UK) using 2016 to 2021 data across procedures for the three surgical methods: da Vinci Xi (n=166), open (n=162) and laparoscopic surgery (n=53). Hence, the results do not factor in learning curve experience, given the surgeon was well trained in robotic surgery.

			• The results do not account for the cost of the robotic platform itself, as well as additional costs such as maintenance or additional instruments. As such, the results are only reflecting the potential benefits of RAS, not the additional costs from using the platform. • An important limitation to this analysis was it was intended only as providing “directional data” aimed at potential payers and has not been peer-reviewed. The authors declared it should not be considered as substitute for published clinical studies.
Niclauss et al. (2019) Switzerland	A comparison of the da Vinci Xi vs. the da Vinci Si Surgical System for Roux-En-Y gastric bypass	Cost-comparison analysis	• Da Vinci Xi was compared with da Vinci Si Surgical System (both Intuitive) in Switzerland. It was a retrospective cost-comparison analysis of Roux-En-Y gastric bypass procedures used in clinical practice: da Vinci Si (n=195) used from January 2013 to March 2015); da Vinci Xi (n=144) used from April 2015 to September 2016. • 2018 costs were used for acquisition costs, maintenance costs and costs of instruments, provided by intuitive (total costs were not reported). Clinical outcomes (and their associated costs) were very similar between the two devices, with the difference in results driven by the robotic platform costs. For instance, acquisition costs were higher for da Vinci Xi (robot simple console: EUR 1,850,000 versus EUR 1,590,000; second console costs were both EUR 450,000). • Annual maintenance costs were the same (simple console EUR 150,000, double console 175,000). • A standard set of robotic instruments (without stapling device) used for the procedure were slightly more costly for the da Vinci Xi (EUR 2,258 versus EUR 2,123).

			• Limitations to this analysis included: no consideration for stapling devices (the authors cite a published study that reports higher costs for this for RAS), different time spans used with different surgeons (which is likely to impact learning curves) and evolving surgical techniques over time.
Senhance			
Coussons et al. (2021) US and Europe	Senhance surgical system in benign hysterectomy: A real-world comparative assessment of case times and instrument costs versus da Vinci robotics and laparoscopic-assisted vaginal hysterectomy procedures	Cost-comparison analysis	• Senhance was compared with the da Vinci robot (unspecified model iteration) and laparoscopic surgery for vaginal hysterectomy procedures. The study used data from six surgeons' patients across four US and European hospitals, so used a multi-country perspective, with costs provided in US dollars. • The study reported differences in console time, surgery elapsed time, instrument costs and median cost savings. The analysis did not take into account other factors associated with robot, such as the platform costs, maintenance costs, or training costs. • The results indicated that Senhance resulted in lower median instrument costs when compared with the da Vinci robot ($559 vs. $1393, respectively), as well as comparable console times (91.5 minutes vs 96 minutes, p=0.898). The results also indicated similar costs between standard laparoscopic surgery and RAS with Senhance ($559 vs $498, p=0.336). • Limitations to this analysis included: no consideration of other cost factors associated with RAS, such as the robotic platform, maintenance and training costs. The multi-country perspective is likely not robust given the lack of generalisability between European and US healthcare systems.

Key: EUR – Euros, RAS – Robot assisted surgery, US – United States.

8.2 Conceptual model

The primary purpose of this analysis was to assess whether it is plausible that using robot-assisted surgery could be a cost-effective intervention. RAS, a form of MIS, was compared with conventional MIS (without robotic platforms) or open surgery for soft-tissue procedures. However, there may be specific sub-populations (such as those at high risk of complications) for specific disease areas or conditions, where surgery may not be viable under standard surgical care. Comparators beyond standard surgical care are not considered within this early evaluation. We discuss subpopulations, additional benefits, and future economic modelling recommendations later in this report. The secondary aims of the analysis were to identify the value of future research, to understand the likely key drivers of the results, and to identify the current evidence gaps.

A cost-comparison model was designed to capture the potential benefit that could be provided from these technologies over a 1-year time horizon. We did not conduct an evaluation over a long-term time horizon due to existing evidence gaps. Furthermore, evidence available to populate the model is often based on one specific procedure, where common short-term outcomes are likely to differ substantially between procedures and populations. There are also likely variations in the costs associated with different surgical settings. Some of these cost differences may include the pricing structures of robotic platforms, staff involved in the procedure, maintenance, training, and the learning curve associated with the platforms. Finally, technologies within scope for this EVA have all collected evidence with varying degrees of quality.

This evaluation is not intended to capture one base case that represents all RAS procedures and platforms. However, the model can be used to highlight how changes in key-short term features impact the ranges of results or ‘ballpark’ that the technology may operate in, at least with respect to short-term outcomes. The model can be used to

conduct specific scenarios, including pricing structures or more specific elements of the technologies. The EAG considers that the cost-comparison model can provide an indication of the potential results, given the base case assumptions. Therefore, this should be useful for decision-makers to evaluate the potential of robotic platforms to support surgical care. In line with the purposes and scope of this EVA, it will not evaluate every possible scenario in relation to robotic surgery for soft-tissue procedures.

Population

The EAG considered adults who require a soft-tissue surgical procedure. This differs from the NICE final Scope, with the intended populations adults or children. The difference in scope is because 3 of the 4 technologies within scope are yet to be indicated for use in paediatrics. Current evidence is primarily captured in adult populations. The available evidence focuses on specific procedures and studies. Therefore, the EAG took a pragmatic approach, which mixes evidence across procedures. This is then varied in sensitivity analysis to capture ranges reported across the literature, and to understand the impact on the results. The generalisability of evidence across procedures and clinical specialties should be considered by decision-makers. The results of the analysis should be interpreted with caution, focusing on the potential ranges reported, rather than a specific base-case result.

Model structure

The model used by the EAG was a cost-comparison model with a 1-year time horizon. The model estimated resource use across the different treatment arms, and then applied costs to the different resource use. QALYs were not captured given the model only takes a short-term time horizon. The EAG considered it was more useful to reflect potential health outcomes from other economic evaluations of specific procedures at

this early evaluation stage. The one-year time horizon was used because the long-term benefit of RAS was highly uncertain, and varied substantially based on the procedures that the robotic platform is used for. It was not plausible to capture long-term outcomes which were generalisable to each clinical specialty and procedure. Furthermore, even within procedures, there is likely to be substantial heterogeneity within populations undergoing procedures, also limiting the ability to quantify any long-term impacts. The EAG considered in the context of the existing evidence, a 1-year time horizon is appropriate, although, future evaluations should incorporate longer time horizons (Erskine et al. 2023) as highlighted in a recent international consensus expert panel. A discussion of potential future modelling approaches is covered in Section 10.2. The short-term impact captured in the model was presented as incremental cost of RAS. The results presented throughout indicate the long-term benefit required to be cost-effective, with respect to health outcomes. Furthermore, Section 0 compares the required long-term benefit with existing studies in RAS for soft-tissue procedures. Cost-effectiveness is determined by using a threshold of £20,000 per QALY.

The model structure was limited by the level of evidence available, and assumptions have been needed to populate it. The model should therefore be seen as an initial exploration of the economic impact of RAS for soft-tissue surgical procedures.

The model captured different resource use that can be attributed to care associated with soft-tissue surgical procedures. In the base case, the modelling approach took the perspective of the NHS and personal social services. The key aspect of the model was to capture key short-term resource use based on the available evidence and clinical assumptions, that was generalisable to each clinical specialty and procedure type. The first step of the model is differentiating the proportion of MIS relative to open (and their associated costs), as well as conversion rates, with and without RAS. This is because a value proposition of RAS is increasing the proportion of MIS, since RAS is a form of

MIS, as well as reducing conversions to open surgery, which may improve surgical outcomes. The next step is assigning differences in resource use associated with different surgery types, including:

- LoS
- complication rates, stratified by Clavien-Dindo grades
- staff time
- operating theatre time and resources
- readmissions.

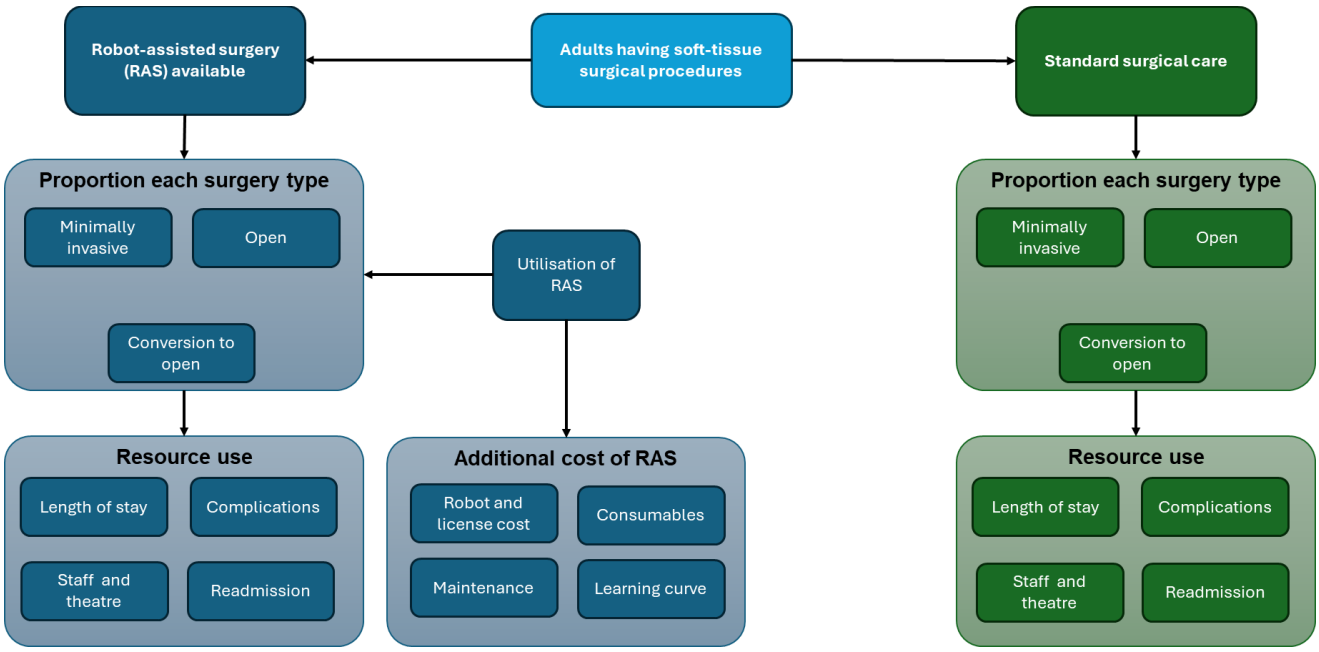
Stratification by Clavien-Dindo grades were validated with clinical experts, which guided the costs based on common complications in their respective specialties (York Health Economic Consortium 2024). We ran scenarios on length of stay and readmission rates independently to reduce risk of double counting reported complications. This is because the available studies did not stipulate whether complications were associated with increased length of stay or readmissions or did not report each metric.

The estimated resource use is not exhaustive. This is because of the wide variability across soft-tissue procedures. Resource use is likely to differ substantially depending on the specialties and surgery types involving robotic platforms. Furthermore, our evaluation does not capture any future resource savings, which may stem from more precise or accurate surgeries, or reduction in open surgeries. We assumed that there are no costs associated with mortality (such as grade V complications on the Clavien-Dindo scale), this is because the length of time to death cannot be extracted. This means we have assumed that if the person died during the surgery, it is unlikely there would be significantly higher costs when compared with other surgeries. This may be an underestimate of resource use to not capture mortality-related costs, which should be considered when interpreting any results. Mortality rates in the identified clinical

studies were minimal, not exceeding more than 3 people in any treatment arm, and in 1 of the 3 prioritised studies, zero deaths were reported.

Future modelling as more evidence is collected should consider longer-term outcomes. Potential approaches for future economic evaluations are detailed in Section 10.2. The cost-comparison model diagram is presented in Figure 8.1.

Figure 8.1: Cost-comparison model structure



Outcomes from the model included incremental cost between treatment arms, breakdown in resource use, and clinical outcomes such as differences in LoS and surgery time. The results also include the uncaptured benefit (such as long-term outcomes) required from RAS to be cost-effective, presented in QALYs. This is due to potentially uncaptured benefit from different procedures, which may occur in the long-

term from RAS compared with standard surgical care. Benefits of RAS may include differences in survival, improved quality of life or reductions in future resource use.

Deterministic sensitivity analysis (DSA) was conducted and represented graphically using a tornado diagram, which highlights the key drivers of the model results. Economically justifiable price (EJP) was also calculated for different scenarios. EJP should be interpreted with caution and should be considered with respect to a range rather than a specific value. This is because the results of the analysis are designed to be indicative due to the substantial heterogeneity across outcomes and procedures.

Probabilistic sensitivity analysis (PSA) was conducted, with 1,000 simulations of the model run (enough for the results to stabilise), and the results averaged. The results consistently stabilised after 500 simulations. Where possible, confidence intervals or appropriate ranges (based on clinical experts or ranges from available evidence) were used to inform parameter uncertainty. Where no appropriate ranges could be determined, a standard error of 20% of the mean was assumed to inform parameter uncertainty. Although this is an arbitrary variation, the EAG notes this still allows for greater understanding of the key drivers. Future modelling should look to determine appropriate confidence intervals for all parameters of interest.

This report provides a range of deterministic and probabilistic results and sensitivity analysis. The EAG recommends that the committee considers the potential ranges at this early stage of evaluation, rather than a central estimated result, given the substantial heterogeneity in this evaluation. Not every input used in the economic model reported standard errors to vary in PSA. Therefore, PSA may be less useful due to the unknown uncertainty among the inputs. It is therefore more likely to be useful to view the deterministic and probabilistic values alongside each other.

8.2.1 Assumptions and limitations

A number of assumptions were required to produce the cost-comparison model using the available data. These assumptions may not completely reflect all soft-tissue procedures that are included within scope. These assumptions are discussed in Table 8.4

Table 8.2: Assumptions and limitations of the current model

Assumption	Discussion
Costs of the robotic platforms can be scaled down to a per surgery cost based on utilisation of the robot (expected number of surgeries)	The running cost of the robotic platform is included per surgery. These costs vary between companies as listed on NHS supply chain, and these costs do not include commercial discounts or alternative payment structures offered by companies to the NHS. Ranges are therefore included in sensitivity analysis to capture potential differences in costings, as well as leasing structure provided as a scenario analysis. Costs are annutised based on the lifespan of the technology, rather than an upfront cost.
The impact on total number of surgeries is not captured in the model	The impact on the total number of surgeries conducted is likely to be very specific to the case mix for the robotic platforms. Based on clinical advice received by the EAG (York Health Economic Consortium 2024), it is likely in the short-term less surgeries will be conducted due to the learning curve with surgeons adapting to the robotic platform. In the longer-term, surgeries may return to a similar number before RAS was introduced, or for more specific procedures, may increase the number of surgeries that can be performed. Reasons for potentially increasing the number of surgeries may be due to the reduced physical burden of RAS. The impact of RAS on total surgical capacity is highly uncertain but may be beneficial in the long-term. This is discussed further in Section 0.
The impact on physicians' health is not captured in the model	It is reported that improving the physical burden on surgical staff is one benefit of RAS (Cole A et al. 2018). At a per surgery impact, it is not feasible to quantify the potential impact of reducing physical burden on surgical staff with respect to economic outcomes. However, the EAG notes this is a valuable potential impact of RAS, as this may also lead to increased workforce retention or less absenteeism among surgical staff. This is discussed further in Section 9.2.
There may be double counting of resource from capturing readmissions, complications and LoS in the model	All the listed outcomes are reported across available evidence. It is plausible that those who have complications, or more severe complications, have a longer LoS. Differences in LoS may be indirectly reflecting differences in complications. Furthermore, specific complications may occur after discharge, but are a result of surgery and so may be reflected in complication rates already. The EAG acknowledges this potential double counting and has conducted a range of scenarios to determine the potential impact of including different combinations in the model.

Assumption	Discussion
Long-term outcomes of RAS are not captured. The model uses a time horizon of 1 year due to the diverse range of long-term outcomes from soft-tissue procedures	People who undergo RAS may realise benefits, such as improved quality or quantity of life or reduction in healthcare resource use over time. For example, those undergoing surgeries related to cancer, may see improvements in overall or progression free survival. The long-term follow up evidence is currently for very specific use cases of RAS, and outcomes are not generalisable to other procedures. Furthermore, even for specific procedures, there is likely substantial heterogeneity in people undergoing those procedures, meaning estimates of long-term impacts are likely to be very diverse and uncertain. A short-term perspective is taken for this analysis, with results presented and contextualized with respect the required long-term outcomes required for RAS to be cost-effective. The EAG notes this should be discussed among the committee, and the available evidence should be considered to determine if the required long-term benefits are expected to be realised.
Evidence used to populate the model contains a mix of different populations undergoing soft tissue procedures.	Evidence available to populate the model was mostly related to very specific procedures, rather than a case mix of different soft-tissue procedures. It is likely that the case-mix of the robotic platform will lead to different outcomes. The modelling approach focuses more on the ranges across the available data, and manipulating the model to estimate the impact this may have on the results. It is not likely that one representative base case result can be provided, rather, a range of different estimates. As a result, the model may overestimate or underestimate the true cost impact of RAS for specific procedures. The impact of generalisability should be considered as part of decision-making.
The model does not necessarily reflect the impact of RAS in children	There is limited evidence available for RAS in children. Three of the 4 scoped interventions are not indicated for use in children. Therefore, the model is not likely to be representative of RAS in children.
The model only captures the impact of introducing one robotic platform for soft-tissue surgical procedures	If more than one robotic platform is introduced, it is more likely the platforms will be used across a greater range of specialties. Of the scoped technologies, only Versius and the Hugo Robotic-Assisted Surgery System were portable across surgical theatres (though, the degree of portability between the two systems may differ). The da Vinci X / Xi and SP Surgical Systems are likely to be used on a more specific population when implemented. Portable systems may be more beneficial for adoption of RAS in low-volume surgical specialties, if it can be shared more easily. However, portable systems may incur additional costs from staff time having to move the system between surgical theatres. These potential impacts on costs or utilisation have not been explicitly captured in the early analysis but are explored further qualitatively in Section 0.

Assumption	Discussion
Cleaning costs for surgical instruments were not captured within the model	From our past experience of costing cleaning of instruments within the NHS, the processes (and therefore costs) differ significantly at each local hospital. For example, some hospitals conduct this onsite, whereas others transport them elsewhere. Furthermore, there is a wide range of providers for this service (or parts of this service), who all have their own costings. There is likely to be large variation within costing for cleaning of instruments. Clinical experts highlighted there is likely a substitution effect to the instruments required from RAS and other types of surgery, rather than just additional instruments being required (York Health Economic Consortium 2024). This means that the cleaning costs are dependent on what instruments are no longer required (and therefore do not need to be cleaned) and the new instruments from conducting RAS. In cases where there is a substitution of instruments, the difference in cleaning costs may be minimal.
Energy and IT software costs associated with RAS have not been included	No suitable evidence could be identified to estimate difference in energy costs, and the IT costs associated with adopting a robotic platform. From the company information provided, it is not clear if in some cases this is provided as part of the service offered by company. This may mean that costs are underestimated from adopting the robotic platform, and this may differ across companies.
Cost associated with theatre installation have not been included	No suitable evidence could be identified to estimate the cost of theatre installation. Furthermore, it is not clear if the robot will need significant theatre adaptations, or if the theatre is already suitable. This cost is likely to vary substantially based on the theatre, the robotic platform and the requirements of the surgeries it will be used for. This installation cost may be a high up front expense but may only be small when spread over the cost per procedure.
For specific conditions, the comparator may not be standard surgical care	For example, people with cancer who are at very high risk of surgery, may not undergo surgery in standard of care, but may do with RAS. In this case, the comparator is more likely to be non-surgical treatment, such as radiotherapy. We have not modelled every possible case for every procedure given the scope of an early value assessment. The aim is to look at the plausibility of robotic platforms for use in soft tissue procedures as a whole. We have therefore not considered the specifics of individual procedures at this stage, but this should be considered in detail in any future guidance.
The learning curve is included in the model by adjusting the impact on length of stay and surgery time until the learning curve is complete.	Clinical feedback indicated that the learning curve is heterogenous based on the surgeons' characteristics. Factors impacting the learning curve are likely the complexity of the procedure and experience with robotic platforms. Based on the feedback, the EAG captured the learning curve in the model, assuming it would take surgeons 4 months (a quarter of their surgeries in the first year) to become proficient. An additional 30 minutes of procedure time and no benefit to length of stay is included while on the learning curve.

Assumption	Discussion
	However, it is important to note that the learning curve may already be captured within the clinical parameters used in the model. Therefore, we have conducted scenarios with this assumption toggled on and off, which should be considered when evaluating the cost-effectiveness of RAS.
The impact of converting from a RAS to traditional MIS was not captured in the model	RAS is a form of MIS, and there is evidence that RAS may be converted to a traditional MIS during surgery. This was not captured in the model as the evidence not routinely reported within clinical studies. Furthermore, the true cost of conversion from a RAS to traditional MIS is unknown. Outcomes from traditional MIS are relatively similar to RAS, unlike when comparing with open surgeries. Therefore, the greatest impact is more likely to be related to length of surgery and additional instruments that are required for the conversion. Not capturing this outcome in the model is likely to underestimate the costs within the RAS treatment arm. The extent to which this omission is likely to bias the overall results should be considered by clinical experts. Initial feedback from clinical experts indicates if it does happen, its much more likely to be in the learning curve time period.

Key: EAG – External assessment group, LoS – Length of stay, MIS – Minimally invasive surgery, NHS – National Health Service, RAS – Robot-assisted surgery, SP – Single port.

8.2.2 Model inputs

Model inputs were derived via company evidence submissions, clinical correspondence and existing evaluations in this area. A range of study data have been combined from the robotic platforms, with only a subset of the technologies having evidence that is suitable for the economic analysis. We have supplemented the economic analysis with data from studies which do not refer to a specific robotic platform to support surgery.

There is a wide range of soft-tissue procedures and potential populations, and the evidence surrounding the use of these platforms is broad. Therefore, the base case model is intended to represent an indicative average, rather than a definitive representation of every RAS system for adults undergoing soft-tissue surgery. One important consideration for all clinical data is the extent to which the learning curve impacts the parameter, and if this would change once the learning curve is complete. It

is difficult to identify in reported studies where on the learning curve surgeons involved in the study are, which could impact overall study conclusions.

Where there was a paucity of data, assumptions have been made that are explained throughout this section and, where possible, clinically verified. The range of values from the identified evidence were used as uncertainty intervals for sensitivity analyses where possible.

8.2.3 Set-up parameters

The model compared RAS with standard surgical procedures. The annual number of procedures (performed using one RAS system), the expected life cycle of a robotic platform, and the time-to-proficiency (learning curve) were estimated from clinical and company consultation. The annual number of procedures and time-to-proficiency parameters were found to vary between procedure types, surgeon experience, and experience with RAS. A mean estimate was applied in the base case and then varied within sensitivity analysis. The discount rate (for cost annutisation of the robotic platform) and the cost-effectiveness threshold (for QALY threshold analysis) were set as 3.5% and £20,000 per QALY respectively (National Institute for Health and Care Excellence 2022). Set up parameters are detailed in Table 8.3.

8.2.4 Types of surgery

The proportions of each type of soft-tissue surgery (MIS, RAS, open) and the conversion rate for each arm of the model were derived from a variety of clinical studies and company submissions data (Morton et al. 2023a, Safiejko et al. 2021). These are detailed in Table 8.5.

8.2.5 Resource use

Operative time, LoS, the rate of complications, and readmissions were derived from company submissions, a mixture of cost-effectiveness analysis for specific procedures, national population-based studies, and meta-analyses. These are outlined in Table 8.5Table 8.5.

8.2.6 Costs

RAS costs, alongside excess bed day and readmission costs, were derived from the company evidence submissions, the Personal Social Services Research Unit (PSSRU) (Personal Social Services Research Unit 2023), and the National Cost Collection (all 2023 cost values) (NHS England 2023). Standard surgical procedure costs were sourced from a cost-comparison study. Complication costs were sourced from the National Cost Collection, with alternative costs sourced from a published cost-effectiveness study (Moss et al. 2021, Labban et al. 2022). Technology costs, primary care costs and secondary care costs are outlined in Table 8.7. Cost parameters were based on the available evidence. Therefore, some costs such as energy, IT software or other costs may have been omitted due to a lack of evidence. The impact of omitting these costs should be considered as part of any decision-making process.

Set-up parameters

Table 8.3: Set-up parameters

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Annual utilisation of RAS (per robot)	400	Clinical feedback (York Health Economic Consortium 2024)	Values from clinicians ranged from 300 to 1,000 which have been used in scenario analysis. This value will vary depending on the complexity of the surgeries (case-mix), the engagement of clinical staff, and other hospital factors.
Number of years robot expected to be operational	[redacted]	Company consultation (York Health Economic Consortium 2024)	[redacted]
Time-to-proficiency	0.33 years (4 months)	Clinical feedback (York Health Economic Consortium 2024)	Wide range of values provided by clinical feedback for this input. Ranged from 1-6 months. Assumed that for first year of procedures, around a third would be part of the learning curve. Will be very heterogenous depending on surgeon RAS experience, complexity of procedures and the case-mix of the robotics platform.
Discount rate	3.5%	National Institute for Health and Care Excellence. NICE health technology evaluations: the manual. 2022. (National Institute for Health and Care Excellence 2022)	N/A
Cost-effectiveness threshold	£20,000 per QALY		

Key: EAG – External assessment group, NICE - National Institute for Health and Care Excellence, RAS – Robot-assisted surgery, QALY – Quality-adjusted life year.

Types of surgery

Table 8.4: Types of surgery

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Standard surgical care			
Proportion MIS	63.7%	(Morton et al. 2023a)	• Retrospective analysis of CPRD healthcare database linked to HES data for all adults having elective colorectal resectional surgery in England from 1 January 2006 to 31 March 2020. • Lack of available evidence to capture a range of procedures. This is varied in sensitivity analysis to capture the heterogeneity across procedures. Due to the 14-year time period, this may provide a slight underestimation of the number of MIS procedures carried out as this value has tended to increase over past 20 years. • However, this proportion will also be highly dependent on the case mix for soft tissue procedures as a whole.
Proportion open	36.3%		
MIS → open conversion rate	7.3%	(Safiejko et al. 2021)	• Meta analysis of 42 global studies for rectal cancer resection including 19 from Asia and 1 from the UK. Reliability of global estimates should be considered for model representative of England and Wales. • Value will be dependent on the relative case-mix, of which rectal resection may or may not be a suitable average to take. Pragmatic

			decision based on the scope of an EVA and varied widely in sensitivity analysis.
Robot-assisted surgery			
Proportion MIS (with or without or RAS)	[redacted]	[redacted]	[redacted]
Proportion open	[redacted]		
Proportion of MIS that are RAS	[redacted]	[redacted]	[redacted]
MIS → open conversion rate	2.6%	(Safiejko et al. 2021)	• Meta analysis of 42 global studies for rectal cancer resection including 19 from Asia and 1 from the UK. Reliability of global estimates should be considered for model representative of England and Wales. • Value will be dependent on the relative case-mix, of which rectal resection may or may not be a suitable average to take. Pragmatic

			decision based on the scope of an EVA and varied widely in sensitivity analysis.

Key: CPRD - Clinical Practice Research Datalink, EAG – External assessment group, EVA – Early value assessment, HES – Hospital episodes statistics, MIS – Minimally invasive surgery, NHS – National Health Service, RAS – Robot-assisted surgery, QALY – Quality-adjusted life year.

Table 8.5: Resource use

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
MIS	6.00 days	(Byrne et al. 2018)	An English population-based study on 134,713 laparoscopic colorectal cancer procedures between 2002 to 2012 (2011/2012 year taken). Average LoS may have dropped since 20212 as technology has improved so this may be an overestimation. Is likely to differ significantly between treatment types.
Open	8.00 days		
RAS (relative impact on MIS)	[redacted]	Company submission (via NICE)	[redacted]
MIS → Open (converted)	8.00 days	(Byrne et al. 2018, Moghadamyeghaneh et al. 2014) (assumed the same as open)	A previous study suggests an increase in length of stay of 2 days. Therefore, this is the same as with open, so assumed the same as standard open surgery.
Time difference RAS vs MIS	[redacted]	Company submission (via NICE)	[redacted]
Additional learning curve time	30 minutes	Assumption	This input is an assumption based on what has been observed from available clinical evidence on length of surgery for RAS.

Key: EAG – External assessment group, LoS – Length of stay, MIS – Minimally invasive surgery, NICE - National Institute for Health and Care Excellence, RAS – robot-assisted surgery.

Table 8.6: Rates of Complications

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
MIS			
Grade I	[redacted]	Company submission (via NICE)	[redacted]
Grade II	[redacted]		
Grade III	[redacted]		
Grade IV	[redacted]		
RAS			
Grade I	8.3%	(Bansal et al. 2018)	Retrospective analysis of 221 RAS and 68 open cystectomy procedures in patients in Bristol (England). Small sample size, one procedure and only one location. Large heterogeneity expected across all soft-tissue procedure.
Grade II	16.7%		
Grade III	5.7%		
Grade IV	0.5%		
Open			
Grade I	13.2%	(Bansal et al. 2018)	Retrospective analysis of 221 RAS and 68 open cystectomy procedures in patients in Bristol (England). Small sample size, one procedure and only one location. Large heterogeneity expected across all soft-tissue procedure.
Grade II	23.5%		
Grade III	4.4%		
Grade IV	2.9%		

Converted (MIS or RAS; all grades)	Same as open	(Bansal et al. 2018) (assumed same as open)	Due to paucity of available data, these values have been assumed equal to complication rates of open surgery.
Readmission rates			
MIS	3.6%	Carmine Lacovazzo. et al. 2023 (Iacovazzo et al. 2023)	A systematic review and meta-analysis of complications associated with RAS and laparoscopic (non-RAS) procedures in gastrointestinal surgery. 18 reviews included from a range of countries globally.
RAS	2.7%		
Open	3.9%	(Gavriilidis et al. 2020)	A systematic review and meta-analysis comparing RAS, laparoscopic and open hepatectomy. 79 studies (including 25,210 patients) were used in this analysis from a wide range of countries. Table 5, odds ratio converted to risk ratio and applied to MIS (risk ratio =1.087).
MIS → Open (converted)	3.9%	(Gavriilidis et al. 2020) (assumed same as open)	Due to paucity of available data, this value has been assumed equal to readmission rate for open surgery.

Key: EAG – External assessment group, MIS – Minimally invasive surgery, NICE - National Institute for Health and Care Excellence, RAS – robot-assisted surgery.

Table 8.7: Costs

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
NHS RAS costs			
Training cost per procedure	£30.15	PSSRU hourly staff costs. Clinical feedback for staff numbers and time required for training	1 surgical consultant (£141p/h), 2 surgical assistant (band 7; £61p/h), 1 anesthetist (band 9; £139p/h). 30 hours per member of staff required for training, all divided by total number of procedures (400 – see Table 8.3). Assumed this is per robotic platform.
Additional staff time per RAS procedure	£389	PSSRU hourly staff costs (Personal Social Services Research Unit 2023); operating costs from Jayne et al (Jayne et al. 2019) Clinical feedback for staff numbers	1 surgical consultant (£141p/h), 2 surgical assistant (band 7; £61p/h), 1 anesthetist (band 9; £139p/h). Additional time as detailed in Table 8.5 . Number and pay grade of staff sourced from clinical feedback via email.
RAS technology costs			
da Vinci X and Xi	[redacted]	Provided by company (via NICE) in request for information documents. It was assumed that the	[redacted]

		leasing costs was half of the upfront annutised purchase cost.	
da Vinci SP	[redacted]	Provided by NHSSC (via NICE). It was assumed that the leasing costs was half of the upfront annutised purchase cost.	[redacted]
Hugo RAS system	[redacted]	Provided by company (via NICE) in request for information documents. It was assumed that the leasing costs was half of the upfront annutised purchase cost.	[redacted]
Senhance	[redacted]	Provided by NHSSC (via NICE). It was assumed that the leasing costs was half of the upfront annutised purchase cost.	[redacted]
Versius	[redacted]	Provided by company (via NICE) in request for information documents. It was assumed that the leasing costs was half of the	[redacted]

		upfront annutised purchase cost.	
RAS training costs (annual)			
da Vinci X and Xi	[redacted]		[redacted]
da Vinci SP	[redacted]		[redacted]
Hugo RAS system	[redacted]	Provided by company (via NICE)	[redacted]
Senhance	Not provided		
Versius	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]

RAS maintenance cost (annual)			
da Vinci X and Xi	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
da Vinci SP	Not provided		
Hugo RAS system	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
Senhance	[redacted]	Provided by NHSSC (via NICE) in an excel document	[redacted]
Versius	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
RAS disposable components (per procedure when robot paid upfront or leased)			
da Vinci X and Xi	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
da Vinci SP	Not provided		

Hugo RAS system	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
Senhance	Not provided		
Versius	[redacted]	Provided by company (via NICE) in request for information documents	[redacted]
RAS disposable components (per procedure when robot is on free loan)			
da Vinci X and Xi	Not provided		
da Vinci SP	Not provided		
Hugo RAS system	[redacted]	Provided by company (via email)	[redacted]
Senhance	Not provided		
Versius	Not provided		
Standard surgical care costs			
Cost of MIS	£3,583	Moss EL et al. 2021	Retrospective cohort economic evaluation of 34,304 endometrial cancer procedures. Costs scaled up from 2019 to 2023 costs using PSSRU inflation indices.

Relative cost difference multiplier (open)	1.09	Calculated from open and MIS costs from Moss EL et al. 2021	Retrospective cohort economic evaluation of 34,304 endometrial cancer procedures. Ratio of cost between MIS and open. Used as an indicator of relative difference, but likely to vary significantly between procedures.
Relative cost difference multiplier (converted)	1.09 (assumed same as open)	Moss EL et al. 2021. Assumed the same as open	Retrospective cohort economic evaluation of 34,304 endometrial cancer procedures. Ratio of cost between MIS and open. Used as an indicator of relative difference, but likely to vary significantly between procedures. No evidence of difference with converted surgeries and open surgeries.
Other surgery-related costs			
Excess bed days	£503	NHS Reference Costs 2017/2018. Inflated to 2023 costs using PSSRU inflation indices	NHS Reference Costs 2017/2018. Elective Inpatients Excess Bed Days (EL_XS) = £431. Costs inflated to 2023 costs using PSSRU inflation indices
Readmission	£857	K. Jones et al. PSSRU Unit Costs of Health and Social Care. 2023.	Section 6.1. Non-elective inpatient stays (short stays)
Complication costs (NHS Cost Collection source)			
Grade I	£402	NHS Cost Collection. Accessed July 2024	These values were calculated as a weighted average of a selection of common surgery-related complications. Selected complications (per C-D grade) were informed by literature and clinical consultation. These were weighted based on the total number of complications treated across the NHS as a whole and, as such, will include procedures not originating from surgery. This may over- or under-estimate the prevalence of specific complications and impact the total cost calculated.
Grade II	£573		
Grade III	£1,290		
Grade IV	£2,330		

			A second source for complication costs was also sourced (detailed below) and scenario analysis using these figures was run.
Complication costs (Labban M et al. data)			
Grade I	£562	Labban M. et al. 2019. Inflated using PSSRU inflation indices	Economic analysis of prostatectomy in the UK. Complication costs were calculated only according to the additional LoS and therefore only represent the average cost of additional treatment per additional bed-day. Prostatectomy is out of scope for this evaluation but may give an indication of the different grade costs reflective of soft-tissue procedures in general.
Grade II	£1,124		
Grade III	£1,686		
Grade IV	£2,248		

Key: C-D – Clavien-Dindo, EAG – External assessment group, LoS – Length of stay, MIS – Minimally invasive surgery, NHSSC – National Health Service supply chain, NICE – National Institute for Health and Care Excellence, NHS – National Health Service, PSSRU – Personal Social Services Research Unit, RAS – robot-assisted surgery, VAT – value added tax.

8.3 Results from the economic modelling

Exploratory results from the cost-comparison model are presented in sections 8.3.1 to 8.3.3. Due to the heterogeneity across the digital technologies, procedures, patient populations and available evidence to populate the economic model, the base case is intended to be indicative of the potential impact of RAS. The model is not intended to reflect every possible case-mix, potential soft-tissue procedure and individual robotic platform. The base case has been split into three sections to represent the three different RAS costing structures. The base case should be considered alongside the range of scenarios conducted in Section 8.3.1, given the heterogeneity in soft-tissue procedures.

Under the base case assumptions, the deterministic base case model results indicate that the integration of RAS technologies to the NHS are potentially cost incurring compared with standard surgical procedures across all three costing scenarios in the short-term. The technologies are estimated to increase health care costs, driven by the upfront cost (for upfront and leasing) of the robot and additional consumable equipment required to carry out the procedure. Alongside the cost-comparison results, we also present the required QALYs to be cost-effective at a £20,000 per QALY threshold, given the potential long-term benefits of more successful surgery with RAS. This includes both the required QALYs from the intervention arm of the model, as well from RAS procedures specifically (given that not all surgeries will be eligible for RAS). The implication of the required long-term benefit is discussed further in Section 0.

The deterministic base case results are presented in Table 8.8 to Table 8.10. The results suggest that the additional costs from a reduction in complications/readmissions and surgery conversions are not likely to outweigh the cost of using RAS technologies, at least in the short-term.

Table 8.8: Deterministic results (upfront costing structure)

Summary	SoC	RAS+SoC	Incremental
Average cost per procedure	£7,453	£7,927	£474
Required QALYs to be cost effective between treatment arms			0.02
Required QALYs from RAS procedures specifically to be cost effective			0.10

Key: RAS – Robot-assisted surgery, SoC – Standard of care, QALY – Quality adjusted life year.

Table 8.9: Deterministic results (leasing costing structure)

Summary	SoC	RAS+SoC	Incremental
Average cost per procedure	£7,453	£7,852	£400
Required QALYs to be cost effective between treatment arms			0.02
Required QALYs from RAS procedure specifically to be cost effective			0.09

Key: RAS – Robot-assisted surgery, SoC – Standard of care, QALY – Quality adjusted life year.

Table 8.10: Deterministic results (free loan costing structure)

Summary	SoC	RAS+SoC	Incremental
Average cost per procedure	£7,453	£8,056	£603
Required QALYs to be cost effective between treatment arms			0.03
Required QALYs from RAS procedures specifically to be cost effective			0.13

Key: RAS – Robot-assisted surgery, SoC – Standard of care, QALY – Quality adjusted life year.

8.3.1 Scenario analysis

Given the potential variation in RAS systems for soft tissue procedures, such as pricing, and the uncertainty in input values, a range of scenarios were considered. These scenarios are described, and the results reported in Table 8.13. Due to the high number of scenarios, these have been colour coded (red = more cost incurring, green = more cost saving).

Table 8.11: Scenario analysis for the intervention

Scenario analyses description	EAG description	Incremental cost per person (by costing structure)		
		Upfront	Leasing	Free loan
EAG base case		£474	£400	£603
Lowest scenario cost	These results represent the highest cost (most cost-saving / closest to being cost-saving) scenarios	£195	£35	£46
Highest scenario cost	These results represent the highest cost (least cost-saving) scenarios	£1,417	£1,212	£1,771
Highest cost of a technology (deterministic result).	Cost of the technology is set to take the highest cost for each aspect of the technology. These figures are: [redacted]	£546	£449	£614

Lowest cost of a technology (deterministic result).	Cost of the technology is set to take the lowest cost for each aspect of the technology. These figures are: [redacted]	£416	£35	£527
Impact of a potential learning curve	The impact of a learning curve is toggled off. This will exclude the assumed additional time taken (+30 minutes) to complete RAS surgery whilst a clinician is gaining proficiency	£437	£362	£566
Alternative values for complications costs (from the Labban et al. study) applied	NHS Cost collection data used in the base case is a weighted average of assumed complications which may under- or over-estimate the true cost of complications. Values derived from Labban et al. are used as an alternative.	£469	£394	£597
Utilisation of RAS set to 1,000 procedures per year	The number of procedures carried out by RAS per year was derived from clinical consultation and was highly varied due to the wide range in complexity of procedures that can be carried out by RAS. These scenarios will represent the use of RAS in clinical areas where it is possible to complete more or less surgeries in a given amount of time, and potentially at different utilisation rates.	£335	£305	£553
Utilisation of RAS set to 300 procedures per year		£552	£452	£631
Robotic platform lifetime set to 10 years	The total expected lifetime of a robotic platform was derived from clinical consultation and was highly varied due to range of procedures and technologies involved. These scenarios will represent the use of RAS where the expected lifetime is greater than the base case (and at the higher end of the estimations received via clinical consultation)	£435	£380	£603
Proportion of MIS that are RAS increased	[redacted]	£1,417	£1,212	£1,771

Cost of RAS per-procedure consumables not included	Assumption that the RAS consumables are replacing other surgical instruments, and therefore, the cost is a substitution rather than additional cost.	£195	£120	£46
Cost of standard surgical procedures halved	These assumptions are to reflect the fact that soft-tissue surgical costs can vary depending on complexity / time taken for MIS. Open will also change accordingly, given a multiplier is applied for open surgeries, meaning the absolute difference between conventional MIS and open will change. For example, a higher absolute cost of open results in a greater capacity to benefit from RAS.	£483	£408	£611
Cost of standard surgical procedures doubled		£458	£383	£586
No LoS difference between RAS, MIS and open surgery	Including the LoS or length of surgery can lead to double counting as complication costs may already incorporate some or all of these additional costs. Scenarios conducted where these are omitted from the analysis.	£573	£498	£701
No Length of surgery difference between RAS and MIS		£415	£341	£544
Only the impact of converting open procedures to RAS are estimated	In order to capture the impact of individual caseload changes, this scenario estimated the outcomes when 25% of open cases are instead carried out via RAS (i.e., in SoC, the only procedure carried out is open, and in the intervention arm of the model, 25% of these are RAS)	£258	£177	£396
Only the impact of converting conventional MIS procedures to RAS are modeled	In order to capture the impact of individual caseload changes, this scenario estimated the outcomes where only SoC MIS procedures are carried out in the comparator arm of the model. The proportion of procedures carried out by RAS in the intervention arm of the model remains the same as in the base case.	£784	£675	£971

Key: EAG – External assessment group, LoS – Length of stay, MIS – Minimally invasive surgery , RAS – Robot-assisted surgery.

Based on the scenarios listed in Table 8.11, All 16 of the scenarios led to cost-incurring results, across all costing structures. One scenario, where the cost of RAS per-procedure consumables was not included, led to additional costs of between £46 and £195 which was lowest for the free loan costing structure and highest for the upfront costing structure. The scenario where the lowest RAS costs were taken (and a leading cost structure was used) led to additional costs of £35, when a leasing structure was used. This was the scenario with the lowest estimated additional cost. Higher utilisation of RAS for MIS procedures increased the average cost-per procedure.

We expect the true short-term base case to be within the scenarios conducted based on a range of factors included case-mix, utilisation of RAS, costing strategies, and the heterogeneity in the patient population. The required long-term QALY gain from RAS to be cost-effective based on the scenarios conducted ranged from 0.01 to 0.14. Hence, if RAS could lead to QALY gains of over 0.14 on average across soft-tissue procedures, it could plausibly be a cost-effective intervention in all scenarios. This can be visualised as each patient gaining approximately 51 days (14% of one year) of perfect health on average over the course of their lifetime.

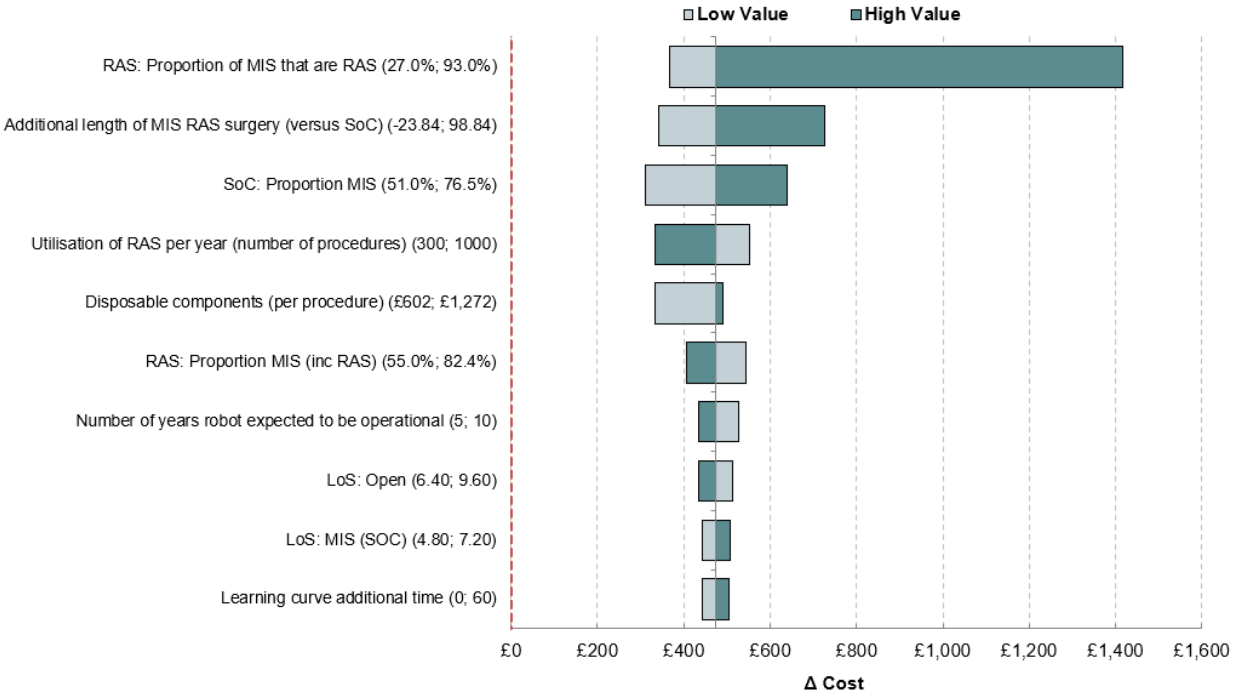
8.3.2 Deterministic sensitivity analysis

One-way sensitivity analysis was conducted on all model parameters. The results of this analysis are presented in a tornado diagram in Figure 8.2 for the upfront costing structure (with the results for other costing structures being very similar). The analysis suggests the key drivers of the model results are the:

- proportion of MIS surgeries that are RAS for the intervention arm
- additional length of surgery time for RAS per person
- proportion of surgeries that are MIS in either treatment arm
- conversion rate from MIS to open in either treatment arm

- disposable component costs of RAS.

Figure 8.2: Deterministic sensitivity analysis (upfront costing structure)

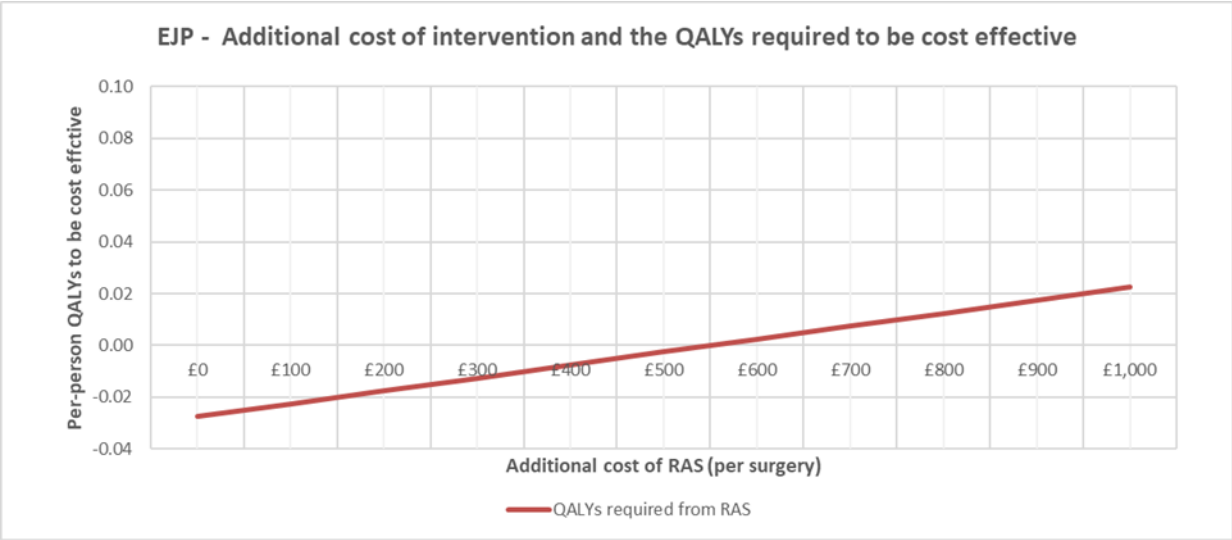


Additional DSA included EJP analysis with respect to cost-savings. In the base case, the additional cost of RAS (compared to conventional MIS procedures) was £2,585, £2,263, and £3,138 for the upfront, leasing, and free loan costing structures respectively. These figures did not account for differences in length of stay, complications or readmissions. For the intervention to break even (cost-neutral), the additional cost of RAS would need to be a maximum of £277 per procedure when compared with conventional MIS. When compared with open surgeries, the additional cost of RAS was £2,292, £1,970, £2,845 for the upfront, leasing and free loan costing

structures respectively. For the intervention to break even (cost-neutral), the additional cost of RAS would need to be a maximum of £1,565 per procedure when compared with open surgeries. This indicates a higher capacity to benefit from converting open surgeries to RAS, rather than conventional MIS.

The EJP should be interpreted with caution due to the early nature of the analysis, the heterogeneity across surgical procedures and patient populations, and long-term potential benefits omitted from the analysis. However, the results can be used as an indication of the potential cost impacts of RAS in the short-term, as well as indicate the potential health benefit required to be cost-effective, at a £20,000 per QALY threshold. Figure 8.3 displays the additional costs of RAS, and the required QALY benefit threshold (per surgery) to be cost-effective for a range of values. This value is an average for the treatment arm, not just RAS. If 50% of surgeries in the intervention arm of the model lead to no additional QALYs (non-RAS), then the remaining 50% would need to be twice that of the threshold (RAS). For reference, a QALY gain of 0.1 would represent approximately 36.5 extra days of full health over each person's lifetime, or 10% of one year (not taking into account discounting). This analysis includes the relative impact on the treatment arm, as well as RAS specifically, assuming that there will not be 100% uptake of RAS.

Figure 8.3: EJP analysis (compared with standard surgical procedures)



8.3.3 Probabilistic sensitivity analysis

The PSA indicated similar results to the deterministic base case. The probabilistic incremental cost per person was calculated as £490, based on 1,000 model iterations. The results of the PSA are displayed in Table 8.12 and graphical representation of the base case results for each of the costing structures are presented in Figure 8.5 - Figure 8.7. Various scenarios on the PSA are presented in Table 8.13. All PSA scenarios were run for 1,000 iterations. A cost-effectiveness curve was also plotted which demonstrates the likelihood that the intervention would be considered cost-effective (at a threshold of £20,000/QALY) if the use of RAS leads to an increase in the total number of QALYs per-procedures. This is displayed in Figure 8.4.

Table 8.12: PSA summary results

Summary results	SoC	RAS+SoC	Incremental
Upfront costing structure			
Cost per procedure	£7,683	£8,173	£490
95% CI: Lower	£5,864	£6,389	-£490
95% CI: Upper	£9,931	£10,415	£1,583
Probability that the intervention is cost saving			14.9%
Leasing costing structure			
Cost per procedure	£7,698	£8,086	£388
95% CI: Lower	£5,926	£6,385	-£464
95% CI: Upper	£9,920	£10,475	£1,436
Probability that the intervention is cost saving			18.0%
Free loan costing structure			
Cost per procedure	£7,682	£8,268	£586
95% CI: Lower	£5,829	£6,472	-£394
95% CI: Upper	£9,885	£10,442	£1,641
Probability that the intervention is cost saving			9.7%

Key: CI – Confidence interval, SoC – Standard of Care, RAS – Robot-assisted surgery.

Figure 8.4: Cost-effectiveness likelihood curve for the theoretical incremental QALYs following RAS procedures (upfront costing structure)

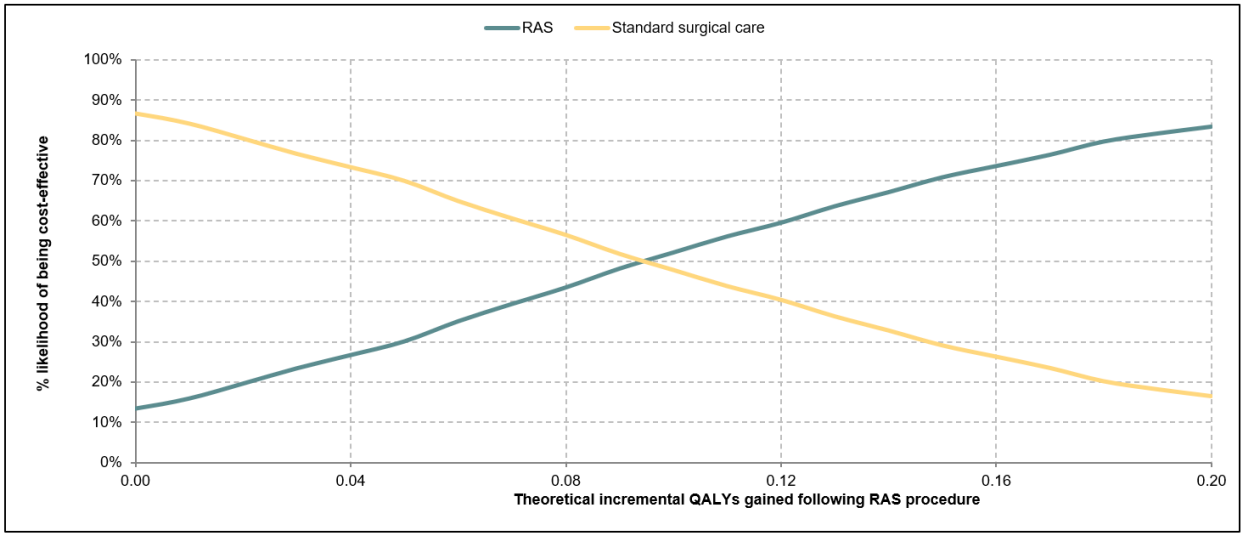


Figure 8.5: PSA distribution of results (upfront costing structure)

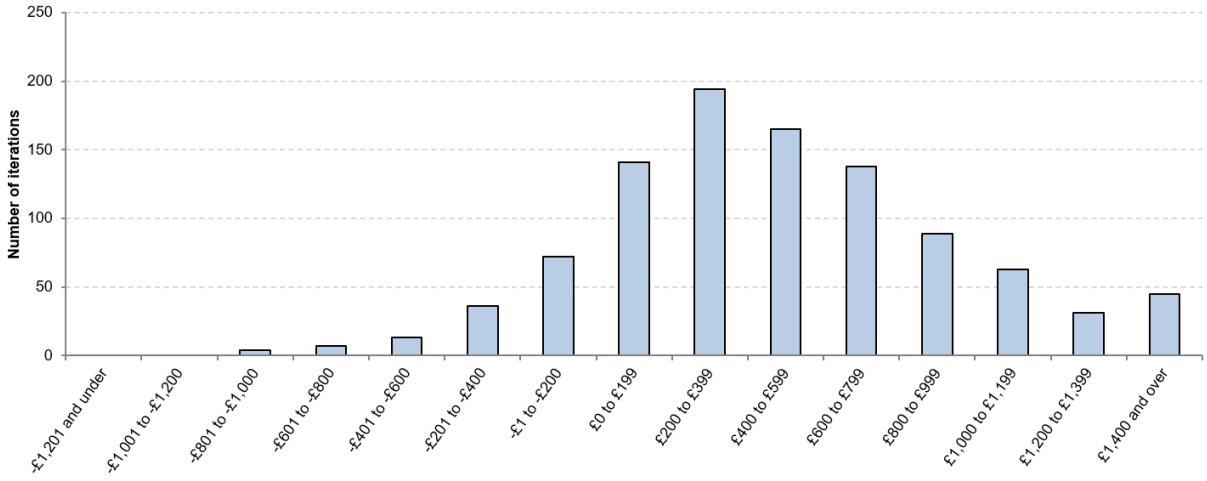


Figure 8.6: PSA distribution of results (leasing costing structure)

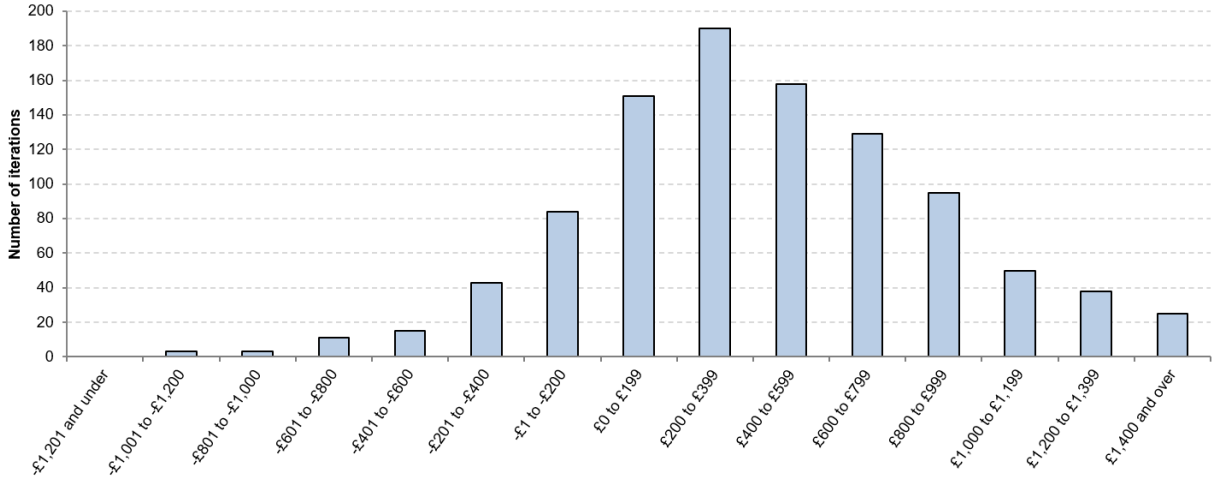


Figure 8.7: PSA distribution of results (free loan costing structure)

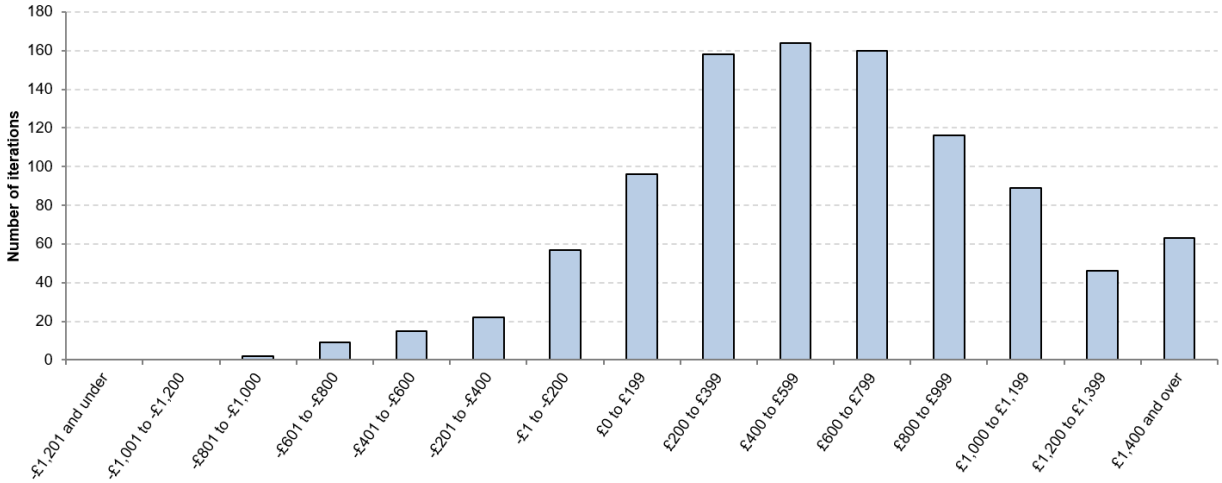


Table 8.13: PSA scenario analysis results

PSA Scenario: Incremental costs per person	Upfront	Leasing	Free loan
Higher RAS utilisation (1,000 procedures per robotic platform annually)			
Incremental cost per procedure	£290	£262	£530
95% CI: Lower	-£705	-£626	-£466
95% CI: Upper	£1,292	£1,307	£1,591
Probability that the intervention is cost saving	24.5%	25.5%	18.0%
Lowest cost RAS technology used			
Incremental cost per procedure	£420	£6	£490
95% CI: Lower	-£600	-£949	-£475
95% CI: Upper	£1,539	£957	£1,648
Probability that the intervention is cost saving	17.0%	48.9%	13.5%
Highest cost RAS technology used			
Incremental cost per procedure	£579	£477	£587
95% CI: Lower	-£347	-£497	-£481
95% CI: Upper	£1,628	£1,686	£1,721
Probability that the intervention is cost saving	10.0%	13.7%	10.9%

8.4 Summary and interpretation of the economic modelling

The results of the economic modeling are that the use of RAS is likely to be cost incurring, with respect to short-term outcomes. These results do not factor in long-term cost outcomes, and do not capture the potential impact on health outcomes (QALYs) from RAS when compared with non-RAS based procedures. The estimated results are not intended to capture every robotic platform perfectly but are intended to provide an indication of the potential impact from implementing these technologies, based on a range of different scenarios. It is important to note that the results were more favourable for scenarios where RAS was replacing open surgeries, than RAS replacing conventional MIS. This result stems from the capacity to benefit from reducing open

surgeries, such as greater reduction in complications and length of stay, than compared with replacing conventional MIS

The required long-term QALY gain from RAS to be cost-effective based on the scenarios conducted ranged from 0.01 (where RAS is the least cost-incurring, with the assumption that the lowest RAS costs are used and a leasing cost structure is taken) to 0.14 (where RAS is the most cost-incurring, with the assumption that 93% of all procedures in the intervention arm of the model are carried out by RAS and when a free loan cost structure is taken).

If RAS could lead to average QALY gains of over 0.14 across soft-tissue procedures over a lifetime (approximately 51 days of full health per person, or 14% of one year, not including discounting), it is more likely to be a cost-effective intervention at a £20,000 per QALY threshold, in all scenarios. In the base case, 0.10 QALYs would be required per procedure (approximately 36.5 or 10% of one year, not including discounting). If RAS could lead to long-term cost reductions (such as reduced severity of disease or progression), then less QALY gains would be required to be cost-effective. As demonstrated in Figure 8.4, the lower the potential long-term QALY gains from RAS, the less likely it is to be a cost-effective intervention. A QALY gain of around 0.10 leads to approximately a 50% chance that RAS is cost-effective for soft-tissue procedures, for an upfront purchase costing structure. Previous economic studies, including deprioritised studies, estimated a range of QALY scores (between 0.014-0.105).

These did not consider long term outcomes but are summarised as follows:

- Ferri et al. (Ferri et al. 2021) estimated an incremental QALY gain of 0.105 per person for robotic-assisted colectomy compared with standard laparoscopic approaches from a Spanish healthcare perspective over a 1-year time horizon.

- Jayne et al. (Jayne et al. 2019) estimated an incremental QALY gain of 0.014 per person for robotic-assisted rectal resection compared with standard laparoscopic approaches from a UK perspective over a 6-month time horizon.
- Machleid et al. (Machleid et al. 2022) estimated an incremental QALY gain of 0.06 per person for robotic-assisted radical cystectomy compared with open cystectomy from a UK perspective over a 90-day time horizon. It is important to note, however, that the QALYs estimated in this paper are incorrect as they exceed the plausible number of QALYs within a 90-day time horizon.
- Kord et al. (Kord et al. 2022) estimated an incremental QALY gain of 0.018 per person for robotic-assisted radical cystectomy compared with open cystectomy from a US perspective over an unspecified time horizon.
- Lundin et al. (Lundin et al. 2020) estimated an incremental QALY gain of 0.018 per person for robotic-assisted hysterectomy compared with open hysterectomy from a Swedish perspective over a 43-day time horizon.

The results of this analysis should be interpreted with caution due to paucity of existing data, as well as the substantial heterogeneity across soft-tissue procedures and patient populations. The evidence available to populate the model is extracted from procedures where RAS is more commonly used, so may not be representative of all soft-tissue procedures. Companies have mixed evidence for each of the scoped robotic platforms, meaning wider evidence is used from unspecified robotic platforms to populate the model. Simplifying assumptions were made throughout the model to provide a useful tool for an early evaluation of robotic platforms for soft tissue procedures, as described in Section 8.2.1. Section 8.2.1 also details any omissions from the model, because of limited evidence, and how this may bias the estimated results at this early stage.

Likelihood of long-term impacts

It is important to consider the feasibility of long-term health outcomes from RAS, which has not been captured in this model. More successful surgeries from RAS may lead to

improved survival outcomes (from a greater success rate of surgeries),), improved quality of life, or a combination of both. These surgeries may also reduce future healthcare costs, if a more successful surgery prevents the need for future treatments.

Previous economic evidence on RAS such as those studies highlighted above, indicates that our base case requirement of 0.10 QALYs falls within the upper range of QALY gains currently estimated in other studies. However, the current economic evidence for RAS for soft-tissue procedures does not cover a long enough time horizon to estimate the long-term health outcomes of RAS. It is less likely that RAS would be cost-effective compared with standard surgical care for surgical procedures which do not (or are unlikely to) lead to long-term benefit. Future evidence should be collected where extrapolations can be made surrounding potential long-term impacts, to better understand the impact of RAS. This is discussed further in Section 10.1.

Key drivers of the economic results

The key drivers of the results, as demonstrated in the tornado diagram, were:

- the proportion of MIS that are RAS in the intervention arm
- the additional length of surgery time for RAS
- the proportion of surgeries that are MIS (either RAS of SoC) in either treatment arm
- the conversion rates to open surgery in either treatment arm
- the disposable component costs of RAS.

Current clinical and resource use data is based on studies for specific soft-tissue procedures, which may not be generalisable to different types of soft-tissue procedures. Clinical advice has also indicated that there is substantial variation across different soft-

tissue procedures. It is difficult to say with the current evidence base where RAS is more or less likely to be cost-effective within soft-tissue procedures.

For example, clinical advice and previous studies have indicated that the potential impact of RAS on operative times will likely differ depending on the procedure undertaken, and operative time is a key driver of the model results. In procedures where operative times are reduced, it is more likely that these will be cost-effective than procedures which are longer with RAS.

Furthermore, evidence is difficult to interpret with respect to the learning curve effects. It is reported in multiple studies that surgeons will remain 'on' their learning curve throughout the study, which is likely to underestimate the potential impact of RAS. Being able to isolate learning curve effects within future studies will be important to understand the optimal clinical effect of RAS after periods of training are undertaken. It is also important to note that junior surgeons may take just as long, if not longer to learn conventional MIS procedures, than RAS procedures. Hence, learning curve time may be less important for more novice surgeons.

In the base case model, we have assumed additional training costs associated with RAS, however, for junior surgeons, learning RAS instead of conventional MIS may reduce training costs. Analysis indicates that training costs are not a key driver of the model, but it is important to note for junior surgeons, training costs may actually be reduced.

Another system level consideration is the utilisation of RAS, which will also potentially impact the cost-effectiveness of RAS, depending on the costing model for the robotic platform. If the robotic platform is outright purchased or leased, the marginal costs of additional procedures using RAS is relatively lower, compared to the overall fixed cost of purchasing or leasing the platform. Hence, if robotic platforms can be utilised highly

within the NHS, their implementation is more likely to be cost-effective. Drivers of utilisation may be placement within departments which are more willing to use robotic platforms for a range of procedures, or portable platforms to maximise output. Clinical experts and company responses indicated that where robotic platforms are already used within the NHS, each robotic platform is used in at least 300 procedures per year, and in some cases, up to 1,000 procedures a year (York Health Economic Consortium 2024).

The cost of the technologies differed between the companies:

[redacted]

Depending on the values and scenarios selected, current estimates suggest that RAS will cost an additional £1,970 to £3,138 to conduct the surgery per person, depending on if RAS replaces open surgery, or the costing structure selected. The breakeven (cost-neutral) point with RAS is £277 when compared with conventional MIS, and £1,565 when compared with open surgeries. As a result, long-term cost savings or improvement in health outcomes will likely be required for RAS to be cost-effective, based on the current evidence.

Finally, since there is likely substantial heterogeneity in costs and outcomes across soft-tissue procedures, a range of scenarios were conducted. These scenarios (presented in Table 8.5) indicate that it is unlikely that robotic platforms will be cost-saving, at least with respect to short-term outcomes. Scenarios are conducted to test a range of assumptions and the impact they have on the results. Although there is a fixed cost aspect to adoption of robotic platforms, it is important to note that as the proportion of surgeries conducted with RAS increase, the budgetary cost to the NHS will likely be higher. This is because the marginal costs per procedure of using RAS will still increase the budgetary spend. Examples of these marginal costs include disposable components, or staff time. Therefore, even if greater utilisation of robotic platforms

reduces the fixed costs per procedure, and improves the cost-effectiveness, greater utilisation will still increase the impact on the healthcare budget.

Alternative costings of robotic platforms

An important consideration is the availability of alternative costing models. This includes upfront purchase of the robotic platform, leasing the platform, or a ‘free loan’ system, where there is additional capital expenditure attached to disposable components for each procedure undertaken. Based on the current available evidence, it is likely that the free loan option is less cost-effective than a leasing or upfront purchase as the cost per procedure (consumable) [redacted]. However, this also assumes that, in an upfront or leasing costing structure, the robotic platform is well utlised by NHS providers (at least 300 procedures per year). This would allow the fixed costs to be spread over a wider number of cases. It is also important to note that per-procedure costing information for a free loan structure was provided by only one company ([redacted] which is therefore less representative of all RAS systems.

Another important consideration is whether there is available budget to purchase or lease the robotic platform, which will result in higher upfront costs. If a surgical robot platform were to be used sparingly for very specific, and less common soft-tissue procedures, it is feasible that the free loan model could be the most cost-effective strategy of the three costing strategies (providing that RAS was overall cost-effective). If robotic platforms are recommended as part of this EVA, consideration should be given to how the platforms are funded as RAS costs are a key driver of the modelling results.

Previous economic studies

As discussed in Section 8.1, the 3 economic costing studies identified in this area have estimated a range of different results and do not align with the EAG model. These previous economic evaluations do not always consider all relevant costs associated with adopting robotic platforms (e.g., upfront robot cost, or costs associated with a change in the number of complications), leading the results to suggest that RAS is cost-saving.

Furthermore, previous economic evaluations (including deprioritised studies) have generally considered the cost-effectiveness of RAS for specific procedures, which is a very different population to the EAG model, which covers a wide range of different procedures. Where specific procedures economic evaluations have been conducted, outcomes are mixed, ranging from dominant results, to ICERs of £70,000 per QALY and $180,755 USD (Lundin et al. 2020) (Jayne et al. 2019). Ranges occur across different procedures and are likely dependent on the economic methods employed, procedure evaluated, and patient population.

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

20 studies were prioritised that provided clinical evidence for robotic surgery. For the primary outcomes at a patient level (conversion rate, intraoperative complications, postoperative complications, Clavien-Dindo score HRQoL and LoS), there was little evidence to suggest a difference between robotic surgery and MIS or open surgery. Only one study reported a significant difference in the rate of conversion to open surgery and this was in favour of MIS (Galata et al. 2019). Significant differences were found when comparing Da Vinci Xi to open surgery, suggesting a shorter LoS for robotic surgery (Di Franco et al. 2022, Grenabo Bergdahl et al. 2022). When compared with MIS, the difference in LoS was only significant in one study and favoured the Hugo robot (Prata et al. 2024). None of the remaining studies reported a significant difference between robotic surgery and MIS or open surgery in any patient-level outcome. Some significant differences were identified in surgeon-level primary outcomes (procedure-related discomfort and ergonomics). However, these were only reported by one study which found a significantly lower ergonomic risk and lower overall cognitive strain when conducting robotic surgery with Versius (Dixon et al. 2024) compared with MIS in major colorectal resection. At an organisation-level, studies did not report data for any outcomes.

The only secondary outcome where studies consistently reported significant differences between the arms was operating time. Operative time was significantly longer for robotic surgery than MIS in 12/17 studies where p-values were reported (one study compared with open surgery reported no significant difference (Di Franco et al. 2022)). One study (evaluating the Hugo robot) found that robotic surgery was significantly shorter than MIS (Prata et al. 2024). Only four studies reported no significant difference in operating time.

The EAG noted some concerns around the clinical evidence. There was one RCT prioritized in the review (Dixon et al. 2024), and the remaining studies were either non-randomised or cohort studies (10 of which were retrospective in design) which are open to a higher risk of bias. Only three studies were conducted in the UK (Dixon et al. 2024, Butnari et al. 2024, Aggarwal et al. 2020) and it was unclear how generalizable the results are to a UK population. Patient populations also varied across the studies, and different indications and types of surgery were evaluated. It is unclear whether results for one type of surgery are comparable with other types of surgery. This approach was taken in order to estimate the average impact of the incorporation of RAS platforms, as opposed to specifically focusing on one area. This means that the results are more generalisable for the adoption of RAS, which is not likely to be commissioned on a procedure-specific basis. In general, results for each technology were aligned with one another where evidence was available. However, the Hugo robot reported shorter operating times and hospital LoS when compared with MIS, whereas the other robots did not. Hugo was only evaluated in one prioritised study, which was a retrospective cohort study of 27 patients so it is not possible to determine whether these results are due to the robot or other confounding factors (Prata et al. 2024). The EAG also noted that results for some outcomes (such as learning curve and operating time) were not widely reported and could be affected by surgeon experience and complexity of surgery.

3 economic costing studies were identified, which included:

- An unpublished company submitted cost-comparison analysis in England for da Vinci Xi.
- A published cost- comparison analysis of da Vinci Xi compared with da Vinci Si set in a Swiss context.
- A published cost-comparison analysis for Senhance compared with a previous iteration of the da Vinci robot and standard laparoscopic surgery.

The studies noted the high acquisition and maintenance costs of RAS, which was not always factored into the analysis. The quality of the evidence was low. The England cost-comparison analysis that reported potential areas of cost savings was unpublished and subject to biases due to lack of peer review, as well as modelling potential savings using one data source (one clinician). Deprioritised studies which did not identify specific robotic platforms highlighted a range of cost-effectiveness results, ranging from dominant ICERs to ICERs over £100,000 per QALY, across a range of specific procedures. Previous published evidence only considered specific procedures, rather than soft-tissue procedures as a whole.

9.2 Integration into the NHS

Of the 5 robotic platforms included within the scope of this evaluation, 3 providers for 4 technologies submitted relevant evidence [redacted].

All technologies have appropriate regulatory approval to be used in the NHS. However, 3 of the 4 technologies who provided information to NICE are not yet indicated for use in children. Therefore, any recommendations for use of robotic platforms for surgical care in children should be conditional on receiving the appropriate regulatory approval. As outlined in sections 4 to 6, adverse events and complications were at least comparable between RAS and other surgical care. This indicates that technologies would be at very low risk of leading to unsafe outcomes, relative to standard surgical care, if technologies are recommended as part of an EVA to collect future evidence.

Training and learning curve considerations

Healthcare staff will be required to undertake training to perform RAS. The expected time of training is highly uncertain and will depend on a number of factors including:

- The surgical staff familiarity with robotic platforms. Those using robotic platforms for the first time are likely to require more training than those who have used them for other procedures. Furthermore, hospitals with more than one surgeon already comfortable using RAS are more likely to be able to train up new staff quicker. Junior surgical staff may learn MIS using robotic platforms, rather than conventional MIS, which may result in shorter learning curves for more junior surgeons.
- The type of procedure. As indicated in clinical feedback, the training requirement varies between different procedures. Initial estimates suggested the training period could last up to 6 months and require between 50-100 procedures to be fully trained (York Health Economic Consortium 2024) (post-learning curve), including 10-20 observation sessions. However, more complex procedures, or procedures which are carried out less frequently, could take longer.

Previous systematic reviews have also indicated the heterogeneity of overcoming the learning curve, ranging from 15 to 150 procedures, depending on the metric chosen to measure the learning curve (Soomro et al. 2020, Müller et al. 2022). The training time required will likely put strain on existing resource use in the NHS, if people are initially observing additional surgeries, or attending training sessions. Once the surgeon is trained to a level where they support or lead a RAS, the learning curve to optimal surgery performance is likely to lead to longer surgery times in the short-term, and potentially, limited effectiveness until optimal performance is reached.

Therefore, the adoption of RAS in the short-term is likely to lead to additional requirements on already constrained staff time, and clinical outcomes which are not a reflection of RAS at optimal performance. It is likely that training requirements and

structural changes in the long-term are required, in order to optimise RAS across the workforce, which would include adoption into training programmes, both for experienced surgeons and trainee and junior surgeons (Lawrie et al. 2022). Wider upskilling and investment in training would reduce the time to overcome the learning curve across the workforce who are not experienced with RAS.

Price and funding structures

The adoption of a robotic platform for hospitals is a relatively expensive investment. The current list prices for the robotic platforms within scope are [redacted] This cost does not include consumables, maintenance and other budgetary factors for the hospital. Therefore, within constrained hospital budgets, how this is funded should be considered by decision-makers, and funding arrangements will need to be made for procurement of any recommended robotic platforms. The EAG recommends that implementation and commercialisation staff from NICE and NHS England engage with any recommended companies to support sustainable payment structures for hospitals, within the context of constrained budgets. It is important to note that 4 of the 5 models are on the NHS supply chain framework [redacted]

The EAG also encourages companies within the scope of this EVA to engage and support payment structures which are sustainable for NHS hospitals. [redacted] Different contracts are likely to suit different providers, therefore, the EAG does not advocate for a one-size-fits-all for contracting, and the optimal financing option should be decided with the NHS provider if recommended as part of the EVA programme.

Physical impact on surgical staff

Previous literature has indicated the physical strain that surgery can have on surgical staff, across a range of specialties and procedures (Gabrielson et al. 2021, Shugaba et al. 2022, Kokosis G et al. 2020). This issue is one of several issues which are contributing towards staffing shortages within surgery (Royal College of Surgeons of England 2023). Previous evidence has reflected that RAS significantly reduces the physical burden on a surgeon, which was also confirmed with clinical experts available to the EAG (York Health Economic Consortium 2024, Shugaba et al. 2022). It is likely that RAS will mean that surgeons are able to spend longer in the workforce before retirement, if this is related to physical issues. This is a potential benefit of RAS which was not incorporated into the early economic modelling but is an important benefit of RAS.

Clinician and patient attitudes towards RAS

An important consideration for the implementation of robotic platforms into the NHS is the acceptance and attitudes of clinical staff and patients. Using robotic technology within healthcare may be a concern for some of the population, which will affect the uptake of RAS, particularly among certain groups of people. For instance, previous evidence has highlighted that lower education levels, age and gender may impact the perceptions of RAS (Torrent-Sellens et al. 2021, McDermott et al. 2020, Aldousari et al. 2021). Hence, without patient engagement, the uptake of RAS may be limited, both from clinical staff wanting to use the technology, as well as patients not wanting surgery using a robotic platform. Research has also indicated that use of RAS is an important consideration for surgical staff, meaning its adoption in some cases may improve staff recruitment or retention (Pucher et al. 2024). Further research should be taken to understand the attitudes to RAS and how this may differ across the population.

Understanding the factors which drive both clinician and patient engagement will help improve uptake and success of any practical implementation.

Health inequalities

Use of MIS, including RAS, has increased over time, with significant regional and socioeconomic variations. Previous evidence suggests that 14.6% of surgeries are MIS in the most deprived areas, and 24.8% are MIS in the least deprived for colorectal cancer across the NHS (Morton et al. 2023b). Furthermore, Lam et al. (2021) highlighted the regional and rural disparities of RAS uptake across England, demonstrating that East Midlands and the North West were underserved regions, compared with other areas of England (Lam et al. 2021).

Johnson et al. (2024) highlighted the key barriers and inequalities in access to care associated with MIS and RAS (Johnson SM et al. 2024). Inequalities are likely to present themselves through:

- geographical barriers
- socioeconomic barriers
- barriers for ethnic minority groups.
- Clinical and patient attitudes towards using robotic platforms. As outlined previously, those with lower education are more likely to have negative attitudes towards robotic platforms.

These barriers for groups in society, and resulting inequalities, are likely to stem from difficulty attracting specialist surgeons to regions or areas, or inability to allocate healthcare budgets to RAS where wide inequalities are already present.

However, there is also evidence that RAS may reduce health inequalities within some parts of society. For instance, elderly people, or people with co-morbidities, may be

more likely to receive MIS instead of open surgery, if a robotic platform can be used (Cole A et al. 2018).

If RAS were to be implemented more widely, national strategies for procurement, implementation, equitable distribution, and training must be considered to avoid worsening health inequalities.

9.3 Ongoing studies

Studies taking place in the UK were prioritised for consideration. Several other ongoing studies were identified from company submissions but they were not comparative, prospective ongoing studies that might be considered in a future assessment.

[redacted]

[redacted]Four studies ongoing in the UK were identified for the scoped interventions through company communications as part of the NICE fact check process. Two studies (ISRCTN18159384(Portsmouth Hospitals NHS Trust (UK) 2023) and NCT06038227(Intuitive Surgical 2024)) were identified for the Da Vinci Xi system and two studies (NCT06112535 (CMR Surgical Ltd 2024a) and NCT06539442(CMR Surgical Ltd 2024b)) for the Versius system.

The MAYFLY study (ISRCTN18159384) (Portsmouth Hospitals NHS Trust, 2023) is a single arm prospective study designed to evaluate the clinical, economic and efficiency outcomes of the use of robotic surgery in a multi-disciplinary outpatient department. The study is taking place in Portsmouth, UK and is due to complete in September 2026. Primary outcomes include quality of life assessed by EQ-5D and QoR-15 questionnaires, cost-effectiveness, operational effectiveness and perioperative outcomes (operating time, anaesthetic time and theatre time). The outcomes will be

compared with routinely collected Trust-level metrics for laparoscopic and robotic surgery.

The LARCS study (NCT06038227) (Intuitive Surgical, 2023) compares video-assisted thoracic surgery with robot-assisted thoracic surgery in people with non-small cell lung cancer. It is recruiting in London, UK and is scheduled to end in December 2027. The primary outcome is patient-reported quality of life assessed by EQ 5D 5L and by the Reintegration to Normal Living Index.

NCT06112535 (CMR Surgical 2023) is a single-arm prospective feasibility trial taking place in Liverpool, UK. The primary objective of the study is to evaluate the safe use and performance of Versius in transoral surgeries. The study began in December 2023 and is scheduled to end in February 2025. Primary outcomes include the incidence rate of adverse events and the rate of successful completion of surgery without conversion.

NCT06539442 (CMR Surgical 2024) is a single-arm prospective proof-of-concept study which began in July 2024. Phase three of this study will take place at three sites in the UK (Southampton, Manchester and London) to assess the efficacy and safety of Versius in paediatric urological procedures. Phase three of the study is scheduled to end in January 2027. The primary outcome measure is the incidence of adverse events up to three months post-operation.

Due to the volume of references retrieved from the EAG searches, only the ongoing studies supplied by company communications were screened and assessed.

10 Evidence gap analysis

Table 10.1. Summary and conclusions of evidence gap analysis

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Primary – patient level					
Conversion to open surgery	10 cohort studies (6 retrospective, 1 prospective; 3 historically controlled [9 Europe, 1 UK] 2 prospective non-randomised studies (Europe) **AMBER**	No studies **RED**	1 retrospective cohort study (Europe) **AMBER**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) **AMBER**	1 RCT (UK) 1 prospective non-randomised study (Asia) **AMBER**
Conversion to conventional MIS from RAS	1 prospective non-randomised study (Europe) 4 cohort studies (3 retrospective; 1 historically controlled [4 Europe]) **AMBER**	No studies **RED**	1 retrospective cohort study (Europe) **AMBER**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) **AMBER**	1 RCT (UK) 1 prospective non-randomised study (Asia) **AMBER**
Length of hospital stay	9 cohort studies (6 retrospective, 1 prospective, 2 historically controlled [1 UK; 8 Europe]	1 prospective cohort study (Asia) **AMBER**	1 retrospective cohort study (Europe) **AMBER**	2 retrospective cohort studies (1 UK, 1 Europe)	1 RCT (UK)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
	2 prospective non-randomised studies (Europe) **AMBER**			1 historically controlled cohort study (Europe) **AMBER**	1 prospective non-randomised study (Asia) **AMBER**
Intraoperative complications	6 cohort studies (4 retrospective; 1 prospective; 1 historically controlled [6 Europe]) **AMBER**	1 prospective cohort study (Asia) **AMBER**	1 retrospective cohort study (Europe) **AMBER**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) **AMBER**	1 RCT (UK) **AMBER**
Postoperative complications	Overall complications: 4 cohort studies (2 retrospective studies; 1 historically controlled [4 Europe]) **AMBER**	1 prospective cohort study (Asia) **AMBER**	No studies **RED**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) **AMBER**	1 RCT (UK) 1 prospective non-randomised study (Asia) **AMBER**
Clavien-Dindo score	8 cohort studies (5 retrospective, 1 prospective, 2 historically controlled [1 UK, 7 Europe]	No studies **RED**	No studies **RED**	2 cohort studies (1 retrospective, 1 historically controlled [1 UK, 1 Europe]) **AMBER**	1 RCT (UK) **AMBER**

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
	2 prospective non-randomised studies (2 Europe) **AMBER**				
HRQoL	1 historically controlled cohort study (Europe) **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Primary – surgeon level					
Procedure-related discomfort and ergonomics	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT (UK) **AMBER**
Primary – organisation level					
Rate of MIS compared with open surgery after RAS was introduced	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Volume of procedures	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Hospital capacity and wait-list reduction	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Secondary – patient level					
Days alive and out of hospital	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Post-operative pain	4 cohort studies (1 prospective, 1 retrospective, 2 historically controlled [4 Europe] **AMBER**	No studies **RED**	No studies **RED**	1 retrospective cohort study (UK) **AMBER**	1 RCT (UK) 1 prospective non-randomised study (Asia) **AMBER**
Satisfaction	1 retrospective cohort study (Europe) **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Revision surgery for the same indication	2 prospective non-randomised studies (2 Europe) 5 cohort studies (4 retrospective; 1 prospective [1 UK; 4 Europe])	No studies **RED**	No studies **RED**	1 historically controlled cohort study (Europe) **AMBER**	No studies **RED**

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
	AMBER				
Secondary – patient level (specific study types)					
Intraoperative blood loss (compared with open surgery)	1 prospective randomized study (Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Survival rate (in cancer studies)	3 retrospective cohort studies (1 UK; 2 Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Need for adjuvant treatment (in cancer studies)	1 prospective non-randomized study (Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Feeding tube dependency (for head and neck studies)	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Secondary outcomes – surgeon level					
Career longevity and musculoskeletal injury	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Human factors	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT (UK) **AMBER**
Learning curve	3 cohort studies (2 retrospective; 1 historically controlled [3 Europe]) **AMBER**	No studies **RED**	No studies **RED**	1 retrospective cohort study (UK) 1 historically controlled cohort study (Europe) **AMBER**	1 prospective non-randomised study (Asia) **AMBER**
Secondary outcomes – organization level					
Readmission at 30 days	1 prospective non-randomised study (Europe) 5 cohort studies (3 retrospective, 1 prospective; 1 historically controlled [1 UK, 4 Europe]) **AMBER**	No studies **RED**	1 retrospective cohort study (Europe) **AMBER**	1 historically controlled cohort study (Europe) **AMBER**	1 RCT (UK) **AMBER**
Operating time	11 cohort studies (7 retrospective, 1 prospective; 3 historically controlled [10 Europe, 1 UK]	1 prospective cohort study (Asia) **AMBER**	1 retrospective cohort study (Europe) **AMBER**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe)	1 RCT (UK) 1 prospective non-randomised study (Asia) **AMBER**

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
	2 prospective non-randomised studies (Europe) **AMBER**			**AMBER**	
Staffing requirements	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

RED indicates no comparative evidence for the scoped population; **AMBER** indicates weak comparative evidence for the scoped population; **GREEN** indicates robust comparative evidence for the scoped population.

Nb. Studies conducted in Turkey were considered as European studies

Key: RCT – Randomised controlled trial.

Table 10.2: Evidence gap analysis for key economic outcomes

Outcomes	Gap in current evidence
Effectiveness evidence: Difference in proportion of MIS from introducing robotic platforms	One of the value propositions from implementing robotic platforms is the increased provision of MIS. However, there is currently no UK evidence to indicate how much more likely MIS will be for the range of soft-tissue procedures within scope. **RED**
Effectiveness evidence: Long-term outcomes	If RAS is improving surgical outcomes, it is feasible that this may lead to improvements in long-term health outcomes. Current studies do not have sustained follow up, usually less than one year for specific soft-tissue procedures. Therefore, it is not currently possible draw any conclusions of the average long-term benefit of RAS across all soft-tissue procedures. **AMBER**
Effectiveness evidence: Impact of subgroups	Evidence is currently of low-quality for how outcomes differ between different groups of procedures by speciality, or by other patient characteristics (such as co-morbidities) for the scoped technologies. Co-morbidities, or specific groups of procedures within 'soft-tissue' may lead to significantly different outcomes AMBER
Resource use: Utilisation of robotic platforms when introduced across relevant case-mix	There are currently reports available from companies and anecdotal evidence from clinical experts on the utilisation of robotic platforms. However, this is in clinical specialities which have much higher uptake of RAS, and may not reflect all of soft-tissue procedures. If RAS is going to be recommended across a range of soft-tissue procedures, then greater evidence needs collecting on the utilisation of the robot. **AMBER**
Resource use: Impact on capacity across all healthcare settings	There is some anecdotal evidence from clinical experts and some specific procedures that RAS may increase capacity of surgeries in the system. This is due to a combination of reduced physical strain on surgical staff, and for some of the scoped procedures, reduced operative times. However, other procedures indicate longer waiting times, so more evidence is required on the likely impact if RAS is recommended for all soft-tissue procedures. **AMBER**

Outcomes	Gap in current evidence
Resource use: Impact of learning curve	There is very limited evidence available to quantify the impact of the clinician learning curve on the costs or efficacy of RAS. While this impact is likely to be short-term, potentially affecting outcomes primarily within the first 1-2 years, it is important to consider. Furthermore, modelling the effects of introducing RAS at new sites or with new clinicians will be important in assessing the feasibility of its implementation. **RED**
Costs: Set up and training costs	Companies provide some evidence of the implementation, training and learning curve effects and the associated costs to embed their technologies within the NHS, but the quality of evidence is mixed and is likely heterogenous across soft-tissue procedures. Further clarification should be sought on the required training and learning curve effects for all procedures in scope for this evaluation. **AMBER**
Costs: Alternative cost structures	Only one company provided information on the cost of RAS under a free loan structure, and no data was available regarding leasing cost structures. This introduces uncertainty into the outcomes of the economic modelling and is a key driver of uncertainty for this evaluation. A more robust understanding of the available costing structures will be important for the procurement and successful implementation of robotic surgery platforms within the NHS. **RED**

Key: **RED** indicates no evidence for the scoped population; **AMBER** indicates weak evidence for the scoped population; **GREEN** indicates robust evidence for the scoped population.

Please note that objectives and scope of the EVA process does not include exhaustive consideration of all studies identified in the review, thus the evidence gap analysis is based on the prioritised studies only. The EAG notes that the deprioritised studies may include evidence for some of the areas identified in the evidence gap analysis and may have evidence on outcomes which were not captured by the included studies.

Comparative clinical evidence meeting the scope was available for all five scoped technologies. Of the 20 included studies, 13 reported on the Da Vinci Xi (of which 2 were non-randomised prospective studies, 4 were prospective cohort studies and 7 were retrospective cohort studies), 1 prospective cohort reported on the Da Vinci SP, 1 retrospective cohort reported on Hugo, 3 reported on Senhance (1 prospective cohort study in children and 2 retrospective cohort studies) and 2 reported on Versius (1 RCT and 1 prospective non-randomised study).

Moderate to low quality comparative evidence was identified for a number of the patient level primary outcomes including conversion to open surgery, intra operative and post operative complications and the Clavien-Dindo score. However, half the studies were retrospective in nature and 4 used historic controls. Even where prospective, comparative evidence was available, studies were of too short a duration to understand the impact of the learning curve, and had small sample sizes. Studies evaluated the use of RAS in a range of indications (both benign and malignant) and the outcomes assessed were generic across indications. Each study tended to focus on one specific type of surgery (e.g. colorectal resection). There may be indication specific outcomes that are clinically relevant that have not been considered as part of this evaluation.

With the exception of length of hospital stay, other primary surgeon level and organisation level outcomes were not well reported. There was insufficient long-term evidence to take into account the learning curve and to understand the surgeon and

organisation outcomes from the point that optimal performance and use of the robot is reached. Finally, it is also important to note that given the scoped population was soft-tissue procedures, where evidence was available, it only captured specific procedures. Therefore, it is not clear if this evidence is generalisable to the rest of the scoped population, based on 1 or 2 procedures within the entire scoped population. The EAG would not expect this evidence for every procedure at this stage, but a greater number of procedures captured would produce more confidence in the available evidence from RAS for the scoped technologies.

10.1 Key areas for evidence generation

Suggestions for future evidence generation are summarised in Table 10.3. Evidence generation should focus on settings in which the use of RAS to support soft tissue surgery has shown early potential to have a beneficial impact on key health and resource use outcomes when compared with standard surgical care, to develop the evidence base further (MIS or open depending on the indication). Filling evidence gaps where potential is already highlighted will enable a more complete evaluation to inform decision making.

To understand the potential benefit of the robotic platforms, it is important to generate evidence across a long enough timeframe to understand the learning curve and to evaluate the outcomes and resource use implications when the robot has reached its optimal performance in the hospital (both short- and long-term). It is also important to generate evidence on the long-term outcomes associated with RAS compared with standard surgical care.

There is a need for evidence from large multi-center studies, across a range of indications or surgeries in settings where the robotic platform is being introduced and in settings where it is already established. As discussed in Section 9.2, previous evidence

suggests that there are regional and socioeconomic differences in the access to surgical care. It is important for any future studies to evaluate the geographical variation in resource use, uptake, efficacy, and health outcomes.

We understand from the clinical feedback that RAS may increase the availability of MIS for people who were not eligible for open surgery (due to co-morbidities or risk factors), but where surgeons do not feel comfortable performing conventional MIS (York Health Economic Consortium 2024). This is because the robot may ease the technical application of MIS. None of the identified studies reported data on the proportion of patients who were able to undergo MIS due to the introduction of RAS.

Because of the broad range of procedures covered under the umbrella of soft tissue procedures, the approach to the evidence generation will guide future economic evaluations. Options include one single model with a high-level approach and weighted average across a range of procedures, evaluating RAS at a procedure level, or a hybrid approach grouping procedures based on clinical area (e.g. urology), common outcomes (e.g. cancer-related procedures), or by anatomy. Section 10.2 provides further detail on potential future modelling approaches.

With respect to the optimal approach to evidence generation, there is a balance between pragmatism and granularity. It is likely not feasible to conduct large-multi-centre studies for each soft-tissue procedure, to determine the effectiveness and cost-effectiveness of RAS for all possible indicated soft-tissue procedures. However, trying to capture all soft-tissue procedures in one study is likely to focus only on generalisable outcomes, omitting key potential benefits of RAS. This high-level approach to evidence generation is likely to be highly dependent on the case-mix of where the robotic platforms are used, so may not be representative of all soft-tissue procedures.

Therefore, we believe the optimal approach to evidence generation is likely a hybrid approach, conducting studies based on grouped procedures either by similar clinical outcomes (both short-term and long-term), clinical specialty, or anatomy. For instance, if a robotic platform is purchased for a urology department, it would make sense to evaluate urological procedures together, evaluating the impact within the department. We believe this will find the balance between generating appropriate evidence to support decision-making, without needing to conduct an unmanageable level of studies.

Finally, successful implementation of RAS will require optimal staff acceptability, patient acceptability and uptake to ensure that benefits are realised across as large a population as possible. Further evidence is required to establish the patient and staff acceptability of the technologies.

Producing evidence for all listed evidence gaps will help inform the clinical and cost-effectiveness of RAS for soft-tissue procedures. We have not listed cost-effectiveness of RAS as an evidence gap, as filling all other evidence gaps would support this objective. Risk management and governance structures should also be put in place for any adoption of RAS, in line with required evidence generation and previous guidance on the adoption of RAS (Royal College of Surgeons of England 2024). Further important guidelines are outlined in the NICE Scope.

Table 10.3. Evidence generation recommendations

Objective	Recommended study design	Outcomes
Long term outcomes and resource use associated with RAS beyond first 30 days.	Large multi-centre, prospective, comparative studies of robotic vs. current standard of care (open or MIS) Further studies in a UK setting for all robots over at least a 1 year follow up.	• Patient level, surgeon level and organisation level outcomes. • Understand the learning curve associated with RAS introduction. • Studies are needed to address outcomes for Da Vinci SP, Hugo, Senhance and Versius
Understanding the difference in outcomes between introduction of RAS and optimal performance (accounting for learning curve)		• Patient level, surgeon level and organisation level outcomes. • Understand the learning curve associated with RAS introduction.
The resource use associated with staff training for RAS	Prospective observational studies, documenting staff time associated with training Conducted in the UK.	• Time spent training for different procedures
Patient uptake of RAS and facilitators of acceptability.	Mixed methods studies assessing patient preference data and ensuring adequate communication of the benefits and risks of RAS Conducted in the UK.	• Patient preference • Facilitators and barriers of uptake

Surgeon uptake of RAS and facilitators of acceptability.	Mixed methods studies assessing surgeon preference.	• Surgeon preference and perceived facilitator and barriers to use of RAS
Understanding the value of different features between robotic platforms, and if they are valuable to the surgeon or healthcare system	Mixed methods studies assessing the importance of features such as single port versus multi-port, portability of robotic platform etc.	• Understanding of components and factors which make a more optimal robotic platform.
Understanding of the impact RAS has on the numbers of MIS.	Difference-in-differences approach could be taken to evaluate uptake. This includes having control hospitals (without robotic platforms) and comparing to those where they are implemented. Data can be looked back retrospectively for the before period.	• System level outcomes to determine if RAS is driving differences in MIS.
Understanding on how surgery types could be grouped to streamline evidence generation (also see Section 10.2)	With clinical input, deciding which groupings are most appropriate to generate evidence and model the potential benefits of RAS.	• Quality of life • Clinical outcomes • Resource use • Cost
Identification of generalisable outcome measures, either for all soft-tissue procedures, or by specific groupings	Qualitative research including engagement with clinical experts to identify clear groupings.	• Identification of patient, clinician and system level outcomes for grouped areas of research

Key: MIS – Minimally invasive surgery, RAS – Robot-assisted surgery, SP – Single port.

10.2 Potential future modelling approaches

When evidence is collected to bridge current evidence gaps on the use of robotic platforms to support surgical care, we have outlined three possible approaches which could be taken.

The first approach would be to develop one model with a high-level approach, using weighted average data from a range of procedures. Hence, the focus of this approach, similar to the early model in this report, would not be to capture the results for any one specific group of procedures, but focus the model on generalisable outcomes to all surgical procedures within the scope of soft tissue. After a data collection period, more robust aggregated data could be used to model key generalisable outcomes. Furthermore, long-term outcomes may still be captured within this structure, but in a simplified capacity. For instance, overall survival differences, regardless of procedure, could be extrapolated using survival analysis. It is likely survival outcomes would be heterogeneous depending on the populations undergoing RAS. However, scenario analysis on different curve extrapolation could help provide an understanding of the potential impact.

This could use a generalisable decision tree structure in the short-term, mapping out key surgical outcomes sequentially (if data is available sequentially). This structure will likely capture similar outcomes as contained in the early model, such as proportion undergoing MIS, conversion rates to open surgery, complication rates and readmission rates. Key high-level outcomes in the long-term can then be incorporated into this long-term structure. For example, the approach could capture weighted average differences in survival, in which case a partition survival model could be used. The benefit of this approach is that outcomes that are more easily generalised across a range of soft-tissue procedures can be captured, matching the scope of the evaluation. However, by

taking a less granular approach, it may be that the benefit of RAS in relation to specific procedures is not captured.

The second approach would be to group procedures based on clinical area, or where key clinical and economic outcomes are similar between surgical procedures. This approach would be a hybrid approach between modelling specific procedures, or a high-level approach capturing all procedures. In this approach, several different models could be developed, one for each grouped area. For instance, it may be plausible to group soft-tissue procedures related to cancer, where the key clinical outcomes are similar, such as survival, progression, adverse events and healthcare appointments. Equally, the specialties could be grouped by clinical area such as urology, thoracic, head and neck etc. Grouping the surgeries into more specific sets of procedures, may allow for greater granularity to be captured in outcomes, where key economic outcomes are more likely to be similar.

The final approach would be to continue to evaluate RAS at a procedure specific level, as identified in the literature. This would be less preferrable to the alternative approaches, given it does not truly evaluate RAS in a wider range of applications, and it is not feasible to conduct potentially over 100 studies across each procedure, for each robotic platform.

A hybrid approach may be the optimal approach, which could capture where robotic platforms are not moved across NHS operating theatres, meaning they are more likely to be used in specific departments for groups of procedures. The approach could also capture where robotic platforms are used for a similar group of procedures, with respect to outcomes, but may be moved between operating theatres. The exact approach would be tailored to the specific robotic platform and what is feasible. The hybrid approach may be much more time intensive than a very generalised approach.

Furthermore, the number of models to be developed for a hybrid approach would need to be informed by clinical guidance around the feasibility of grouping different procedures. The feasibility and number of different models required would help determine the usefulness of this approach for decision makers.

Particularly if a more generalised or hybrid approach is taken to the evaluation, a patient simulation model is likely the optimal approach to modelling. This is to account for individual characteristics and the case-mix of procedures, which are likely to have significant impact on the outcomes. The exact structure of the patient simulation is likely to differ between each grouping for the hybrid approach. For a generalised high-level approach, it is likely to capture similar factors to the EAG early model.

The hybrid and generalised approaches outlined have strengths and limitations, and the usefulness of either approach is likely to be determined by multiple factors including:

- The data collection plans of any recommended companies. For instance, where RAS is more commonly conducted in the NHS will likely drive available data and inform if more specific grouped models can be developed.
- If NICE were to make an optimised recommendation for the use of RAS within soft tissue procedures, where the number of included procedures is less.
- The willingness of decision makers to consider more pragmatic approaches, which may quantify less of the potential impact. The wider the scope of the evaluation, the less likely very granular and specific models can be developed. In this case, either the scope of the model would have to be reduced, or a more pragmatic high-level approach has to be taken.

Regardless of the approach taken, there is likely to be some benefits which cannot be quantified as part of the economic evaluation. For instance, the physical impact of RAS on surgical staff compared with other types of surgery is not likely to be feasible to

quantify in any structure. This is because although there are benefits of reducing physical strain, scaling this to an impact per procedure is not likely to be accurate or useful for decision makers. Furthermore, the benefits of RAS on staff retention and recruitment may also be difficult to quantify. There is potential to link the physical impact and staff retention to difference in waiting times, and the outcomes this could have on surgical outcomes. Similarly, if evidence can be directly linked to improved staff retention due to the adoption from RAS, this may be linked to the cost of recruiting and training new staff, scaled to a per procedure cost. Even if this evidence cannot be collected and quantified this would still be an important consideration for any future decision makers, and should be factored into any future evaluation.

Finally, it will still be important to reflect the impact of the learning curve effect in any future model. As highlighted in the clinical feedback, this effect will differ on a number of factors including surgeon experience with robotic platforms, the type of procedure and clinical specialty (York Health Economic Consortium 2024). This can be reflected in the model by length of surgery and modifying the effectiveness of outcomes for the first number of surgeries as indicated by the literature or data collection. It will be important for companies to collect data for a long-enough time period, where the learning curve effect has diminished, to see the true impact of RAS after implementation.

11 Conclusions

11.1 Conclusions from the clinical evidence

The comparative evidence identified suggests that RAS is generally comparable with current standard of care for primary patient outcomes, for the procedures identified. However, we note that the prioritised studies used unclear or different definitions for some outcomes such as intraoperative and perioperative complications and operative

time, or used different scales to measure the same outcome. This makes it difficult to compare the results across studies. There was either no or limited evidence for a range of primary and secondary outcomes for the prioritised evidence. For some outcomes, such as HRQoL and procedure-related discomfort and ergonomics, results were only reported for one robot. Gaps in the evidence made comparisons across the different technologies difficult. However, in general, results for each technology aligned with one another where there was evidence available.

The majority of the evidence (19/20 studies) were either cohort or non-randomised studies. Therefore, there could be exaggerated treatment effects due to selection bias and an increased risk of confounding. Even where prospective, comparative evidence was available, studies were of too short a duration to understand the impact of the learning curve, and had small sample sizes. Studies conducted in the UK were sparse (3/20 studies) and so the results may not all be generalisable to a UK population. There were also a variety of indications and types of surgery, and it is unclear whether the results from one type of surgery are comparable with other types of surgery. However, it important to reiterate that this approach was taken in order to gain a broader estimate of the potential impact of RAS, given that implementation of RAS within hospitals is not likely to be on a procedure specific-basis.

11.2 Conclusions from the economic evidence

Previous economic evidence

Three economic costing studies were identified. This included

- An unpublished company submitted cost-comparison analysis in England for da Vinci Xi.
- A published cost comparison analysis of da Vinci Xi versus da Vinci Si set in a Swiss context.

- A multi-country cost-comparison analysis of Senhance compared with an unspecified iteration of a da Vinci robotic platform.

The English cost-comparison analysis was the only UK-based study. This study reported potential cost savings versus open and laparoscopic surgery due to reduced LoS, fewer blood transfusions, conversion to open surgery, reduction in post operative complications and readmissions. However, this study omitted key costs from implementing the robot, only including the cost of purchasing the platform. The quality of the evidence for the scoped robotic platforms was low.

Economic model results

The economic analysis conducted by the EAG was a simple cost-comparison model to indicate the potential benefit of RAS platforms for soft tissue surgical procedures, over a time horizon of one year. This analysis suggests that, based on the limited evidence available, the incorporation of RAS into the NHS may increase per-procedure costs to the NHS when compared with standard surgical care.

Cost per procedure results ranged from £35 to £1,771, depending on the scenario selected, with a base case estimation of £474 per procedure. RAS was cost-incurring all scenarios, and in PSA had less than 50% chance of being cost-saving in all scenarios. Scenario results indicated that lower costs would be incurred from RAS replacing open surgeries rather than conventional MIS, £177-£396 per procedure compared with £675-£971 per procedure respectively. Base case results indicate that, to be cost-effective, RAS would likely need to generate over 0.10 QALYs per procedure, when compared with standard surgical care (36.5 additional days in perfect health, or 10% of one year). The additional required QALYs assumes that robotic platforms are used in approximately 33 per cent of surgeries, and with a cost-effectiveness threshold of £20,000 per QALY.

However, these results are based on uncertain data from a range of studies on specific procedures, which may not be generalisable to all types of soft-tissue procedures.

Furthermore, case-mixes are likely to be very heterogenous between RAS sites and therefore may lead to a wide range of outcomes. Overall, the costing methods (upfront, leasing or free-loan) for the robotic platforms, the case-mix where the platform is used, and the heterogeneity in the patient population are likely to impact the cost-effectiveness of RAS for soft-tissue procedures.

Key drivers of the model results

The DSA indicated the likely key drivers of the economic results were:

- additional length of surgery time for RAS per person.
- proportion of surgeries that are MIS in either treatment arm.
- conversion rate from MIS to open in either treatment arm.
- proportion of MIS surgeries in that are RAS for the intervention arm.
- disposable component costs of RAS.

Furthermore, the learning curve experienced by surgical staff may also have impacted the outcomes captured in the model, but this could not be disentangled from the data. This was only captured through operative time and potential LoS differences. Better understanding the optimal performance of RAS and the impact of the learning curve is important.

11.3 Conclusions on the gap analysis

Comparative data was available for all of the five technologies, however it was generally moderate to low quality and each study only looked at one specific type of surgery. Primary surgeon-level and organisation-level outcomes were not well-reported, and the evidence was not long-term enough to determine outcomes from when the optimal performance of the robot was reached. Future evidence should therefore be generated across a longer timeframe to understand the learning curve. This should be

done in large multi-centre prospective studies across a range of surgeries with at least twelve-month follow-up. It would be beneficial to do this in settings where robotic surgery is already established and also where it is in the process of being introduced.

A key outcome which was not addressed by the studies was the number of people who may be eligible for RAS who were not able to have either open surgery or MIS. Data should be collected on the number of people who are able to undergo MIS due to the introduction of RAS. This could be achieved using control hospitals without robotic platforms and comparing the data in settings where RAS is established. There is also a need for mixed-methods studies within the UK to determine patient acceptability of RAS, surgeon preference and the benefits of the different features of the robotic systems.

RAS presents a challenge for future evidence generation as previous studies have concentrated on one surgery type with specific outcomes, and studies which attempt to capture all soft-tissue procedures may focus only on generalisable outcomes and may be heavily dependent on the case-mix in the setting. A hybrid approach is therefore recommended, where procedures are grouped by similar clinical outcomes, specialty or anatomy. This requires qualitative research with clinical experts to establish clear groupings. In line with similar guidance for RAS, risks surrounding governance, management and co-ordination will need to be identified and managed across any implementation.

Future conceptual model

Limited evidence was available to model the potential impact of RAS over a longer period of time, or for procedures in a variety of indications separately. A hybrid future set of models could be developed which groups procedures based on similar clinical outcomes or clinical speciality, which would:

- capture the impact of RAS in groups of procedures
- capture differences in HRQoL
- consider the impact of costing structures and utilisation of robotic platforms.
- provide greater understanding of the potential long-term impact of RAS, including long-term complication, disease progression and the associated impact on costs and QALYs.

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13 Appendices

Appendix A – Search methods

A MEDLINE (OvidSP) search strategy was designed to identify studies of the four eligible RAS technologies for eligible soft-tissue surgical procedures. It is presented below (see Section A.1).

The strategy comprised search terms for the brand names of the four eligible RAS technologies (search lines 1 to 4), combined with OR in search line 5.

The strategy excluded animal studies from MEDLINE using a standard algorithm (search line 6). The strategy also excluded some ineligible publication types which were unlikely to yield relevant study reports (editorials, news items and case reports) and records with the phrase 'case report' in the title (search line 7).

Reflecting the eligibility criteria, the strategy was restricted to studies published in English in the last ten years (search line 9).

Searches were not restricted by study design or outcome so were appropriate to retrieve both clinical and economic evidence.

The final Ovid MEDLINE strategy was peer-reviewed before execution by a second Information Specialist. Peer review considered the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

Search limitations

The search was designed only to retrieve studies where the named eligible technologies were mentioned in the title, abstract, keyword heading word or original title

fields of the database record. Studies where the database record did not explicitly refer to the named technologies could have been missed by the search strategy. The approach taken in the search strategy was designed to strike an appropriate balance of sensitivity and precision to meet project resources and timelines. The risk of missing eligible studies was mitigated by checking company submissions and the reference lists in recent systematic reviews (see below for details).

Resources searched

We conducted the literature search in the databases and information resources shown in Table A.1.

Table A.1: Databases and information sources searched

Resource	Interface / URL
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library/Wiley
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
HTA Database	https://database.inahta.org/
Conference Proceedings Citation Index - Science (CPCI-S)	Web of Science
NHS Economic Evaluation Database (NHS EED)	https://www.crd.york.ac.uk/CRDWeb/HomePage.asp
EconLit	OvidSP
Trials Registers	
ClinicalTrials.gov	https://clinicaltrials.gov/
WHO International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/
Other	

Reference list checking	n/a
Company submissions	n/a

The trials register sources listed above (ClinicalTrials.gov and ICTRP) were searched to identify information on studies in progress.

Reflecting the eligibility criteria, records indexed as conference abstracts were excluded from Embase search results.

We also checked included studies lists of any industry submissions to NICE as well as retrieved relevant systematic reviews published since 2022, for additional eligible studies.

Additional searches: the Senhance robotic system

A further technology was added following the publication of the Scope. NICE undertook additional searches for the Senhance robotic system on 25 July 2024. The searches include only the Senhance technology and were based on the MEDLINE EAG strategy, however there are some differences in search syntax. The search strategy for MEDLINE searches "all fields" in the record using the syntax .af., where the EAG search is targeted to the title, abstract, keyword heading word and original title fields.

Running the search strategies and downloading results

Where possible, we conducted searches using each database or resource listed above, translating the agreed Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The final translated database strategies were peer-reviewed by a second Information Specialist. Peer review considered the

appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote)(Clarivate 2021). The results were deduplicated using several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources that did not allow export in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually deduplicated.

The results of the additional searches for the Senhance technology were de-duplicated and screened for relevance by NICE. They were supplied to the EAG for loading to EndNote on 30 July 2024.

Literature search results

The initial searches were conducted on 5 July 2024 and identified 4,903 records (Table A.2). Additional searches for the Senhance technology were conducted on 25 July 2024 and identified a further 219 records. 67 records were identified via other sources (reference list checking and company evidence). Following deduplication, 4,090 records were assessed for relevance.

Table A.2: Literature search results

Resource	Number of records identified: initial searches	Number of records identified: additional Senhance searches	Total number of records identified
Databases			
MEDLINE	866	76	942
Embase	1975	135	2110
Cochrane Database of Systematic Reviews (CDSR)	0	0	0
Cochrane Central Register of Controlled Trials (CENTRAL)	1382	1	1383
HTA Database	4	0	4
NHS Economic Evaluation Database (NHS EED)	0	0	0
EconLit	0	0	0
Total records identified through database searching	**4227**	**212**	**4439**
Trials Registers			
ClinicalTrials.gov.	339	5	344
WHO International Clinical Trials Registry Portal (ICTRP)	337	2	339
Total records identified through trials register searching	**676**	**7**	**683**
Other sources			
Reference list checking	3	0	3
Company evidence	64	0	64
Total additional records identified through other sources	**67**	**0**	**67**
Total number of records retrieved	**4970**	**219**	**5189**
Total number of records after deduplication	**3941**	**149**	**4090**

Search strategies

A.1: Source: MEDLINE ALL

Interface / URL: OvidSP

Database coverage dates: 1946 to 3 July 2024

Search date: 5 July 2024

Retrieved records: 866

Search strategy:

1 versius*.ti,ab,kf,ot. 70

2 ((da vinci* or davinci*) adj6 (x* or sp*)).ti,ab,kf,ot. 980

3 (davincix* or davincisp* or IS4200 or IS4000 or SP1098).ti,ab,kf,ot. 12

4 (hugo* and robot*).ti,ab,kf,ot. 102

5 or/1-4 1137

6 exp animals/ not humans/ 5237020

7 (news or editorial or case reports).pt. or case report.ti. 3384512

8 5 not (6 or 7) 950

9 limit 8 to (english language and yr="2014 -Current") 866

Additional MEDLINE ALL search conducted by NICE: Senhance only

Interface / URL: OvidSP

Database coverage dates:1946 to 24 July 2024

Search date: 25 July 2024

Retrieved records: 76

1 Senhance*.af. (89)

2 (Asensus and (laparoscop* or robot* or surgical-system*)).af. (13)

3 or/1-2 (94)

4 exp animals/ not humans/ (5241653)

5 (news or editorial or case reports).pt. or case report.ti. (3391147)

6 3 not (4 or 5) (81)

7 limit 6 to (english language and yr="2014 -Current") (76)

A.2: Source: Embase

Interface / URL: OvidSP

Database coverage dates: 1974 to 3 July 2024

Search date: 5 July 2024

Retrieved records: 1975

Search strategy:

1 versius*.ti,ab,kf,dq,dv,my,ot,dm. 148

2 ((da vinci* or davinci*) adj6 (x* or sp*)).ti,ab,kf,dq,dv,my,ot,dm. 3517

3 (davincix* or davincisp* or IS4200 or IS4000 or SP1098).ti,ab,kf,dq,dv,my,ot,dm. 34

4 (hugo* and robot*).ti,ab,kf,dq,dv,my,ot,dm. 186

5 or/1-4 3810

6 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ 7021859

7 editorial.pt. or case report.ti. 1220080

8 conference abstract.pt. 5198159

9 or/6-8 13066037

10 5 not 9 2106

11 limit 10 to (english language and yr="2014 -Current") 1975

Additional Embase search conducted by NICE: Senhance only

Interface / URL: OvidSP

Database coverage dates: 1974 to 24 July 2024

Search date: 25 July 2024

Retrieved records: 135

1 Senhance*.af. (161)

2 (Asensus and (laparoscop* or robot* or surgical-system*)).af. (23)

3 or/1-2 (163)

4 nonhuman/ not human/ (5499187)

5 (letter or editorial).pt. (2151720)

6 3 not (4 or 5) (142)

7 limit 6 to (english language and yr="2014 -Current") (135)

Source: Cochrane Database of Systematic Reviews (CDSR)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 7 of 12, July 2024

Search date: 5 July 2024

Retrieved records: 0

Search strategy:

#1 versius*:ti,ab,kw 9

#2 ((da vinci* or davinci*) near/6 (x* or sp*)):ti,ab,kw 408

#3 (davincix* or davincisp* or IS4200 or IS4000 or SP1098):ti,ab,kw 0

#4 (hugo* and robot*):ti,ab,kw 4

#5 #1 or #2 or #3 or #4 with Cochrane Library publication date Between Jan 2014 and Jul 2024, in Cochrane Reviews, Cochrane Protocols 0

Source: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 7 of 12, July 2024

Search date: 5 July 2024

Retrieved records: 1,382

Search strategy:

#1 versius* 10

#2 ((da vinci* or davinci*) near/6 (x* or sp*))3238

#3 (davincix* or davincisp* or IS4200 or IS4000 or SP1098) 0

#4 (hugo* and robot*) 18

#5 #1 or #2 or #3 or #4 with Publication Year from 2014 to 2024, in Trials 1382

Source: CDSR and CENTRAL combined

The additional searches for the Senhance technology were undertaken by NICE as one combined search in the CDSR and CENTRAL databases on 25 July 2024.

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issues searched: Issues 7 of 12, July 2024

Search date: 25 July 2024

Retrieved records: 1

Search strategy:

#1 Senhance* 5

#2 (Asensus and (laparoscop* or robot* or surgical-system*)) 0

#3 #1 or #2 with Cochrane Library publication date Between Jan 2014 and Jul 2024, in Cochrane Reviews 0

#4 #1 or #2 with Publication Year from 2014 to 2024, in Trials 4

#5 "conference":pt or (clinicaltrials or trialsearch):so 765632

#6 #4 not #5 1

Source: HTA database

Interface / URL: https://database.inahta.org/

Database coverage dates: Information not found. The former database was produced by the CRD until March 2018, at which time the addition of records was stopped as INAHTA was in the process of rebuilding the new database platform. In July 2019, the database records were exported from the CRD platform and imported into the new platform that was developed by INAHTA. The rebuild of the new platform was launched in June 2020.

Search date: 5 July 2024

Retrieved records: 4

Search strategy:

Applied filter, Year: 2014 to 2024 = 4 hits

1	versius*	0
2	(da vinci* OR davinci*)	29
3	(IS4200 OR IS4000 OR SP1098)	0
4	(hugo* AND robot*)	0
5	#4 OR #3 OR #2 OR #1	29

Additional HTA database search conducted by NICE: Senhance only

Interface / URL: https://database.inahta.org/

Database coverage dates: See above

Search date: 25 July 2024

Retrieved records: 0

1 (Senhance*) OR (Asensus and (laparoscop* or robot* or surgical-system*)) 0

Source: EconLit

Interface / URL: OvidSP

Database coverage dates: 1866 to 27 June 2024

Search date: 5 July 2024

Retrieved records: 0

Search strategy:

1 versius*.af. 0

2 ((da vinci* or davinci*) adj6 (x* or sp*)).af. 0

3 (davincix* or davincisp* or IS4200 or IS4000 or SP1098).af. 0

4 (hugo* and robot*).af. 0

5 or/1-4 0

6 limit 5 to yr="2014 -Current" 0

Additional EconLit search conducted by NICE: Senhance only

Interface / URL: OvidSP

Database coverage dates: 1886 to 11 July 2024

Search date: 25 July 2024

Retrieved records: 0

1 Senhance*.af. (0)

2 (Asensus and (laparoscop* or robot* or surgical-system*)).af. (0)

3 or/1-2 (0)

Source: NHS Economic Evaluation Database (NHS EED)

Interface / URL: https://www.crd.york.ac.uk/CRDWeb

Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.

Search date: 5 July 2024

Retrieved records: 0

Search strategy:

1 (versius) 0

2 (da vinci* OR davinci* OR IS4200 or IS4000 or SP1098) 41

3 (hugo* AND robot*) 0

4 #1 OR #2 OR #3 41

5 (#4) IN NHSEED FROM 2014 TO 2024 0

Additional NHS EED search conducted by NICE: Senhance only

Interface / URL: https://www.crd.york.ac.uk/CRDWeb

Database coverage dates: See above

Search date: 25 July 2024

Retrieved records: 0

1 (Senhance*) 0

2 (Asensus) 0

Source: ClinicalTrials.gov

Interface / URL: https://clinicaltrials.gov/ct2/home

Database coverage dates: Information not found. ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The site was made available to the public in February 2000.

Search date: 5 July 2024

Retrieved records: 339

Search strategy:

The following search terms were entered into the "Other terms" box on the home page.

(versius OR versiustm OR versiusr OR "da vinci" OR "da vincir" OR "da vincitm" OR davinci OR davincir OR davincitm OR "da vincix" OR "da vincixr" OR "da vincixtm" OR davincix OR davincixr OR davincixtm OR "da vincixi" OR "da vincixir" OR "da vincixitm" OR davincixi OR davincixir OR davincixitm OR "da vincisp" OR "da vincispr" OR "da vincisptm" OR davincisp OR davincispr OR davincisptm OR IS4200 OR IS4000 OR SP1098) OR ((hugo OR hugor OR hugotm) AND (robot OR robots OR robotic OR robotics OR robotically OR robotise OR robotize OR robotisation OR robotization))

Additional ClinicalTrials.gov search conducted by NICE: Senhance only

Interface / URL: https://clinicaltrials.gov/ct2/home

Database coverage dates: See above

Search date: 25 July 2024

Retrieved records: 5

Search terms not supplied.

Source: WHO International Clinical Trials Registry Portal (ICTRP)

Interface / URL: https://trialsearch.who.int/

Database coverage dates: Information not found. On the date of search, files had been imported from data providers between 27 May 2024 and 26 June 2024.

Search date: 5 July 2024

Retrieved records: 337

Search strategy:

The following search was conducted using the search interface at the above URL. 'Without Synonyms' was selected.

(versius* OR da vinci* OR davinci* OR IS4200 or IS4000 or SP1098) OR (hugo* AND robot*)

Additional WHO ICTRP search conducted by NICE: Senhance only

Interface / URL: https://trialsearch.who.int/

Database coverage dates: See above

Search date: 25 July 2024

Retrieved records: 2

Search terms not supplied.

Appendix B - Deprioritised and excluded studies

Table B. 1: Deprioritised studies (n=73)

Reference	Deprioritisation reason
Abaza R, Murphy C, Bsatee A, et al. (2021) Single-port robotic surgery allows same-day discharge in majority of cases. Urology 148**:** 159-165	Comparator out of scope
Abendstein B, Prugger M, Rab A, et al. (2024) Exploring robotic total hysterectomies: a multi-site experience with the Senhance Surgical System. J Robot Surg 18(1)**:** 268	Single arm
Aikawa M, Oshima Y, Kato T, et al. (2024) Comparative study of senhance digital laparoscopy system and Da Vinci surgical system in liver resection. Hpb 26**:** S244	Comparator out of scope
Alessandrini M, Pavone I, Micarelli A, et al. (2018) Transoral robotic surgery for the base of tongue squamous cell carcinoma: a preliminary comparison between da Vinci Xi and Si. Journal of Robotic Surgery 12(3)**:** 417-423	Comparator out of scope
Bianco FM, Dreifuss NH, Chang B, et al. (2022) Robotic single-port surgery: preliminary experience in general surgery. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 18(6)**:** e2453	Comparator out of scope
Billah M, Sheckley F, Nguyen J, et al. (2024) Single port modified partial nephrectomy: novel simultaneous access to peritoneal and retroperitoneal partial nephrectomy, initial clinical experience. Journal of Endourology 38(5)**:** 444-449	Comparator out of scope
Borse M, Godbole G, Kelkar D, et al. (2022) Early evaluation of a next-generation surgical system in robot-assisted total laparoscopic hysterectomy: a prospective clinical cohort study. Acta Obstetricia Et Gynecologica Scandinavica 101(9)**:** 978-986	Single arm

Reference	Deprioritisation reason
Bravi CA, Mottaran A, Sarchi L, et al. (2023) Transitioning from Da Vinci Si to Xi: assessing surgical outcomes at a high-volume robotic center. World Journal of Urology 41(12): 3737-3744	Comparator out of scope
Chen CH, Huang KH, Wang SM, et al. (2023) Comparison between two da vinci surgical systems in trifecta and pentafecta rates for robot-assisted partial nephrectomy. Urological Science 34(2): 99-106	Comparator out of scope
Choi YJ, Sang NT, Jo H-S, et al. (2023) A single-center experience of over 300 cases of single-incision robotic cholecystectomy comparing the da Vinci SP with the Si/Xi systems. Scientific Reports 13(1): 9482	Comparator out of scope
Chowbey P, Dewan A, Sharma A, et al. (2023) A review of the first 100 robotic cholecystectomies with a new cart-based surgical robot at a tertiary care centre. Journal of Minimal Access Surgery 19(3): 390-394	Single arm
Darwich I, Stephan D, Klöckner-Lang M, et al. (2020) A roadmap for robotic-assisted sigmoid resection in diverticular disease using a Senhance™ Surgical Robotic System: results and technical aspects. J Robot Surg 14(2): 297-304	Single arm
Dixon F, Vitish-Sharma P, Khanna A, et al. (2024) Robotic assisted surgery reduces ergonomic risk during minimally invasive colorectal resection: the VOLCANO randomised controlled trial. Langenbecks Archives of Surgery 409(1): 142	Single arm
Dreifuss NH, Chang B, Schlottmann F, et al. (2023) Robotic inguinal hernia repair: is the new Da Vinci single port platform providing any benefit? Surgical Endoscopy 37(3): 2003-2013	Comparator out of scope
El-Ahmar M, Peters F, Green M, et al. (2023) Robotic colorectal resection in combination with a multimodal enhanced recovery program - results of the first 100 cases. International Journal of Colorectal Disease 38(1): 95	Single arm

Reference	Deprioritisation reason
Farr DE, Haddock NT, Tellez J, et al. (2024) Safety and feasibility of single-port robotic-assisted nipple-sparing mastectomy. Journal of the American Medical Association Surgery 159(3)**:** 269-276	Single arm
Feldbrugge L, Ortiz Galindo SA, Frisch O, et al. (2022) Safety and feasibility of robotic liver resection after previous abdominal surgeries. Surgical Endoscopy 36(5)**:** 2842-2849	Single arm
Felmerer G, Behringer D, Emmerich N, et al. (2021) Donor defects after lymph vessel transplantation and free vascularized lymph node transfer: a comparison and evaluation of complications. World Journal of Transplantation 11(4)**:** 129-137	Single arm
Ferrari L, Nicolaou S and Adams K (2024) Implementation of a robotic surgical practice in inflammatory bowel disease. Journal of Robotic Surgery 18(1)**:** 57	Single arm
Galetta D, Casiraghi M, Pardolesi A, et al. (2017) New stapling devices in robotic surgery. Journal of Visualized Surgery 3**:** 45	Single arm
Garcia Rojo E, Hevia Palacios V, Brime Menendez R, et al. (2024) Da Vinci and Hugo RAS Platforms for robot-assisted partial nephrectomy: a preliminary prospective comparative analysis of the outcomes. Minerva Urology and Nephrology 76(3)**:** 303-311	Comparator out of scope
Gioe A, Monterossi G, Gueli Alletti S, et al. (2024) The new robotic system HUGO RAS for gynecologic surgery: first European experience from Gemelli Hospital. International Journal of Gynaecology and Obstetrics 166(1)**:** 258-265	Single arm
Glass Clark S, Shepard J, Sassani J, et al. (2022) Cost utilization of robotic-assisted sacrocolpopexy: a comparison of two robotic platforms International Urogynecology Journal 33(Suppl 2)	Comparator out of scope

Reference	Deprioritisation reason
Glass Clark S, Shepard J, Sassani J, et al. (2022) Cost utilization of robotic-assisted sacrocolpopexy: a comparison of two robotic platforms. Female Pelvic Medicine and Reconstructive Surgery 28(Suppl 1)	Comparator out of scope
Glass Clark S, Shepherd JP, Sassani JC, et al. (2023) Surgical cost of robotic-assisted sacrocolpopexy: a comparison of two robotic platforms. International Urogynecology Journal 34(1)**:** 87-91	Comparator out of scope
Gross JT, Vetter JM, Sands KG, et al. (2021) Initial experience with single-port robot-assisted radical cystectomy: comparison of perioperative outcomes between single-port and conventional multiport approaches. Journal of Endourology 35(8)**:** 1177-1183	Comparator out of scope
Hayakawa S, Ogawa R, Ueno S, et al. (2022) Impact of the indocyanine green fluorescence method for anastomotic blood flow in robotic distal gastrectomy. Surgery Today 52(10)**:** 1405-1413	Single arm
Heo JE, Han HH, Lee J, et al. (2024) Single-port robot-assisted pyeloplasty using the da vinci SP system versus multiport pyeloplasty: comparison of outcomes and costs. Asian Journal of Surgery 12**:** 12	Comparator out of scope
Huang J, Tian Y, Li C, et al. (2021) Robotic-assisted thoracic surgery reduces perioperative complications and achieves a similar long-term survival profile as posterolateral thoracotomy in clinical N2 stage non-small cell lung cancer patients: a multicenter, randomized, controlled trial. Translational Lung Cancer Research 10(11)**:** 4281-4292	Non-UK or EU
Hussein AA, Mohsin R, Qureshi H, et al. (2023) Transition from da Vinci to Versius robotic surgical system: initial experience and outcomes of over 100 consecutive procedures. Journal of Robotic Surgery 17(2)**:** 419-426	Comparator out of scope
Kang SK, Jang WS, Kim SH, et al. (2021) Comparison of intraoperative and short-term postoperative outcomes between robot-assisted laparoscopic multi-port pyeloplasty using the da Vinci Si system and single-port pyeloplasty using the da Vinci SP system in children. Investigative And Clinical Urology 62(5)**:** 592-599	Comparator out of scope

Reference	Deprioritisation reason
Kauffels A, Reichert M, Askevold I, et al. (2023) Establishing robotic bariatric surgery at an academic tertiary hospital: a learning curve analysis for totally robotic Roux-en-Y gastric bypass. Journal of Robotic Surgery 17(2): 577-585	Single arm
Kelkar DS, Kurlekar U, Stevens L, et al. (2023) An early prospective clinical study to evaluate the safety and performance of the Versius Surgical System in robot-assisted cholecystectomy. Annals of Surgery 277(1): 9-17	Single arm
Khanna S and Barua A (2022) Robotic assisted cholecystectomy - A retrospective cohort study of experience of 106 first robotic cholecystectomies in versius robotic platform. International Journal of Surgery Open 47: 100554	Single arm
Kim J, Na JC, Lee JS, et al. (2022) Clinical implications for da Vinci SP partial nephrectomy in high-complexity tumors: propensity score-matching analysis. Journal of Endourology 36(10): 1290-1295	Comparator out of scope
Kim KH, Ahn HK, Kim M, et al. (2023) Technique and perioperative outcomes of single-port robotic surgery using the da Vinci SP platform in urology. Asian Journal of Surgery 46(1): 472-477	Single arm
King K, Galvez A, Stoltzfus J, et al. (2020) Cost analysis of robotic Roux-en-Y gastric bypass in a single academic center: how expensive Is expensive? Obesity Surgery 30(12): 4860-4866	Non-UK or EU
Kneuertz PJ, Singer E, D'Souza DM, et al. (2019) Hospital cost and clinical effectiveness of robotic-assisted versus video-assisted thoracoscopic and open lobectomy: a propensity score–weighted comparison. The Journal of Thoracic and Cardiovascular Surgery 157(5): 2018-2026.e2	Non-UK or EU
Kolehmainen CSJ, Ukkonen MT, Tomminen T, et al. (2023) Short learning curve in transition from laparoscopic to robotic-assisted rectal cancer surgery: a prospective study from a Finnish Tertiary Referral Centre. Journal of Robotic Surgery 17(5): 2361-2367	Single arm

Reference	Deprioritisation reason
Lee JH, Yoo HK, Park SY, et al. (2022) Robotic single-port myomectomy using the da Vinci SP surgical system: A pilot study. Journal of Obstetrics and Gynaecology Research 48(1): 200-206	Comparator out of scope
Lee SR, Roh AM, Jeong K, et al. (2021) First report comparing the two types of single-incision robotic sacrocolpopexy: single site using the da Vinci Xi or Si system and single port using the da Vinci SP system. Taiwanese Journal of Obstetrics and Gynecology 60(1): 60-65	Single arm
Marks JH, Yang J, Spitz EM, et al. (2023) A prospective phase II clinical trial/IDEAL Stage 2a series of single-port robotic colorectal surgery for abdominal and transanal cases. Colorectal Disease 25(12): 2335-2345	Single arm
Meulemans J, Vanermen M, Goeleven A, et al. (2022) Transoral robotic surgery (TORS) using the da Vinci Xi: prospective analysis of feasibility, safety, and outcomes. Head and Neck 44(1): 143-157	Single arm
Mintz Y, Pikarsky AJ, Brodie R, et al. (2023) Robotic inguinal hernia repair with the new Hugo RASTM system: first worldwide case series report. Minimally Invasive Therapy and Allied Technologies: Mitat 32(6): 300-306	Single arm
Morelli L, Di Franco G, Lorenzoni V, et al. (2019) Structured cost analysis of robotic TME resection for rectal cancer: a comparison between the da Vinci Si and Xi in a single surgeon's experience. Surgical Endoscopy 33(6): 1858-1869	Comparator out of scope
Morelli L, Furbetta N, Palmeri M, et al. (2023) Initial 50 consecutive full-robotic pancreatoduodenectomies without conversion by a single surgeon: a learning curve analysis from a tertiary referral high-volume center. Surgical Endoscopy 37(5): 3531-3539	Single arm
Morelli L, Guadagni S, Di Franco G, et al. (2017) Use of the new da Vinci Xi R during robotic rectal resection for cancer: a pilot matched-case comparison with the da Vinci Si R. The International Journal Of Medical Robotics and Computer Assisted Surgery 13(1): e1728	Comparator out of scope

Reference	Deprioritisation reason
Morgantini LA, Alzein A, Bharadwaj A, et al. (2024) A prospective study on single-port versus multiport patient-reported surgical outcomes. BJUI Compass 5(1): 84-89	Comparator out of scope
Ngu JC-Y, Sim S, Yusof S, et al. (2017) Insight into the da Vinci R Xi - technical notes for single-docking left-sided colorectal procedures. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 13(4)	Single arm
Niclauss N, Morel P, Jung MK, et al. (2019) A comparison of the da Vinci Xi vs. the da Vinci Si Surgical System for Roux-En-Y gastric bypass. Langenbecks Archives of Surgery 404(5): 615-620	Comparator out of scope
Ojima T, Nakamura M, Hayata K, et al. (2021) Comparison of short-term surgical outcomes using da Vinci S, Si and Xi Surgical System for robotic gastric cancer surgery. Scientific Reports 11(1): 11063	Comparator out of scope
Oko M, Kycler W, Janowski J, et al. (2021) The use of the da Vinci Xi robot system in colorectal cancer resections - why is it worth it? Polski Przeglad Chirurgiczny 94(2): 12-18	Single arm
Oldani A, Bellora P, Monni M, et al. (2017) Colorectal surgery in elderly patients: our experience with DaVinci Xi R System. Aging-Clinical and Experimental Research 29(Suppl 1): 91-99	Single arm
Olsen RG, Karas V, Bjerrum F, et al. (2024) Skills transfer from the DaVinci R system to the Hugo TM RAS system. International Urology and Nephrology 56(2): 389-397	Comparator out of scope
Panico G, Mastrovito S, Campagna G, et al. (2023) Robotic docking time with the Hugo TM RAS system in gynecologic surgery: a procedure independent learning curve using the cumulative summation analysis (CUSUM). Journal of Robotic Surgery 17(5): 2547-2554	Single arm
Panico G, Vacca L, Campagna G, et al. (2023) The first 60 cases of robotic sacrocolpopexy with the novel HUGO RAS system: feasibility, setting and perioperative outcomes. Frontiers in Surgery 10: 1181824	Single arm

Reference	Deprioritisation reason
Panteleimonitis S, Pickering O, Ahmad M, et al. (2020) Robotic rectal cancer surgery: results from a European multicentre case series of 240 resections and comparative analysis between cases performed with the da Vinci Si and Xi systems. Laparoscopic, Endoscopic, and Robotic Surgery 3(1)**:** 6-11	Single arm
Panteleimonitis S, Popeskou S, Aradaib M, et al. (2018) Implementation of robotic rectal surgery training programme: importance of standardisation and structured training. Langenbecks Archives of Surgery 403(6)**:** 749-760	Non-UK or EU
Pellegrino AA, Calvo RS, Pellegrino F, et al. (2024) Outpatient vs inpatient single-port robotic urologic surgery: perioperative outcomes and complications. Urology Practice 11(2)**:** 422-429	Non-UK or EU
Puentes MC, Lobe TE, Bianchi FM, et al. (2023) The initial US experiance using the Senhance robot in pediatric surgery Surgical Endoscopy 37**:** 345-664	Single arm
Puntambekar S, Bharambe S, Pawar S, et al. (2022) Feasibility of transthoracic esophagectomy with a next-generation surgical robot. Scientific Reports 12(1): 17925	Single arm
Samalavicius NE, Dulskas A, Janusonis V, et al. (2022) Robotic colorectal surgery using the Senhance(®) robotic system: a single center experience. Techniques In Coloproctology 26(6)**:** 437-442	Single arm
Samalavicius NE, Dulskas A, Sirvys A, et al. (2022) Inguinal hernia TAPP repair using Senhance(®) robotic platform: first multicenter report from the TRUST registry. Hernia 26(4)**:** 1041-1046	Single arm
Samalavicius NE, Janusonis V, Klimasauskiene V, et al. (Robotic colorectal surgery using Senhance robotic system: single center experience). 16th Scientific and Annual Meeting of the European Society of Coloproctology, 2021.	Single arm

Reference	Deprioritisation reason
Samalavicius NE, Janusonis V, Siaulys R, et al. (2020) Robotic surgery using Senhance(®) robotic platform: single center experience with first 100 cases. J Robot Surg 14(2): 371-376	Single arm
Sasaki M, Hirano Y, Yonezawa H, et al. (2022) Short-term results of robot-assisted colorectal cancer surgery using Senhance Digital Laparoscopy System. Asian Journal of Endoscopic Surgery 15(3)	Single arm
Schmitz R, Willeke F, Barr J, et al. (2019) Robotic inguinal hernia repair (TAPP) first experience with the new Senhance robotic system. Surg Technol Int 34: 243-249	Single arm
Siaulys R, Klimasauskiene V, Janusonis V, et al. (2021) Robotic gynaecological surgery using Senhance® robotic platform: single centre experience with 100 cases. Journal of Gynecology Obstetrics and Human Reproduction 50(1): 102031	Single arm
Somashekhar SP, Deshpande AY, Ashwin KR, et al. (2020) A prospective randomized controlled trial comparing conventional Intuitive R procedure card recommended port placement with the modified Indian (Manipal) technique. Journal of Minimal Access Surgery 16(3): 246-250	Comparator out of scope
Staib L, Poth C, Schilcher F, et al. (2023) Safety in Senhance™ robotic gastrointestinal surgery in 530 patients. Surg Technol Int 42	Single arm
Stephan D, Darwich I and Willeke F (2021) The TransEnterix European patient registry for robotic-assisted laparoscopic procedures in urology, abdominal, thoracic, and gynecologic surgery ("TRUST"). Surg Technol Int 38: 103-107	Single arm
Sun Z, Ma T, Huang Z, et al. (2024) Robot-assisted radical resection of colorectal cancer using the KangDuo surgical robot versus the da Vinci Xi robotic system: short-term outcomes of a multicentre randomised controlled noninferiority trial. Surgical Endoscopy 38(4): 1867-1876	Comparator out of scope

Reference	Deprioritisation reason
Tran T, Irizarry F, Gunda S, et al. (2024) Early experience with the Senhance surgical system in bariatric surgery. JSLS 28(1)	Non-UK or EU
Yuh B, Yu X, Raytis J, et al. (2016) Use of a mobile tower-based robot--The initial Xi robot experience in surgical oncology. Journal of Surgical Oncology 113(1)**:** 5-7	Single arm

Table B. 2: Excluded studies (n=426)

Reference	Exclusion reason
Abdel Raheem A, Sheikh A, Kim DK, et al. (2017) Da Vinci Xi and Si platforms have equivalent perioperative outcomes during robot-assisted partial nephrectomy: preliminary experience. Journal of Robotic Surgery 11(1): 53-61	Retrospective study
Abou-Mrad A, Caiazzo R and Chetboun M (2023) Robotic bipartition the Orleans technique. Obesity Surgery: 472	Ineligible comparator
Acar O, Sofer L, Dobbs RW, et al. (2020) Single port and multiport approaches for robotic vaginoplasty with the Davydov technique. Urology 138: 166-173	Retrospective study
Afonina M, Colla Ruvolo C, Gaia G, et al. (2024) New horizons in gynecological surgery: first-year experience with HUGO TM robotic-assisted surgery system at two tertiary referral robotic centers. Updates in Surgery 10: 10	Single arm prospective study <50 patients
Agarwal DK, Hebert KJ, Gettman MT and Viers BR (2020) How to perform a robotic pyeloplasty utilizing the da Vinci SP platform: tips and tricks. Translational Andrology and Urology 9(2): 919-924	Ineligible study design
Aiolfi A, Cavalli M, Micheletto G, et al. (2019) Robotic inguinal hernia repair: is technology taking over? Systematic review and meta-analysis. Hernia 23(3): 509-519	Pre 2022 systematic review
Alhossaini RM, Altamran AA, Choi S, et al. (2019) Similar operative outcomes between the da Vinci Xi R and da Vinci Si R Systems in robotic gastrectomy for gastric cancer. Journal of Gastric Cancer 19(2): 165-172	Retrospective study
Alipouriani A, Ozgur I, Bhatt A, et al. (2024) Early experience with EndoRobotic Submucosal Dissection (ERSD): pathologic and short-term outcomes in the first 28 patients. Annals of Surgery 17: 17	Retrospective study
Aliyev V, Arslan NC, Goksoy B, et al. (2022) Is robotic da Vinci Xi R superior to the da Vinci Si R for sphincter-preserving total mesorectal excision? Outcomes in 150 mid-low rectal cancer patients. Journal of Robotic Surgery 16(6): 1339-1346	Retrospective study

Reference	Exclusion reason
Alkatout I, Salehiniya H and Allahqoli L (2022) Assessment of the Versius robotic surgical system in minimal acess surgery: a systematic review. Journal of Clinical Medicine 11(13): 28	Systematic review for reference checking
Alshalawi W, Lee CS and Lee YS (2023) Single-port robotic intersphincteric resection for very low rectal cancer with the da Vinci SP platform. Asian Journal of Surgery 46(2): 1056-1057	Ineligible study design
Alshalawi W, Lee CS, Kim BC, et al. (2023) A comparative study on the short-term clinical outcomes of Da Vinci SP versus Da Vinci Xi for rectal cancer surgery. The International Journal Of Medical Robotics + Computer Assisted Surgery: MRCAS 20(1): e2558	Retrospective study
Ambrosini F, Caracino V, Frazzini D, et al. (2021) Robot-assisted laparoscopic subtotal gastrectomy for early-stage gastric cancer: Case series of initial experience. Annals of Medicine and Surgery 61: 115-121	Retrospective study
Andrade GM, Lau C, Olivares R, et al. (2024) Implementation of robot-assisted urologic surgeries using Hugo TM RAS System in a high-volume robotic "Da vinci Xi" center: outcomes and initial experience. Urology 28: 28	Retrospective study
Arcieri M, Romeo P, Vizzielli G, et al. (2023) Robotic Single-Port da Vinci surgical system (SP1098) in gynecologic surgery: a systematic review of literature. Clinical and Experimental Obstetrics and Gynecology 50(8): 158	Systematic review for reference checking
Ashmore S, Kenton K, Collins S, et al. (2024) Short-term outcomes of single port robotic hysterectomy with concomitant sacrocolpopexy. Journal of Robotic Surgery 18(1): 260	Retrospective study
Aslaner A, Cakir T, Eyvaz K, et al. (2022) Comparison of robotic-assisted resection alone and with natural orifice specimen extraction for rectal cancer by using Da Vinci Xi. European Review for Medical and Pharmacological Sciences 26(18): 6665-6670	Retrospective study
Atife M, Okondo E, Jaffer A, et al. (2024) Intuitive's da Vinci vs Medtronic's Hugo: real life observations from a robot naive perspective. Journal of Robotic Surgery 18(1): 4	Ineligible study design
Australasian Gastrointestinal Trials Group. *RoLaCaRT-1: a randomized trial of robotic surgery versus laparoscopic surgery for colon cancer*. Identifier: ACTRN12620001378910. In: Australian New Zealand Clinical Trials Registry [internet].	Trial registry record

Reference	Exclusion reason
Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2020. Available from https://trialsearch.who.int/Trial2.aspx?TrialID=ACTRN12620001378910	
Aydin H, Dural AC, Sahbaz NA, et al. (2023) Comparison of DaVinci Si and Xi robotic platforms for adrenal surgery. Effects on short term outcomes. Annali Italiani Di Chirurgia 94: 173-178	Retrospective study
Bae SU, Jeong WK and Baek SK (2024) Robotic anterior resection for rectosigmoid colon cancer using single-port access. Diseases of the Colon and Rectum 67(1): E1	Ineligible study design
Baekelandt J (2016) Robotic vaginal NOTES hysterectomy: two new surgical techniques. Journal of Gynecologic Surgery 32(5): 270-277	Single arm prospective study <50 patients
Baldari L, Boni L, Cassinotti E, et al. (2023) Right hemicolectomy with complete mesocolic excision using the Versius surgical system: a step-by-step guide. Chirurgia (Bucuresti) 118(1): 54-62	Ineligible study design
Bang S, Shin D, Moon HW, et al. (2023) Comparison of transperitoneal and retroperitoneal partial nephrectomy with single-port robot. Journal of Endourology 37(5): 551-556	Single arm prospective study <50 patients
Barchi LC, Souza WP, Franciss MY, et al. (2020) Oncological robot-assisted gastrectomy: technical aspects and ongoing data. Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A 30(2): 127-139	Ineligible study design
Bauer K, Heinzelmann F, Vogel R, et al. (2022) Establishment of minimally invasive ventral hernia repair with extraperitoneal mesh placement in a primary care hospital using the robotic platform. Frontiers in Surgery 9: 964643	Retrospective study
Beckmann JH, Bernsmeier A, Kersebaum J-N, et al. (2020) The impact of robotics in learning Roux-en-Y gastric bypass: a retrospective analysis of 214 laparoscopic and robotic procedures : robotic Vs. laparoscopic RYGB. Obesity Surgery 30(6): 2403-2410	Retrospective study
Beckmann JH, Mehdorn A-S, Kersebaum J-N, et al. (2020) Pros and cons of robotic revisional bariatric surgery. Visceral Medicine 36(3): 238-245	Retrospective study

Reference	Exclusion reason
Beltzer C, Gradinger K, Bachmann R, et al. (2020) Robotic multiport versus robotic single-site cholecystectomy: a retrospective single-centre experience of 142 cases. European Surgery - Acta Chirurgica Austriaca 52(1): 16-21	Retrospective study
Beltzer C, Knoerzer L, Bachmann R, et al. (2019) Robotic versus laparoscopic sigmoid resection for diverticular disease: a single-center experience of 106 cases. Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A 29(11): 1451-1455	Retrospective study
Belyaev O, Fahlbusch T, Slobodkin I and Uhl W (2023) Safety and feasibility of cholecystectomy with the HugoTM RAS: proof of setup guides and first-in-human german experience. Visceral Medicine 39(3-4): 76-86	Retrospective study
Benlice C, Aghayeva A, Yavuz E, et al. (2019) Robotic left colectomy with complete mesocolic excision and intracorporeal side-to-side anastomosis for splenic flexure cancer with the da Vinci Xi robotic platform - a video vignette. Colorectal Disease 21(12): 1454	Ineligible study design
Benlice C, Aytac E, Baca B, et al. (2019) Robotic sigmoidectomy for giant diverticula with the da Vinci Xi - a video vignette. Colorectal Disease 21(8): 977-978	Ineligible study design
Bentivegna E, Koual M, Nguyen-Xuan H-T, et al. (2021) Docking for robotic extraperitoneal para-aortic lymphadenectomy with Da Vinci Xi surgical system. Journal of Gynecology Obstetrics and Human Reproduction 50(8): 102131	Ineligible study design
Bergmann J, Lehmann-Dorl B, Witt L and Aselmann H (2022) Using the da Vinci X - system for esophageal surgery. JSLS : Journal of the Society of Laparoendoscopic Surgeons 26(2)	Retrospective study
Bianchi G, De'Angelis N, Musa N, et al. (2022) Short-term outcomes of da Vinci Xi versus Si robotic systems for minor hepatectomies. Acta Bio-Medica De L Ateneo Parmense 93(5): e2022223	Retrospective study
Bianchini M, Guadagni S and Morelli L (2019) Costs-benefits of robot-assisted colorectal surgery: a different perspective. Journal of Robotic Surgery 13(4): 607-608	Ineligible study design

Reference	Exclusion reason
Bianchini M, Palmeri M, Stefanini G, et al. (2020) The role of robotic-assisted surgery for the treatment of diverticular disease. Journal of Robotic Surgery 14(1): 239-240	Ineligible study design
Biardeau X, Rizk J, Marcelli F and Flamand V (2015) Robot-assisted laparoscopic approach for artificial urinary sphincter implantation in 11 women with urinary stress incontinence: surgical technique and initial experience. European Urology 67(5): 937-42	Single arm prospective study <50 patients
Billah MS, Stifelman M, Munver R, et al. (2020) Single port robotic assisted reconstructive urologic surgery-with the da Vinci SP surgical system. Translational Andrology and Urology 9(2): 870-878	Single arm prospective study <50 patients
Bindi E, Todesco C, Nino F, et al. (2022) Robotic surgery: is there a possibility of increasing Its application in pediatric settings? a single-center experience. Children 9(7): 08	Retrospective study
Bizon M, Olszewski M, Grabowska A, et al. (2024) Efficacy of single- and dual-docking robotic surgery of paraaortic and pelvic lymphadenectomy in high-risk endometrial cancer. Journal of Personalized Medicine 14(5): 23	Single arm prospective study <50 patients
Bliznakova K, Kolev N, Zlatarov A, et al. (2023) Feasibility and safety of robotic-assisted surgery for rectal cancer: short-term outcomes of a pilot study with da Vinci Xi platform during COVID-19. Chirurgia 118(1): 27-38	Ineligible comparator
Bosi HR, Rombaldi MC, Zaniratti T, et al. (2022) Does single-site robotic surgery makes sense for gallbladder surgery? The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 18(3): e2363	Single arm prospective study <50 patients
Bracale U, Corcione F, Neola D, et al. (2021) Transversus abdominis release (TAR) for ventral hernia repair: open or robotic? Short-term outcomes from a systematic review with meta-analysis. Hernia 25(6): 1471-1480	Pre 2022 systematic review
Bravi CA, Paciotti M, Sarchi L, et al. (2022) Robot-assisted Radical Prostatectomy with the Novel Hugo Robotic System: Initial Experience and Optimal Surgical Set-up at a Tertiary Referral Robotic Center. European Urology 82(2): 233-237	Ineligible study design
Broe MP, Bolger JM, Norton S, et al. (2021) A prospective study of the components of operating room utilisation time for robotic urological surgery in a public teaching hospital setting. Journal of Clinical Urology 14(5): 316-321	Single arm prospective study <50 patients

Reference	Exclusion reason
Brownlee EM and Slack M (2022) The role of the Versius surgical robotic system in the paediatric population. Children 9(6): 30	Ineligible study design
Bruzzi M (2019) Robotic reversal of one-anastomosis gastric bypass into sleeve gastrectomy for severe malnutrition: interest of the manual gastro-gastric anastomosis? Obesity Surgery 29(9): 2976-2978	Ineligible study design
Buffi N, Uleri A, Paciotti M, et al. (2023) Techniques and outcomes of robot-assisted partial nephrectomy for the treatment of multiple ipsilateral renal masses. Minerva Urology and Nephrology 75(2): 223-230	Retrospective study
Buffi NM, Saita A, Lughezzani G, et al. (2020) Robot-assisted partial nephrectomy for complex (PADUA Score >=10) tumors: techniques and results from a multicenter experience at four high-volume centers. European Urology 77(1): 95-100	Ineligible comparator
Byeon HK, Holsinger FC, Duvvuri U, et al. (2018) Recent progress of retroauricular robotic thyroidectomy with the new surgical robotic system. Laryngoscope 128(7): 1730-1737	Retrospective study
Cacciatore L, Costantini M, Tedesco F, et al. (2023) Robotic Medtronic Hugo TM RAS system is now reality: introduction to a new simulation platform for training residents. Sensors 23(17): 23	Ineligible study design
Cadeddu JA (2018) Re: does advancing technology improve outcomes? Comparison of the da Vinci standard/S/Si to the Xi robotic platforms during robotic nephroureterectomy. Journal of Urology 200(5): 926-927	Ineligible comparator
Cadeddu JA (2020) Re: Robotic-assisted adrenalectomy using da Vinci Xi vs. Si: are there differences? Journal of Urology 204(4): 860	Ineligible comparator
Cakir T and Aslaner A (2021) Early results of novel robotic surgery-assisted low anterior resection for rectal cancer and transvaginal specimen extraction by using Da Vinci XI: initial clinical experience. Revista Da Associacao Medica Brasileira 67(7): 971-974	Retrospective study
Calpin GG, Ryan FR, McHugh FT and McGuire BB (2023) Comparing the outcomes of open, laparoscopic and robot-assisted partial nephrectomy: a network meta-analysis. BJU Int 132(4): 353-364	Systematic review for reference checking

Reference	Exclusion reason
Camp C, O'Hara J, Hughes D and Adshead J (2018) Short-term outcomes and costs following partial nephrectomy in england: a population-based study. Eur Urol Focus 4(4): 579-585	Ineligible comparator
Campagna G, Panico G, Vacca L, et al. (2023) Robotic sacrocolpopexy plus ventral rectopexy as combined treatment for multicompartment pelvic organ prolapse using the new Hugo RAS system. Techniques In Coloproctology 27(6): 499-500	Ineligible study design
Carneiro A and Andrade GM (2023) Technology description, initial experience and first impression of HUGOTM RAS robot platform in urologic procedures in Brazil. International Braz J Urol 49(6): 763-774	Ineligible study design
Casale P, Lughezzani G, Buffi N, et al. (2019) Evolution of robot-assisted partial nephrectomy: techniques and outcomes from the transatlantic robotic nephron-sparing surgery study group. European Urology 76(2): 222-227	Ineligible comparator
Cassese G, Montalti R and Troisi RI (2023) Robotic liver resection of caudate lobe with 3-D rendering and intraoperative ICG-fluorescence for giant hemangioma. Surgical Oncology 51: 101999	Ineligible study design
Catto JWF, Khetrapal P, Ricciardi F, et al. (2022) Effect of robot-assisted radical cystectomy with intracorporeal urinary diversion vs open radical cystectomy on 90-day morbidity and mortality among patients with bladder cancer: a randomized clinical trial. JAMA 327(21): 2092-2103	Model not specified
Centurioni MG, Barra F, Gustavino C, et al. (2019) Sentinel-node mapping by intraoperative near-infrared fluorescence in the robotic surgical treatment of endometrial cancer. Journal of Gynecologic Surgery 35(4): 205-207	Ineligible study design
Chammas J, Sauer A, Pizzuto J, et al. (2017) Da Vinci Xi robot-assisted penetrating keratoplasty. Translational Vision Science and Technology 6(3): 21	Single arm prospective study <50 patients
Chan JYK, Tsang RK, Holsinger FC, et al. (2019) Prospective clinical trial to evaluate safety and feasibility of using a single port flexible robotic system for transoral head and neck surgery. Oral Oncology 94: 101-105	Single arm prospective study <50 patients
Chan JYK, Wong EWY, Tsang RK, et al. (2017) Early results of a safety and feasibility clinical trial of a novel single-port flexible robot for transoral robotic surgery. European Archives of Oto-Rhino-Laryngology, 274(11): 3993-3996	Single arm prospective study <50 patients

Reference	Exclusion reason
Chen K, Zhang J, Beeraka NM, et al. (2023) Robot-assisted nipple-sparing mastectomy and immediate breast reconstruction with gel implant and latissimus dorsi muscle flap: our initial experience. The International Journal Of Medical Robotics and Computer Assisted Surgery 19(5): e2528	Single arm prospective study <50 patients
Chen Q-Y, Zhong Q, Zheng C-H and Huang C-M (2019) Robotic spleen-preserving splenic hilar lymphadenectomy for advanced proximal gastric cancer: A feasible and simplified procedure. Surgical Oncology 28: 67-68	Ineligible intervention
Chen Y, Zheng Y and Yang F (2023) Primary debulking surgery for advanced epithelial ovarian cancer with isolated enlarged para-aortic lymph node by robotic transumbilical single port approach. International Journal of Gynecological Cancer 33(12): 1976-1977	Ineligible study design
Cheng C, Tagkalos E, Ng CB, et al. (2024) Single-port robotic trans-subxiphoid surgery for anterior mediastinal disease: a pilot trial. Innovations: Technology and Techniques In Cardiothoracic and Vascular Surgery: 15569845241248641	Single arm prospective study <50 patients
Cheng C, Tagkalos E, Ng CB, et al. (2024) Subcostal uniportal robotic anatomic lung resection: a pilot trial. JTCVS Technique 25: 160-169	Single arm prospective study <50 patients
Cheon JH, Kim HE, Park SH and Yoon ES (2022) Ten-year experience of robotic latissimus muscle flap reconstructive surgery at a single institution. Journal of Plastic, Reconstructive and Aesthetic Surgery: JPRAS 75(10): 3664-3672	Retrospective study
Cheong JY, Choo JM, Kim JS, et al. (2022) Da Vinci SP system optimized for intersphincteric resection of very low rectal cancer. Diseases of the Colon and Rectum 65(3): E174	Ineligible study design
Cheong JY, Shin SH, Kim J and Kim SH (2021) How to do robotic lateral pelvic lymph node dissection for low rectal cancer using Da Vinci-Xi system. ANZ Journal of Surgery 91(11): 2521-2523	Ineligible study design
Cheong JY, Shin SH, Kim J and Kim SH (2022) Robotic excision of rectal GI stromal tumor using the Da Vinci Xi System. Diseases of the Colon and Rectum 65(5): e323	Ineligible study design

Reference	Exclusion reason
Chierigo F, Caviglia A, Cellini V, et al. (2024) Transperitoneal and retroperitoneal robot-assisted partial nephrectomy with the HugoTM RAS system: video instructions and initial experience from a tertiary care referral centre. Urology Video Journal 21: 100255	Single arm prospective study <50 patients
Cho HJ and Kim WR (2024) Early single-center experience of DaVinci R Single-Port (SP) robotic surgery in colorectal patients. Journal of Clinical Medicine 13(10): 19	Retrospective study
Choi YS, Kim KD, Choi MS, et al. (2023) Initial experience of robot-assisted transabdominal preperitoneal (TAPP) inguinal hernia repair by a single surgeon in South Korea. Medicina 59(3): 15	Retrospective study
Chong JU, Lee JY and Lim JH (2023) Early experiences in robotic single-site plus one port platform for complex hepatobiliary and pancreatic surgery. The International Journal Of Medical Robotics and Computer Assisted Surgery 20(1): e2602	Ineligible study design
Choudhry V, Patel YK, McIntosh BB, et al. (2024) Retrospective multi-center study of robotic-assisted cholecystectomy: after-hours surgery and business-hours surgery outcomes. Journal of Robotic Surgery 18(1): 48	Retrospective study
Colla Ruvolo C, Afonina M, Balestrazzi E, et al. (2023) A comparative analysis of the HUGOTM robot-assisted surgery system and the Da Vinci R Xi surgical system for robot-assisted sacrocolpopexy for pelvic organ prolapse treatment. The International Journal Of Medical Robotics + Computer Assisted Surgery: MRCAS 20(1): e2587	Retrospective study
Collins D, Paterson HM, Skipworth RJE and Speake D (2021) Implementation of the Versius robotic surgical system for colorectal cancer surgery: first clinical experience. Colorectal Disease 23(5): 1233-1238	Single arm prospective study <50 patients
Colwell CJ, Lindquist JR and Werntz RP (2022) Bilateral nerve-sparing robot-assisted retroperitoneal lymph node dissection: a minimally invasive approach. Journal of Endourology 36(Suppl 2)	Ineligible study design
Copaescu C and Dumbrava B (2023) Is the robotic assisted hybrid approach increasing the MIS efficiency for pancreaticoduodenectomy? Chirurgia (Bucuresti) 118(3): 302-313	Single arm prospective study <50 patients

Reference	Exclusion reason
Corrado G, Vizza E, Cela V, et al. (2018) Laparoscopic versus robotic hysterectomy in obese and extremely obese patients with endometrial cancer: A multi-institutional analysis. European Journal of Surgical Oncology 44(12): 1935-1941	Retrospective study
Corrigan N, Marshall H, Croft J, et al. (2018) Exploring and adjusting for potential learning effects in ROLARR: a randomised controlled trial comparing robotic-assisted vs. standard laparoscopic surgery for rectal cancer resection. Trials [Electronic Resource] 19(1): 339	Robot model not specified
Costantino A, Sampieri C, Meliante PG, et al. (2024) Reply to: Comment on "Transoral robotic surgery in oropharyngeal squamous cell carcinoma: a comparative study between da Vinci Single-Port and da Vinci Xi systems". Oral Oncology 150: 106700	Ineligible study design
Costantino A, Sampieri C, Meliante PG, et al. (2024) Transoral robotic surgery in oropharyngeal squamous cell carcinoma: A comparative study between da Vinci Single-Port and da Vinci Xi systems. Oral Oncology 148: 106629	Retrospective study
Covas Moschovas M, Bhat S, Rogers T, et al. (2021) Applications of the da Vinci single port (SP) robotic platform in urology: a systematic literature review. Minerva Urology and Nephrology 73(1): 6-16	Pre 2022 systematic review
Cruz CJ, Huynh F, Kang I, et al. (2021) Initial experiences of robotic SP cholecystectomy: a comparative analysis with robotic Si single-site cholecystectomy. Annals of surgical treatment and research 100(1): 1-7	Retrospective study
Cunningham W, Brooks D and PC M (2021) Accuracy of robotic-assisted spinal surgery-comparison to TJR robotics, da Vinci Robotics, and Optoelectronic Laboratory Robotics. International Journal of Spine Surgery 15(s2): S38-S55	Ineligible patient population
Dae JY, Ginjupalli M, Rickmeyer Z, et al. (2023) Assessing visualization in robotic-assisted surgery: demystifying a misty lens. Journal of Robotic Surgery 17(3): 915-922	Single arm prospective study <50 patients
Dalsgaard T, Jensen MD, Hartwell D, et al. (2020) Robotic surgery is less physically demanding than laparoscopic surgery: paired cross sectional study. Annals of Surgery 271(1): 106-113	Robot model not specified

Reference	Exclusion reason
Darwiche F, Swain S, Kallingal G, et al. (2015) Operative technique and early experience for robotic-assisted laparoscopic nephroureterectomy (RALNU) using da Vinci Xi. Springerplus 4(298): 5	Retrospective study
Davidson JTt, Clanahan JM, Vachharajani N, et al. (2023) A novel assessment model for teaching robot-assisted living donor nephrectomy in abdominal transplant surgery fellowship. American Journal of Surgery 225(2): 420-424	Ineligible outcomes
de Araujo Lopes NV, Alves PM and Silva Cunha JL (2024) Comment on "Transoral robotic surgery in oropharyngeal squamous cell carcinoma: a comparative study between da Vinci Single-Port and da Vinci Xi systems". Oral Oncology 148: 106653	Ineligible study design
De Maria M, Meneghetti I, Mosillo L, et al. (2024) Versius robotic surgical system: case series of 18 robot-assisted radical prostatectomies. BJU Int 133(2): 197-205	Ineligible intervention
De Pastena M, Bannone E, Andreotti E, et al. (2023) Pancreatic anastomosis in robotic-assisted pancreaticoduodenectomy: different surgical techniques. Digestive Surgery 40(1-2): 1-8	Ineligible study design
de Rezende BB, Assumpcao LR, Haddad R, et al. (2023) Characteristics of the learning curve in robotic thoracic surgery in an emerging country. Journal of Robotic Surgery 17(4): 1809-1816	Retrospective study
Department of Urology Royal Prince Alfred Hospital. *Randomised study assessing reconstruction of the urinary tract via robotic (intracorporeal) or open (extracorporeal) method during removal of the bladder*. Identifier: ACTRN12622000614796. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2022. Available from https://trialsearch.who.int/Trial2.aspx?TrialID=ACTRN12622000614796	Trial registry record
D'Hondt M and Wicherts DA (2023) Pure robotic major hepatectomy with biliary reconstruction for hepatobiliary malignancies: first European results. Surgical Endoscopy 37(6): 4396-4402	Single arm prospective study <50 patients
D'Hondt M and Wicherts DA (2023) Robotic biliary surgery for benign and malignant bile duct obstruction: a case series. Journal of Robotic Surgery 17(1): 55-62	Retrospective study

Reference	Exclusion reason
Di Donna MC, Lucidi A, Gallotta V, et al. (2019) Robotic aortic lymphadenectomy during multiquadrant surgery for gynecological cancers with the new "Da Vinci Xi" system. Italian Journal of Gynaecology and Obstetrics 31(1): 59-65	Single arm prospective study <50 patients
Di Franco G, Gianardi D, Bianchini M, et al. (2019) The role of hand-assisted laparoscopic splenectomy for mega spleens in the da Vinci era. Journal of Robotic Surgery 13(6): 791-792	Ineligible study design
Di Maida F, Mari A, Morselli S, et al. (2020) Robotic treatment for urinary tract endometriosis: preliminary results and surgical details in a high-volume single-Institutional cohort study. Surgical Endoscopy 34(7): 3236-3242	Ineligible study design
Ding X, Lin Q-G, Zou X, et al. (2021) Transoral robotic retropharyngeal lymph node dissection in nasopharyngeal carcinoma with retropharyngeal lymph node recurrence. Laryngoscope 131(6): E1895-E1902	Single arm prospective study <50 patients
Dixon F, O'Hara R, Ghuman N, et al. (2021) Major colorectal resection is feasible using a new robotic surgical platform: the first report of a case series. Techniques In Coloproctology 25(3): 285-289	Single arm prospective study <50 patients
Dixon F, Qureshi A, Vitish-Sharma P, et al. (2023) Implementation of robotic hernia surgery using the Versius R system. Journal of Robotic Surgery 17(2): 565-569	Single arm prospective study <50 patients
Dixon F, Vitish-Sharma P, O'Hara R, et al. (2022) Right hemicolectomy and anterior resection using the Versius robotic surgical system: a technical note. Laparoscopic, Endoscopic, and Robotic Surgery 5(4): 142-145	Ineligible study design
Duran M, Briceno J, Padial A, et al. (2022) Short-term outcomes of robotic liver resection: an initial single-institution experience. World Journal of Hepatology 14(1): 224-233	Retrospective study
E H, Yang C, Wu J, et al. (2023) Hybrid uniportal robotic-assisted thoracoscopic surgery using video-assisted thoracoscopic surgery staplers: technical aspects and results. Annals of Cardiothoracic Surgery 12(1): 34-40	Retrospective study
Egberts J-H, Moller T and Becker T (2019) Robotic-assisted sleeve lobectomy using the four-arm technique in the DaVinci Si R and Xi R Systems. Thoracic and Cardiovascular Surgeon 67(7): 603-605	Ineligible study design

Reference	Exclusion reason
Egberts J-H, Schlemminger M, Hauser C and Becker T (2019) Robot-assisted McKeown procedure via a cervical mediastinoscopy avoiding an abdominal and thoracic incision. Thoracic and Cardiovascular Surgeon 67(7): 610-614	Ineligible study design
El Dahdah J, Halabi M, Kamal J, et al. (2023) Initial experience with a novel robotic surgical system in abdominal surgery. Journal of Robotic Surgery 17(3): 841-846	Retrospective study
Elorrieta V, Villena J, Kompatzki A, et al. (2023) ROBOT assisted laparoscopic surgeries for nononcological urologic disease: initial experience with Hugo ras system. Urology 174: 118-125	Retrospective study
Eoh KJ, Lee DW, Lee JH, et al. (2021) Comparative survival outcome of robot-assisted staging surgery using three robotic arms versus open surgery for endometrial cancer. Yonsei Medical Journal 62(1): 68-74	Retrospective study
Eu EW, Ngu JC and Chiow AKH (2018) How to do a combined robotic anterior resection and liver resection: da Vinci Xi. ANZ Journal of Surgery 88(10): 1076-1077	Ineligible study design
Fang AM, Saidian A, Magi-Galluzzi C, et al. (2020) Single-port robotic partial and radical nephrectomies for renal cortical tumors: initial clinical experience. Journal of Robotic Surgery 14(5): 773-780	Retrospective study
Fang C, Zhang L, Liang H, et al. (2024) Surgical technique of da Vinci robotic-assisted minimally invasive esophagectomy(RAMIE) expert experiences. Intelligent Surgery 7: 12-20	Ineligible study design
Farinha R, Sarchi L, Paciotti M, et al. (2022) New robotic platforms for gynecology. are we achieving one of the golden goals? Clinical and Experimental Obstetrics and Gynecology 49(11): 246	Ineligible study design
Faulkner J, Arora A, McCulloch P, et al. (2024) Prospective development study of the Versius Surgical System for use in transoral robotic surgery: an IDEAL stage 1/2a first in human and initial case series experience. European Archives of Oto-Rhino-Laryngology 281(5): 2667-2678	Retrospective study
Faulkner J, Naidoo R, Arora A, et al. (2020) Combined robotic transorbital and transnasal approach to the nasopharynx and anterior skull base: feasibility study. Clinical Otolaryngology 45(4): 630-633	Ineligible patient population

Reference	Exclusion reason
Feng Q, Yuan W, Li T, et al. (2022) Robotic versus laparoscopic surgery for middle and low rectal cancer (REAL): short-term outcomes of a multicentre randomised controlled trial. The Lancet Gastroenterology & Hepatology 7(11): 991-1004	Ineligible intervention
Feng Z, Feng MP, Feng DP and Solorzano CC (2020) Robotic-assisted adrenalectomy using da Vinci Xi vs. Si: are there differences? Journal of Robotic Surgery 14(2): 349-355	Retrospective study
Ferguson SE, Panzarella T, Lau S, et al. (2018) Prospective cohort study comparing quality of life and sexual health outcomes between women undergoing robotic, laparoscopic and open surgery for endometrial cancer. Gynecologic Oncology 149(3): 476-483	Robot model not specified
Ferrari D, Violante T, Gomaa IA and Cima RR (2024) Robotic modified Sugarbaker technique for parastomal hernia repair: a standardized approach. Updates in Surgery 76(3): 1115-1119	Ineligible outcomes
Fiacchini G, Vianini M, Dallan I and Bruschini L (2021) Is the Da Vinci Xi system a real improvement for oncologic transoral robotic surgery? A systematic review of the literature. Journal of Robotic Surgery 15(1): 1-12	Pre 2022 systematic review
Finotti M, Testa G, Koon EC and Johannesson L (2023) Graft hysterectomy after uterus transplantation with robotic-assisted techniques. Transplantation 107(9): E236-E237	Single arm prospective study <50 patients
Forcada C, Gomez-Hernandez MT, Fuentes MG, et al. (2023) Assessment of feasibility and prognostic value of sentinel lymph node identification by near-infrared fluorescence in non-small cell lung cancer in patients undergoing robotic anatomic lung resections. Open Respiratory Archives 5(4): 100273	Single arm prospective study <50 patients
Fu S, Shi H, Fan Z, et al. (2024) Robot-assisted radical cystectomy with intracorporeal urinary diversion: an updated systematic review and meta-analysis of its differential effect on effectiveness and safety. International Journal of Surgery 110(4): 2366 - 2380	Systematic review for reference checking
Fuchs HF, Muller DT, Leers JM, et al. (2019) Modular step-up approach to robot-assisted transthoracic esophagectomy-experience of a German high volume center. Translational Gastroenterology and Hepatology 4: 62	Ineligible outcomes

Reference	Exclusion reason
Fulla J, Small A, Kaplan-Marans E and Palese M (2020) Magnetic-assisted robotic and laparoscopic renal surgery: initial clinical experience with the Levita magnetic surgical system. Journal of Endourology 34(12): 1242-1246	Single arm prospective study <50 patients
Gabrysz-Forget F, Mur T, Dolan R and Yarlagadda B (2020) Perioperative safety, feasibility, and oncologic utility of transoral robotic surgery with da Vinci Xi platform. Journal of Robotic Surgery 14(1): 85-89	Retrospective study
Gaia G, Sighinolfi MC, Terzoni S, et al. (2023) Versius robotic surgery training. Minerva obstetrics and gynecology 76(3): 298-300	Ineligible study design
Galetta D and Spaggiari L (2022) Robotic-assisted resection of intralobar and extralobar pulmonary sequestration. JTCVS Techniques 16: 160-162	Ineligible study design
Gallioli A, Territo A, Boissier R, et al. (2020) Learning curve in robot-assisted kidney transplantation: results from the European Robotic Urological Society Working Group. European Urology 78(2): 239-247	Retrospective study
Gallioli A, Uleri A, Gaya JM, et al. (2023) Initial experience of robot-assisted partial nephrectomy with Hugo TM RAS system: implications for surgical setting. World Journal of Urology 41(4): 1085-1091	Single arm prospective study <50 patients
Gallo F, Sforza S, Luciani L, et al. (2022) Simultaneous robotic partial nephrectomy for bilateral renal masses. World Journal of Urology 40(4): 1005-1010	Retrospective study
Gandhi S, Novoa Valentin NM, Brunelli A, et al. (2024) Results of an exploratory survey within ESTS membership in 2022 on current trend of robotic-assisted thoracic surgery and its training perspectives. Interdisciplinary Cardiovascular and Thoracic Surgery 38(4): 29	Ineligible study design
Ganesan V, Goueli R, Rodriguez D, et al. (2020) Single-port robotic-assisted laparoscopic sacrocolpopexy with magnetic retraction: first experience using the SP da Vinci platform. Journal of Robotic Surgery 14(5): 753-758	Ineligible study design
Gangemi A, Bernante P, Rottoli M, et al. (2023) Surgery of the alimentary tract for benign and malignant disease with the novel robotic platform HUGOTM RAS. A first world report of safety and feasibility. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 19(4): e2544	Single arm prospective study <50 patients

Reference	Exclusion reason
Garas G and Arora A (2018) Robotic head and neck surgery: history, technical evolution and the future. ORL 80(3-4): 117-124	Ineligible study design
Garcia JC (2022) Robotic transfer of the latissimus dorsi for irreparable subscapularis tear. Arthroscopy Techniques 11(6): e1059-e1064	Ineligible study design
Garden EB, Al-Alao O, Razdan S, et al. (2021) Robot-assisted single-port donor nephrectomy using the da Vinci Single-Port (SP) surgical platform. Urology Video Journal 10: 100086	Ineligible study design
Garisto J, Bertolo R, Reese SW, et al. (2021) Minimizing minimally invasive surgery: current status of the single-port robotic surgery in urology. Actas Urologicas Espanolas 45(5): 345-352	Ineligible study design
Gettman M and Rivera M (2016) Innovations in robotic surgery. Current Opinion In Urology 26(3): 271-6	Ineligible study design
Gianardi D, Palmeri M and Morelli L (2019) The use of da Vinci Xi and the increased surgeon's experience could change the perspective over the cost-benefit ratio of robot-assisted surgery. Updates in Surgery 71(2): 399-400	Ineligible study design
Giannini A, Malacarne E, Sergiampietri C, et al. (2021) Comparison of perioperative outcomes and technical features using da Vinci Si and Xi robotic platforms for early stages of endometrial cancer. Journal of Robotic Surgery 15(2): 195-201	Retrospective study
Giannini A, Russo E, Mannella P, et al. (2017) First series of total robotic hysterectomy (TRH) using new integrated table motion for the da Vinci Xi: feasibility, safety and efficacy. Surgical Endoscopy 31(8): 3405-3410	Single arm prospective study <50 patients
Giannini A, Russo E, Mannella P, et al. (2018) Early experience using new integrated table motion for the da Vinci Xi in gynecologic surgery: feasibility, safety, efficacy. Journal of Gynecologic Surgery 34(3): 144-149	Single arm prospective study <50 patients
Gijsen AF, Vaassen HGM, Vahrmeijer AL, et al. (2023) Robot-assisted and fluorescence-guided remnant-cholecystectomy: a prospective dual-center cohort study. Hpb 25(7): 820-825	Single arm prospective study <50 patients

Reference	Exclusion reason
Gitas G, Alkatout I, Proppe L, et al. (2021) Surgical outcomes of conventional laparoscopic and robotic-assisted hysterectomy. The International Journal Of Medical Robotics and Computer Assisted Surgery 17(3): e2225	Retrospective study
Golusinski W, Pienkowski P and Majchrzak E (2019) Robotic surgery (da Vinci Xi system) in head and neck cancer - own experience. Otolaryngologia Polska 74(1): 1-5	Retrospective study
Goncalves MR, Novo de Matos J, Oliveira A, et al. (2023) Robotic4all project: results of a hands-on robotic surgery training program. Laparoscopic, Endoscopic, and Robotic Surgery 6(1): 1-8	Ineligible study design
Goonewardene SS, Catterwell R, Brown M and Challacombe B (2017) Robotic surgery with the Da Vinci Xi: simultaneous upper and lower tract surgery. Journal of Robotic Surgery 11(3): 373-374	Ineligible study design
Gorphe P, Von Tan J, El Bedoui S, et al. (2017) Early assessment of feasibility and technical specificities of transoral robotic surgery using the da Vinci Xi. Journal of Robotic Surgery 11(4): 455-461	Single arm prospective study <50 patients
Granell J, Ramirez-Rosa A, Fernandez-Rastrilla I, et al. (2023) Feasibility of the set-up for the different approaches in robotic head and neck surgery with the Versius Surgical System. Journal of Robotic Surgery 17(6): 3035-3038	Ineligible study design
Grimminger PP, Hadzijusufovic E and Lang H (2017) Robotic-assisted minimal-invasive oesophagectomy (RAMIE) - Feasibility, potential and advantages. European Surgical Research 58: 275-328	Ineligible study design
Grimminger PP, Hadzijusufovic E and Lang H (2018) Robotic-assisted Ivor Lewis esophagectomy (RAMIE) with a standardized intrathoracic circular end-to-side stapled anastomosis and a team of two (surgeon and assistant only). Thoracic and Cardiovascular Surgeon 66(5): 404-406	Ineligible study design
Grimminger PP, Hadzijusufovic E, Ruurda JP-H, et al. (2018) The da Vinci Xi Robotic four-arm approach for robotic-assisted minimally invasive esophagectomy. Thoracic and Cardiovascular Surgeon 66(5): 407-409	Ineligible study design
Guadagni S, di Franco G, Palmeri M, et al. (2019) Total abdominal proctocolectomy: what is new with the da Vinci Xi? Journal of Robotic Surgery 13(5): 711-712	Ineligible study design

Reference	Exclusion reason
Guadagni S, Morelli L, Di Franco G, et al. (2016) Robotic-assisted spleen-preserving left pancreatectomy: a case-matched comparison with pure laparoscopic technique. Surgical Endoscopy and Other Interventional Techniques 30: S1-S62	Ineligible study design
Guan X, Lovell DY and Zurawin R (2024) The evolution of transvaginal robot-assisted surgery in gynecology. Surgical Technology International 44(5): 22	Ineligible study design
Gupta N, Mohling S, McKendrick R, et al. (2018) Perioperative outcomes of robotic hysterectomy with mini-laparotomy versus open hysterectomy for uterus weighing more than 250g. Journal of Robotic Surgery 12(4): 641-645	Retrospective study
Hagen ME, Jung MK, Ris F, et al. (2017) Early clinical experience with the da Vinci Xi Surgical System in general surgery. Journal of Robotic Surgery 11(3): 347-353	Retrospective study
Halabi M, Khoury K, Alomar A, et al. (2024) Operative efficiency: a comparative analysis of Versius and da Vinci robotic systems in abdominal surgery. Journal of Robotic Surgery 18(1): 132	Retrospective study
Hamilton AER, Chatfield MD, Johnson CS and Stevenson ARL (2020) Totally robotic right hemicolectomy: a multicentre case-matched technical and peri-operative comparison of port placements and da Vinci models. Journal of Robotic Surgery 14(3): 479-491	Retrospective study
Hamzaoglu I, Baca B, Esen E, et al. (2020) Short-term results after totally robotic restorative total proctocolectomy with ileal pouch anal anastomosis for ulcerative colitis. Surgical Laparoscopy, Endoscopy and Percutaneous Techniques 30(1): 40-44	Single arm prospective study <50 patients
Harichane A, Chauvet D and Hans S (2018) Nasopharynx access by minimally invasive transoral robotic surgery: anatomical study. Journal of Robotic Surgery 12(4): 687-692	Ineligible patient population
Heo JE, Kang SK, Lee J, et al. (2023) Outcomes of single-port robotic ureteral reconstruction using the da Vinci SP R system. Investigative And Clinical Urology 64(4): 373-379	Retrospective study

Reference	Exclusion reason
Hesse UJ, Lenz J, Dubecz A and Stein HJ (2022) Intraoperative conversion and complications in robotic assisted primary and redo gastric bypass surgery. Journal of Robotic Surgery 16(1): 235-239	Single arm prospective study <50 patients
Hill A and McCormick J (2020) In experienced hands, does the robotic platform impact operative efficiency? Comparison of the da Vinci Si versus Xi robot in colorectal surgery. Journal of Robotic Surgery 14(5): 789-792	Retrospective study
Ho J, Kim D, Lee J-E, et al. (2023) Single-port transaxillary robotic modified radical neck dissection (STAR-RND): initial experiences. Laryngoscope 133(3): 709-714	Retrospective study
Hofeldt M and Richmond B (2023) Elective robotic partial colon and rectal resections: series of 170 consecutive robot procedures involving the Da Vinci Xi robot by a community general surgeon. Journal of Robotic Surgery 17(4): 1535-1539	Retrospective study
Hollandsworth HM, Li K, Zhao B, et al. (2022) Robotic left-stapled total intracorporeal bowel anastomosis versus stapled partial extracorporeal anastomosis: operative technical description and outcomes. Surgical Endoscopy 36(5): 3645-3652	Retrospective study
Holsinger FC, Birkeland AC and Topf MC (2021) Precision head and neck surgery: robotics and surgical vision technology. Current Opinion in Otolaryngology and Head and Neck Surgery 29(2): 161-167	Ineligible study design
Holzgang M, Dowsett D, El-Hadi A and Shaikh I (2022) Economizing on a 12 mm port incision site: modification of robotic bowel stapling technique in Da Vinci X/Xi left colonic resections-the modified Norfolk and Norwich robotic stapling technique. Journal of Robotic Surgery 16(6): 1491-1492	Ineligible study design
Hotton J, Bogart E, Le Deley MC, et al. (2023) Ergonomic assessment of the surgeon's physical workload during robot-assisted versus standard laparoscopy in a French multicenter randomized trial (ROBOGYN-1004 Trial). Annals of Surgical Oncology 30(2): 916-923	Robot model not specified
Huang YL, Chen MC and Chiang FF (2023) Robotic platform da Vinci Xi Is feasible and beneficial in both colon and rectal surgery in short-term outcome and recovery. Gastroenterology Insights 14(4): 538-552	Retrospective study

Reference	Exclusion reason
Huang Y-M, Huang YJ and Wei P-L (2019) Colorectal cancer surgery using the Da Vinci Xi and Si systems: comparison of perioperative outcomes. Surgical Innovation 26(2): 192-200	Retrospective study
Huddy JR, Crockett M, Nizar AS, et al. (2022) Experiences of a "COVID protected" robotic surgical centre for colorectal and urological cancer in the COVID-19 pandemic. Journal of Robotic Surgery 16(1): 59-64	Ineligible outcomes
Hummel B, Nagel A, Susoy B, et al. (2021) Robot-assisted laparoscopic rectal surgery: operative technique and initial experiences. European Surgery 53(4): 175-180	Retrospective study
Intuitive Surgical. *Lung cancer robotic comparative study (LARCS)*. Identifier: NCT06038227. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2024. Available from https://clinicaltrials.gov/study/NCT06038227	Ongoing study
Ito H, Yanagida S, Toyonaga Y, et al. (2021) Single assistant versus dual assistant robotic surgery for robot-assisted laparoscopic hysterectomy using da Vinci Xi or X. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 17(6): e2315	Single arm prospective study <50 patients
Jara RD, Guerrón AD and Portenier D (2020) Complications of Robotic Surgery. Surgical Clinics of North America 100(2): 461-468	Ineligible study design
Jayakumaran J, Wiercinski K, Buffington C and Caceres A (2018) Robotic laparoendoscopic single-site benign gynecologic surgery: a single-center experience. Journal of Robotic Surgery 12(3): 447-454	Retrospective study
Jayne D, Pigazzi A, Marshall H, et al. (2019) Robotic-assisted surgery compared with laparoscopic resection surgery for rectal cancer: the ROLARR RCT. Efficacy and Mechanism Evaluation 6(10)	Robot model not specified
Jeelani S, Dany A, Anand B, et al. (2015) Robotics and medicine: a scientific rainbow in hospital. Journal of Pharmacy and Bioallied Sciences 7(Suppl 2): S381-3	Ineligible study design
Jeon DN, Kim J, Ko BS, et al. (2021) Robot-assisted breast reconstruction using the prepectoral anterior tenting method. Journal of Plastic, Reconstructive and Aesthetic Surgery: JPRAS 74(11): 2906-2915	Retrospective study

Reference	Exclusion reason
Jeong MH, Kim HJ, Choi G-S, et al. (2023) Single-port versus multiport robotic total mesorectal excision for rectal cancer: initial experiences by case-matched analysis of short-term outcomes. Annals of surgical treatment and research 105(2): 99-106	Retrospective study
Jeong R, Kim M-S, Lee C-M, et al. (2023) Trans-umbilical lymphadenectomy using an articulating bipolar vessel-sealing device (TULAB) during robotic surgery for gastric cancer: enhancing the surgeon's eye for reduced-port robotic gastrectomy. Cancers 15(22): 11	Retrospective study
Jiang Y, Liu Y, Qin S, et al. (2023) Perioperative, function, and positive surgical margin in extraperitoneal versus transperitoneal single port robot-assisted radical prostatectomy: a systematic review and meta-analysis. World Journal of Surgical Oncology 21(1): 383	Ineligible intervention
Jimenez-Rodriguez RM, Quezada-Diaz F, Tchack M, et al. (2019) Use of the Xi robotic platform for total abdominal colectomy: a step forward in minimally invasive colorectal surgery. Surgical Endoscopy 33(3): 966-971	Retrospective study
Johar A, Brush T, Collins B, et al. (2022) Novel process for three-dimensional anatomy and surgical video production: a potential pedagogical tool. Journal of Robotic Surgery 16(6): 1493-1496	Ineligible study design
Joseph JP, O'Malley P and Su L-M (2021) Robot-assisted radical nephroureterectomy. Journal of Endourology 35(S2): 122-131	Ineligible study design
Julien-Marsollier F, Loiselle M, Brouns K, et al. (2022) Perioperative management of surgical correction of ureteropelvic junction obstruction in children: a comparison of robotic-assisted versus conventional minimally invasive techniques. Paediatric Anaesthesia 32(8): 973-975	Retrospective study
Jung J-M, Kim YI, Yoon YS, et al. (2023) Short-term outcomes of da Vinci SP versus Xi for colon cancer surgery: a propensity-score matching analysis of multicenter cohorts. Journal of Robotic Surgery 17(6): 2911-2917	Retrospective study
Kadioglu BG, Kumtepe Y and Baran FS (2018) Gynaecological robotic surgery at a state hospital - our own experience. Ginekologia Polska 89(9): 495-499	Retrospective study

Reference	Exclusion reason
Kallingal GJS, Swain S, Darwiche F, et al. (2016) Robotic partial nephrectomy with the Da Vinci Xi. Advances In Urology (9675095): 5	Single arm prospective study <50 patients
Kaneda H, Nakano T, Utsumi T and Murakawa T (2024) Feasibility and safety of uniport robotic-assisted thoracoscopic surgery in initial series of anatomical pulmonary resections under learning curve. General Thoracic and Cardiovascular Surgery 15: 15	Retrospective study
Kang YH, Kang JS, Cho YS, et al. (2022) A retrospective multicentre study on the evaluation of perioperative outcomes of single-port robotic cholecystectomy comparing the Xi and SP versions of the da Vinci robotic surgical system. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 18(1): e2345	Retrospective study
Kaouk JH and Bertolo R (2019) Single-site robotic platform in clinical practice: first cases in the USA. Minerva Urologica E Nefrologica 71(3): 294-298	Single arm prospective study <50 patients
Kaouk JH, Haber G-P, Autorino R, et al. (2014) A novel robotic system for single-port urologic surgery: first clinical investigation. European Urology 66(6): 1033-43	Single arm prospective study <50 patients
Kauffels A, Reichert M, Askevold I, et al. (2023) Establishing robotic bariatric surgery at an academic tertiary hospital: a learning curve analysis for totally robotic Roux-en-Y gastric bypass. Journal of Robotic Surgery 17(2): 577-585	Ineligible patient population
Kauffels A, Reichert M, Sauerbier L, et al. (2023) Outcomes of totally robotic Roux-en-Y gastric bypass in patients with BMI >= 50 kg/m2: can the robot level out "traditional" risk factors? Journal of Robotic Surgery 17(6): 2881-2888	Ineligible patient population
Kelkar D, Borse MA, Godbole GP, et al. (2021) Interim safety analysis of the first-in-human clinical trial of the Versius surgical system, a new robot-assisted device for use in minimal access surgery. Surgical Endoscopy 35(9): 5193-5202	Single arm prospective study <50 patients
Kelly JD, Kowalewski TM, Brand T, et al. (2021) Virtual reality warm-up before robot-assisted surgery: a randomized controlled trial. Journal of Surgical Research 264: 107-116	Ineligible study design

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Kim B-C, Kwon D, Pak SJ, et al. (2023) Safety and feasibility of single-port surgery for posterior retroperitoneal adrenalectomy using the da Vinci SP robotic system: a retrospective cohort study. Surgical Endoscopy 37(11): 8269-8276	Retrospective study
Kim HK, Kim HY, Chai YJ, et al. (2018) Transoral robotic thyroidectomy: comparison of surgical outcomes between the da Vinci Xi and Si. Surgical Laparoscopy, Endoscopy and Percutaneous Techniques 28(6): 404-409	Ineligible comparator
Kim HS, Oh BY, Cheong C, et al. (2023) Single-incision robotic colorectal surgery with the da Vinci SP R surgical system: initial results of 50 cases. Techniques In Coloproctology 27(7): 589-599	Retrospective study
Kim HS, Oh B-Y, Chung SS, et al. (2023) Short-term outcomes of single-incision robotic colectomy versus conventional multiport laparoscopic colectomy for colon cancer. Journal of Robotic Surgery 17(5): 2351-2359	Retrospective study
Kim IK and Han S-R (2023) Single-port robotic extended totally extraperitoneal (eTEP) with transverse abdominis release (TAR) for lateral ventral hernia repair using the da Vinci SP platform. Asian Journal of Surgery 46(7): 2829-2830	Ineligible study design
Kim JC (2016) A universal port design for the da Vinci Xi R system allowing access to the entire colon for colorectal cancer surgery. Journal of Surgical Oncology 114(8): 1029-1030	Ineligible study design
Kim JK, Choi SH, Choi SM, et al. (2022) Single-port transaxillary robotic thyroidectomy (START): 200-cases with two-step retraction method. Surgical Endoscopy 36(4): 2688-2696	Ineligible outcomes
Kim JM, Lee YH, Chong GO, et al. (2022) Comparison of multi- and single-site robotic myomectomy using the Da Vinci R SP Surgical System: a propensity score matching analysis. Journal of Clinical Medicine 11(23): 6905	Retrospective study
Kim K, Kang S-W, Kim JK, et al. (2020) Robotic transaxillary hemithyroidectomy using the da Vinci SP Robotic System: initial experience with 10 consecutive cases. Surgical Innovation 27(3): 256-264	Retrospective study
Kim MP and Chan EY (2017) "Five on a dice" port placement for robot-assisted thoracoscopic right upper lobectomy using robotic stapler. Journal of Thoracic Disease 9(12): 5355-5362	Ineligible study design

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Kim SJ, Park M-H and Lee JH (2023) Comparison of operative and fertility outcomes of single-incision robotic myomectomy: a retrospective single-center analysis of 286 cases. Journal of Robotic Surgery 17(6): 2945-2953	Retrospective study
Kim T-K, Seo M, Park SH, et al. (2022) Feasibility of robotic thyroidectomy via hairline incision using da Vinci single port system: initial experience with 40 consecutive cases. Head and Neck 44(10): 2197-2205	Retrospective study
Kim W-J, Choi S-B and Kim W-B (2022) Feasibility and efficacy of single-port robotic cholecystectomy using the da Vinci SP R platform. Journal of the Society of Laparoendoscopic Surgeons 26(2): e2021.00091	Retrospective study
King K, Galvez A, Stoltzfus J, et al. (2021) Correction to: cost analysis of robotic Roux-en-Y gastric bypass in a single academic center: how expensive Is expensive? Obesity Surgery 31(1): 472-473	Ineligible comparator
Klazura G, Graf A, Sims T, et al. (2022) Assessment of the da Vinci Single Port Robotic Platform on cholecystectomy in adolescents. Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A 32(4): 438-441	Paediatric population
Ko SY, Chang YW, Ku D, et al. (2023) Comparison of robotic and laparoscopic lateral transperitoneal adrenalectomies. Annals of surgical treatment and research 105(2): 69-75	Retrospective study
Koga H, Yamada S, Takeda M, et al. (2024) Optical Trocar Access for Retroperitoneal Robotic-Assisted Pyeloplasty in Children with Ureteropelvic Junction Obstruction. Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A 04: 04	Paediatric population
Komatsu H, Sawada M, Iida Y, et al. (2024) New surgery technique combining robotics and laparoscopy using the Hugo TM RAS system. Asian Journal of Endoscopic Surgery 17(3): e13344	Ineligible study design
Komatsu H, Wada I, Harada T and Taniguchi F (2024) First report of robotic-assisted total hysterectomy using the Hugo TM RAS system. Updates in Surgery 76(1): 315-318	Ineligible study design
Kuckelman JP and Marshall MB (2023) Robotic first rib resection utilizing the Da Vinci Xi System. Operative Techniques in Thoracic and Cardiovascular Surgery 28(3): 227-236	Ineligible study design

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Kuo LJ, Ngu JC, Lin YK, et al. (2020) A pilot study comparing ergonomics in laparoscopy and robotics: beyond anecdotes, and subjective claims. Journal of Surgical Case Reports 2020(2): rjaa005	Robot model not specified
Kurt G, Guvenc G, Dede M, et al. (2022) Comparison of health-related quality of life of women undergoing robotic surgery, laparoscopic surgery or laparotomy for gynecologic conditions: a cross-sectional study. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 159(2): 583-591	Robot model not specified
Kwak YH, Lee H, Seon K, et al. (2022) Da Vinci SP single-port robotic surgery in gynecologic tumors: single surgeon's initial experience with 100 cases. Yonsei Medical Journal 63(2): 179-186	Retrospective study
Larkins KM, Mohan HM, Gray M, et al. (2023) Transferability of robotic console skills by early robotic surgeons: a multi-platform crossover trial of simulation training. Journal of Robotic Surgery 17(3): 859-867	Ineligible study design
Latif MJ and Park BJ (2017) Robotics in general thoracic surgery procedures. Journal of Visualized Surgery 3: 44	Ineligible study design
Laverty RB, Khan MT, Patnaik R, et al. (2023) Intentional enterotomies: validation of a novel robotic surgery training exercise. Journal of Robotic Surgery 17(5): 2109-2115	Ineligible study design
Lavery HJ, Thaly R, Albala D, et al. (2008) Robotic equipment malfunction during robotic prostatectomy: a multi-institutional study. Journal of Endourology 22(9): 2165-8	Ineligible intervention
Leang YJ, Kong JCH, Mosharaf Z, et al. (2024) Emerging multi-port soft tissue robotic systems: a systematic review of clinical outcomes. Journal of Robotic Surgery 18(1): 145	Systematic review for reference checking
Lee CS, Chin JH and Han S-R (2023) How to do a single-port robotic totally extraperitoneal (TEP) inguinal hernia repair using the da Vinci SP platform. ANZ Journal of Surgery 93(5): 1357-1359	Ineligible study design
Lee HH, Na JC, Yoon YE, et al. (2020) Robot-assisted laparoendoscopic single-site upper urinary tract surgery with da Vinci Xi surgical system: initial experience. Investigative And Clinical Urology 61(3): 323-329	Retrospective study

Reference	Exclusion reason
Lee J, Park HS, Lee H, et al. (2020) Axillary lymph node dissection using a robotic surgical system: initial experience. Journal of Surgical Oncology 122(6): 1252-1256	Ineligible study design
Lee JH, Hong JI and Kim HK (2024) Single-port robotic subcostal major pulmonary resection using the single-port robotic system. World Journal of Surgery 48(3): 713-722	Single arm prospective study <50 patients
Leitao MM, Jr., Kreaden US, Laudone V, et al. (2023) The RECOURSE study: long-term oncologic outcomes associated with robotically assisted minimally invasive procedures for endometrial, cervical, colorectal, lung, or prostate cancer: a systematic review and meta-analysis. Annals of Surgery 277(3): 387-396	Systematic review for reference checking
Leitao MM, Narain WR, Boccamazzo D, et al. (2016) Impact of robotic platforms on surgical approach and costs in the management of morbidly obese patients with newly diagnosed uterine cancer. Annals of Surgical Oncology 23(7): 2192-8	Ineligible intervention
Lenfant L, Canlorbe G, Belghiti J, et al. (2023) Robotic-assisted benign hysterectomy compared with laparoscopic, vaginal, and open surgery: a systematic review and meta-analysis. Journal of Robotic Surgery 17(6): 2647-2662	Systematic review for reference checking
Lenfant L, Wilson CA, Sawczyn G, et al. (2020) Single-port robot-assisted dismembered pyeloplasty with mini-pfannenstiel or peri-umbilical access: initial experience in a single center. Urology 143: 147-152	Single arm prospective study <50 patients
Leung A, Abitbol J, Ramana-Kumar AV, et al. (2017) Outside the operating room: How a robotics program changed resource utilization on the inpatient Ward. Gynecologic Oncology 145(1): 102-107	Robot model not specified
Li K-P, Chen S-Y, Wang C-Y and Yang L (2023) Perioperative and oncologic outcomes of single-port versus conventional robotic-assisted partial nephrectomy: an evidence-based analysis of comparative outcomes. Journal of Robotic Surgery 17(3): 765-777	Systematic review for reference checking
Liatsikos E, Tsaturyan A, Kyriazis I, et al. (2022) Market potentials of robotic systems in medical science: analysis of the Avatera robotic system. World Journal of Urology 40(1): 283-289	Ineligible outcomes

Reference	Exclusion reason
Lim JH, Yun SH, Lee WY, et al. (2023) Single-port laparoscopic versus single-port robotic right hemicolectomy: postoperative short-term outcomes. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 19(3): e2509	Retrospective study
Lim SK, Ng FC, Yam WL and Rha KH (2016) Modified transperitoneal ports configuration and docking technique for renal surgeries with the da Vinci Surgical System Xi. International Journal of Urology 23(9): 801-2	Ineligible study design
Lin C-Y, Liu Y-C, Chen M-C and Chiang F-F (2022) Learning curve and surgical outcome of robotic assisted colorectal surgery with ERAS program. Scientific Reports 12(1): 20566	Retrospective study
Liu H, Cao Y, Li L, et al. (2022) Effectiveness of robotic surgery for endometrial cancer: a systematic review and meta-analysis. Arch Gynecol Obstet 305(4): 837-850	Ineligible study design
Loniewski S, Farah K, Malikov S and Fuentes S (2023) Da Vinci robotic-assisted anterolateral lumbar arthrodesis: operative technique. Acta Neurochirurgica 165(9): 2711-2716	Ineligible study design
Lönnerfors C, Reynisson P and Persson J (2015) A randomized trial comparing vaginal and laparoscopic hysterectomy vs robot-assisted hysterectomy. Journal of Minimally Invasive Gynecology 22(1): 78-86	Ineligible intervention
Lopez-Lopez V, Sanchez-Esquer I, Crespo MJ, et al. (2022) Development and validation of advanced three-dimensional navigation device integrated in da Vinci Xi R surgical robot for hepatobiliary surgery: pilot study. British Journal of Surgery 110(1): 108-110	Ineligible study design
Lundin ES, Carlsson P, Wodlin NB, et al. (2020) Cost-effectiveness of robotic hysterectomy versus abdominal hysterectomy in early endometrial cancer. International Journal of Gynecologic Cancer 30(11): 1719	Ineligible intervention
Lundin ES, Wodlin NB, Nilsson L and Kjölhede P (2019) A prospective randomized assessment of quality of life between open and robotic hysterectomy in early endometrial cancer. International Journal of Gynecologic Cancer 29(4): 721-727	Robot model not specified

Reference	Exclusion reason
Lv Z, Chen G, Chen X, et al. (2023) Open versus robot-assisted partial nephrectomy for highly complex renal masses: a meta-analysis of perioperitive and functional outcomes. Journal of Robotic Surgery 17(5): 1955-1965	Systematic review for reference checking
Machado MA, Mattos BH, Lobo Filho M and Makdissi F (2023) Robotic partial resection of the caudate lobe for recurrent colorectal liver metastasis after open left hepatectomy and open rectosigmoidectomy. Surgical Oncology 50: 101985	Ineligible study design
Mala T, Forland D, Skagemo C, et al. (2022) Early experience with total robotic D2 gastrectomy in a low incidence region: surgical perspectives. BMC Surgery 22(1): 137	Single arm prospective study <50 patients
Martinello N and Loshak H (2020) Experiences with and expectations of robotic surgical systems: a rapid qualitative review. 22. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562938/pdf/Bookshelf_NBK562938.pdf	Ineligible study design
Matsuura M, Nagao S, Kurokawa S, et al. (2024) Early outcomes of three new robotic surgical systems in patients undergoing hysterectomy. Updates in Surgery 24: 24	Retrospective study
Matsuura M, Nagao S, Kurokawa S, et al. (2024) Surgical outcomes of da Vinci Xi TM and da Vinci SP TM for early-stage endometrial cancer in patients undergoing hysterectomy. Journal of Clinical Medicine 13(10): 13	Retrospective study
Matulewicz RS, Chesnut GT, Huang CC, et al. (2019) Evolution in technique of robotic intracorporeal continent catheterizable pouch after cystectomy. Urology Video Journal 4	Ineligible study design
Maurissen J, Schoneveld M, Van Eetvelde E and Allaeys M (2019) Robotic-assisted repair of perineal hernia after extralevator abdominoperineal resection. Techniques In Coloproctology 23(5): 479-482	Ineligible study design
McCulloch P (2023) IDEAL, Versius, reality. Annals of Surgery 277(1): 18-20	Ineligible study design
McGuire DA, Rodney JP and Vasan NR (2017) Improved glottic exposure for robotic microlaryngeal surgery: a case series. Journal of Voice 31(5): 628-633	Ineligible study design

Reference	Exclusion reason
Meneghetti I, Sighinolfi MC, Dibitetto F, et al. (2024) Partial nephrectomy series using Versius robotic surgical system: technique and outcomes of an initial experience. Journal of Robotic Surgery 18(1): 73	Single arm prospective study <50 patients
Meredith LT, Nooromid MJ and Okusanya OT (2024) A robotic minimally invasive technique for resecting a retro-oesophageal aberrant right subclavian artery. European Journal of Vascular and Endovascular Surgery 67(6): 1033	Ineligible study design
Meyer CD, Wu MP, Miller LE, et al. (2024) Robotic thyroidectomy via posterior neck approach using the Da Vinci Single Port System. Laryngoscope 134(6): 2779-2782	Retrospective study
Mikhail D, Sarcona J, Mekhail M and Richstone L (2020) Urologic robotic surgery. Surgical Clinics of North America 100(2): 361-378	Ineligible study design
Miyamura H, Takada K, Ohwaki A, et al. (2024) Initial experience and surgical outcomes of robotic-assisted total hysterectomy using the da Vinci SP surgical system. Asian Journal of Endoscopic Surgery 17(2): e13298	Retrospective study
Monterossi G, Pedone Anchora L, Oliva R, et al. (2023) The new surgical robot Hugo TM RAS for total hysterectomy: a pilot study. Facts Views and Vision in Obgyn 15(4): 331-337	Single arm prospective study <50 patients
Morelli L, Di Franco G, Furbetta N, et al. (2023) Delayed gastric emptying after pylorus-preserving pancreatoduodenectomy: comparison between traditional open surgery and full-robotic approach with da Vinci Xi. The International Journal Of Medical Robotics and Computer Assisted Surgery 20(1): e2571	Retrospective study
Morelli L, Di Franco G, Guadagni S, et al. (2017) Full robotic colorectal resections for cancer combined with other major surgical procedures: early experience with the da Vinci Xi. Surgical Innovation 24(4): 321-327	Retrospective study
Morelli L, Di Franco G, Guadagni S, et al. (2018) Robot-assisted total mesorectal excision for rectal cancer: case-matched comparison of short-term surgical and functional outcomes between the da Vinci Xi and Si. Surgical Endoscopy 32(2): 589-600	Ineligible outcomes
Morelli L, Guadagni S, Di Franco G, et al. (2015) Use of the new Da Vinci Xi during robotic rectal resection for cancer: technical considerations and early experience. International Journal of Colorectal Disease 30(9): 1281-3	Ineligible study design

Reference	Exclusion reason
Morgantini LA, Del Pino M, Bharadwaj A, et al. (2022) Single-port versus multi-port robotic-assisted procedures from the patient's perspective: a retrospective cohort study. Urology Practice 9(6): 575-579	Retrospective study
Morizane S, Yumioka T, Iwamoto H, et al. (2022) Initial experience of robot-assisted laparoscopic nephroureterectomy in Japan: a useful technique using a vessel sealing device for securing a good surgical field and efficient sealing. Asian Journal of Endoscopic Surgery 15(2): 458-462	Single arm prospective study <50 patients
Morrell ALG, Charles Morrell-Junior A, Morrell AG, et al. (2021) Technical essential aspects in robotic colorectal surgery: mastering the Da Vinci Si and Xi platforms. Revista do Colegio Brasileiro de Cirurgioes 48: e20213007	Single arm prospective study <50 patients
Moschovas MC, Seetharam Bhat KR, Onol FF, et al. (2021) Single-port technique evolution and current practice in urologic procedures. Asian Journal of Urology 8(1): 100-104	Ineligible study design
Motoyama D, Aki R, Matsushita Y, et al. (2019) Early single-center experience with robotic partial nephrectomy using the da Vinci Xi: comparative assessment with conventional open partial nephrectomy. Current Urology Reports 13(1): 13-18	Retrospective study
Motoyama D, Matsushita Y, Watanabe H, et al. (2020) Improved perioperative outcomes by early unclamping prior to renorrhaphy compared with conventional clamping during robot-assisted partial nephrectomy: a propensity score matching analysis. Journal of Robotic Surgery 14(1): 47-53	Retrospective study
Motoyama D, Matsushita Y, Watanabe H, et al. (2020) Initial learning curve for robot-assisted partial nephrectomy performed by a single experienced robotic surgeon. Asian Journal of Endoscopic Surgery 13(1): 59-64	Retrospective study
Muaddi H, Hafid ME, Choi WJ, et al. (2021) Clinical Outcomes of Robotic Surgery Compared to Conventional Surgical Approaches (Laparoscopic or Open): A Systematic Overview of Reviews. Annals of Surgery 273(3): 467-473	Ineligible study design
Na Y-H, Kim W-B, Kang J-S, et al. (2024) Early outcomes of single-port robotic left lateral sectionectomy in patients with hepatic tumor. Annals of surgical treatment and research 106(2): 78-84	Retrospective study

Reference	Exclusion reason
Nabi J, Friedlander DF, Chen X, et al. (2020) Assessment of out-of-pocket costs for robotic cancer surgery in US adults. JAMA Netw Open 3(1): e1919185	Ineligible outcomes
National Institute for Health and Care Excellence (2020) Optimal surgical technique for rectal cancer. 226. Available from: https://www.nice.org.uk/guidance/ng151/evidence/c3-optimal-surgical-technique-for-rectal-cancer-pdf-7029391218	Robot model not specified
Naujokat H, Spille J, Bergholz R, et al. (2022) Robot-assisted scaffold implantation and two-stage flap raising of the greater omentum for reconstruction of the facial skeleton: description of a novel technique. The International Journal Of Medical Robotics and Computer Assisted Surgery 18(5): e2429	Ineligible patient population
Ngu JC-Y, Shannon NB, Eu EW, et al. (2023) Technical insights to multivisceral resections using the da Vinci Xi. ANZ Journal of Surgery 93(1-2): 166-172	Single arm prospective study <50 patients
Nguyen JH, Chen J, Marshall SP, et al. (2020) Using objective robotic automated performance metrics and task-evoked pupillary response to distinguish surgeon expertise. World Journal of Urology 38(7): 1599-1605	Ineligible outcomes
Niederberger C (2022) Re: Interim safety analysis of the first-in-human clinical trial of the Versius Surgical System, a new robot-assisted device for use in minimal access surgery. Journal of Urology 207(4): 908-910	Ineligible study design
Nik-Ahd F, Souders CP, Houman J, et al. (2019) Robotic urologic surgery: trends in food and drug administration-reported adverse events over the last decade. Journal of Endourology 33(8): 649-654	Ineligible study design
Nikolopoulos M, Mitsopoulos V, Innamaa A, et al. (2024) En bloc resection of sentinel lymph nodes with the hysterectomy specimen in endometrial cancer. Annals of Surgical Oncology 31(7): 4576-4577	Ineligible study design
Noh GT, Chung SS, Lee R-A and Kim KH (2021) Robotic single-incision right hemicolectomy with extended lymphadenectomy using the da Vinci SP Surgical Platform. Journal of minimally invasive surgery 24(2): 109-112	Ineligible study design
Nonaka T, Tominaga T, Akazawa Y, et al. (2022) Cross-dominant surgery using the da Vinci (Xi) surgical system in advanced rectal cancer surgery. Techniques In Coloproctology 26(1): 77-78	Ineligible study design

Reference	Exclusion reason
Norasi H, Hallbeck MS, Elli EF, et al. (2023) Impact of preferred surgical modality on surgeon wellness: a survey of workload, physical pain/discomfort, and neuromusculoskeletal disorders. Surgical Endoscopy 37(12): 9244-9254	Ineligible intervention
Oh S, Bae N, Cho H-W, et al. (2023) Learning curves and perioperative outcomes of single-incision robotic sacrocolpopexy on two different da Vinci R surgical systems. Journal of Robotic Surgery 17(4): 1457-1462	Retrospective study
Oh SM, Han WY, Eom JS, et al. (2024) Robot-assisted capsulectomy with immediate reimplantation in breast reconstruction. Plastic and Reconstructive Surgery 153(3): 523e-526e	Ineligible outcomes
Ojima H, Yamada K, Takada T, et al. (2022) Robotic surgery for simultaneous gastric and rectal cancers. Asian journal of endoscopic surgery 16(2): 297-300	Ineligible study design
Okazaki M, Suzawa K, Shien K, et al. (2024) Effective division of the intersegmental plane using a robotic stapler in robotic pulmonary segmentectomy. Surgery Today 18: 18	Retrospective study
Okhawere KE, Milky G, Shih I-F, et al. (2022) Comparison of 1-year health care expenditures and utilization following minimally invasive vs open nephrectomy. JAMA Network Open 5(9): e2231885	Robot model not specified
Olsen RG, Bjerrum F, Konge L, et al. (2024) How experienced robotic nurses adapt to the Hugo TM RAS system. Journal of Robotic Surgery 18(1): 114	Ineligible outcomes
Olsen RG, Hartwell D, Dalsgaard T, et al. (2024) First experience with the Hugo TM robot-assisted surgery system for endometriosis: a descriptive study. Acta Obstetricia Et Gynecologica Scandinavica 103(2): 368-377	Single arm prospective study <50 patients
Olson B, Cahill E and Imanguli M (2023) Feasibility and safety of the da Vinci Xi surgical robot for transoral robotic surgery. Journal of Robotic Surgery 17(2): 571-576	Retrospective study
Oner M (2024) Initial experience of a single surgeon for safety and feasibility of the Versius Robotic System in robot-assisted cholecystectomy and hernia repair. Journal of Robotic Surgery 18(1): 162	Retrospective study

Reference	Exclusion reason
Ozben V, Cengiz TB, Atasoy D, et al. (2016) Is da Vinci Xi better than da Vinci Si in robotic rectal cancer surgery? Comparison of the 2 generations of da Vinci systems. Surgical Laparoscopy, Endoscopy and Percutaneous Techniques 26(5): 417-423	Ineligible comparator
Ozben V, Cengiz TB, Bayraktar O, et al. (2016) Identification of mesenteric lymph nodes in robotic complete mesocolic excision by near-infrared fluorescence imaging. Techniques In Coloproctology 20(3): 195-196	Ineligible study design
Ozgur I, Cheong JY, Liska D, et al. (2024) Endorobotic submucosal dissection of rectal lesions using the single port robot DaVinci-SP: initial experience of the first 10 cases. ANZ Journal of Surgery 94(4): 691-696	Single arm prospective study <50 patients
Palmeri M, Gianardi D, Guadagni S, et al. (2018) Robotic colorectal resection with and without the use of the new Da Vinci table motion: a case-matched study. Surgical Innovation 25(3): 251-257	Ineligible intervention
Panteleimonitis S, Harper M, Hall S, et al. (2018) Precision in robotic rectal surgery using the da Vinci Xi system and integrated table motion, a technical note. Journal of Robotic Surgery 12(3): 433-436	Retrospective study
Panteleimonitis S, Popeskou SG, Domingos H, et al. (2017) Adoption of standardised technique fro robotic rectal surgery with the da vinci Xi system and integrated table motion. Surgical Endoscopy and Other Interventional Techniques 31: 1-59	Ineligible study design
Park A, Lee G, Seagull FJ, et al. (2010) Patients benefit while surgeons suffer: an impending epidemic. Journal of the American College of Surgeons 210(3): 306-13	Retrospective study
Park SE and Hong TH (2023) Gasless robotic single-port cholecystectomy using the DaVinci SP system: a feasible way to minimise surgical derangement while obtaining critical view of safety. The International Journal Of Medical Robotics and Computer Assisted Surgery 20(1): e2547	Single arm prospective study <50 patients
Park SH, Kim YN, Hwang J, et al. (2023) Safety and feasibility of reduced-port robotic distal gastrectomy for gastric cancer: a phase I/II clinical trial using the da Vinci Single Port(SP) robotic system. Scientific Reports 13(1): 18578	Single arm prospective study <50 patients

Reference	Exclusion reason
Park SY, Cho EH, Jeong K, et al. (2023) Robotic single-port hysterectomy versus robotic multisite hysterectomy in benign gynecologic diseases: a retrospective comparison of clinical and surgical outcomes. Journal of Obstetrics and Gynaecology Research 49(11): 2746-2752	Retrospective study
Park SY, Lee JH, Stein H, et al. (2022) Initial experience with and surgical outcomes of da Vinci single-port system in general thoracic surgery. Journal of Thoracic Disease 14(6): 1933-1940	Retrospective study
Park Y, Song A, Jee J, et al. (2024) Changes in anti-Mullerian hormone values for ovarian reserve after minimally invasive benign ovarian cystectomy: comparison of the Da Vinci robotic systems (Xi and SP) and the laparoscopic system. Scientific Reports 14(1): 9099	Retrospective study
Park YM, Choi EC, Kim S-H and Koh YW (2022) Recent progress of robotic head and neck surgery using a flexible single port robotic system. Journal of Robotic Surgery 16(2): 353-360	Retrospective study
Park YM, Kim DH, Moon YM, et al. (2019) Gasless transoral robotic thyroidectomy using the DaVinci SP system: Feasibility, safety, and operative technique. Oral Oncology 95: 136-142	Retrospective study
Patel MN and Hemal AK (2018) Does advancing technology improve outcomes? comparison of the Da Vinci standard/S/Si to the Xi Robotic Platforms during robotic nephroureterectomy. Journal of Endourology 32(2): 133-138	Ineligible comparator
Patel MN, Aboumohamed A and Hemal A (2015) Does transition from the da Vinci Si to Xi robotic platform impact single-docking technique for robot-assisted laparoscopic nephroureterectomy? BJU International 116(6): 990-4	Ineligible outcomes
Pavone M, Seeliger B, Alesi MV, et al. (2024) Initial experience of robotically assisted endometriosis surgery with a novel robotic system: first case series in a tertiary care center. Updates in Surgery 76(1): 271-277	Retrospective study
Pellegrino AA, Chen G, Morgantini L, et al. (2023) Simplifying retroperitoneal robotic single-port surgery: novel supine anterior retroperitoneal access. European Urology 84(2): 223-228	Single arm prospective study <50 patients
Pergamo MJ, Granieri MA, Weinberg A, et al. (2019) The use of ureteral stents with indocyanine green (ICG) in robotic colon surgery. Surgical Endoscopy 33(6): S406	Ineligible study design

Reference	Exclusion reason
Petz W, Ribero D, Bertani E, et al. (2017) Suprapubic approach for robotic complete mesocolic excision in right colectomy: oncologic safety and short-term outcomes of an original technique. European Journal of Surgical Oncology 43(11): 2060-2066	Single arm prospective study <50 patients
Pham CT, Hanna B, Samra J and Winter M (2022) Robotic repair of indirect inguinoscrotal bladder hernia. Urology Video Journal 13: 100122	Ineligible study design
Pham TD, Larach T, Othman B, et al. (2023) Robotic natural orifice specimen extraction surgery (NOSES) for anterior resection. Annals of Coloproctology 39(6): 526-530	Ineligible study design
Piccolo G, Barabino M, Lecchi F, et al. (2024) Robot-assisted fenestration of giant hepatic cysts in posterosuperior segments. European Surgery	Single arm prospective study <50 patients
Piozzi GN, Kim JS, Choo JM, et al. (2022) Da Vinci SP robotic approach to colorectal surgery: two specific indications and short-term results. Techniques In Coloproctology 26(6): 461-470	Ineligible study design
Piozzi GN, Lee DY, Kim JS and Kim SH (2022) Da Vinci Single-Port (SP) robotic transverse colectomy for mid-transverse colon cancer. Techniques In Coloproctology 26(8): 681-682	Ineligible study design
Piper M, Ligh CA, Shakir S, et al. (2021) Minimally invasive robotic-assisted harvest of the deep inferior epigastric perforator flap for autologous breast reconstruction. Journal of Plastic, Reconstructive and Aesthetic Surgery 74(4): 890-930	Ineligible study design
Pisani Ceretti A, Mariani NM, Perego M, et al. (2024) Proposal of set-up standardization for general surgery procedures with the CMR Versius system, a new robotic platform: our initial experience. Langenbecks Archives of Surgery 409(1): 107	Ineligible intervention
Prata F, Basile S, Tedesco F, et al. (2024) Skill transfer from laparoscopic partial nephrectomy to the Hugo TM RAS System: a novel proficiency score to assess surgical quality during the learning curve. Journal of Clinical Medicine 13(8): 11	Single arm prospective study <50 patients

Reference	Exclusion reason
Prata F, Iannuzzi A, Tedesco F, et al. (2024) Surgical outcomes of Hugo TM RAS robot-assisted partial nephrectomy for cystic renal masses: technique and initial experience. Journal of Clinical Medicine 13(12): 19	Single arm prospective study <50 patients
Prata F, Ragusa A, Anceschi U, et al. (2024) Three-arms off-clamp robot-assisted partial nephrectomy with the new Hugo robot-assisted surgery system. BJU International 133(1): 48-52	Single arm prospective study <50 patients
Prata F, Raso G, Ragusa A, et al. (2023) Robot-assisted renal surgery with the New Hugo Ras System: trocar placement and docking settings. Journal of Personalized Medicine 13(9): 13	Single arm prospective study <50 patients
Prete FP, Marzaioli R, Lattarulo S, et al. (2019) Transaxillary robotic-assisted thyroid surgery: technique and results of a preliminary experience on the Da Vinci Xi platform. BMC Surgery 18(Suppl 1): 19	Single arm prospective study <50 patients
Protyniak B, Jorden J and Farmer R (2018) Multiquadrant robotic colorectal surgery: the da Vinci Xi vs Si comparison. Journal of Robotic Surgery 12(1): 67-74	Ineligible intervention
Puntambekar SP, Goel A, Chandak S, et al. (2021) Feasibility of robotic radical hysterectomy (RRH) with a new robotic system. Experience at Galaxy Care Laparoscopy Institute. Journal of Robotic Surgery 15(3): 451-456	Ineligible intervention
Puntambekar SP, Rajesh KN, Goel A, et al. (2022) Colorectal cancer surgery: by Cambridge Medical Robotics Versius Surgical Robot System-a single-institution study. Our experience. Journal of Robotic Surgery 16(3): 587-596	Single arm prospective study <50 patients
Quezada N, Irarrazaval MJ, Chen DC, et al. (2024) Robotic transversus abdominis release using HUGO RAS system: our initial experience. Surgical Endoscopy 38(6): 3395-3404	Single arm prospective study <50 patients
Rabe SM, Burmeister E, Niebisch S and Gockel I (2023) Clinical and functional outcome following robotic Heller-myotomy with partial fundoplication in patients with achalasia. Journal of Robotic Surgery 17(4): 1689-1696	Retrospective study
Raffaelli M, Greco F, Pennestri F, et al. (2024) Robotic-assisted Roux-en-Y gastric bypass with the novel platform HugoTM RAS: preliminary experience in 15 patients. Updates in Surgery 76(1): 179-185	Single arm prospective study <50 patients

Reference	Exclusion reason
Raffone A, Travaglino A, Raimondo D, et al. (2022) Laparotomic versus robotic surgery in elderly patients with endometrial cancer: a systematic review and meta-analysis. Int J Gynaecol Obstet 157(1): 1-10	Systematic review for reference checking
Ramachandra C, Sugoor P, Karjol U, et al. (2020) Robotic complete mesocolic excision with central vascular ligation for right colon cancer: surgical technique and short-term outcomes. Indian Journal of Surgical Oncology 11(4): 674-683	Ineligible intervention
Rao AR (2014) Is it possible to achieve anything MORE going down the LESS route? BJU International 114(4): 561-562	Ineligible outcomes
Rebuffo S, Ticonosco M, Ruvolo CC, et al. (2024) Robot-assisted pyeloplasty with HUGO TM Robotic System: initial experience and optimal surgical set-up at a tertiary referral robotic center. Journal of Endourology 38(4): 323-330	Single arm prospective study <50 patients
Reeves F, Challacombe B, Ribbits A, et al. (2022) Idea, development, exploration, assessment, long-term follow-up study (IDEAL) Stage 1/2a evaluation of urological procedures with the Versius robot. BJU International 130(4): 441-443	Single arm prospective study <50 patients
Ricciardi R, Goldstone RN, Francone T, et al. (2022) Healthcare resource utilization after surgical treatment of cancer: value of minimally invasive surgery. Surg Endosc 36(10): 7549-7560	Robot model not specified
Riegelnegg M, Gassner L and Grössmann-Waniek N (2023) Robot-assisted surgery in thoracic and visceral indications – Update 2023. Available from: https://eprints.aihta.at/1461/1/HTA-Projektbericht_Nr.108_Update2023.pdf	Robot model not specified
Ritschl PV, Miller HK, Hillebrandt K, et al. (2022) Feasibility of robotic-assisted pancreatic resection in patients with previous minor abdominal surgeries: a single-center experience of the first three years. BMC Surgery 22(1): 86	Ineligible intervention
Rizzo KR, Grasso S, Ford B, et al. (2023) Status of robotic assisted surgery (RAS) and the effects of coronavirus (COVID-19) on RAS in the department of defense (DoD). Journal of Robotic Surgery 17(2): 413-417	Ineligible outcomes

Reference	Exclusion reason
Rodriguez-Luna MR, Vilallonga R, Roriz-Silva R, et al. (2021) A comparison of clinical outcomes between two different models of surgical robots in Roux-en-Y gastric bypass. Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A 31(9): 969-977	Retrospective study
Rogalska M, Antkowiak L, Kasperczuk A, et al. (2023) Transoral robotic surgery in the management of submandibular gland sialoliths: a systematic review. Journal of Clinical Medicine 12(8): 3007	Systematic review for reference checking
Romero-Marcos J-M, Sampson-Davila J-G, Cuenca-Gomez C, et al. (2024) Colorectal procedures with the novel Hugo TM RAS system: training process and case series report from a non-robotic surgical team. Surgical Endoscopy 38(4): 2160-2168	Single arm prospective study <50 patients
Roy N, Alessandro CJ, Ibelli TJ, et al. (2023) The expanding utility of robotic-assisted flap harvest in autologous breast reconstruction: a systematic review. Journal of Clinical Medicine 12(15): 4951	Systematic review for reference checking
Saito T, Fukami Y, Uchino T, et al. (2020) Preliminary results of robotic inguinal hernia repair following its introduction in a single-center trial. Annals of Gastroenterological Surgery 4(4): 441-447	Ineligible intervention
Salem SA, Marom G, Shein GS, et al. (2024) Robotic Heller's myotomy using the new Hugo TM RAS system: first worldwide report. Surgical Endoscopy 38(3): 1180-1190	Single arm prospective study <50 patients
Sampieri C, Pirola F, Costantino A, et al. (2023) Single-port versus multiport da vinci system for transoral robotic surgery of hypopharyngeal and laryngeal carcinoma. Otolaryngology - Head and Neck Surgery 169(3): 548-555	Retrospective study
Sarchi L, Mottaran A, Bravi CA, et al. (2022) Robot-assisted radical prostatectomy feasibility and setting with the Hugo TM robot-assisted surgery system. BJU International 130(5): 671-675	Ineligible intervention
Saqib SU and Bajwa AA (2023) The role of Da Vinci Xi robotic simulation curriculum in enhancing skills in robotic colorectal surgery. Annals of Medicine and Surgery 85(12): 6001-6007	Ineligible outcomes
See WA, Jacobson K, Derus S and Langenstroer P (2014) A comparison of case volumes among urologic surgeons identified on an industry-sponsored website to an all provider peer group. Urologic Oncology 32(8): 1095-100	Ineligible study design

Reference	Exclusion reason
Sef D, Wei LM, Rankin JS, et al. (2020) Robotic-assisted two-patch repair of right partial anomalous pulmonary venous connection and sinus venosus defect. JTCVS Techniques 4: 262-264	Ineligible study design
Sendag F, Akdemir A and Oztekin MK (2014) Robotic single-incision transumbilical total hysterectomy using a single-site robotic platform: initial report and technique. Journal of Minimally Invasive Gynecology 21(1): 147-151	Single arm prospective study <50 patients
Seon KE, Lee YJ, Lee J-Y, et al. (2023) Comparing surgical outcomes of da Vinci SP and da Vinci Xi for endometrial cancer surgical staging in a propensity score-matched study. Scientific Reports 13(1): 11752	Retrospective study
Seon KE, Lee YJ, Lee J-Y, et al. (2023) Initial experience with the da Vinci SP robot-assisted surgical staging of endometrial cancer: a retrospective comparison with conventional laparotomy. Journal of Robotic Surgery 17(6): 2889-2898	Retrospective study
Shen A, Barmparas G, Melo N, et al. (2024) Incorporating robotic cholecystectomy in an acute care surgery practice model is feasible. American Surgeon 0(0)	Retrospective study
Shen MY and Fingerhut A (2024) Robotic right colectomy with complete mesocolic excision, D3 lymph node dissection, and intracorporeal anastomosis. Diseases of the Colon and Rectum 67(2): E122-E123	Ineligible study design
Shi X, Feng D, Han P and Wei W (2023) Upper urinary tract surgery through robotic single-port system vs multiport and laparoendoscopic single-site systems: a systematic review and meta-analysis. Journal of Endourology 37(5): 542-550	Ineligible study design
Shin HR, Lee K, Yu HW, et al. (2021) Comparison of perioperative outcomes using the da Vinci S, Si, X, and Xi Robotic Platforms for BABA robotic thyroidectomy. Medicina 57(10): 19	Retrospective study
Shugaba A, Lambert JE, Bampouras TM, et al. (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. Journal of Gastrointestinal Surgery 26(7): 1520-1530	Systematic review for reference checking

Reference	Exclusion reason
Sighinolfi MC, De Maria M, Meneghetti I, et al. (2024) Correction: The use of Versius CMR for pelvic surgery: a multicentric analysis of surgical setup and early outcomes. World Journal of Urology 42(1): 86	Ineligible intervention
Sighinolfi MC, De Maria M, Meneghetti I, et al. (2024) The use of Versius CMR for pelvic surgery: a multicentric analysis of surgical setup and early outcomes. World Journal of Urology 42(1): 31	Ineligible intervention
Sighinolfi MC, Terzoni S, Scanferla E, et al. (2023) Prior robotic console expertise may improve basic skills at the new Hugo RAS simulator: results from a cohort trial and implications for skill transference across platforms. European Urology Open Science 53: 83-89	Ineligible study design
Sikkenk DJ, Sterkenburg AJ, Burghgraef TA, et al. (2023) Robot-assisted fluorescent sentinel lymph node identification in early-stage colon cancer. Surgical Endoscopy 37(11): 8394-8403	Ineligible outcomes
Silva ESA, de Carvalho JPM, Anton C, et al. (2018) Introduction of robotic surgery for endometrial cancer into a Brazilian cancer service: a randomized trial evaluating perioperative clinical outcomes and costs. Clinics (Sao Paulo) 73(suppl 1): e522s	Robot model not specified
Sofer A, Magnezi R, Eitan R, et al. (2020) Robotic vs. open surgery in obese women with low-grade endometrial cancer: comparison of costs and quality of life measures. Israel Journal of Health Policy Research 9(1): 60	Robot model not specified
Soliman BG, Nguyen DT, Chan EY, et al. (2020) Impact of da Vinci Xi robot in pulmonary resection. Journal of Thoracic Disease 12(7): 3561-3572	Retrospective study
Soputro NA and Olivares R (2023) Current urological applications of the Hugo TM RAS system. World Journal of Urology 41(9): 2555-2561	Ineligible study design
Soto Beauregard C, Rodriguez de Alarcon Garcia J, Dominguez Amillo EE, et al. (2022) Implementing a pediatric robotic surgery program: future perspectives. Cirugia Pediatrica 35(4): 187-195	Ineligible patient population
Soumpasis I, Nashef S, Dunning J, et al. (2023) Safe implementation of surgical innovation: a prospective registry of the Versius Robotic Surgical System. BMJ Surgery, Interventions, and Health technologies 5(1): e000144	Ineligible outcomes

Reference	Exclusion reason
Soumpasis I, Nashef S, Dunning J, et al. (2023) Safe implementation of a next-generation surgical robot: first analysis of 2,083 cases in the Versius surgical registry. Annals of Surgery 278(4): e903-e910	Retrospective study
Spinoglio G, Petz W, Borin S, et al. (2019) Robotic right colectomy with complete mesocolic excision and indocyanine green guidance. Minerva Chirurgica 74(2): 165-169	Single arm prospective study <50 patients
Studniarek A, Pan J, Gantt G, et al. (2021) Single-port, robot-assisted transanal excision of rectal lesion. Diseases of the Colon and Rectum 64(2): E25	Ineligible study design
Su KW, Luketich JD and Sarkaria IS (2022) Robotic-assisted minimally invasive thymectomy for myasthenia gravis with thymoma. JTCVS Techniques 13: 270-274	Ineligible study design
Su M-C, Zheng Y, Yang F and Liu Y-Y (2023) Placement of robotic single-site surgery with the tumor-free technique for early cervical cancer using the da Vinci Xi platform. Asian Journal of Surgery 46(3): 1492-1493	Ineligible study design
Sucandy I, Benzie AL, Spence J, et al. (2020) Robotic partial right hepatectomy with temporary ipsilateral inflow vascular occlusion: how we do it. American Surgeon 86(4): 185-187	Ineligible study design
Sucandy I, Castro M, Krill E, et al. (2023) Robotic RY hepaticojejunostomy for Strasberg E4 Iatrogenic bile duct injury: a modern minimally invasive technique. American Surgeon 89(4): 1239-1240	Ineligible study design
Sucandy I, Durrani H, Giovannetti A, et al. (2023) Robotic roux-en-Y hepaticojejunostomy with arterial repair for biliovascular injury following laparoscopic cholecystectomy. American Surgeon 89(4): 1034-1035	Ineligible study design
Sucandy I, Jacob K, Spence J, et al. (2023) Robotic left hepatectomy for giant hemangioma: technical approach in minimally invasive liver surgery. American Surgeon 89(4): 1200-1201	Ineligible study design
Sucandy I, Sang W, Giovannetti A, et al. (2023) Robotic right adrenalectomy for metastatic sarcoma. American Surgeon 89(4): 1249-1250	Ineligible study design

Reference	Exclusion reason
Suda T, Nagano H, Kawai H and Hoshikawa Y (2020) Subxiphoid robot-assisted thymectomy with vascular prosthetic replacement. Seminars In Thoracic and Cardiovascular Surgery 32(4): 1133-1134	Ineligible study design
Takase Y, Takahashi Y, Miyajima M and Watanabe A (2022) Robotic free pericardial fat pledget technique for treating pulmonary air leak. JTCVS Techniques 16: 153-156	Ineligible study design
Takayasu K, Yoshida K, Mishima T, et al. (2018) Analysis of the posture pattern during robotic simulator tasks using an optical motion capture system. Surgical Endoscopy 32(1): 183-190	Ineligible outcomes
Tamhankar AS, Ahluwalia P, Patil SR, et al. (2020) Implementation of ERAS protocol in robot-assisted radical cystectomy with intracorporeal ileal conduit urinary diversion: an outcome analysis beyond the learning curve. Indian Journal of Urology 36(1): 37-43	Single arm prospective study <50 patients
Tamhankar AS, Jatal S and Saklani A (2016) Total robotic radical rectal resection with da Vinci Xi system: single docking, single phase technique. The International Journal Of Medical Robotics and Computer Assisted Surgery: MRCAS 12(4): 642-647	Single arm prospective study <50 patients
Thornton R, Davey MG and Kerin MJ (2024) Evaluating the utility of robotic axillary lymph node dissection in patients with invasive breast cancer: a systematic review. Irish Journal of Medical Science 193(3): 1163-1170	Systematic review for reference checking
Timsit MO, Terrier N, Toinet T, et al. (2022) Posterior transperitoneal robot-assisted partial nephrectomy in the treatment of renal tumors: Feasibility of a hybrid approach. Progres En Urologie 32(3): 217-225	Single arm prospective study <50 patients
Tsang RK and Chung JCK (2020) Adapting electromagnetic navigation system for transoral robotic-assisted skull base surgery. Laryngoscope 130(8): 1922-1925	Ineligible study design
Tschann P, Szeverinski P, Weigl MP, et al. (2022) Short- and long-term outcome of laparoscopic- versus robotic-assisted right colectomy: a systematic review and meta-analysis. Journal of Clinical Medicine 11(9): 13	Systematic review for reference checking
Ueda K, Umehara T, Maeda K, et al. (2021) Three-incision robotic major lung resection for cancer. Translational Cancer Research 10(11): 4617-4623	Retrospective study

Reference	Exclusion reason
Uniklinikum DresdenAbteilung für Viszeral- T-uG. *Surgical tissue handling following virtual reality simulator training and real box training in robotic surgery: a randomized prospective trial*. Identifier: DRKS00025312. In: German Clinical Trials Register [internet]. Freiburg: Institute for Medical Biometry and Statistics - University of Freiburg: 2023. Available from https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00025312	Trial registry record
Van Abel KM, Yin LX, Price DL, et al. (2020) One-year outcomes for da Vinci single port robot for transoral robotic surgery. Head and Neck 42(8): 2077-2087	Retrospective study
van der Schans EM, Hiep MAJ, Consten ECJ and Broeders IAMJ (2020) From Da Vinci Si to Da Vinci Xi: realistic times in draping and docking the robot. Journal of Robotic Surgery 14(6): 835-839	Ineligible outcomes
van der Sluis PC, Tagkalos E, Hadzijusufovic E, et al. (2021) Robot-assisted minimally invasive esophagectomy with intrathoracic anastomosis (Ivor Lewis): promising results in 100 consecutive patients (the European experience). Journal of Gastrointestinal Surgery 25(1): 1-8	Ineligible intervention
Vinit N, Vatta F, Broch A, et al. (2023) Adverse events and morbidity in a multidisciplinary pediatric robotic surgery program. A prospective, observational study. Annals of Surgery 278(5): e932-e938	Paediatric population
Wang P, Fu YH, Qi HF, et al. (2024) Evaluation of the efficacy and safety of robot-assisted and video assisted thoracic surgery for early non-small cell lung cancer: A meta-analysis. Technol Health Care 32(2): 511-523	Systematic review for reference checking
Watanabe H, Motoyama D, Sato R, et al. (2021) Health-related quality of life in patients with small renal mass who underwent robot-assisted partial nephrectomy: a prospective evaluation. Journal of Endourology 35(11): 1644-1649	Ineligible patient population
Wehrmann S, Tischendorf K, Mehlhorn T, et al. (2023) Clinical implementation of the Versius robotic surgical system in visceral surgery-a single centre experience and review of the first 175 patients. Surgical Endoscopy 37(1): 528-534	Retrospective study
Wile RK, Brian R, Rodriguez N, et al. (2023) Home practice for robotic surgery: a randomized controlled trial of a low-cost simulation model. Journal of Robotic Surgery 17(5): 2527-2536	Ineligible outcomes

Reference	Exclusion reason
Winder A, Strauss DC, Jones RL, et al. (2020) Robotic surgery for gastric gastrointestinal stromal tumors: A single center case series. Journal of Surgical Oncology 122(4): 691-698	Single arm prospective study <50 patients
Wu H, Guo R and Li H (2023) Short-term and long-term efficacy in robot-assisted treatment for mid and low rectal cancer: a systematic review and meta-analysis. International Journal of Colorectal Disease 39(1): 7	Systematic review for reference checking
Würnschimmel C, Di Pierro GB, Moschini M, et al. (2020) Robot-assisted laparoscopic partial nephrectomy Vs conventional laparoscopic partial nephrectomy: functional and surgical outcomes of a prospective single surgeon randomized study. Journal of Endourology 34(8): 847-855	Robot model not specified
Xie J, Yang J, Wang M, et al. (2024) Robotic distal gastrectomy using a novel pre-emptive supra-pancreatic approach without duodenal transection in the dissection of D2 lymph nodes for gastric cancer. Frontiers In Oncology 14: 1388626	Retrospective study
Xue R and Liu R (2022) Statistical analysis of da Vinci procedure volumes of 2021 in mainland China. Intelligent Surgery 4: 18-22	Ineligible study design
Yamada S, Koga H, Seo S, et al. (2023) Comparison of robotic assistance and laparoscopy for pediatric choledochal cyst: advantages of robotic assistance. Pediatric Surgery International 40(1): 1	Paediatric population
Yang M-Z, Tan Z-H, Abbas AE, et al. (2023) Defining the learning curve of robotic portal segmentectomy in small pulmonary lesions: a prospective observational study. Journal of Robotic Surgery 17(4): 1477-1484	Ineligible intervention
Yoshida T, Homma S, Ichikawa N, et al. (2023) Feasibility of laparoscopic and robotic total proctocolectomy for ulcerative colitis-related colorectal cancer. Anticancer Research 43(11): 5245-5252	Retrospective study
Young E, Vissapragada R, Bulamu NB, et al. (2021) Outsourcing robotic-assisted operations to private hospitals: cost analysis of a retrospective cohort. ANZ Journal of Surgery 91(11): 2352-2359	Retrospective study
Yu DY, Chang YW, Lee HY, et al. (2021) Detailed comparison of the da Vinci Xi and S surgical systems for transaxillary thyroidectomy. Medicine 100(3): e24370	Retrospective study

Reference	Exclusion reason
Yu Y, Changyong E, Lin C, et al. (2024) Safety and learning curve analysis of robotic-assisted pancreaticoduodenectomy: experience of a single surgeon. Journal of Robotic Surgery 18(1): 92	Retrospective study
Zambonin D, Giudici F, Ficari F, et al. (2020) Preliminary study of short- and long-term outcome and quality of life after minimally invasive surgery for Crohn's disease: comparison between single incision, robotic-assisted and conventional laparoscopy. Journal of Minimal Access Surgery 16(4): 364-371	Robot model not specified
Zhang C, Wei M-H, Cao L, et al. (2022) Performing robot-assisted pylorus and vagus nerve-preserving gastrectomy for early gastric cancer: A case series of initial experience. World Journal of Gastrointestinal Surgery 14(10): 1107-1119	Single arm prospective study <50 patients
Zhang J, Li Y, Chen X and Wang J (2023) Robot-assisted pericystectomy using Da Vinci Xi surgical system with indocyanine green fluorescence imaging for hepatic cystic echinococcosis. Asian Journal of Surgery 46(1): 417-423	Retrospective study
Zheng J, Li X, Wei J, et al. (2018) Short-term quality of life outcomes after robotic versus laparoscopic sphincter preserving resections for rectal cancer. International Journal of Clinical and Experimental Medicine 11(12): 13297-13307	Robot model not specified
Zirafa CC, Davini F, Romano G and Melfi F (2017) Robotic lobectomy: left Llwer lobectomy by surgery. Operative Techniques in Thoracic and Cardiovascular Surgery 22(1): 43-57	Ineligible study design

Appendix C – Clinical outcomes

Table C:1 Primary outcomes (patient level)

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Da Vinci Xi								
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	**Da Vinci Xi:** 0 (0) **MIS:** 8 (12.5) p=0.052	NR	**Da Vinci Xi:** 8 (4 to 23) **MIS:** 6 (5 to 34) p=0.84	NR	NR	**Total score:** **Da Vinci Xi**: 6 (20.0) **MIS:** 21 (32.8) **Da Vinci Xi:** 1-2: 2 (6.7) 3a: 4 (13.4) 3b: 0 (0) 4: 0 (0)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
							5: 0 (0) **MIS:** 1-2: 14 (21.9) 3a: (1.6) 3b: 4 (6.3) 4: 0 (0) 5: 2 (3.1) p=0.23	
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain	Da Vinci Xi (n=22) MIS (n=35)	**Da Vinci Xi:** 3 (13.6) **MIS:** 4 (11.4)	0 (0)	**Median hospital stay days (IQR)**	NR	NR	**Grade ≥III:** **Da Vinci**: 2 (8.7) **MIS:** 2 (6.4)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Setting: Mutua de Terrassa University Hospital and Germans Trias i Pujol University hospital **Indication:** Pancreatic disease, pancreatectomy		p=0.85		**Da Vinci Xi:** 5.6 (5-22) **MIS:** 6 (5-34) p=ns			p=0.66	
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location**: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer,	Da Vinci Xi (n=29) Open surgery (n=58)	**Da Vinci Xi:** 1 (3.4*) **Open surgery**: NR	NR	**Median LOS in days (IQR)** **Da Vinci:** 3.0 (2.0–4.0) **Open surgery:**	NR	NR	**Clavien-Dindo 3** **Da Vinci Xi**: 4 (13.8*) **Open surgery**: 9 (15.5*)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
retroperitoneal lymph node dissection				7.0 (5.0–9.0) p < 0.01			**Clavien-Dindo 4** **Da Vinci Xi**: 0 (0) **Open surgery**: 2 (3.4*) Clavien-Dindo 5 Da Vinci Xi: 0 (0) Open surgery: 2 (3.4*)	

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre **Indication:** Left sided colonic diverticulitis, colectomy	Da Vinci Xi (n=20) MIS (n=22)	**Da Vinci Xi:** 0 (0) **MIS:** 3 (14) p=0.233	NR	**Median (IQR)** **Da Vinci Xi:** 5 (4 to 6) **MIS:** 5 (4 to 6.3) p=0.928	NR	**Da Vinci Xi:** 6 (30) **MIS:** 6 (27.3) p=0.845	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Butnari et al 2024 (Butnari et al. 2024) **Location**: UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	**Da Vinci Xi:** 5 (5) **MIS:** 5 (4.46) OR [95% CI]: 1.1 [0.35–3.57], P >0.95	NR	**Mean (IQR) number of nights** **Da Vinci Xi**: 5 (3-8) **MIS:** 6 (4-10.3) p=0.09	NR	NR	**Clavien-Dindo 3–4** **Da Vinci Xi**: 13(13) **MIS:** 9(8.03) OR [95% CI]: 1.7 [0.6–4.0], P = 0.2	NR
Di Franco et al 2022 (Di Franco et al. 2022)	Da Vinci Xi (n=20)	**Da Vinci Xi**: 0 (0)	0 (0)	**Median (IQR)**	**Da Vinci:** 10 (50)	**Da Vinci:** 8* (37.5) **Open surgery:**	**Grade ≥III:** **Da Vinci:** 2 (10.0)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Location: Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery) **Indication:** Pancreatic disease, pancreatoduodenectomy	Open surgery (n=40)	**Open surgery**: NR		**Da Vinci:** 10 (7.5 to 18) **Open surgery:** 16 (13 to 24.5) p=0.001	**Open surgery:** 25 (62.5) p=0.355	20* (50) p=0.355	**Open surgery:** 4 (10.0) p=1.000	
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital	Da Vinci Xi (n=7) MIS (n=15)	**Da Vinci Xi:** 0 (0) **MIS**: 0 (0)	0 (0)	**Da Vinci:** 7 (6 to 11) Mean (SD): 7.71 (1.79) **MIS:** 8 (6 to 10)	**Perioperative** **Da Vinci Xi**: 1* (14.3*) **MIS:** 1* (6.7*)	NR	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Indication: Colorectal cancer, hemicolectomy				Mean (SD): 7.67 (1.23) p=0.857				
Galata 2019 (Galata et al. 2019) **Location:** Germany **Setting:** University hospital	Da Vinci Xi (n=18) MIS (n=33)	**Da Vinci Xi:** 4 (22.2*) **MIS:** 0 (0) p=0.012	NR	**Mean (SD) (range)** **Da Vinci:** 12.6 (10.6) (6 to 49) **MIS:** 13.2 (7.5) (7 to 32) p=0.319	**Perioperative** **Da Vinci Xi**: 6 (33.3*) **MIS:** 12 (36.4*) p=1.000	NR	**Grade 0 to II:** **Da Vinci:** 15* (83.3*) **MIS**: 26* (78.8*) **Grade ≥III:** **Da Vinci:** 3* (16.7*) MIS:	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Indication: Rectal adenocarcinoma, anterior resection							7* (21.2*) p=1.000	
Gitas et al 2022 (Gitas et al. 2022) **Location**: Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	Da Vinci Xi (n=42) MIS (n=97)	NR	NR	NR	**Da Vinci**: 1 (2.4) **MIS:** 1 (1) p=0.515	**Da Vinci**: 1 (2.4) **MIS:** 3 (3.1) p=0.307	**Grade IIIa:** **Da Vinci**: 3 (7.1) **MIS:** 7 (7.2) p=0.647	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Ozben 2019 (Ozben et al. 2019) **Location**: Turkey **Setting:** Two specialised centres **Indication:** Colorectal indications, Colectomy	Da Vinci Xi (n=26) MIS (n=56)	**Da Vinci Xi:** 0 (0) **MIS:** 8 (14.3) p=0.051	0 (0)	**Mean (SD)** **Da Vinci:** 7.9 (5.7) **MIS:** 9.5 (6.0) p=0.08	**Da Vinci Xi:** 0 (0) **MIS:** 4 (7.1) p=0.30	**Cardiac complications** **Da Vinci Xi:** 1 (3.8) **MIS:** 2 (3.6) p>0.99 **Pulmonary complications:** **Da Vinci Xi**: 2 (7.7) **MIS:** 4 (7.1) p>0.99	**Grade I to II:** **Da Vinci**: 6* (23*) **MIS:** 18* (32.1*) **Grade ≥III:** **Da Vinci:** 3* (11.3*) **MIS:** 7* (12.5*) p=0.90	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
						No overall complications reported		
Muysoms et al 2018 (Muysoms et al. 2018) **Location:** Belgium **Setting:** Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair	Da Vinci Xi (n=49) MIS (n=64)	No Conversions to open	0 (0)	NR	No intraoperative complications	**Da Vinci Xi unilateral**: 9% (3/34) **Da Vinci Xi bilateral:** 13% (2/15) **MIS unilateral: 9%** (2/22) p=0.27 **MIS bilateral:** **Tertile** 1: 15% (2/13)	NR	**EuraHS QoL score, median (IQR):** **1-month postoperative** **Da Vinci Xi:** 4 (1–12) **MIS:** 6 (3–14) p=0.344

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
						Tertile 2: 0% (0/13) **Tertile 3**: 7% (1/15) p=0.54		
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting**: NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	4 patients were excluded prior to analysis due to conversion to open surgery	NR	**Median LoS (min – max)** **RRC-IA:** 4 (2-17) **LRC-EA:** 4 (2-16) **RRC-EA:** 5 (3-7) p=ns	NR	**In hospital surgical complications :** Bleeding **RRC-IA**: 1 (2.9*) Bowel paralysis/ileus **RRC-IA:** 5 (14.3*) **LRC-EA:** 1 (2.5*)	‘**Other’ complication Calvien-Dindo ⩾3** **RRC-IA:** 1 (2.9*) **LRC-EA:** 2 (5*) ‘Surgical’ complication	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
						Wound abscess **LRC-EA:** 1 (2.5*) Anastomotic leakage **RRC-IA:** 1 (2.9*) **LRC-EA**: 1 (2.5*)	Calvien-Dindo ⩾3 **LRC-EA:** 1 (2.5*)	
Schmelzle 2022** (Schmelzle et al. 2022) **Location**: Germany	Da Vinci Xi (n=129)	**Da Vinci (to open or MIS, not reported separately) :** 7 (5)	NR	**Da Vinci**: 8 (4 to 94) **MIS matched**	NR	NR	**90 day complications** **Da Vinci** None: 80 (62)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Setting: University hospital **Indication:** Liver indications, liver resection	MIS (n=471; matched: n =129)	**MIS matched population** (to open surgery): 6 (5) p=1.000 (vs. Da Vinci) **MIS unmatched population** (to open surgery): 16 (3)		**population**: 8 (3 to 52) p=0.816 (vs. Da Vinci) **MIS unmatched population**: 8 (3 to 59) p=0.471 (vs. Da Vinci)			1 to 2: 19 (15) 3 to 5: 30 (23) **MIS matched population** None: 83 (64) 1 to 2: 22 (17) 3 to 5: 24 (19) p=0.625 (vs. Da Vinci) **MIS unmatched population** None: 296 (63)	

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
		p=0.302 (vs. Da Vinci)					1 to 2: 103 (22) 3 to 5: 72 (15) p=0.042	
Da Vinci SP								
Lee et al 2023 (Lee and Hong 2023) **Location:** Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NR	NR	**Mean hospital stay in days (± SD)** **Da Vinci SP:** 3.94 ± 0.68 **MIS:** 3.71 ± 1.07	**Da Vinci SP:** 1 (3.2) **MIS:** 1 (2.1) p=1.00	**Da Vinci SP:** 1 (3.2) **MIS:** 0 (0.0) p=0.39	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
				p=0.3				
Hugo								
Prata et al 2024 (Prata et al. 2024) **Location**: Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	Hugo (n=27) MIS (n=62)	**Hugo**: 0 (0) **MIS:** 0 (0)	No conversions	**Median (IQR)** **Hugo:** 3 (3 to 4) **MIS:** 5 (4 to 5) p=0.002	Perioperative: **Hugo:** 3 (11.1) **MIS:** 6 (9.7) p=0.07	NR	NR	NR
Senhance								
Aggarwal 2020 (Aggarwal et al. 2020)	Senhance (n=20)	No conversions	1* (5)	**Senhance**: All cases	**Senhance:** 1(5)	**Senhance:** 5(25)	**Clavien-Dino 1:**	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Location: UK **Setting:** St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy	MIS (n=20)	to open surgery		were discharged on the day of surgery except one patient who stayed in hospital overnight due to acute urinary retention **MIS:** All patients were discharged	**MIS:** 0(0) 95% CI, Senhance – MIS:5.0% (−27.7 to 37.0)	**MIS**: 5(25) 95% CI, Senhance – MIS: 0.0% (−32.4 to 32.4)	Senhance: 3(15) MIS: 1(5) 95% CI, Senhance – MIS: 10.0% (−23.0 to 41.5) **Clavien-Dino 2:** Senhance: 3(15) MIS: 3(15)	

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
				on the day of surgery			95% CI, Senhance – MIS: 0.0% (−32.4 to 32.4) **Clavien-Dino 3b:** Senhance: 0(0) MIS: 1(5) 95% CI, Senhance – MIS: −5.0% (−37.0 to 27.7)	

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication	Senhance (n=20) MIS (n=20)	**Senhance**: 0 (0) **MIS**: 2 (10) p=0.5	2 (10)	Mean (SD) Senhance: 3.3 (2) **MIS:** 5.9 (7.5) p=0.154	**Perioperative:** **Senhance:** 2 (10) **MIS:** 3 (15) p=1.000	**Senhance:** 1 (5) **MIS:** 3 (15) p=0.625	**Clavien-Dindo classification:** **I-II:** Senhance: 1* (5*) MIS: 3* (15*) **≥III:** Senhance: 2* (10*) MIS: 3* (15*)	NR
Samalavicius et al 2022 (Samalavicius et al. 2022)	Senhance (n=20)	**Senhance**: 0 (0) **MIS:** 0 (0)	0 (0)	**Mean (SD)** **Senhance:** 1.5 (1.1)	No significant intraoperative complications	**Senhance:** 1 (5) **MIS:** 0 (0)	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Location: Lithuania **Setting:** University hospital **Indication:** cholelithiasis, Cholecystectomy	MIS (n=20)			**MIS:** 1.55 (0.6) p=0.855	p=ns	p=0.69		
Versius								
Dixon et al 2024 (Dixon et al. 2024) **Location:** UK **Setting:** NR	Versius (n=40) MIS (n=20)	No conversions from planned modality	No conversions from planned modality	**Median (IQR)** **Versius:** 6 (2) **MIS:** 6 (3) p=0.79	**During primary admission** Versius: 6 (15) MIS: 2 (10) p=0.59	**Post-discharge (<30 days)** Versius: 7 (17.5) MIS: 6 (30) P=0.27	**During primary admission:** **Grade 1** Versius: 2(5) MIS: 0(0)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Indication: Colorectal indications, Major colorectal resection							**Grade 2** Versius: 4(10) MIS: 1(5) **Grade 3a** Versius: 0 MIS: 0 **Grade 3b** Versius: 0 MIS: 0 **Grade 4a** Versius: 0 MIS: 1(5)	

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
							Post-discharge: **Grade ≥3a:** Versius: 1 (2.5) MIS: 0 (0)	
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location:** India **Setting:** Hospital and research centre **Indication:** Inguinal hernia, totally	Versius (n=44) MIS (n=44)	**Versius:** 0 (0) **MIS:** 0 (0)	0 (0)	All patients were discharged on post-operative day 1	NR	**Versius:** 1 (2.3*) **MIS:** 1 (2.3*)	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with MIS techniques) N (%)	Conversion to conventional MIS from RAS N (%)	Length of hospital stay Median (range) days	Complications			HRQoL Score n (%)
					Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
extraperitoneal hernia repair								

Key: CI – Confidence interval, HRQoL – Health related quality of life, IQR – Interquartile range, LRC-EA - laparoscopic operation with extracorporeal anastomosis, LoS – Length of stay, MIS – Minimally invasive surgery, NR – Not reported, OR – Odds ratio, RAS – Robot-assisted surgery, RRC-EA - robotic operations with extracorporeal anastomosis, RRC-IA - robotic operation with intracorporal anastomosis, SP – Single port.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*calculated by reviewer

**for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:2 Primary outcomes (surgeon level)

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Da Vinci XI		
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NR
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location:** Spain **Setting:** Mutua de Terrassa University Hospital and Germans Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy	Da Vinci Xi (n=22) MIS (n=35)	NR
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022)	Da Vinci Xi (n=29)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Location: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Open surgery (n=58)	
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre **Indication:** Left sided colonic diverticulitis, colectomy	Da Vinci Xi (n=20) MIS (n=22)	NR
Butnari et al 2024 (Butnari et al. 2024) **Location**: UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Di Franco et al 2022 (Di Franco et al. 2022) **Location**: Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery) **Indication:** Pancreatic disease, pancreatoduodenectomy	Da Vinci Xi (n=20) Open surgery (n=40)	NR
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital **Indication:** Colorectal cancer, hemicolectomy	Da Vinci Xi (n=7) MIS (n=15)	NR
Galata et al 2019 (Galata et al. 2019) **Location:** Germany	Da Vinci Xi (n=18) MIS (n=33)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Setting: University hospital **Indication:** Rectal adenocarcinoma, anterior resection		
Gitas et al 2022 (Gitas et al. 2022) **Location**: Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	Da Vinci Xi (n=42) MIS (n=97)	NR
Ozben 2019 (Ozben et al. 2019) **Location:** Turkey **Setting:** Two specialised centres **Indication:** Colorectal indications, Colectomy	Da Vinci Xi (n=26) MIS (n=56)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Muysoms et al 2018 (Muysoms et al. 2018) **Location**: Belgium **Setting:** Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair	Da Vinci Xi (n=49) MIS (n=64)	NR
Rattenborg 2021 (Rattenborg et al. 2021) **Location**: Denmark Setting: NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	NR
Schmelzle 2022* (Schmelzle et al. 2022) **Location**: Germany **Setting:** University hospital **Indication:** Liver indications, liver resection	Da Vinci Xi (n=129) MIS (n=471; matched: n =129)	NR
Da Vinci SP		

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Lee et al 2023 (Lee and Hong 2023) **Location:** Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NR
Hugo		
Prata et al 2024 (Prata et al. 2024) **Location**: Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	Hugo (n=27) MIS (n=62)	NR
Senhance		
Aggarwal 2020 (Aggarwal et al. 2020) **Location**: UK	Senhance (n=20) MIS (n=20)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Setting: St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy		
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication	Senhance (n=20) MIS (n=20)	NR
Samalavicius et al 2022 (Samalavicius et al. 2022) Location: Lithuania **Setting:** University hospital	Senhance (n=20) MIS (n=20)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Indication: cholelithiasis, Cholecystectomy		
Versius		
Dixon et al 2024 (Dixon et al. 2024) **Location:** UK **Setting**: NR **Indication:** Colorectal indications, Major colorectal resection	Versius (n=40) MIS (n=20)	**Operative REBA (Median (IQR))** **Versius**: 3 (1) **MIS:** 5 (0) p<0.001 **Total modified NASA-TLX, mean±SD** **Versius:** 32.4 ± 10.3 **MIS:** 45.6 ± 14.3 p<0.001
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location:** India	Versius (n=44) MIS (n=44)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Setting: Hospital and research centre **Indication:** Inguinal hernia, totally extraperitoneal hernia repair		

Key: IQR – Interquartile range, MIS – Minimally invasive surgery, NASA-LTX – NASA Task Load Index, NR – Not reported, REBA - Rapid Entire Body Assessment, SD – Standard deviation, SP – Single port, SURG-TLX – Surgery task load index.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:3 Primary outcomes (organisation level)

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Da Vinci Xi				
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NR	NR	NR
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain **Setting:** Mutua de Terrassa University Hospital and Germans	Da Vinci Xi (n=22) MIS (n=35)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy				
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location**: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Da Vinci Xi (n=29) Open surgery (n=58)	NR	NR	NR
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre	Da Vinci Xi (n=20) MIS (n=22)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Left sided colonic diverticulitis, colectomy				
Butnari et al 2024 (Butnari et al. 2024) **Location:** UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	NR	NR	NR
Di Franco et al 2022 (Di Franco et al. 2022) **Location:** Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery)	Da Vinci Xi (n=20) Open surgery (n=40)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Pancreatic disease, pancreatoduodenectomy				
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital **Indication:** Colorectal cancer, hemicolectomy	Da Vinci Xi (n=7) MIS (n=15)	NR	NR	NR
Galata et al 2019 (Galata et al. 2019) **Location**: Germany **Setting:** University hospital	Da Vinci Xi (n=18) MIS (n=33)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Rectal adenocarcinoma, anterior resection				
Gitas et al 2022 (Gitas et al. 2022) **Location**: Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	Da Vinci Xi (n=42) MIS (n=97)	NR	NR	NR
Ozben 2019 (Ozben et al. 2019) **Location**: Turkey **Setting:** Two specialised centres	Da Vinci Xi (n=26) MIS (n=56)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Colorectal indications, Colectomy				
Muysoms et al 2018 (Muysoms et al. 2018) **Location**: Belgium **Setting:** Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair	Da Vinci Xi (n=49) MIS (n=64)	NR	NR	NR
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting:** NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Schmelzle 2022* (Schmelzle et al. 2022) **Location:** Germany **Setting:** University hospital **Indication:** Liver indications, liver resection	Da Vinci Xi (n=129) MIS (n=471; matched: n =129)	NR	NR	NR
Da Vinci SP				
Lee et al 2023 (Lee and Hong 2023) **Location:** Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Hugo				
Prata et al 2024 (Prata et al. 2024) **Location**: Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	Hugo (n=27) MIS (n=62)	NR	NR	NR
Senhance				
Aggarwal 2020 (Aggarwal et al. 2020) **Location:** UK **Setting:** St Mary's Hospital, Imperial Collage, London	Senhance (n=20) MIS (n=20)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Cholelithiasis, cholecystectomy				
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication	Senhance (n=20) MIS (n=20)	NR	NR	NR
Samalavicius et al 2022	Senhance (n=20)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
(Samalavicius et al. 2022) Location: Lithuania **Setting:** University hospital **Indication:** cholelithiasis, Cholecystectomy	MIS (n=20)			
Versius				
Dixon et al 2024 (Dixon et al. 2024) Location: UK Setting: NR	Versius (n=40) MIS (n=20)	NR	NR	NR

Study name and location	Technology name and number of patients	Rate of MIS compared with open surgery after RAS was introduced N (%)	Volume of procedures	Hospital capacity and wait-list reduction
Indication: Colorectal indications, Major colorectal resection				
Kakkilaya et al 2023 (Kakkilaya et al. 2023) Location: India **Setting:** Hospital and research centre **Indication:** Inguinal hernia, totally extraperitoneal hernia repair	Versius (n=44) MIS (n=44)	NR	NR	NR

Key:, NR – Not reported,.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:4 Secondary outcomes (patient level)

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Da Vinci Xi					
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NR	NR	NR	NR
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain **Setting:** Mutua de Terrassa University Hospital and Germans	Da Vinci Xi (n=22) MIS (n=35)	NR	NR	NR	**Da Vinci:** 1 (4.3) **MIS:** 1 (3.2)

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy					
Bergdahl et al 2022 (Grenabo Bergdahl et al. 2022) **Location**: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Da Vinci Xi (n=29) Open surgery (n=58)	NR	NR	NR	**Da Vinci XI:** 2 (6.9*) patients were reoperated on after healing for surgical complications
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey	Da Vinci Xi (n=20) MIS (n=22)	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Setting: Tertiary care centre **Indication:** Left sided colonic diverticulitis, colectomy					
Butnari et al 2024 (Butnari et al. 2024) **Location:** UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	NR	NR	NR	**Reoperation needed:** **Da Vinci:** 9 (9) **MIS:** 7(6.25) p=0.6
Di Franco et al 2022 (Di Franco et al. 2022) **Location**: Italy **Setting:** Center for Robotic surgery (Da	Da Vinci Xi (n=20) Open surgery (n=40)	NR	NR	NR	**Reoperation needed:** **Da Vinci:** 0 (0) **Open surgery:** 2 (5) p=0.309

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Vinci); tertiary care center (open surgery) **Indication:** Pancreatic disease, pancreatoduodenectomy					
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital **Indication:** Colorectal cancer, hemicolectomy	Da Vinci Xi (n=7) MIS (n=15)	NR	NR	NR	NR
Galata et al 2019 (Galata et al. 2019) **Location:** Germany	Da Vinci Xi (n=18) MIS (n=33)	NR	**VAS 1 to 10 mean (SD):** **Da Vinci:** 1.1 (0.7) **MIS:** 1.1 (1.1) p=0.657	NR	**Reoperation needed:** **Da Vinci:** 1 (5.6*) **MIS:** 3 (9.1*) p=1.000

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Setting: University hospital **Indication:** Rectal adenocarcinoma, anterior resection					
Gitas et al 2022 (Gitas et al. 2022) **Location**: Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	Da Vinci Xi (n=42) MIS (n=97)	NR	**Pain score** [1=very little pain; 10 = very severe pain]: **1 week:** Da Vinci (n=41): ≤5: 31 (75.6)* >5: 10 (24.4)* MIS (n=92): ≤5: 64 (69.6)*	**Satisfied with cosmetic outcome:** **Da Vinci**: 40 (95.2) **MIS:** 90 (92.8) p=0.723 Benign indications only: p=0.548 Early endometrial cancer:	**Reoperation needed:** **Da Vinci**: 3 (7.1) **MIS:** 8 (8.2) p=0.563

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
			>5: 28 (30.4)* p=0.866 **1 month** Da Vinci (n=42): ≤5: 40 (95.2)* >5: 2 (4.8)* MIS (n=88): ≤5: 82 (93.2)* >5: 6 (6.8)* p=0.580 **Difference in postoperative pain (1 week):** **In benign indications:** p=0.628	p=0.677 **Satisfied with preoperative explanation:** **Da Vinci**: 35 (85.4) **MIS:** 89 (92.7) p=0.208 Benign indications only: p=0.081 Early endometrial cancer: p=0.452 **Reasons for dissatisfaction (Da Vinci, MIS):** **Insufficient explanation of technology:** 4, 1 Postoperative pain: 1, 2	

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
			In early endometrial cancer p=0.543 **Difference in postoperative pain (1 month):** In benign indications: p=0.630 In early endometrial cancer p=0.382	Complications: 1, 2 Mental reasons: 2, 2 **Positive experiences after Da Vinci:** Smaller scars: 4 Faster healing: 4 Less pain: 3 Short hospital stay: 1 Mental reasons:6 Multiple reasons: 12 **Negative experiences after Da Vinci:** More pain: 1	
Muysoms et al 2018 (Muysoms et al. 2018) **Location**: Belgium	Da Vinci Xi (n=49) MIS (n=64)	NR	**Pain domain of the EuraHS QoL score** **Preoperative:** Median (IQR)	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Setting: Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair			**Da Vinci Xi**: 7 (4-13) **MIS:** 4 (2-9) p=0.040 **1 month postoperative: Median (IQR)** **Da Vinci Xi:** 1 (0-3) **MIS:** 2 (0-5) p=0.288		
Ozben 2019 (Ozben et al. 2019) **Location**: Turkey **Setting:** Two specialised centres **Indication:** Colorectal indications, Colectomy	Da Vinci Xi (n=26) MIS (n=56)	NR	NR	NR	**Reoperation needed:** **Da Vinci:** 2 (7.7) **MIS:** 7 (12.5) p=0.71

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting**: NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	NR	**Post operative day 2:** **Median VAS score:** **RRC-IA**: 2 **LRC-EA**: 2 **RRC-EA**: 2 **Additional paracetamol** Total: 78/85 (89%) RRC-IA: 90% LRC-EA: 89% RRC-EA: 90% Not significant **Additional NSAID:** LRC-EA: 2 **Additional gabapentin** **Total**: 59/89 (66%)	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
			RRC-IA: 88% **LRC-EA:** 56% **RRC-EA:** 52% p=0.0006 **Additional opioids (morphine, oxycodone, tramadol, codeine)** **Total**: 33/86 (38%) **RRC-IA**: 29% **LRC-EA:** 43% **RRC-EA**: 45% Not significant		
Schmelzle 2022** (Schmelzle et al. 2022) **Location**: Germany	Da Vinci Xi (n=129)	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Setting: University hospital **Indication:** Liver indications, liver resection	MIS (n=471; matched: n =129)				
Da Vinci SP					
Lee et al 2023 (Lee and Hong 2023) **Location**: Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NR	NR	NR	NR
Hugo					
Prata et al 2024 (Prata et al. 2024) **Location:** Italy	Hugo (n=27) MIS (n=62)	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Setting: University hospital **Indication:** Renal tumours, partial nephrectomy					
Senhance					
Aggarwal 2020 (Aggarwal et al. 2020) **Location:** UK **Setting:** St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy	Senhance (n=20) MIS (n=20)	NR	**Senhance:** 1(5) **MIS:** 1(5) Difference (95% CI) (Senhance − MIS) 0.0% (−32.4 to 32.4)	NR	NR
Killaars et al 2024 (Killaars et al. 2024)	Senhance (n=20) MIS (n=20)	NR	NR	NR	**Reintervention:** **Senhance:** 2 (10) **MIS:** 3 (15)

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Location: The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication					p=1.000
Samalavicius et al 2022 (Samalavicius et al. 2022) **Location:** Lithuania **Setting:** University hospital	Senhance (n=20) MIS (n=20)	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Indication: cholelithiasis, Cholecystectomy					
Versius					
Dixon et al 2024 (Dixon et al. 2024) **Location:** UK **Setting:** NR **Indication**: Colorectal indications, Major colorectal resection	Versius (n=40) MIS (n=20)	NR	**Day 1 (Median (IQR))** **Versius:** 0 (4) **MIS:** 0 (4) p=0.83 **Day 2 (Median (IQR))** **Versius**: 0 (4) **MIS:** 0 (3) p=0.79	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
			Day 3 (Median (IQR)) **Versius**: 0 (2) **MIS:** 0 (0) p=0.34 **Day 28 (Median (IQR))** Versius: 1 (2) **MIS:** 0.5 (2) p=0.62		
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location**: India **Setting:** Hospital and research centre **Indication:** Inguinal hernia, totally	Versius (n=44) MIS (n=44)	NR	VAS 1 to 10 mean (range): Postoperative day 1: **Versius:** 1.43 (0 to 4) **MIS:** 2.06 (0 to 6) p=0.023 **Postoperative week 1:**	NR	NR

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
extraperitoneal hernia repair			No significant difference between groups in pain **Postoperative month 1:** No significant difference between groups in pain		

Key: IQR – Interquartile range, LRC-EA - laparoscopic operation with extracorporeal anastomosis, MIS – Minimally invasive surgery, NR – Not reported, NSAID – Non-steroidal anti-inflammatory drug, RRC-EA - robotic operations with extracorporeal anastomosis, RRC-IA - robotic operation with intracorporal anastomosis, SP – Single port, VAS – Visual analogue scale.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*calculated by reviewer

**for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:5 Secondary outcomes (patient level) – specific study types

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Da Vinci Xi					
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NA	**Mortality at 30 days:** **Da Vinci Xi:** 0 (0) **MIS:** 2 (3.2) p=0.22	NR	NA
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain	Da Vinci Xi (n=22) MIS (n=35)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Setting: Mutua de Terrassa University Hospital and Germans Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy					
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location**: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Da Vinci Xi (n=29) Open surgery (n=58)	**Estimated blood loss (ml):** **Da Vinci Xi:** **Median (IQR):** 50 (25–150) **Open surgery:** Median (IQR): 400 (300–1000) p < 0.01	NR	2 patients received adjuvant chemotherapy in the Da Vinci Xi arm	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre **Indication:** Left sided colonic diverticulitis, colectomy	Da Vinci Xi (n=20) MIS (n=22)	NA	NA	NA	NA
Butnari et al 2024 (Butnari et al. 2024) **Location**: UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	NA	**Mortality at 90 days:** **Da Vinci:** 2 (2) **MIS:** 3 (2.67) p>0.95	NR	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Di Franco et al 2022 (Di Franco et al. 2022) **Location:** Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery) **Indication:** Pancreatic disease, pancreatoduodenectomy	Da Vinci Xi (n=20) Open surgery (n=40)	NR	NA	NA	NA
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location**: Italy **Setting**: University hospital	Da Vinci Xi (n=7) MIS (n=15)	NA	**Mortality within 30 days:** **Da Vinci:** 0 (0) **MIS:** 0 (0)	NR	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Indication: Colorectal cancer, hemicolectomy					
Galata et al 2019 (Galata et al. 2019) **Location:** Germany **Setting:** University hospital **Indication:** Rectal adenocarcinoma, anterior resection	Da Vinci Xi (n=18) MIS (n=33)	NA	NR	NR	NA
Gitas et al 2022 (Gitas et al. 2022)	Da Vinci Xi (n=42)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	MIS (n=97)				
Muysoms et al 2018 (Muysoms et al. 2018) **Location:** Belgium **Setting:** Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair	Da Vinci Xi (n=49) MIS (n=64)	NA	NA	NA	NA
Ozben 2019 (Ozben et al. 2019)	Da Vinci Xi (n=26)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: Turkey **Setting:** Two specialised centres **Indication:** Colorectal indications, Colectomy	MIS (n=56)				
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting:** NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	NA	NR	NR	NA
Schmelzle 2022** (Schmelzle et al. 2022) **Location**: Germany	Da Vinci Xi (n=129)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Setting: University hospital **Indication:** Liver indications, liver resection	MIS (n=471; matched: n =129)				
Da Vinci SP					
Lee et al 2023 (Lee and Hong 2023) **Location**: Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NA	NA	NA	NA
Hugo					
Prata et al 2024 (Prata et al. 2024)	Hugo (n=27)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	MIS (n=62)				
Senhance					
Aggarwal 2020 (Aggarwal et al. 2020) **Location:** UK **Setting:** St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy	Senhance (n=20) MIS (n=20)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication	Senhance (n=20) MIS (n=20)	NA	NA	NA	NA
Samalavicius et al 2022 (Samalavicius et al. 2022)	Senhance (n=20)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: Lithuania **Setting:** University hospital **Indication:** cholelithiasis, Cholecystectomy	MIS (n=20)				
Versius					
Dixon et al 2024 (Dixon et al. 2024) **Location:** UK **Setting:** NR	Versius (n=40) MIS (n=20)	NA	NA	NA	NA

Study name and location	Technology name and number of patients	Compared with open surgery	For cancer studies		For head and neck studies
		Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Indication: Colorectal indications, Major colorectal resection					
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location:** India **Setting:** Hospital and research centre **Indication:** Inguinal hernia, totally extraperitoneal hernia repair	Versius (n=44) MIS (n=44)	NA	NA	NA	NA

Key: IQR – Interquartile range, LoS – Length of stay, , , SD – Standard deviations, SP – Single port.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*calculated by reviewer

**for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:6 Secondary outcomes (surgeon level)

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Da Vinci Xi				
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NR	NR	NR
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain **Setting:** Mutua de Terrassa University Hospital and Germans	Da Vinci Xi (n=22) MIS (n=35)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy				
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location:** Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Da Vinci Xi (n=29) Open surgery (n=58)	NR	NR	NR
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre	Da Vinci Xi (n=20) MIS (n=22)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: Left sided colonic diverticulitis, colectomy				
Butnari et al 2024 (Butnari et al. 2024) **Location:** UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	NR	NR	NR
Di Franco et al 2022 (Di Franco et al. 2022) **Location:** Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery)	Da Vinci Xi (n=20) Open surgery (n=40)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: Pancreatic disease, pancreatoduodenectomy				
Di Lascia et al 2020 (Di Lascia et al. 2020) **Location:** Italy **Setting**: University hospital **Indication:** Colorectal cancer, hemicolectomy	Da Vinci Xi (n=7) MIS (n=15)	NR	NR	**Mean duration of surgery** (first 3 robotic surgeries vs. last 3 robotic surgeries): p=0.009 **Mean duration of total operative time** (first 3 robotic surgeries vs. last 3 robotic surgeries): p=0.033
Galata et al 2019 (Galata et al. 2019) **Location:** Germany **Setting:** University hospital	Da Vinci Xi (n=18) MIS (n=33)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: Rectal adenocarcinoma, anterior resection				
Gitas et al 2022 (Gitas et al. 2022) **Location:** Germany **Setting:** University Hospital **Indication:** Gynaecological indications, hysterectomy	Da Vinci Xi (n=42) MIS (n=97)	NR	NR	**Included cases without follow-up (n=300)** **First 50 robotic surgeries:** 144.38 (86.57) minutes **Last 50 robotic surgeries:** 141.54 (79.4) minutes No significant difference (p=0.945)
Muysoms et al 2018 (Muysoms et al. 2018) **Location:** Belgium	Da Vinci Xi (n=49) MIS (n=64)	NR	NR	**Skin to skin operating time: Mean (SD) minutes** **Da Vinci Xi unilateral:** Tertile 1: 63 (18)

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Setting: Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair				**Tertile 2**: 57 (14) **Tertile 3**: 44 (10) **MIS unilateral:** Tertile 1: 45 (10) **Tertile 2**: 41 (11) **Tertile 3**: 49 (12) **Da Vinci bilateral:** **First half:** 90 (9) **Second half:** 68 (12) **MIS bilateral (all calculated from 0 days):** Tertile 1: 73 (16) **Tertile 2**: 68 (16) **Tertile 3**: 61 (18)

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
				Total operating room time: Mean (SD) minutes **Da Vinci Xi unilateral:** Tertile 1: 99 (19) **Tertile 2**: 99 (16) **Tertile 3**: 85 (15) **MIS unilateral:** Tertile 1: 84 (4) Tertile 2: 72 (9) **Tertile 3**: 87 (11) **Da Vinci bilateral:** First half: 123 (12) Second half: 115 (17) **MIS bilateral (all calculated from 0 days):** Tertile 1: 106 (13)

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
				Tertile 2: 103 (16) **Tertile 3**: 97 (17) **Console time: Mean (SD) minutes** **Da Vinci unilateral:** Tertile 1: 50 (8) Tertile 2: 55 (14) Tertile 3: 36 (9) **Da Vinci bilaterial:** First half: 74 (9) 2nd half: 57 (12)
Ozben 2019 (Ozben et al. 2019) **Location**: Turkey **Setting:** Two specialised centres	Da Vinci Xi (n=26) MIS (n=56)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: Colorectal indications, Colectomy				
Rattenborg 2021 (Rattenborg et al. 2021) **Location**: Denmark **Setting**: NR **Indication**: Colon cancer, right hemicolectomy	Da Vinci Xi (n=57) MIS (n=40)	NR	NR	NR
Schmelzle 2022* (Schmelzle et al. 2022) **Location**: Germany **Setting:** University hospital **Indication:** Liver indications, liver resection	Da Vinci Xi (n=129) MIS (n=471; matched: n =129)	NR	NR	NR
Da Vinci SP				
Lee et al 2023	Da Vinci SP (n=31)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
(Lee and Hong 2023) **Location**: Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	MIS (n=48)			
Hugo				
Prata et al 2024 (Prata et al. 2024) **Location:** Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	Hugo (n=27) MIS (n=62)	NR	NR	NR
S**enhance**				
Aggarwal 2020	Senhance (n=20)	NR	NR	Total operating time: Decreased over series but

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
(Aggarwal et al. 2020) **Location**: UK **Setting:** St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy	MIS (n=20)			was consistently higher for Senhance than in MIS **Mean docking time, Senhance:** First 10 cases: 13.0 (4.1) minutes Cases 11 to 20: 10.6 (1.9) minutes p=0.14 **Mean console time, Senhance:** First 10 cases: 32.8 (10.5) minutes Cases 11 to 20: 28.7 (8.7) minutes p=0.52
Killaars et al 2024 (Killaars et al. 2024)	Senhance (n=20)	NR	NR	**Senhance** **Mean (SD) operative time**

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Location: The Netherlands **Setting:** One children's hospital **Indication:** Gastroesophageal reflux disease, nissen fundoplication	MIS (n=20)			**Period 1 (case 1 to 10):** 164 (42) minutes **Period 2 (case 11 to 20**): 120 (15) minutes p=0.024
Samalavicius et al 2022 (Samalavicius et al. 2022) **Location:** Lithuania **Setting:** University hospital	Senhance (n=20) MIS (n=20)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: cholelithiasis, Cholecystectomy				
Versius				
Dixon et al 2024 (Dixon et al. 2024) **Location**: UK **Setting**: NR **Indication:** Colorectal indications, Major colorectal resection	Versius (n=40) MIS (n=20)	NR	**Total Oxford NOTECHS II (mean ± SD)** **Versius:** 72.6 ± 3.7 **MIS:** 71.6 ± 3.9 p=0.33	NR
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location:** India	Versius (n=44) MIS (n=44)	NR	NR	**Docking time: mean** First 16 cases: 15.8 minutes Second 16 cases: 12.31 minutes Final 12 cases: 9.76 minutes

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Setting: Hospital and research centre **Indication:** Inguinal hernia, totally extraperitoneal hernia repair				

Key: NOTECHS - Oxford Non-Technical Skills Scale, NR – Not reported, SD – Standard deviation, SP – Single port.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Table C:7 Secondary outcomes (organisation level)

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Da Vinci XI				
Aktas et al 2020 (Aktas et al. 2020) **Location**: Turkey **Setting:** Two Hospital Centres **Indication:** Gastro adenocarcinoma, radical gastrectomy	Da Vinci Xi (n=30) MIS (n=64)	NR	**Median (range):** **Da Vinci Xi:** 400 (170 to 520) minutes **MIS:** 250 (180 to 600) minutes p=0.001	NR
Alvarez et al 2023 (Espin Alvarez et al. 2023) **Location**: Spain **Setting:** Mutua de Terrassa University Hospital and Germans	Da Vinci Xi (n=22) MIS (n=35)	**Da Vinci Xi:** 6 (27.3) **MIS**: 3 (8.6) p= 0.126	**Da Vinci Xi**: 247.54 (SD 35.8) **MIS:** 201.2 (SD 47.8) p<0.05	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Trias i Pujol University hospital **Indication**: Pancreatic disease, pancreatectomy				
Bergdhal et al 2022 (Grenabo Bergdahl et al. 2022) **Location**: Sweden **Setting:** Sahlgrenska University Hospital **Indication:** Metastatic germ cell cancer, retroperitoneal lymph node dissection	Da Vinci Xi (n=29) Open surgery (n=58)	NR	**Da Vinci:** Median (IQR) 433 (375– 470) minutes **Open surgery:** Median (IQR) 297 (230–440) minutes	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Bilgin et al 2019 (Bilgin et al. 2020) **Location:** Turkey **Setting:** Tertiary care centre **Indication:** Left sided colonic diverticulitis, colectomy	Da Vinci Xi (n=20) MIS (n=22)	**Da Vinci Xi:** 1 (5) **MIS:** 0 (0) p=0.476	**Da Vinci Xi**: 230 (88.3) **MIS:** 243.6 (68.6) p=0.577	NR
Butnari et al 2024 (Butnari et al. 2024) **Location:** UK **Setting:** District general hospital **Indication:** Colorectal cancer, colorectal resection	Da Vinci Xi (n=100) MIS (n=112)	**Readmission rate** **Da Vinci Xi:** 12(12) **MIS:** 14(12.50) OR [95% CI] 0.95 [0.4–2.1], p > 0.95	**Overall total operating time** **Da Vinci Xi**: 247.5 (IQR 190-315) **MIS:** 200 (IQR 170-270) P<0.05 **Overall console time (minutes)** **Da Vinci Xi**: 140 (IQR 86.3-217)	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			MIS: NR **Overall access and docking time** **Da Vinci Xi**: 28 (IQR 21-39) **MIS:** NR	
Di Franco et al 2022 (Di Franco et al. 2022) **Location:** Italy **Setting:** Center for Robotic surgery (Da Vinci); tertiary care center (open surgery) **Indication:** Pancreatic disease, pancreatoduodenectomy	Da Vinci Xi (n=20) Open surgery (n=40)	NR	**Da Vinci:** 428 (67) minutes **Open surgery:** 404 (68) minutes p=0.212	NR
Di Lascia et al 2020 (Di Lascia et al. 2020)	Da Vinci Xi (n=7) MIS (n=15)	NR	**Total operating time** (time from patient in the room to patient out of the room):	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Location: Italy **Setting**: University hospital **Indication:** Colorectal cancer, hemicolectomy			**Da Vinci Xi**: 251.57 (41.58) minutes **MIS:** 155.26 (29.24) minutes p<0.05 **Operative time (start of incision to completion of skin closure):** **Da Vinci Xi**: 142.22 (22.05) minutes **MIS:** 104.20 (12.03) minutes p<0.05 **Surgical time (start of surgical procedure to completion of skin closure):** **Da Vinci Xi**: 93.57 (17,25) minutes	

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			MIS: 80.33 (11.56) minutes P= 0.083	
Galata et al 2019 (Galata et al. 2019) **Location:** Germany **Setting:** University hospital **Indication:** Rectal adenocarcinoma, anterior resection	Da Vinci Xi (n=18) MIS (n=33)	**Da Vinci Xi:** 2 (11.1*) **MIS:** 0 (0) p=0.120	**Da Vinci Xi**: 394 (78.5) minutes **MIS:** 324 (80.9) minutes p=0.005	NR
Gitas et al 2022 (Gitas et al. 2022) **Location**: Germany	Da Vinci Xi (n=42) MIS (n=97)	NR	**Included cases without follow-up (n=300)** **First 50 robotic surgeries:** 144.38 (86.57) minutes	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Setting: University Hospital **Indication:** Gynaecological indications, hysterectomy			**Last 50 robotic surgeries:** 141.54 (79.4) minutes Times NR for MIS	
Muysoms et al 2018 (Muysoms et al. 2018) **Location:** Belgium **Setting:** Maria Middelares Hospital **Indication**: Groin hernia, transabdominal preperitoneal groin hernia repair	Da Vinci Xi (n=49) MIS (n=64)	NR	**Skin to skin operating time: Mean (SD)** **Da Vinci Xi unilateral:** 54 (16) **MIS unilateral**: 45 (11) **Da Vinci Xi bilateral**: 78 (16) **Total operating room time: Mean (SD)** **Da Vinci Xi unilateral:** 94 (17) **MIS unilateral**: 79 (10) **Da Vinci Xi bilateral**: 119 (15)	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			Console operating time: **Da Vinci Xi unilateral:** 43 (15) **Da Vinci Xi bilateral:** 65 (14)	
Ozben 2019 (Ozben et al. 2019) **Location:** Turkey **Setting:** Two specialised centres **Indication:** Colorectal indications, Colectomy	Da Vinci Xi (n=26) MIS (n=56)	**Da Vinci Xi**: 5 (19.2) **MIS:** 7 (12.5) p=0.51	**Da Vinci Xi**: 386.4 (102.4) minutes **MIS:** 249.2 (80.7) minutes p<0.001	NR
Rattenborg 2021 (Rattenborg et al. 2021) **Location:** Denmark **Setting**: NR	Da Vinci Xi (n=57) MIS (n=40)	**Readmissions for complications**: n (%) **RRC-IA:** 3* (9*)	**Mean minutes (95% CI)** **RRC-IA:** 153 (142-165) **LRC-EA:** 104 (94-113) **RRC-EA:** 138 (125-151)	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Indication: Colon cancer, right hemicolectomy			Reported to be significantly longer in the Da Vinci groups but no statistic provided. Mean difference between RRC-IA and RRC-EA was 15.6 min (not significant).	
Schmelzle 2022** (Schmelzle et al. 2022) **Location:** Germany **Setting:** University hospital **Indication:** Liver indications, liver resection	Da Vinci Xi (n=129) MIS (n=471; matched: n =129)	NR	Median (range) **Da Vinci Xi:** 260 (83 to 568) minutes Console time: 167 minutes (47 to 384) **MIS matched population:** 270 (57 to 580) minutes p=0.613 (vs Da Vinci)	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			MIS unmatched population: 244 (45 to 758) minutes p=0.135 (vs Da Vinci)	
Da Vinci SP				
Lee et al 2023 (Lee and Hong 2023) **Location:** Korea **Setting:** Kyungpook National University Chilgok Hospital **Indication:** Uterine fibroids, hysterectomy	Da Vinci SP (n=31) MIS (n=48)	NR	**Time in minutes ± SD** **Operating time:** **Da Vinci SP**: 111.26 ± 31.60 **MIS:** 76.38 ± 29.27 p<0.01 **Uterus out time:** **Da Vinci SP**: 62.16 ± 26.17 **MIS:** 37.58 ± 12.65	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			p<0.01 **Stump suture time:** **Da Vinci SP:** 11.71 ± 4.19 **MIS:** 8.42 ± 2.59 p<0.01 **Morcellation time:** **Da Vinci SP**: 4.65 ± 3.08 **MIS:** 7.73 ± 5.48 p<0.01 **Finishing time:** **Da Vinci SP**: 29.10 ± 31.29 **MIS:** 22.65 ± 20.19 p=0.31	

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			Docking time: **Da Vinci SP**: 3.59 ± 1.64	
Hugo				
Prata et al 2024 (Prata et al. 2024) **Location**: Italy **Setting:** University hospital **Indication:** Renal tumours, partial nephrectomy	Hugo (n=27) MIS (n=62)	**Hugo**: 0 (0) **MIS**: 0 (0) (time point not specified)	**Median (IQR**) **Hugo:** 91 (50 to 149) minutes **MIS:** 149.5 (83 to 203) p=0.005	NR
Senhance				
Aggarwal 2020 (Aggarwal et al. 2020) **Location:** UK	Senhance (n=20) MIS (n=20)	NR	**Total operating time (minutes), Median (IQR)** **Senhance:** 86.5 (60.5 – 106.5) **MIS:** 31.5 (26-41) p=significant	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Setting: St Mary's Hospital, Imperial Collage, London **Indication:** Cholelithiasis, cholecystectomy			**Docking time (minutes), Median (IQR)** **Senhance:** 11.5 (9-13) **Console time (minutes), Median (IQR)** **Senhance**: 30.8 (23.5-35)	
Killaars et al 2024 (Killaars et al. 2024) **Location:** The Netherlands **Setting:** One children's hospital	Senhance (n=20) MIS (n=20)	**Senhance**: 2 (10) **MIS:** 0 (0) p=0.500	**Mean (SD)** **Senhance:** 142 (38) minutes **MIS:** 93 (33) minutes p<0.001	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Indication: Gastroesophageal reflux disease, nissen fundoplication				
Samalavicius et al 2022 (Samalavicius et al. 2022) **Location:** Lithuania **Setting:** University hospital **Indication:** cholelithiasis, Cholecystectomy	Senhance (n=20) MIS (n=20)	NR	**Mean (SD)** **Senhance:** 88.5 (24.5) minutes **MIS:** 60.8 (16.7) minutes p=0.001	NR
Versius				
Dixon et al 2024 (Dixon et al. 2024) **Location**: UK **Setting**: NR	Versius (n=40) MIS (n=20)	**Versius**: 2(5) **MIS:** 1(5)	**Mean ± SD** **Versius**: 296.7 ± 98.7 **MIS:** 263.9 ± 91.0 p=0.21	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Indication: Colorectal indications, Major colorectal resection				
Kakkilaya et al 2023 (Kakkilaya et al. 2023) **Location**: India **Setting:** Hospital and research centre **Indication:** Inguinal hernia, totally extraperitoneal hernia repair	Versius (n=44) MIS (n=44)	NR	**Overall time, mean (95% CI)** **Versius:** 60.47 (53.87 to 67.08) minutes **MIS:** 38.45 (35.34 to 41.57) minutes p=0.001 **Console time, mean (95% CI)** **Versius:** 49.16 (42.93 to 55.39) minutes **MIS:** 38.45 (35.34 to 41.57) minutes P=0.053	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
			Docking time Versius: 12.7 minutes **MIS:** NA	

IQR – Interquartile range, LRC-EA - laparoscopic operation with extracorporeal anastomosisRRC-EA - robotic operations with extracorporeal anastomosis, RRC-IA - robotic operation with intracorporal anastomosisSP – Single port.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

*calculated by reviewer

**for Schmelzle 2022, priority has been given to comparisons with the matched population in the write up

Appendix D – Economic review study selection

Selection of economic studies was performed alongside the selection of clinical studies. Economic evaluations were considered eligible if they reported total costs, effectiveness, incremental analyses or other economic evaluation outcomes. 'Hypothetical pieces' or evidence that cannot be critiqued (due to being limited in nature) were excluded.

3 full text studies were assessed for relevance to economics outcomes and included at full text review.

Appendix E – Intended patient population exclusions

da Vinci SP Surgical system

Thoracoscopic Procedures

Thoracoscopic surgical procedures performed using the da Vinci SP Surgical System are not recommended for:

- malignant tumours classified as T4
- tumours invading the hilar structure
- tumours invading the lateral or anterior chest wall when using the subcostal approach
- patients who have undergone previous sternotomy when operating in the mediastinum.

Breast Surgical Procedures

The da Vinci SP Surgical System is intended for use in patients undergoing breast surgical procedures.

The da Vinci SP Surgical System has been validated for nipple sparing mastectomy and axillary lymph node dissection procedures for breast surgery. Nipple sparing mastectomy procedures performed using the da Vinci SP Surgical System are not recommended for:

- patients with breast cup size D and above
- tumours involving the nipple areolar complex (NAC) or skin
- patients with inflammatory breast cancer
- malignant tumours classified as T4d or T4b
- tumours invading the chest wall

Transoral Otolaryngology Procedures

The da Vinci SP Surgical System is intended for use for the removal of benign tumors and malignant tumors, and for benign base of tongue resection transoral otolaryngology surgical procedures. Transoral procedures performed using the da Vinci SP Surgical System are not recommended for:

- malignant tumours classified as T3 or T4
- tumours invading the mandible, abutting the carotid artery, or requiring bone resection
- patients with a poor mouth opening
- dental surgery (for example, tooth extraction)

GID-HTE10040 Robot-assisted surgery for soft-tissue procedures

Medical technologies advisory committee: 27 Sep 2024

Committee introducers: Prasanna Sooriakumaran, Neil Hawkins

Lay SCMs: Dave Chuter, Jono Organ

External assessment group: Anne Littlewood, Luc Curtis-Gretton (YHEC)

Technical team: Louisa Robinson, Kimberley Carter and Ivan Maslyankov

NICE National Institute for Health and Care Excellence

Robot-assisted surgery for soft-tissue 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)* - assessment of the included technologies by the EAG. The report has a detailed executive summary which provides an overview of the EAG's work.

* This document is in the Committee pack and will be published at consultation

Technology purpose

- Surgical procedures may be carried out through open surgery, or through minimally invasive surgery (MIS) techniques.
- Open surgery involves the surgeon making a single or multiple, often large, incision(s). MIS is a method of carrying out an operation without having to make a large incision, which may involve using a natural body orifice or a smaller incision. Examples of MIS used often in soft tissue procedures include laparoscopy, endoscopy and hysteroscopy (see the NICE Scope). Robot-assisted surgery (RAS) is a form of MIS.
- Robotic platforms for soft-tissue procedures are used in operating theatres. Robotic platforms are here defined as a technology that enables RAS to be conducted across multiple interventional surgical procedures. They have one or more mechanical arms to which an endoscope and surgical instruments are attached. The operator controls the apparatus from a remote console.
- RAS is complex and requires dedicated training programmes for the whole operating team.

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Potential benefits and unmet need

- Benefits of RAS compared with open surgery may include reductions in pain, complications, length of hospital stay and recovery time.
- The potential clinical benefits of RAS are likely to be similar to conventional MIS, for procedures that conventional MIS is currently possible. But, the benefits of standard MIS may also be amplified in RAS, because of increased precision and reduction in technical demand to do the procedure. It may also reduce the rate of conversions to open surgery from MIS. Reduced strain and technical demand may also benefit the surgeon.
- If surgeons consider there will be a reduction in surgical risk because of RAS compared with conventional MIS, there may be an increase in MIS.

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Current management overview

- RAS is intended to replace other MIS options, or open surgery.
- RAS is already recommended in the NICE guideline for prostate cancer. The Department for Health and Social Care has also predicted that RAS will expand over the next decade (Department of Health and Social Care 2024, NHS 2019).
- Previous NICE guidelines and the NHS long-term plan both highlight the importance of RAS, in supporting the workforce through innovation as well as the effectiveness in specific interventions, such as prostatectomy.
- The introduction of robotic platforms may have led to improvements for patients, surgeons and the wider NHS system.

RAS: robot-assisted surgery; MIS: minimally invasive surgery

The technologies

- 5 robotic technologies were included in this assessment
- 3 companies covering 4 technologies provided information to NICE
    - Versius (CMR Surgical)
    - Da Vinci X/ Xi surgical system (Intuitive)
    - Da Vinci SP (Intuitive)
    - Hugo RAS System (Medtronic)
    - Senhance (Asensus Surgical) was identified after the NICE Scope was published. The company did not provide information to NICE for this assessment.

RAS: robot-assisted surgery

Summary of technologies (1)

	Versius (CMR Surgical)	da Vinci X / Xi IS4200 / IS4000 (Intuitive)	da Vinci SP model SP1908 (Intuitive)	Hugo RAS System (Medtronic)
Regulatory approval	Certified to market in the UK under MDR 757173 R000 Not currently licensed for people under the age of 18 (paediatrics) or for TORS	Certified to market in the UK under MDR 2017/745 Not currently licensed for trans-oral otolaryngology robotic surgery in paediatrics	Certified to market in the UK under MDR 2017/745 Not currently licensed for people under the age of 18 (paediatrics)	Certified to market in the UK under MDR 738197 R000 Not currently licensed for people under the age of 18 (paediatrics)
Indications for use	• Thoracic • Upper GI • Colorectal • Gynaecology • Hepatobiliary • Hernia • Urology	• Urology • General surgery • Gynaecology • Thoracoscopic • Nipple sparing mastectomy with reconstruction • Transoral otolaryngology (restricted to adults, and benign tumours or malignant tumours classified as T1 and T2)	• Endoscopic Abdominopelvic • Thoracoscopic • Transoral otolaryngology • Breast	• Urology • Gynaecology • General surgery

NICE

For further details on indications for use see Appendix E of the AR

MDR: medical device regulation; GI: gastrointestinal; RAS: robot-assisted surgery; MIS: minimally invasive surgery; TORS: transoral robotic surgery

Summary of technologies (2)

	Versius (CMR Surgical)	da Vinci X / Xi IS4200 / IS4000 (Intuitive)	da Vinci SP model SP1908 (Intuitive)	Hugo RAS System (Medtronic)
Main components	Bedside unit with an endoscope (visualisation unit) 2 or 3 bedside units Wristed instruments that attach to bedside units Surgeon console with open 3D video feed from the endoscope	Patient cart with 4 arms that host surgical instruments Wristed instruments that attach to the arms, including the endoscope Surgeon console with closed viewer and open 3D video feed from the endoscope Vision cart that duplicates the endoscope video and has arm cart control functionality	Patient cart with 1 arm hosting endoscope and 3 instruments Surgeon console with closed viewer and open 3D video feed from the endoscope Wristed instruments that attach to the arm, including the endoscope Vision cart that duplicates the endoscope video and has arm cart control functionality	System tower with operating room interactive display Arm cart hosting instruments. Up to 4 arm carts can be connected to the system tower Surgeon console with open display interactive display, hand and foot controls and open 3D video feed from the endoscope
Can be used to support open surgeries	Not supported for open surgery [redacted]	Not supported for open surgery	Not supported for open surgery	Not supported for open surgery

RAS: robot-assisted surgery

Summary of technologies (3)

	Versius (CMR Surgical)	da Vinci X / Xi IS4200 / IS4000 (Intuitive)	da Vinci SP model SP1908 (Intuitive)	Hugo RAS System (Medtronic)
Data collection	Robot telemetry data, and with patient consent, surgical video and clinical data Existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app	Usage metrics such as time, date, kinematic and procedure information	Usage metrics such as time, date, kinematic and procedure information	Storage of technical and usage data
Current NHS usage	[redacted] Procedures undertaken cover: • colorectal [redacted] • general and upper GI [redacted] • gynaecology [redacted] • urology [redacted] • thoracic [redacted] • head and neck [redacted] • HPB [redacted] [redacted]	[redacted] Procedures undertaken cover: • urology [redacted] • general surgery [redacted] • gynaecology [redacted] • thoracic [redacted] • Other [redacted] • commonly used in prostatectomy, but this is outside of the NICE scope [redacted]	At time of this report, used [redacted] for urology and head and neck procedures.	[redacted] Used in urology in the NHS. Procedures include prostatectomy, radical or partial nephrectomy, pyeloplasty, cyst removal, ureteral re-implant. [redacted]

RAS: robot-assisted surgery; HPB: hepato-pancreato-biliary

Summary of technologies (4)

Technology (Company)	
Senhance (Asensus Surgical)	The company did not provide information to NICE. However, from the literature and clinical experts, a brief description of the technology is provided below (Coussons et al 2021): The technology is comprised of an open-platform, modular architecture with four mobile arms that allow for use of existing laparoscopic vision systems. Senhance system's instruments are reusable. The system incorporates eye-tracking camera control, haptic sensing, 3DHD visualisation and joy-sticks during the procedure. Case set-up for Senhance procedures generally includes raising the patient so the camera port is aligned with the front of then arms' collar; setting the patient in Trendelenburg; setting the scope to 0° to provide clearance for anaesthesiology; and using the xyphoid process as the point for arm placement. Both arms use instruments that are 310 mm in length. The platform uses eye and head movements and tracking to control the robotic camera arm

For further details on the technologies see section 2.1 of the AR

3DHD: 3-dimensional high-definition; mm: millimetres; AR: assessment report

Patient group

- The target population for this assessment is adults or children who require a soft-tissue surgical procedure.
- Soft-tissue surgical procedures encompass a range of procedures involving internal organs, the body wall, masses or tumours, and hernias or defects. Soft-tissue procedures do not cover procedures conducted on bones, or wider musculoskeletal conditions (NHS 2021).
- In the UK, it is estimated that approximately 1 in 10 people require a surgical procedure, which includes soft-tissue, orthopaedic and neurological procedures. As people begin to live longer, it is likely that the demand for soft-tissue procedures will increase, as the prevalence of noncommunicable diseases, such as cancers, also increase.

Decision problem

PICO		Changes to PICO after scope publication
Population	People (adults or children) having a soft-tissue surgical procedure.	
Interventions	Robotic system for soft-tissue surgery available for use in the UK	Senhance (Asensus Surgical) was added to the EVA after publication of the final scope.
Comparator	Standard surgical care	
Key Outcomes	Primary and secondary patient, surgeon and organisation level outcomes	Clarification to outcomes and level they were measured at
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.	Given the wide scope of procedures, and the purposes of an early value assessment, only a 1-year time horizon is considered for the economic evaluation. Long-term outcomes are very heterogenous across procedures, and these should be explored further as part of future evidence generation and assessment.

AR: assessment report; EVA: early value assessment

For full decision problem see Table 1.1 of the AR

Equality and diversity (1)

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

- No additional equality issues identified by the EAG
- There is evidence that less MIS happens in the most deprived areas than the least deprived areas of the NHS (Morton et al 2023b). Also, there is evidence that the East Midlands and North West of England are underserved regions in the uptake of RAS (Lam et al 2021).
- Inequalities in access to MIS and RAS are likely to present themselves through (Johnson et al 2024):
  - geographical barriers
  - socioeconomic barriers
  - barriers for ethnic minority groups.
  - clinical and patient attitudes towards using robotic platforms.

RAS: robot-assisted surgery; MIS: minimally invasive surgery; EAG: external assessment group

Equality and diversity (2)

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

- Barriers for these groups in society, and resulting inequalities, are likely to stem from difficulty attracting specialist surgeons to regions or areas, or inability to allocate healthcare budgets to RAS where wide inequalities are already present.

- But, there is also evidence that RAS may reduce health inequalities within some parts of society. For instance, elderly people, or people with co-morbidities, may be more likely to receive MIS instead of open surgery, if a robotic platform can be used (Cole et al 2018).

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Clinical evidence overview

- 110 relevant studies were found. They all evaluated a relevant technology (Versius, da Vinci X and Xi, da Vinci SP, Hugo RAS System, Senhance) in the relevant population.
- 20 comparative studies were prioritised and included in the review. Prioritisation was conducted per technology, with some higher-level evidence deprioritised if there was a high volume of literature for a particular technology. There was evidence for all 5 technologies.
- Most often, the studies evaluated RAS for colorectal surgery (n=7). Other studies included surgery for pancreatic, hernia repair, gynaecological surgery, gastrointestinal, cholelithiasis, testicular cancer and urology.
- Six of 20 studies assessed RAS in people with cancer, 7 in people with benign disease and 7 in mixed patient groups.
- One study assessed RAS in a paediatric patient group.
- Most studies reported evidence for RAS with da Vinci Xi (n=13). One study reported RAS with da Vinci SP, 1 with Hugo, 3 with Senhance and 2 with Versius. Characteristics of these studies are on the next slide.

NICE National Institute for Health and Care Excellence

Detail on the overview of studies is in Section 5.1 of the AR

RAS: robot-assisted surgery; AR: assessment report

Clinical evidence: outcomes reported

Outcomes		Reported in prioritised evidence	Not reported in prioritised evidence
Primary	patient level	• conversion rate • length of hospital stay • intraoperative complications • postoperative complications • Clavien-Dindo score • health related quality of life	
	surgeon level	• procedure-related discomfort and ergonomics	
	organisation level		• rate of MIS compared with open surgery after RAS was introduced • volume of procedures • Hospital capacity and wait list-reduction
Secondary	patient level	• post-operative pain • satisfaction with surgery • revision surgery for same indication • intraoperative blood loss (compared with open surgery) • survival rate (cancer studies) • need for adjuvant therapy (cancer studies)	• days alive and out of hospital (30 days) • feeding tube dependency (head and neck studies)
	surgeon level	• human factors • learning curve	• career longevity and musculoskeletal injury
	organisation level	• readmission at 30 days • operating time	• staffing requirements

RAS= robot-assisted surgery; MIS= minimally invasive surgery

Characteristics of prioritised studies (1)

Technology	Study design	Sample size	Indication	Country
da Vinci X and Xi	Retrospective cohort study (Aktas et al 2020)	RAS n=30 Laparoscopic n=64	Gastro adenocarcinoma, radical gastrectomy	Turkey
	Prospective, non-randomised study (Alvarez et al 2023)	RAS n=22 MIS n=35	Pancreatic disease, pancreatectomy	Spain
	Prospective, non-randomised study (Bergdhal et al 2022)	RAS n=29 Open n=58	Metastatic germ cell cancer, retroperitoneal lymph node dissection	Sweden
	Retrospective cohort study (Bilgin et al 2019)	RAS n=20 MIS n=22	Left-sided colonic diverticulitis, colectomy	Turkey
	Retrospective cohort study (Butnari et al 2024)	RAS n=100 MIS n=112	Colorectal cancer, colorectal resection	UK
	Retrospective cohort study (di Franco et al 2022)	RAS n=20 Open n=40	Pancreatic disease, pancreatoduodenectomy	Italy
	Retrospective cohort study (di Lascia et al 2020)	RAS n=7 Laparoscopic n=15	Colorectal cancer, hemicolectomy	Italy
	Prospective cohort study (Galata et al 2019)	RAS n=18 Laparoscopic n=33	Rectal adenocarcinoma, anterior resection	Germany

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More detail on study characteristics is in Table 4.1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Characteristics of prioritised studies (2)

Technology	Study design	Sample size	Indication	Country
da Vinci X and Xi	Retrospective cohort study (Gitas et al 2022)	RAS n=42 MIS n=97	Gynaecological indications, hysterectomy	Germany
	Historically controlled cohort study (Muysoms et al 2018)	RAS n=50 Laparoscopic n=64	Groin hernia, transabdominal preperitoneal groin hernia repair	Belgium
	Retrospective cohort study (Ozben et al 2019)	RAS n=26 MIS n=56	Colorectal indications, Colectomy	Turkey
	Historically controlled cohort study (Rattenborg et al 2021)	RAS n=57 Laparoscopic n= 40	Colon cancer, right hemicolectomy	Denmark
	Historically controlled cohort study (Schmelzle et al 2022)	RAS n=129 Laparoscopic n=471	Liver indications, liver resection	Germany
da Vinci SP	Prospective cohort study (Lee et al 2023)	RAS n=31 MIS n=48	Uterine fibroids, hysterectomy	Korea
Hugo	Retrospective cohort study (Prata et al 2024)	RAS n=27 Laparoscopic n=62	Renal tumours, partial nephrectomy	Italy

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More detail on study characteristics is in Table 4.1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Characteristics of prioritised studies (3)

Technology	Study design	Sample size	Indication	Country
Senhance	Retrospective cohort study (Aggarwal et al 2020)	RAS n=20 Laparoscopic n=20	Cholelithiasis, cholecystectomy	UK
	Historically controlled cohort study (Killaars et al 2024)	RAS n=20 Laparoscopic n=20	Gastroesophageal reflux disease, nissen fundoplication	Netherlands
	Retrospective cohort study (Samalavicius et al 2022)	RAS n=20 MIS n=20	Cholelithiasis, cholecystectomy	Lithuania
Versius	RCT (Dixon et al 2024)	RAS n=40 MIS n=20	Colorectal indications, Major colorectal resection	UK
	Prospective non-randomised study (Kakkilaya et al 2023)	RAS n=44 Laparoscopic n=44	Inguinal hernia, totally extraperitoneal hernia repair	India

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More detail on study characteristics is in Table 4.1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: EAG critique of evidence (1)

Study design

- 1 RCT: considered low risk of bias
- 3 non-randomised prospective studies: increased likelihood of confounding and a risk of exaggerated treatment effects due to selection bias
    - RAS could be used for patients who would not have otherwise been eligible for MIS, which could lead to a systemic difference in the populations. Surgeon preference for one type of surgery over the other, availability of the robot or other factors such as patient disease severity, complexity of surgery and body type could influence the choice of surgery.
- 10 retrospective cohort studies: at risk of selection bias and confounding
- Blinding was not possible for the surgeons due to the nature of the interventions and there was no information given on blinding of patients or outcome assessors in the non-randomised or cohort studies. There is a particular risk of bias in the collection of subjective patient or surgeon-reported outcomes in unblinded studies, more so than objective outcomes such as operative time.

RCT: randomised controlled trial

Clinical evidence: EAG critique of evidence (2)

Statistical analysis

- 2 cohort studies had matched comparator arm and 4 studies used historically matched controls
- Some studies reported results by intervention arm but did not present comparative estimates or p-values.

Generalisability

- 3 of 20 studies were done in the UK: includes 1 RCT and 2 retrospective cohort studies, all compared with MIS. No UK evidence for da Vinci SP or Hugo. It is unclear how generalisable evidence from other studies is to the UK setting.
- There was a wide range of conditions across the studies but none assessed multiple types of surgery within the same study.
- The effects of learning curve and operating time might affect different procedures differently, depending on how complex they are.

RCT: randomised controlled trial; MIS: minimally invasive surgery; AR: assessment report

For further details see section 5.2 of AR

Clinical evidence: primary patient level outcomes (1)

Conversion rate: 18 studies across 4 technologies, mostly no statistically significant difference between RAS and open or MIS in studies that included comparative analyses

- 12 studies on da Vinci Xi: conversion rates to open from RAS (0 to 22.2%) and conversion to open from MIS (0 to 14.3%).
    - 8 of 9 studies with comparative analysis reported no difference; 1 reported statistically significant difference in rate of conversion to open favouring MIS (p=0.012)
- 3 studies on Senhance: Study 1: no conversions to open or MIS. Study 2: no conversions to open; 1 conversion to MIS (5%) in the RAS arm. Study 3: 2 conversions to open surgery (10%) in the MIS arm and 0 in the RAS arm.
    - In study 3: no statistically significant difference between arms on conversion to open (p=0.5).
- 1 study on Hugo: no conversions in either RAS or MIS arm
- 2 studies on Versius: no conversions in either RAS or MIS arm
- No studies reporting conversion for da Vinci SP

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: primary patient level outcomes (2)

Conversion rate from conventional MIS to RAS: 11 studies across 4 technologies, no or few conversions, no comparative analysis.

- 5 studies on da Vinci Xi: there were no conversions to MIS in the RAS arm.
- 3 studies on Senhance:
  - Study 1: no conversions to MIS from RAS
  - Study 2: 5% (1 of 20) procedures were converted to MIS from RAS
  - Study 3: 10% (2 of 20) procedures were converted to MIS from RAS
- 1 study on Hugo: no conversions from MIS to RAS.
- 2 studies on Versius: no conversions from MIS to RAS.

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: primary patient level outcomes (3)

Length of stay (LoS): 18 studies across all 5 technologies- mostly no difference in LoS between RAS and MIS, but statistically significant shorter LoS in RAS compared with open surgery in studies that assessed.

- 11 studies on da Vinci Xi: Median LoS was 3 to 10 days in the RAS arms, across studies that reported it (9 studies). In studies that compared RAS with MIS (7 studies), median LoS (4 to 8 days) in the MIS arm. Mean LoS was slightly longer in the MIS arm than the RAS arm for studies that reported it (2 studies)
    - No studies reported a statistically significant difference between MIS and RAS arms
    - In 2 studies that compared RAS with open surgery, median LoS was statistically significantly longer in the open surgery arm (range was 7 to 16 days).
- 3 studies in Senhance: in 1 study, all but 1 person was discharged on the day of surgery in the RAS arm.
    - In 2 studies that compared RAS with MIS, there were no statistically significant differences in LoS between arms.
- 1 study in da Vinci SP: no statistically significant difference in LoS between MIS and RAS.
- 2 studies in Versius: no statistically significant difference in LoS between MIS and RAS.
- 1 study in Hugo: LoS was significantly shorter in the RAS arm (p=0.002)

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report; LoS: length of stay

Clinical evidence: primary patient level outcomes (4)

Intraoperative complications: 12 studies across 5 technologies, no statistically significant differences reported between arms in any study that included comparative analyses between RAS and MIS or open

- 6 studies on da Vinci Xi: 5 compared with MIS and 1 with open, intraoperative/perioperative complication rates varied between 0% and 62.5%. The highest rates were in the study comparing Da Vinci Xi (50%) to open surgery (62.5%).
    - No statistically significant differences between RAS and MIS or open when p-values were reported (4 studies)
- 1 study on da Vinci SP compared to MIS: intraoperative and perioperative complication rates were 3.2% in the RAS arm and 2.1% in the MIS arm. No statistically significant difference between arms.
- 1 study on Hugo compared to MIS: intraoperative and perioperative complication rates were 11.1% in the RAS arm. No statistically significant difference between arms.
- 3 studies on Senhance compared to MIS: intraoperative and perioperative complication rates were between 0% to 10% in the RAS arm and 0 to 15% in the MIS arm. No statistically significant difference between arms.
- 1 study on Versius: no significant difference between MIS (15%) and RAS (10%) arms (p=0.59)

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: primary patient level outcomes (5)

Postoperative complications: 10 studies across 4 technologies, mostly no statistically significant differences reported between arms in any study that included comparative analyses between RAS and MIS or open.

4 studies on da Vinci Xi: 3 compared with MIS and 1 compared with open surgery, complication rates varied between 2.4% and 30% in the RAS arm and 3.1% and 27.3% in the MIS arms. Higher rates were reported in the study comparing da Vinci Xi (37.5%) to open surgery (50%).

  - No study found a statistically significant difference between RAS and MIS or open.

- 3 studies on Senhance compared to MIS: postoperative complication rates were between 5% and 25% in the RAS arm and 0% to 25% in the MIS arm.
  - No study found a statistically significant difference between the arms.
- 1 study comparing da Vinci SP to MIS: No statistically significant difference between treatment arms in either study.
- 2 studies comparing Versius to MIS: no statistically significant difference between arms in either study.
- No studies reported postoperative outcomes for Hugo.

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: primary patient level outcomes (6)

Clavien-Dindo score: 13 studies across 3 technologies, no statistically significant differences reported between arms in any study that included comparative analyses between RAS and MIS or open.

- 10 studies on da Vinci Xi: when reported, Clavien-Dindo grade 3 or higher event rates were below 25%.
  - No study found a statistically significant difference between RAS and MIS (7 studies) or open (1 study).
- 2 studies on Senhance compared to MIS: Clavien-Dindo grade 3 or higher event rates were between 0% and 10% in the RAS arm and 5% to 15% in the MIS arm.
  - No study found a statistically significant difference between RAS and MIS.
- 1 study on Versius compared to MIS: 1 person in the RAS arm had a Clavien-Dindo grade 3a event post-discharge and 1 person in the MIS arm had a grave 4a event.
- No studies reported Clavien-Dindo event rates for Hugo or da Vinci SP.

HRQoL: 1 study on 1 technology, no statistically significant difference reported between RAS and MIS

- 1 study on da Vinci Xi: compared with MIS, measured using the EuraHS QoL score. Median (IQR) was 4 (1 to 2) in the robotic arm and 6 (3 to 14) in the MIS arm.
  - No statistically significant difference in the postoperative 1-month scores (p=0.344).

NICE

For further details including subgroups, see section 5.3 and table C1 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report; HRQoL: health related quality of life

Clinical evidence: primary surgeon and organisation level outcomes

Surgeon level

- Procedure related discomfort and ergonomics: 1 study on 1 technology, statistically significant difference reported between arms
    - 1 study on Versius compared with MIS: 2 measures assessing ergonomic risk and cognitive strain.
        - Statistically significant difference in both scales in favour of Versius ($p<0.001$).

Organisation level

- Rate of MIS compared with open surgery after RAS was introduced : no studies
- Volume of procedures: no studies
- Hospital capacity and waitlist reduction: no studies

NICE

For further details including subgroups see section 5.3 and table C2 and C3 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary patient-level outcomes (1)

Post-operative pain: 7 studies on 3 technologies, mostly no difference in patient reported measures, mostly no difference when measuring painkiller use.

- 4 studies on da Vinci Xi compared with MIS: different scales used (numbered scale, pain domain of EuraHS QoL, VAS, additional painkiller use).
  - No statistically significant difference in pain measured on numbered scale or pain domain of EuraHS QoL at 1 month. Similar scores reported across RAS and MIS arms in 2 studies measured on VAS.
  - Statistically significant difference in number of people who had additional gabapentin (p=0.0006), favouring MIS. No statistically significant difference in the amount of additional paracetamol, NSAIDS or opioids.
- 1 study on Senhance compared with MIS: 5% of people reported pain in both the RAS and MIS arms.
- 2 studies on Versius: compared with MIS.
  - In 1 study, at day 1, 2, 3 and 28, the maximum median pain score was of 1 out of 10 in the RAS arm and 0.5 in the MIS arm. No statistically significant difference at any timepoint.
  - In the other study, at day 1 VAS pain was a mean of 1.43 for RAS and 2.06 for MIS (p=0.023). No statistically significant difference between the arms by week one or month one.

NICE

For further details see section 5.3 and table C4 and C5 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report; VAS: visual analogue scale; EuraHS QoL: a health-related quality of life scale

Clinical evidence: secondary patient-level outcomes (2)

Days alive and out of hospital at 30 days: No studies

Satisfaction with surgery: 1 study on 1 technology, no statistically significant difference between RAS and MIS

- 1 study on da Vinci Xi compared with MIS: patient satisfaction with cosmetic outcome and preoperative explanation were both over 85% in both arms.
    - No statistically significant difference between groups on patient satisfaction with cosmetic outcome and preoperative explanation (p=0.723 and p=0.208)

NICE

For further details on secondary patient level outcomes including subgroups and outcomes for specific study designs see section 5.3 and table C4 and C5 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary patient-level outcomes (3)

Revision surgery: 8 studies on 2 technologies, no statistically significant difference in any study that included comparative analyses between RAS and MIS or open.

- 7 studies on da Vinci Xi: 5 compared with MIS, 2 with open. In 4 studies that reported rate per arm compared with MIS, revision surgery for the same indication was up to 9% in the RAS arm, up to 12.5% in the MIS arm. Where reported and compared with open surgery, revision surgery was 0% in 1 study and 6.9% in another for the RAS arm and 5% in 1 study for the open arm.
    - When reported, there was no statistically significant difference between arms in any study or any comparator.
- 1 study on Senhance compared with laparoscopic surgery: 10% of people in the robotic arm and 15% of people in the MIS arm needed reintervention following surgery.
    - No statistically significant difference between groups (p=1.000).

NICE

For further details on secondary patient level outcomes including subgroups and outcomes for specific study designs see section 5.3 and table C4 and C5 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary surgeon-level outcomes (1)

Career longevity and musculoskeletal injury: no studies

Human factors: 1 study on 1 technology, no statistically significant difference between RAS and MIS on intraoperative team communication

- 1 study on Versius compared with MIS: intraoperative team communication on Oxford NOTECHS II was mean (standard deviation (SD)) score of 72.6 (3.7) in the robotic arm and 71.6 (3.9) in the MIS arm.
    - No statistically significant difference between groups (p=0.33)

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For further details on clinical evidence including subgroups see section 5.3 and table C6 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary surgeon-level outcomes (2)

Learning curve: 6 studies on 3 technologies, mixed findings on reduction in duration of surgery.

- 3 studies on da Vinci Xi: all measured duration of surgery as an indicator of learning curve.
  - In 1 study, there was a statistically significant reduction in duration of surgery between the first and last three robotic surgeries.
  - Another study found no statistically significant difference between the duration of the first 50 (mean=144.58 minutes) and last 50 surgeries (mean=141.54 minutes)
  - Another study found time taken to conduct robotic surgery decreased for both unilateral and bilateral hernias over time (significance not reported)
- 2 studies on Senhance compared with MIS: duration of the first 10 compared with last 10 surgeries
  - In 1 study there was a statistically significant difference in the time it took to conduct the first 10 of 20 robotic surgeries (mean (SD) was 164 (42) minutes) compared with the last 10 robotic surgeries (mean (SD) was 120 (15) minutes; p=0.024)
  - In 1 study operating time decreased over 20 surgeries but was consistently higher than MIS. No significant difference between the first and last 10 surgeries for docking and console time.
- 1 study on Versius: reduction in docking time for the first 16 (mean=15.8 minutes), vs next 16 (mean=12.31 minutes) vs last 12 patients (mean=9.76 minutes). No p-value reported.

NICE For further details on clinical evidence including subgroups see section 5.3 and table C6 of the AR

MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary organisation-level outcomes (1)

Readmission at 30 days: 9 studies on 4 technologies, no statistically significant difference in any study that included comparative analyses between RAS and MIS.

- 6 studies on da Vinci Xi: all compared with MIS. 1 study reported 3 readmissions in 1 of 2 RAS arms in the study (no p-value on difference between RAS or MIS arms).
    - 5 studies found no statistically significant difference between RAS and MIS for readmission rates.
- 1 study on Senhance compared with MIS: 2 (10%) patients were readmitted in the Senhance arm and 0 (0%) in the MIS arm
    - No statistically significant difference between arms (p=0.500)
- 1 study comparing Hugo with MIS: the proportion of patients readmitted within 30 days was 0% in both arms
    - This suggests no statistically significant difference
- 1 study comparing Versius with MIS: the proportion of patients readmitted within 30 days was 5% in both arms
    - This suggests no statistically significant difference

NICE

For further details on clinical evidence including subgroups see section 5.3 and table C7 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary organisation-level outcomes (2)

Operating time: 20 studies on all 5 technologies, RAS was mostly longer than MIS, but some studies showed no difference or shorter operating time for RAS.

- 13 studies on da Vinci Xi:
  - When compared with MIS, surgery was significantly longer in the RAS arm in 7 studies, but no statistically significant difference was seen in 2 studies. In 1 study a p value wasn't reported but length of surgery was also longer in RAS. median operating time ranged from 247.5 minutes to 400 minutes for Da Vinci Xi and 200 to 250 minutes for MIS. The mean operating time ranged from 138 to 394 minutes for Da Vinci Xi and 104 to 324 minutes for MIS
  - When compared with open, surgery took longer in the RAS arm in 1 study, but there was no significant difference (p=0.212). A second study also reported longer operating times with RAS did not report a p-value
- 3 studies compared Senhance with MIS: RAS was statistically significantly longer in all 3 studies.
  - Two of the studies reported mean operating time, which was 88.5 and 142 minutes for Senhance, and 60.8 and 93 minutes for MIS. The third study reported the median total operating time, which was 86.5 minutes for Senhance and 31.5 minutes for MIS

NICE

For further details on clinical evidence including subgroups see section 5.3 and table C7 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: secondary organisation-level outcomes (3)

Operating time (continued):

- 1 study on da Vinci SP compared with MIS: mean overall operating time was significantly shorter in the MIS arm (76.38 minutes) compared with Da Vinci SP (111.26 minutes; p<0.01)
- 2 studies on Versius compared with MIS: no statistically significant difference in operating time in 1 study (p=0.21) but there a statistically significant difference in favour of MIS in the other study (mean: 38.45 minutes vs. 60.47 minutes; p=0.001)
- 1 study on Hugo compared with MIS: operating time was statistically significantly shorter for RAS than MIS (median: 91 minutes vs 149.5 minutes; p=0.005)

Staffing requirements: no studies.

NICE

For further details on clinical evidence including subgroups see section 5.3 and table C7 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report

Clinical evidence: adverse events

- The adverse events reported by the studies were already reported as clinical outcomes including perioperative and postoperative complications, Clavien-Dindo scores and rates of conversion to either MIS or open surgery.

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Clinical evidence: summary (1)

- Patient level primary outcomes: among the available evidence, 1 study reported a significant difference in conversion rate in favour of MIS (compared with da Vinci Xi). Differences were found in hospital LoS when comparing robotic (da Vinci Xi) to open surgery. These studies suggested a shorter LoS for RAS. But, only 1 study reported a difference in LoS between RAS and MIS. No other studies reported a significant difference between robotic surgery and MIS or open surgery on any other patient-level primary outcomes.
- Surgeon level primary outcome (procedure-related discomfort and ergonomics): only measured by one study, which reported a significant difference in favour of the Versius robot, compared with MIS.
- Organisation level primary outcomes: No evidence was included in the prioritised studies.

For further details see section 7 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report; LoS: length of stay

Clinical evidence: EAG review (1)

- The comparative evidence suggests that RAS is generally comparable with current standard of care for primary patient outcomes, for the procedures identified.
- Prioritised studies used unclear or different definitions for some outcomes, or used different scales to measure the same outcome. This made it difficult to compare the results across studies.
- There was either no or limited evidence for many primary and secondary outcomes in the prioritised evidence. For some outcomes, results were only reported for one robotic system. Gaps in the evidence made comparisons across the different technologies difficult.
- But, in general, results for each technology aligned with one another when there was evidence available.

For further details see section 11.1 of the AR

RAS: robot-assisted surgery; AR: assessment report

Clinical evidence: EAG review (2)

- Most evidence was from either cohort or non-randomised studies. So, there could be exaggerated treatment effects due to selection bias and an increased risk of confounding. Even where prospective, comparative evidence was available, the duration of studies was too short to understand the impact of the learning curve, and they had small sample sizes.
- There were few studies conducted in the UK and so the results may not all be generalisable to a UK population.
- There were also a variety of indications and types of surgery, and it is unclear whether the results from one type of surgery are comparable with other types of surgery. But, this approach was taken to gain a broader estimate of the potential impact of RAS, given that implementation of RAS within hospitals is not likely to be on a procedure specific-basis.

RAS: robot-assisted surgery; AR: assessment report

For further details see section 11.1 of the AR

Issues for consideration: Clinical evidence

- What are the expectations for RAS to show clinical equivalence or superiority over comparators? Does the evidence meet these expectations?
    - Conversion rate did not show the direction or effect expected.
- There are different amounts of evidence for each technology, and each is of different quality. Some primary patient level outcomes, and all primary organisation level outcomes had no data in the prioritised evidence. No study included a case mix of soft-tissue procedures, they all focused on one type of procedure. Not all soft-tissue procedures have been covered. The definitions and measures used for some of the primary outcomes were inconsistent between studies. In particular, 'learning curve' was measured in different ways between each study, but only in terms of length of surgery.
    - To what extent does learning curve affect these outcomes?
    - What limits the interpretation of this evidence and how generalisable are the findings?
    - What is needed to ensure key outcomes can be usefully interpreted in the future?
- What level of recommendation (per technology, per procedure, technology agnostic) is most useful for translation of the recommendations into practice?
- What is not represented in these outcomes that is important to consider?

RAS: robot-assisted surgery

Economic evidence, model and findings

Robot-assisted surgery for soft-tissue procedures

NICE National Institute for Health and Care Excellence

Summary of published economic evidence

- The EAG prioritised 3 costing studies from evidence searches and documents submitted by companies.
- A company submitted an unpublished cost comparison analysis (Chatterjee, 2022), of da Vinci Xi used in malignant hysterectomy compared with open surgery, from an England perspective. The results did not include the costs of the da Vinci system, annual service costs, and other robot-related surgery costs. So, the results do not account for all costs' impacts to the healthcare system.
- Niclauss et al (2019) assessed the cost impact of da Vinci Xi and da Vinci Si Surgical System in Roux-En-Y gastric bypass procedures in Switzerland. The main cost difference was acquisition cost of a robot console. There was no significant difference in clinical outcomes such as complications (and therefore, the associated costs).
- Coussons et al (2021) evaluated the cost impact of Senhance compared with the da Vinci robot and laparoscopic surgery for vaginal hysterectomy procedures. It was done in 4 US and European hospitals. Senhance had a lower median instrument cost per surgery when compared with da Vinci. Senhance and standard laparoscopic costs were similar, despite surgeons still being within their learning curve period. The study omitted key costs that should be considered within an economic evaluation, and used a multi-country perspective, where outcomes are not likely to be generalisable. So, the results should be interpreted with caution.

NICE

For further details on economic evidence, including deprioritised studies see section 8.1 of the AR

AR: assessment report

Conceptual model purpose

Purpose

The primary purpose of this analysis was to assess whether it is plausible that using robot-assisted surgery could be a cost-effective intervention.

- RAS, a form of MIS, was compared with conventional MIS (without robotic platforms) or open surgery for soft-tissue procedures.
- There may be sub-populations (such as those at high risk of complications) for specific disease areas or conditions, where surgery may not be viable under standard surgical care. Comparators beyond standard surgical care are not considered within this early evaluation.

- The secondary aims of the analysis were to identify the value of future research, to understand the likely key drivers of the results, and to identify the current evidence gaps.
- In line with the purposes and scope of this EVA, the analysis did not evaluate every possible scenario in relation to robotic surgery for soft-tissue procedures.

NICE

For further details on model structure is in section 8.2 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; EVA: early value assessment; AR: assessment report

Conceptual model characteristics (1)

Time horizon

- A cost-comparison model was designed to capture the potential benefit that could be provided from these technologies over a 1-year time horizon.
- The EAG considered it more useful to reflect potential health outcomes from other economic evaluations of specific procedures at this early evaluation stage.
- The 1-year time horizon was used because the long-term benefit of RAS was highly uncertain, and varied substantially based on the procedures that the robotic platform is used for. It was not plausible to capture long-term outcomes which were generalisable to each clinical specialty and procedure. Even within procedures, there is likely to be substantial heterogeneity within populations undergoing procedures, also limiting the ability to quantify any long-term impacts. The EAG considered in the context of the existing evidence, a 1-year time horizon is appropriate. But, future evaluations should incorporate longer time horizons as highlighted in a recent international consensus expert panel (Erskine et al 2023).

NICE

For further details on model structure is in section 8.2 of the AR

RAS: robot-assisted surgery; AR: assessment report; HTAi: Health Technology Assessment International; EAG: external assessment group

Conceptual model characteristics (2)

Approach to variation between settings

- It is likely there are variations in the costs associated with different surgical settings.
    - Cost differences may include the pricing structures of robotic platforms, staff involved in the procedure, maintenance, training, and the learning curve associated with the platforms.
    - Technologies within scope for this EVA have all collected evidence with varying degrees of quality.
- This evaluation is not intended to capture one base case that represents all RAS procedures and platforms. But, the model can be used to highlight how changes in key-short term features impact the ranges of results or 'ballpark' that the technology may operate in, at least with respect to short-term outcomes.
- The model can be used to conduct specific scenarios, including pricing structures or more specific elements of the technologies. The EAG considers that the cost-comparison model can provide an indication of the potential results, given the base case assumptions. So, this should be useful for decision-makers to evaluate the potential of robotic platforms to support surgical care.

NICE

For further details on model structure is in section 8.2 of the AR

RAS: robot-assisted surgery; EVA: early value assessment; EAG: external assessment group; AR: assessment report

Conceptual model characteristics (3)

Population

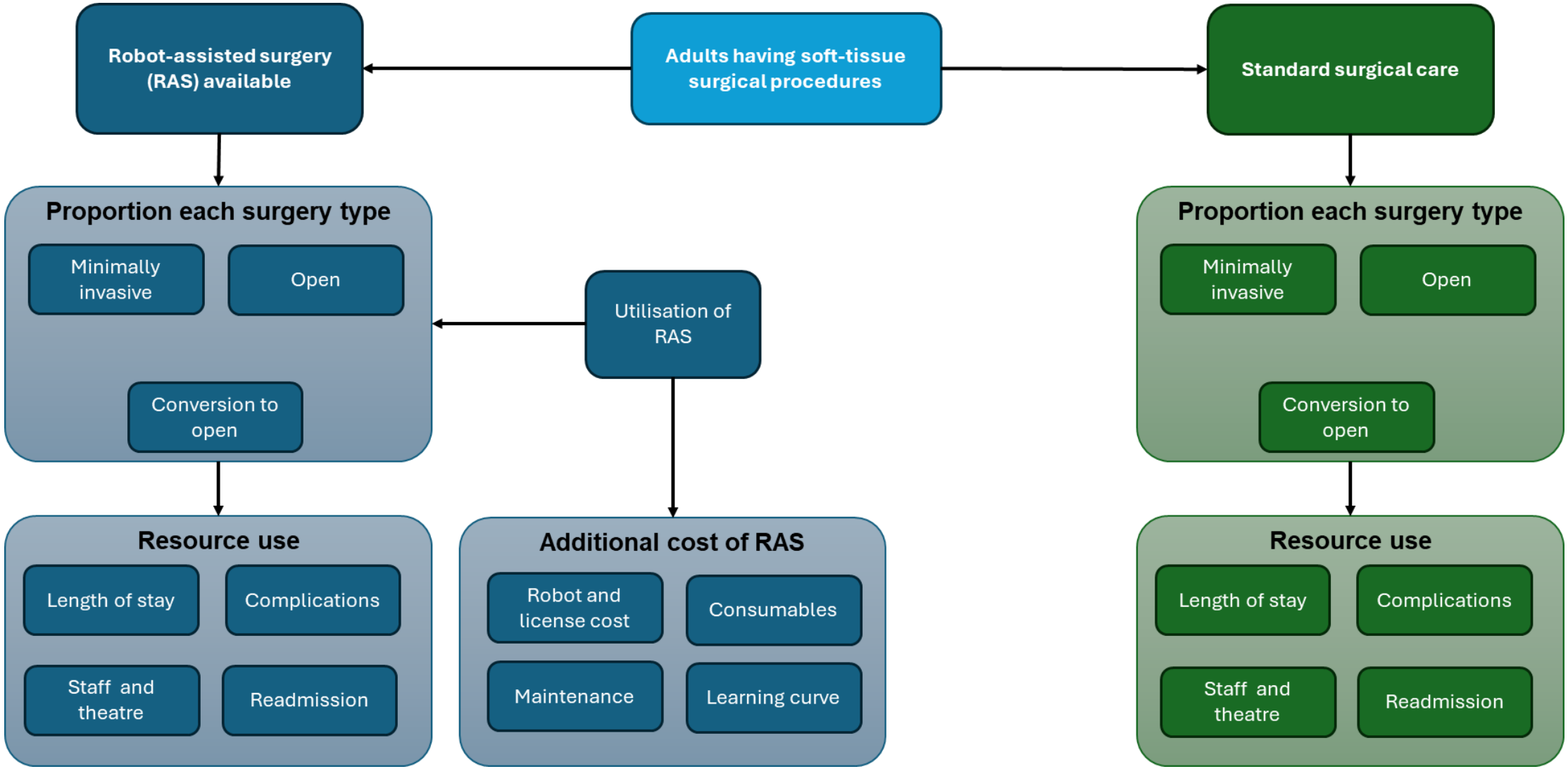
- The EAG considered adults who require a soft-tissue surgical procedure.
- This differs from the NICE final scope, which included adults and children. The difference in scope is because 3 of the 4 technologies within scope are yet to be indicated for use in paediatrics. Current evidence is primarily captured in adult populations.
- The available evidence focuses on specific procedures and studies. So, the EAG took a pragmatic approach, which mixes evidence across procedures. Parameters were varied in sensitivity analyses to capture ranges reported across the literature, and to understand the impact on the results.
- The generalisability of evidence across procedures and clinical specialties should be considered by decision-makers. The results of the analysis should be interpreted with caution, focusing on the potential ranges reported, rather than a specific base-case result.

EAG: external assessment group; AR: assessment report

For further details on model structure is in section 8.2 of the AR

Economic model structure

The model used by the EAG was a cost-comparison model with a 1-year time horizon.



Economic model structure

The model is an initial exploration of the economic impact of technologies for RAS for soft-tissue procedures. For the model, the EAG:

- estimated resource use across the different treatment arms and applied costs to the different resource use
- did not capture QALYs given the model only takes a short-term time horizon
- used 1-year time horizon because of reasons explained on slide 44.

The short-term impact captured in the model was presented as incremental cost of RAS. The results also present the long-term benefit required to be cost-effective, with respect to health outcomes. Cost-effectiveness is determined by using a threshold of £20,000 per QALY.

NICE

For further details on the model structure see section 8.2.2 of the AR

RAS: robot-assisted surgery; AR: assessment report; EAG: external assessment group; QALY: quality adjusted life year

Economic model assumptions (1)

Some assumptions were made to produce the cost-comparison model using the available data. These may not completely reflect all soft-tissue procedures that are included within scope:

- Costs of the robotic platforms can be scaled down to a per surgery cost based on utilisation of the robot (expected number of surgeries)
- The impact on total number of surgeries is not captured in the model
- The impact on physicians' health is not captured in the model
- There may be double counting of resource from capturing readmissions, complications and LoS in the model
- Long-term outcomes of RAS are not captured. The model uses a time horizon of 1 year due to the diverse range of long-term outcomes from soft-tissue procedures
- Evidence used to populate the model contains a mix of different populations undergoing soft tissue procedures.

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Further details about these assumptions including rationale and mitigations are in table 8.2 of the AR

RAS: robot-assisted surgery; AR: assessment report; LoS: length of stay

Economic model assumptions (2)

Continued from previous slide:

- The model does not necessarily reflect the impact of RAS in children
- The model only captures the impact of introducing one robotic platform for soft-tissue surgical procedures
- Cleaning costs for surgical instruments were not captured within the model
- Energy and IT software costs associated with RAS have not been included
- Cost associated with theatre installation have not been included
- For specific conditions, the comparator may not be standard surgical care
- The learning curve is included in the model by adjusting the impact on length of stay and surgery time until the learning curve is complete.
- The impact of converting from a RAS to traditional MIS was not captured in the model

NICE

Further details about these assumptions including rationale and mitigations are in table 8.2 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; AR: assessment report; LoS: length of stay

Economic model – overview of inputs

- Model inputs were derived via company evidence submissions, clinical correspondence and existing evaluations in this area. A range of study data were combined from the robotic platforms, with only a subset of the technologies having evidence that was suitable for the economic analysis. The EAG supplemented the economic analysis with data from studies which do not refer to a specific robotic platform to support surgery.
- When there was a lack of data, assumptions were made and, where possible, clinically verified. The range of values from the identified evidence were used as uncertainty intervals for sensitivity analyses where possible.

EAG: external assessment group; AR: assessment report

Further details see section 8.2.4 of the AR

Economic model – set-up parameters

- The model compared RAS with standard surgical procedures.
- The annual number of procedures (performed using one RAS system), the expected life cycle of a robotic platform, and the time-to-proficiency (learning curve) were estimated from clinical and company consultation.
- The annual number of procedures and time-to-proficiency parameters were found to vary between procedure types, surgeon experience, and experience with RAS.
- A mean estimate was applied in the base case and then varied within sensitivity analysis. The discount rate (for cost annualisation of the robotic platform) and the cost-effectiveness threshold (for QALY threshold analysis) were set as 3.5% and £20,000 per QALY respectively (National Institute for Health and Care Excellence 2022).

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Further details on set-up parameters are in Table 8.3 of the AR

RAS: robot-assisted surgery; AR: assessment report; QALY: quality adjusted life year

Economic model – other input estimates

Type of surgery

- The proportions of each type of soft-tissue surgery (MIS, RAS, open) and the conversion rate for each arm of the model were derived from a variety of clinical studies and company submissions data (Morton et al. 2023a, Safiejko et al. 2021).

Resource use

- Operative time, LoS, the rate of complications, and readmissions were derived from company submissions, a mixture of cost-effectiveness analysis for specific procedures, national population-based studies, and meta-analyses.

Costs

- RAS costs, alongside excess bed day and readmission costs, were derived from the company evidence submissions, the Personal Social Services Research Unit (Personal Social Services Research Unit 2023), and the National Cost Collection (all 2023 cost values, NHS England 2023). Standard surgical procedure costs were sourced from a cost-comparison study. Complication costs were sourced from the National Cost Collection, with alternative costs sourced from a published cost-effectiveness study (Moss et al 2021, Labban et al 2022).

Further details are in Tables 8.4 to 8.7 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; LoS: length of stay; AR: assessment report

Base case results (1)

- Due to the heterogeneity across the digital technologies, procedures, patient populations and available evidence to populate the economic model, the base case is intended to be indicative of the potential impact of RAS. The model is not intended to reflect every possible case-mix, potential soft-tissue procedure and individual robotic platform.
- The base case has been split into three sections to represent the three different RAS costing structures. The base case should be considered alongside the range of scenarios, given the heterogeneity in soft-tissue procedures.
- Use of RAS technologies in the NHS is potentially cost-incurring compared with standard surgical procedures across all three costing scenarios in the short-term.
- The technologies are estimated to increase health care costs, driven by the upfront cost (for upfront and leasing) of the robot and additional consumable equipment required to carry out the procedure.
- The results suggest that the additional costs from a reduction in complications, readmissions and surgery conversions are not likely to outweigh the cost of using RAS technologies, at least in the short-term.

RAS: robot-assisted surgery

Base case results (2)

Deterministic result	Summary	SoC	RAS+SoC	Incremental
Upfront costing structure	Average cost per procedure	£7,453	£7,927	£474
	Required QALYs to be cost effective between treatment arms			0.02
	Required QALYs from RAS procedures specifically to be cost effective (i.e., required QALYs per RAS procedures, given not all procedures will be robot-assisted).			0.10
Leasing costing structure	Average cost per procedure	£7,453	£7,852	£400
	Required QALYs to be cost effective between treatment arms			0.02
	Required QALYs from RAS procedures specifically to be cost effective (i.e. required QALYs per RAS procedures, given not all procedures will be robot-assisted).			0.09
Free loan costing structure	Average cost per procedure	£7,453	£8,056	£603
	Required QALYs to be cost effective between treatment arms			0.03
	Required QALYs from RAS procedures specifically to be cost effective (i.e., required QALYs per RAS procedures, given not all procedures will be robot-assisted).			0.13

RAS – Robot-assisted surgery, SoC – Standard of care, QALY – Quality adjusted life year

Scenario analysis

- The EAG conducted a range of scenario analyses, given the potential variation in RAS systems for soft tissue procedures, such as pricing and the uncertainty in input values, a range of scenarios were considered:
    - All scenarios led to cost-incurring results across all costing structures.
    - Higher utilisation of RAS for MIS procedures increased the average cost-per procedure.
- The EAG expect the true short-term base case to be within the scenarios conducted based on a range of factors including case-mix, utilisation of RAS, costing strategies, and the heterogeneity in the patient population.
- The required long-term QALY gain from RAS to be cost-effective based on the scenarios conducted ranged from 0.01 (where RAS is the least cost-incurring) to 0.14 (where RAS is the most cost-incurring). Hence, if RAS could lead to QALY gains of over 0.14 on average across soft-tissue procedures, it could plausibly be a cost-effective intervention. This can be visualised as each patient gaining approximately 51 days (14% of one year) of perfect health over the course of their lifetime

NICE

For further details see section 8.3.1 and Table 8.11 of the AR

RAS: robot-assisted surgery; MIS: minimally invasive surgery; QALY: quality adjusted life-year; AR: assessment report

Deterministic sensitivity analysis

The EAG conducted a deterministic sensitivity analysis to explore the uncertainty of key parameters in the model.

- 1-way sensitivity analysis on the upfront costing structure suggests the following parameters are the key drivers of the model:
    - proportion of MIS surgeries that are RAS for the intervention arm
    - additional length of surgery time for RAS per person
    - proportion of surgeries that are MIS in either treatment arm
    - conversion rate from MIS to open in either treatment arm
    - disposable component costs of RAS.
- The EAG state the results of the other costing structures was very similar.

NICE

For further details see section 8.3.2 and figure 8.2 of the AR

RAS: robot-assisted surgery; EAG: external assessment report; AR: assessment report

Economically justifiable price

The EAG did additional deterministic sensitivity analysis to explore the economically justifiable price with respect to cost-savings.

- In the base case, the additional cost of RAS (compared to conventional MIS procedures) was £2,585, £2,263, and £3,138 for the upfront, leasing, and free loan costing structures respectively. For the intervention to break even (cost-neutral), the additional cost of RAS would need to be a maximum of £277 per procedure.
- In the base case, the additional cost of RAS (compared to open procedures) was £2,292, £1,970 and £2,845 for the upfront, leasing, and free loan costing structures respectively. For the intervention to break even (cost-neutral), the additional cost of RAS would need to be a maximum of £1,565 per procedure. This indicates a higher capacity to benefit from replacing open surgeries with RAS, rather than conventional MIS.
- The economically justifiable price should be interpreted with caution due to the early nature of the analysis, the heterogeneity across surgical procedures and patient populations, and long-term potential benefits omitted from the analysis. The figures did not account for differences in length of stay, complications or readmissions.
- However, the results can be used as an indication of the potential cost impacts of RAS in the short-term, as well as indicate the potential health benefit required to be cost-effective, at a £20,000 per QALY threshold.

NICE

For further details see section 8.3.2 and Figure 8.3 of the AR

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report; QALY: quality adjusted life year; MIS: minimally invasive surgery

Probabilistic sensitivity analysis

The EAG did a probabilistic sensitivity analysis to explore the economically justifiable price with respect to cost-savings.

Similar results to the base case (upfront costing structure), the probabilistic incremental cost per procedure was calculated as £490, based on 1,000 model iterations. This includes a mix of RAS replacing both open and conventional MIS surgeries and does not assume 100% uptake of RAS.

Summary results	SoC	RAS+ SoC	Incremental
Upfront costing structure			
Cost per procedure	£7,683	£8,173	£490
95%CI: lower	£5,884	£6,389	-£490
95% CI: upper	£9,931	£10,145	£1,583
Probability that the intervention is cost saving			14.9%
Leasing costing structure			
Cost per procedure	£7,698	£8,086	£388
95%CI: lower	£5,926	£6,385	-£464
95% CI: upper	£9,920	£10,475	£1,436
Probability that the intervention is cost saving			18.0%
Free loan costing structure			
Cost per procedure	£7,682	£8,268	£586
95%CI: lower	£5,829	£6,472	-£394
95% CI: upper	£9,885	£10,442	£1,641
Probability that the intervention is cost saving			9.7%

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report; CI: confidence interval; SoC: standard of care

For further details see section 8.3.3 of the AR

Summary of economic results (1)

- The results indicate RAS is likely to be cost incurring, with respect to short-term outcomes.
- The results were more favourable for scenarios where RAS was replacing open surgeries, than RAS replacing SoC MIS.
- If RAS could lead to average QALY gains of over 0.1 across soft-tissue procedures over a lifetime, it is more likely to be a cost-effective intervention at a £20,000 per QALY threshold in the base case.
- The required long-term QALY gain from RAS to be cost-effective based on the scenarios conducted ranged from 0.01 (where RAS is least cost-incurring, with the assumption that the lowest RAS costs are used and a leasing cost structure is taken) to 0.14 (where RAS is the most cost-incurring, with the assumption that 93% of all procedures in the intervention arm of the model are carried out by RAS and when a free loan cost structure is taken).
- For context, 0.01 QALYs would represent approximately 4 additional days in perfect health, or 1% of one year, whilst 0.14 QALYs would represent approximately 51 days of additional days in perfect health, or 14% of one year.

RAS: robot-assisted surgery; QALY: quality adjusted life year; SoC: standard of care

Summary of economic results (2)

- If RAS could lead to long-term cost reductions (such as reduced severity of disease or progression), then less QALY gains would be required to be cost-effective.
- The lower the potential long-term QALY gains from RAS, the less likely it is to be a cost-effective intervention. A QALY gain of approximately 0.1 leads to approximately a 50% chance that RAS is cost-effective for soft-tissue procedures, for an upfront purchase costing structure
    - Previous economic studies, including deprioritised studies, estimated a range of QALY scores (between 0.014-0.105). These did not consider long term outcomes

RAS: robot-assisted surgery; QALY: quality adjusted life-year

Summary of economic results (3)

- The results do not:
    - factor in long-term cost outcomes
    - capture the potential impact on health outcomes (QALYs) from RAS when compared with non-RAS based procedures.
- The estimated results are not intended to capture every robotic platform perfectly but are intended to provide an indication of the potential impact from implementing these technologies, based on a range of different scenarios
- Simplifying assumptions and omissions were made, and the analysis should be treated as a tool for an early evaluation of RAS for soft-tissue procedures, and interpreted with caution because:
    - there is a lack of existing data, and substantial heterogeneity across soft-tissue procedures and patient populations.
    - the evidence available to populate the model is extracted from procedures where RAS is more commonly used, so may not be representative of all soft-tissue procedures.
    - companies have mixed evidence for each of the scoped robotic platforms, so evidence was used from unspecified robotic platforms to populate the model.

RAS: robot-assisted surgery; QALY: quality adjusted life-year

Considerations for the economic results (1)

The EAG recommend the following should be considered because it was not captured in the model:

Likelihood of long-term health impacts

Better surgical success rates when using RAS may lead to:

- Improved survival, quality of life or both
- Reduced healthcare costs

It is less likely that RAS would be cost-effective compared with standard surgical care for surgical procedures which do not (or are unlikely to) lead to long-term benefit.

RAS: robot-assisted surgery; AR: assessment report

For further details see section 8.3.3 of the AR

Considerations for the economic results (2)

The EAG recommend the following should be considered in relation to the key drivers of the results:

Operative time

Operative time was a key driver of the model. Clinical advice and studies show different findings for the impact of RAS on operative time depending on procedure. If operative time is reduced, it is more likely RAS will be cost-effective.

The impact of learning curve

Multiple studies reported that surgeons will remain 'on' the learning curve throughout the study which may mean effects of RAS have been underestimated. But, training time may be as long or shorter for RAS than conventional MIS procedures for novice surgeons. So, this might reduce training costs instead of increase them.

Utilisation of RAS

If the robotic platform is outright purchased or leased, the marginal costs of additional procedures using RAS is relatively lower, compared to the overall fixed cost of purchasing or leasing the platform. So, if robotic platforms can be utilised highly within the NHS, their implementation is more likely to be cost-effective. Drivers of utilisation may be placement within departments which are more willing to use robotic platforms for a range of procedures, or portable platforms to maximise output.

RAS: robot-assisted surgery; AR: assessment report

For further details see section 8.3.3 of the AR

Considerations for the economic results (3)

The EAG recommend the following should be considered in relation to the key drivers of the results:

Need for improvement in health outcomes

- Estimates suggest that RAS will cost an additional £2,585 to £3,138 to conduct the surgery per person when compared with conventional MIS. The estimated break-even (cost-neutral) point is approximately £277 per procedure in this group.

- Estimates suggest that RAS will cost an additional £1,970 to £2,845 to conduct the surgery per person when compared with open procedures. Estimates suggest that the breakeven (cost-neutral) point is approximately £1,565 per procedure in this group.

- Long-term cost savings or improvement in health outcomes will likely be required for RAS to be cost-effective, based on the current evidence.

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RAS: robot-assisted surgery; AR: assessment report

For further details see section 8.3.3 of the AR

Considerations for the economic results (4)

The EAG recommend the following should be considered in relation to the key drivers of the results:

Budgetary cost increases with increased utilisation

Although there is a fixed cost aspect to adoption of robotic platforms, it is important to note that as the proportion of surgeries conducted with RAS increase, the budgetary cost to the NHS will likely be higher. This is because RAS is still cost-incurring even if it is more cost-effective at greater utilisation.

Examples of these marginal costs include disposable components, or staff time. Therefore, even if greater utilisation of robotic platforms reduces the fixed costs per procedure, and improves the cost-effectiveness, greater utilisation will still increase the impact on the healthcare budget.

RAS: robot-assisted surgery; AR: assessment report

For further details see section 8.3.3 of the AR

Considerations for the economic results (5)

The EAG recommend the following should be considered in relation to the key drivers of the results:

Alternative costings of RAS platforms

Costing structure was a key driver of the results. It is likely that the free loan option is less cost-effective than a leasing or upfront purchase.

- This assumes that, in an upfront or leasing costing structure, the robotic platform is well utilised by NHS providers (at least 300 procedures per year), so the fixed costs can be spread over a wider number of cases.
- Also, per-procedure costing information for a free loan structure was provided by only one company, so may not be representative of all RAS systems.
- This also depends on whether there is available budget to purchase or lease the robotic platform, which will result in higher upfront costs.
- If a surgical robot platform were to be used sparingly for very specific, and less common soft-tissue procedures, it is feasible that the free loan model could be the most cost-effective strategy of the three costing strategies (providing that RAS was overall cost-effective).

RAS: robot-assisted surgery; AR: assessment report

For further details see section 8.3.3 of the AR

Considerations for the economic results (6)

The EAG recommend the following should be considered in relation to the results:

Previous economic studies

The prioritised economic evidence presented a range of results which did not align with the EAG model results.

- They often missed relevant costs, like upfront cost of the robot, maintenance costs for the robot, or costs associated with complications.
- Generally, they focused on specific procedures rather than the wide range of procedures RAS may be used for in soft-tissue
- The England cost-comparison analysis that reported potential areas of cost savings was unpublished and subject to biases due to lack of peer review, as well as modelling potential savings using 1 data source (1clinician).

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report

For further details see section 8.3.3 of the AR

Further considerations for integration into the NHS (1)

Availability of the robotic platforms included in this assessment

- [redacted]The current usage of Senhance in the NHS is unclear.
- 3 of the 4 technologies that submitted evidence are not yet indicated for use in children.
- Adverse events and complications were at least comparable between RAS and other surgical care. So, it is likely that technologies would be at very low risk of leading to unsafe outcomes, relative to standard surgical care, if technologies are recommended as part of an EVA to collect future evidence.

RAS: robot-assisted surgery; EVA: early value assessment; AR: assessment report

For further details see section 9.2 of the AR

Further considerations for integration into the NHS (2)

Training and learning curve

RAS needs specially trained surgical teams. The time it takes to train for specific procedures will depend on:

- staff familiarity with robotic platforms and availability of competent staff to train others
- the type of procedure- more complex procedures or procedures that are carried out less frequently could take longer than the EAG's initial estimates.

Training time will likely put strain on NHS resources because of:

- staff time spent observing surgeries or attending training sessions
- extended surgery time and potential reduced effectiveness of surgery whilst surgeon is learning

Training and structural changes may be needed to optimise RAS across the workforce.

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report

For further details see section 9.2 of the AR

Further considerations for integration into the NHS (3)

Price and funding structures

The current list prices for the robotic platforms within scope are high cost, [redacted], not including consumables, maintenance and other budgetary factors for the hospital.

- How this is funded should be considered by decision-makers, and funding arrangements will need to be made for procurement of any recommended robotic platforms.
- Sustainable payment structures for hospitals, within the context of constrained budgets are needed, and this may need support from NICE, NHS England and companies.
- 4 of the 5 models are on the NHS supply chain framework.
- Different contracts are likely to suit different providers, so the EAG recommends optimal financing option should be decided with the NHS provider if recommended as part of the EVA programme.

RAS: robot-assisted surgery; GBP: great British pounds; EAG: external assessment group; AR: assessment report; EVA: early value assessment

For further details see section 9.2 of the AR

Further considerations for integration into the NHS (4)

Physical impact on surgical staff

Evidence, reiterated by clinician statements, shows that RAS significantly reduces the physical burden on a surgeon. This was not captured in the model. It should be considered as it could mean that surgeons are able to spend longer in the workforce, which may help alleviate staffing shortages.

Clinician and patient attitudes towards RAS

Socioeconomic status, age and gender may impact perceptions of RAS. Without patient engagement, RAS uptake may be limited. But, RAS may improve staff recruitment and retention. Understanding the factors which drive both clinician and patient engagement will help improve uptake and success of any practical implementation.

Health inequalities

Health inequalities were presented at the start of the slide deck. If RAS were to be implemented more widely, national strategies for procurement, implementation, equitable distribution, and training must be considered to avoid worsening health inequalities

RAS: robot-assisted surgery; AR: assessment report

For further details see section 9.2 of the AR

Key economic considerations

- The results found RAS is likely to be cost incurring, at least in the short term. But, if RAS could lead to average QALY gains of over 0.1 across soft-tissue procedures over a lifetime (approximately 36.5 days of full health per person, or 10% of one year), it is plausible that it could be a cost-effective intervention at a £20,000 per QALY threshold, under base case assumptions (this ranged from 0.01 to 0.14 in scenario analysis). How clinically feasible is this?
- Key drivers of the model in the DSA were: proportion of MIS surgeries that are RAS for the intervention arm, additional length of surgery time for RAS per person, proportion of surgeries that are MIS in either treatment arm, conversion rate from MIS to open in either treatment arm, disposable component costs of RAS. Results were more favourable for scenarios where RAS was replacing open surgeries, than RAS replacing standard MIS.
- Some cost structures are offered by companies that were not captured in this model.
- The results are not specific to technology, sub-population or procedure. They are an indication of the potential impact from implementing these technologies, based on a range of different scenarios. Were the simplifying assumptions and omissions that were made appropriate for the assessment of these technologies, at this stage? How confident are you in the results?
- What clinical areas do the committee think are likely to have been underestimated or overestimated in the model, given the broad approach taken?
- There are many implementation challenges associated with introducing RAS, do these affect interpretation of the results?

RAS: robot-assisted surgery, MIS: minimally invasive surgery, QALY: quality adjusted life year; DSA: deterministic sensitivity analysis

Gap analysis – clinical outcomes (1)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Primary clinical- patient level					
Conversion to open surgery	10 cohort studies (6 retrospective, 1 prospective; 3 historically controlled [9 Europe, 1 UK] 2 prospective non-randomised studies (Europe) AMBER	No studies RED	1 retrospective cohort study (Europe) AMBER	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) 1 prospective non-randomised study (Asia) AMBER
Conversion to conventional MIS from RAS	1 prospective non-randomised study (Europe) 4 cohort studies (3 retrospective; 1 historically controlled [4 Europe]) AMBER	No studies RED	1 retrospective cohort study (Europe) AMBER	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) 1 prospective non-randomised study (Asia) AMBER
Length of hospital stay	9 cohort studies (6 retrospective, 1 prospective, 2 historically controlled [1 UK; 8 Europe] 2 prospective non-randomised studies (Europe) AMBER	1 prospective cohort study (Asia) AMBER	1 retrospective cohort study (Europe) AMBER	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) 1 prospective non-randomised study (Asia) AMBER
Intraoperative complications	6 cohort studies (4 retrospective; 1 prospective; 1 historically controlled [6 Europe]) AMBER	1 prospective cohort study (Asia) AMBER	1 retrospective cohort study (Europe) AMBER	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) AMBER

NICE

RED: no comparative evidence for the scoped population; AMBER: weak comparative evidence for the scoped population, GREEN: robust comparative evidence for the scoped population

Gap analysis – clinical outcomes (2)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Primary clinical- patient level					
Postoperative complications	Overall complications: 4 cohort studies (2 retrospective studies; 1 historically controlled [4 Europe]) **AMBER**	1 prospective cohort study (Asia) **AMBER**	No studies **RED**	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) **AMBER**	1 RCT 1 prospective non-randomised study (Asia) **AMBER**
Clavien-dindo score	8 cohort studies (5 retrospective, 1 prospective, 2 historically controlled [1 UK, 7 Europe] 2 prospective non-randomised studies (2 Europe) **AMBER**	No studies **RED**	No studies **RED**	2 cohort studies (1 retrospective, 1 historically controlled [1 UK, 1 Europe]) **AMBER**	1 RCT (UK) **AMBER**
HRQoL	1 historically controlled cohort study (Europe) **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Primary clinical- surgeon level					
Procedure-related discomfort and ergonomics	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 RCT (UK) **AMBER**

NICE

RED: no comparative evidence for the scoped population; AMBER: weak comparative evidence for the scoped population, GREEN: robust comparative evidence for the scoped population

Gap analysis – clinical outcomes (3)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Primary clinical- organisation level					
Rate of MIS compared with open surgery after RAS was introduced	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Volume of procedures	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Capacity and wait-list reduction	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Secondary clinical- patient level					
Days alive and out of hospital	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Post-operative pain	4 cohort studies (1 prospective, 1 retrospective, 2 historically controlled [4 Europe] AMBER	No studies RED	No studies RED	1 retrospective cohort study (UK) AMBER	1 RCT (UK) 1 prospective non-randomised study (Asia) AMBER
Satisfaction	1 retrospective cohort study (Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Revision surgery for the same indication	2 prospective non-randomised studies (2 Europe) 5 cohort studies (4 retrospective; 1 prospective [1 UK; 4 Europe]) AMBER	No studies RED	No studies RED	1 historically controlled cohort study (Europe) AMBER	No studies RED

RED: no comparative evidence for the scoped population; **AMBER:** weak comparative evidence for the scoped population, **GREEN:** robust comparative evidence for the scoped population

Gap analysis – clinical outcomes (4)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Secondary clinical - patient-level (specific study types)					
Intraoperative blood loss (compared with open surgery)	1 prospective randomized study (Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Survival rate (in cancer studies)	3 retrospective cohort studies (1 UK; 2 Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Need for adjuvant treatment (in cancer studies)	1 prospective non-randomized study (Europe) AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Feeding tube dependency (for head and neck studies)	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Secondary clinical - surgeon level					
Career longevity and musculoskeletal injury	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Human factors	No studies RED	No studies RED	No studies RED	No studies RED	1 RCT (UK) AMBER
Learning curve	3 cohort studies (2 retrospective; 1 historically controlled [3 Europe]) AMBER	No studies RED	No studies RED	1 retrospective cohort study (UK) 1 historically controlled cohort study (Europe) AMBER	1 retrospective non-randomised study (Asia) AMBER

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Gap analysis – clinical outcomes (5)

Outcomes	Da Vinci Xi	Da Vinci SP	Hugo	Senhance	Versius
Secondary clinical - organisation-level					
Readmission at 30 days	1 prospective non-randomised study (Europe) 5 cohort studies (3 retrospective, 1 prospective; 1 historically controlled [1 UK, 4 Europe]) AMBER	No studies RED	1 retrospective cohort study (Europe) AMBER	1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) AMBER
Operating time	11 cohort studies (7 retrospective, 1 prospective; 3 historically controlled [10 Europe, 1 UK] 2 prospective non-randomised studies (Europe) AMBER	1 prospective cohort study (Asia) AMBER	1 retrospective cohort study (Europe) AMBER	2 retrospective cohort studies (1 UK, 1 Europe) 1 historically controlled cohort study (Europe) AMBER	1 RCT (UK) 1 prospective non-randomised study (Asia) AMBER
Staffing requirements	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

NICE

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Gap analysis – economic outcomes (1)

Outcome	Gap in current evidence
Effectiveness evidence: Difference in proportion of MIS from introducing robotic platforms	One of the value propositions from implementing robotic platforms is the increased provision of MIS. However, there is currently no UK evidence to indicate how much more likely MIS will be for the range of soft-tissue procedures within scope. RED
Effectiveness evidence: Long-term outcomes	If RAS is improving surgical outcomes, it is feasible that this may lead to improvements in long-term health outcomes. Current studies do not have sustained follow up, usually less than one year for specific soft-tissue procedures. Therefore, it is not currently possible draw any conclusions of the average long-term benefit of RAS across all soft-tissue procedures. AMBER
Effectiveness evidence: Impact of subgroups	Evidence is currently of low-quality for how outcomes differ between different groups of procedures by speciality, or by other patient characteristics (such as co-morbidities) for the scoped technologies. Co-morbidities, or specific groups of procedures within 'soft-tissue' may lead to significantly different outcomes AMBER
Resource use: Utilisation of robotic platforms when introduced across relevant case-mix	There are currently reports available from companies and anecdotal evidence from clinical experts on the utilisation of robotic platforms. However, this is in clinical specialities which have much higher uptake of RAS, and may not reflect all of soft-tissue procedures. If RAS is going to be recommended across a range of soft-tissue procedures, then greater evidence needs collecting on the utilisation of the robot. AMBER

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Gap analysis – economic outcomes (2)

Outcome	Gap in current evidence
Resource use: Impact on capacity across all healthcare settings	There is some anecdotal evidence from clinical experts and some specific procedures that RAS may increase capacity of surgeries in the system. This is due to a combination of reduced physical strain on surgical staff, and for some of the scoped procedures, reduced operative times. However, other procedures indicate longer waiting times, so more evidence is required on the likely impact if RAS is recommended for all soft-tissue procedures. AMBER
Resource use: Impact of learning curve	There is very limited evidence available to quantify the impact of the clinician learning curve on the costs or efficacy of RAS. While this impact is likely to be short-term, potentially affecting outcomes primarily within the first 1-2 years, it is important to consider. Furthermore, modelling the effects of introducing RAS at new sites or with new clinicians will be important in assessing the feasibility of its implementation. RED
Costs: Set up and training costs	Companies provide some evidence of the implementation, training and learning curve effects and the associated costs to embed their technologies within the NHS, but the quality of evidence is mixed and is likely heterogenous across soft-tissue procedures. Further clarification should be sought on the required training and learning curve effects for all procedures in scope for this evaluation. AMBER
Costs: Alternative cost structures	Only one company provided information on the cost of RAS under a free loan structure, and no data was available regarding leasing cost structures. This introduces uncertainty into the outcomes of the economic modelling and is a key driver of uncertainty for this evaluation. A more robust understanding of the available costing structures will be important for the procurement and successful implementation of robotic surgery platforms within the NHS. RED

RED: no comparative evidence for the scoped population; AMBER: weak comparative evidence for the scoped population, GREEN: robust comparative evidence for the scoped population

Gap analysis summary

- Evidence gap analysis is based on prioritised studies
- Moderate to low quality comparative evidence was identified for many patient-level outcomes:
  - Conversion to open surgery, intra operative and post operative complications and the Clavien-Dindo score, length of hospital stay
  - Half studies were retrospective and 4 used historic controls
  - Even where prospective, comparative evidence was available, studies were of too short a duration to understand the impact of the learning curve, and had small sample sizes
- Each study tended to focus on one specific type of surgery (like colorectal resection). There may be indication specific outcomes that are clinically relevant that have not been considered as part of this evaluation.
- Primary surgeon and organisational level outcomes were not well reported.
- There was insufficient long-term evidence to consider the learning curve and to understand the surgeon and organisation outcomes from the point that optimal performance and use of the robot is reached.

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RAS: robot-assisted surgery

Ongoing studies

Studies taking place in the UK were prioritised for consideration. Several other ongoing studies were identified from company submitted information but they were not comparative, prospective ongoing studies that might be considered in a future assessment.

- 4 ongoing, UK prospective studies were found
- The MAYFLY study (ISRCTN18159384)
  - Da Vinci Xi; 1 year follow-up
  - Single arm prospective, but outcomes will be compared with routinely collected Trust-level metrics for laparoscopic and robotic surgery, in multidisciplinary department
  - Portsmouth, UK; estimated completion September 2026
- The LARCS study (NCT06038227)
  - Da Vinci Xi; 1 month follow-up
  - Comparative, video-assisted thoracic surgery vs RAS in non-small cell lung cancer
  - London, UK; estimated completion December 2027
- NCT06112535
  - Versius; 30 day follow-up
  - Single-arm prospective feasibility trial for transoral surgery
  - Liverpool, UK; estimated completion February 2025
- NCT06539442
  - Versius; 12 month follow-up
  - Single-arm prospective proof-of-concept for paediatric urological procedures
  - 3 UK sites; estimated completion January 2027

RAS: robot-assisted surgery; AR: assessment report

For further details see section 9.3 of the AR

Gap analysis- EAG recommended key areas for evidence generation (1)

Objective	Recommended study design	Outcomes
Long term outcomes and resource use associated with RAS beyond first 30 days.	Large multi-centre, prospective, comparative studies of robotic vs. current standard of care (open or MIS) Further studies in a UK setting for all robots over at least a 1 year follow up.	• Patient level, surgeon level and organisation level outcomes. • Understand the learning curve associated with RAS introduction. • Studies are needed to address outcomes for Da Vinci SP, Hugo, Senhance and Versius
Understanding the difference in outcomes between introduction of RAS and optimal performance (accounting for learning curve)		• Patient level, surgeon level and organisation level outcomes. • Understand the learning curve associated with RAS introduction.
Resource use associated with training staff	Prospective observational studies, documenting staff time associated with training. Conducted in the UK.	• Time spent training for different procedures
Patient uptake of RAS and facilitators of acceptability.	Mixed methods studies assessing patient preference data and ensuring adequate communication of the benefits and risks of RAS Conducted in the UK.	• Patient preference • Facilitators and barriers of uptake
Surgeon uptake of RAS and facilitators of acceptability.	Mixed methods studies assessing surgeon preference.	• Surgeon preference and perceived facilitator and barriers to use of RAS

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Gap analysis- EAG recommended key areas for evidence generation (2)

Objective	Recommended study design	Outcomes
Understanding the value of different features between robotic platforms, and if they are valuable to the surgeon or healthcare system	Mixed methods studies assessing the importance of features such as single port versus multi-port, portability of robotic platform etc.	• Understanding of components and factors which make a more optimal robotic platform.
Understanding of the impact RAS has on the numbers of MIS.	Difference-in-differences approach could be taken to evaluate uptake. This includes having control hospitals (without robotic platforms) and comparing to those where they are implemented. Data can be looked back retrospectively for the before period.	• System level outcomes to determine if RAS is driving differences in MIS.
Understanding on how surgery types could be grouped to streamline evidence generation (also see Section 10.3)	With clinical input, deciding which groupings are most appropriate to generate evidence and model the potential benefits of RAS.	• Quality of life • Clinical outcomes • Resource use • Cost
Identification of generalisable outcome measures, either for all soft-tissue procedures, or by specific groupings	Qualitative research including engagement with clinical experts to identify clear groupings.	• Identification of patient, clinician and system level outcomes for grouped areas of research

RAS: robot-assisted surgery; MIS: minimally invasive surgery

Gap analysis- summary of key areas for evidence generation

The EAG recommend that evidence generation should:

- focus on filling evidence gaps in settings in which the use of RAS to support soft tissue surgery has shown early potential to have beneficial impact on key health and resource use outcomes when compared with SoC (MIS or open, depending on the indication).
- be done across a long enough timeframe to understand the learning curve and to evaluate the outcomes and resource use implications when the robot has reached its optimal performance in the hospital (both short- and long-term).
- explore the long-term clinical effects of RAS compared with SoC
- evaluate the geographical variation in resource use, uptake, efficacy, and health outcomes.
- report data on the proportion of patients who were able to undergo MIS due to the introduction of RAS
- establish the patient and staff acceptability of the technologies.
- explore the value of different features between robotic platforms, and if they are valuable to the surgeon or healthcare system
- be done across a range of indications or surgeries in settings where the robotic platform is being introduced and in settings where it is already established.

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For further details see section 10.1 and 11.3 of the AR

EAG: external assessment group; RAS: robot-assisted surgery; MIS: minimally invasive surgery; SoC: standard of care; AR: assessment report

Gap analysis- potential approaches to evidence generation

Balance between pragmatism and granularity is needed

- Likely infeasible to do large-multi-centre studies for all possible indicated soft-tissue procedures.
- But, studies that capture all soft-tissue procedures in one study are likely to focus on generalisable outcomes, omitting key potential benefits of RAS. This approach to evidence generation is likely to be highly dependent on the case-mix of where the robotic platforms are used, so may not be representative of all soft-tissue procedures.

The optimal approach may be a hybrid approach

- Studies based on grouped procedures either by similar clinical outcomes (both short-term and long-term), clinical specialty or anatomy.
- EAG suggests this will find the balance between generating appropriate evidence to support decision-making, without needing to conduct an unmanageable level of studies.

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For further details see section 10.1 of the AR

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report

Potential future modelling approaches

Three potential approaches for future modelling were proposed by the EAG.

Approach 1: high-level, one model

- Aim is to focus on generalisable outcomes using robust aggregated data.
- The benefit of this approach is that outcomes that are more easily generalised across a range of soft-tissue procedures can be captured, matching the scope of the evaluation. Long term outcomes could be captured, but would be simplified. For example, the model could do a survival analysis with scenarios for different expected survival outcomes.
- The limitation of his approach is that benefits of RAS for specific procedures is not captured.

Approach 2: hybrid approach, multiple models, each for a grouped clinical area (EAG suggested optimal approach)

- Aim is to evaluate a group of soft-tissue procedures where key clinical outcomes are similar
- Benefit is that it may enable more granularity to be captured in outcomes, where economic outcomes are more similar.
- The limitation is it may be more time intensive than generalised approach. It would need clinical guidance to inform the groupings and wider discussions about the feasibility of the level of assessment.

Approach 3: granular-level, one model for each procedure

- Less preferable as does not evaluate RAS in context of the range of applications.
- Likely infeasible to collect the evidence needed as it would need lots of studies for each procedure, on each robotic platform.

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Further details on these approaches are in section 10.2 of the AR

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report

Issues for consideration: Clinical evidence

- What are the expectations for RAS to show clinical equivalence or superiority over comparators? Does the evidence meet these expectations?
    - Conversion rate did not show the direction or effect expected.
- There are different amounts of evidence for each technology, and each is of different quality. Some primary patient level outcomes, and all primary organisation level outcomes had no data in the prioritised evidence. No study included a case mix of soft-tissue procedures, they all focused on one type of procedure. Not all soft-tissue procedures have been covered. The definitions and measures used for some of the primary outcomes were inconsistent between studies. In particular, 'learning curve' was measured in different ways between each study, but only in terms of length of surgery.
    - To what extent does learning curve affect these outcomes?
    - What limits the interpretation of this evidence and how generalisable are the findings?
    - What is needed to ensure key outcomes can be usefully interpreted in the future?
- What level of recommendation (per technology, per procedure, technology agnostic) is most useful for translation of the recommendations into practice?
- What is not represented in these outcomes that is important to consider?

RAS: robot-assisted surgery

Key economic considerations

- The results found RAS is likely to be cost incurring, at least in the short term. But, if RAS could lead to average QALY gains of over 0.1 across soft-tissue procedures over a lifetime (approximately 36.5 days of full health per person, or 10% of one year), it is plausible that it could be a cost-effective intervention at a £20,000 per QALY threshold, under base case assumptions (this ranged from 0.01 to 0.14 in scenario analysis). How clinically feasible is this?
- Key drivers of the model in the DSA were: proportion of MIS surgeries that are RAS for the intervention arm, additional length of surgery time for RAS per person, proportion of surgeries that are MIS in either treatment arm, conversion rate from MIS to open in either treatment arm, disposable component costs of RAS. Results were more favourable for scenarios where RAS was replacing open surgeries, than RAS replacing standard MIS.
- Some cost structures are offered by companies that were not captured in this model.
- The results are not specific to technology, sub-population or procedure. They are an indication of the potential impact from implementing these technologies, based on a range of different scenarios. Were the simplifying assumptions and omissions that were made appropriate for the assessment of these technologies, at this stage? How confident are you in the results?
- What clinical areas do the committee think are likely to have been underestimated or overestimated in the model, given the broad approach taken?
- There are many implementation challenges associated with introducing RAS, do these affect interpretation of the results?

RAS: robot-assisted surgery, MIS: minimally invasive surgery, QALY: quality adjusted life year; DSA: deterministic sensitivity analysis

Gap analysis: summary of key considerations

- Moderate to low quality comparative evidence was identified for many patient-level outcomes. Primary surgeon and organisation-level outcomes were not well reported. There was insufficient long-term evidence to consider the learning curve and to understand the surgeon and organisation outcomes from the point that optimal performance and use of the robot is reached. Which outcomes would benefit from specific guidance on what and how to collect evidence?
- Because of the implementation challenges associated with RAS, further evidence generation beyond the primary and secondary outcomes is needed. The EAG suggests this should establish: acceptability for patients and staff, geographical variations in uptake and outcomes, implications when the robot has reached its optimal performance in the hospital, the value of different features between robotic platforms.
- Which costs, outcomes and implementation challenges will be difficult to capture in future evidence generation?
- A hybrid approach was recommended by the EAG for clinical evidence generation and future modelling approaches, where procedures are grouped by similar clinical outcomes or specialty. Qualitative research with clinical experts would be needed to establish clear groupings. Is this approach the most appropriate? Is it feasible?

RAS: robot-assisted surgery; EAG: external assessment group; AR: assessment report

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Thank you.

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

Document cover sheet

Assessment report: Robot-assisted Surgery for Soft-tissue Procedures (addendum)

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EAG sign-off: Hayden Holmes

Version number	Brief description of changes	Author/reviewer (e.g. J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
1.0	Draft addendum report submitted to NICE	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Emma Carr Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	14.11.2024	14.11.2024
2.0	Updated addendum following NICE comments	Rachael McCool Hayden Holmes Robert Malcolm Chris Bartlett Anne Littlewood Emma Carr Alice Sanderson Luc Curtis-Gretton Emma Bishop Benjamin Hyde	25.11.2024	25.11.2024

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

[GID-HTE10040] - Robot-assisted Surgery for Soft-tissue Procedures

External Assessment Group Report Addendum

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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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Responsibly 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.

Contents

Abbreviations

Term	Definition
AE	Accidence and emergency
BMI	Body mass index
CI	Confidence intervals
EQ-5D	EuroQol 5 dimension
EQ-5D-5L	EuroQol 5 dimension 5 level
GOALS	Global operative assessment of laparoscopic skills
GRADE	Grading of recommendations assessment, development and evaluation
H&N35	Head and neck questionnaire
HRQoL	Health related quality of life
ICER	Incremental cost-effectiveness ratio
IQR	Inter-quartile range
ITT	Intention to treat
Los	Length of stay
M0	Cancer has not spread
MINORS	Methodological index for non-randomized studies
MIS	Minimally invasive surgery
MITT	Modified intention to treat
N.S	Not significant
N0	No cancer in nearby lymph nodes
N2b	1 lymph node contains cancer cells on the same side of the neck as the cancer
NASA-TLX	NASA task load index
NR	Not reported
NSCLC	Non-small cell lung cancer
NSQIP	National surgical quality improvement program
OR	Odds ratio
QALY	Quality adjusted life year
QLQ C30	Quality of life questionnaire 30 item
RAS	Robot-assisted surgery
RCT	Randomised controlled trial
ROBINS-1	Risk of bias in non-randomised studies - of interventions
RPL-4	Robot assisted lobectomy
SD	Standard deviation
SF-36v2	Short form questionnaire 36 items

SMEQ	Subjective mental effort questionnaire
SP	Single port
T1	Cancer is small and non-spreading
T3	Cancer has grown into nearby tissues
TLM	Transoral laser microsurgery
TMN	Cancer staging system
TORS	Transoral robotic surgery
VAS	Visual analogue scale
VATS	Video-assisted thoracic surgery lobectomy

1 Background to the addendum

The NICE Final Scope for 'GID-HTE10040 - Robot-assisted Surgery for Soft-tissue Procedures' determined 4 technologies should be evaluated as part of the early value assessment. One additional technology (Senhance) was identified at a later date than the original assessment and was considered relevant for evaluation. Following the first committee meeting for this topic, the companies were encouraged to submit further evidence to ensure that the evidence considered was the most appropriate to the decision problem. Clinical experts were also invited to submit further evidence for consideration. In addition, a number of systematic reviews and meta-analyses were identified during the early value assessment and used to identify relevant studies that may have been missed by the EAG searches. As these were not an eligible study design for the original assessment, their results were not extracted. The EAG has extracted the data for this addendum, to find out whether the results of recent systematic reviews align with the conclusions of the original assessment report and if the reviews provide additional evidence that may provide data for outstanding evidence gaps.

As a result of these developments the EAG has prepared an addendum:

- summarising the new evidence submitted by the companies and clinical experts
- summarising the evidence presented in systematic reviews and evidence syntheses
- discussing the implications of the new evidence on the conclusions raised from the original external assessment report, covering clinical and economic considerations
- updating the evidence gap analysis, in line with the initial external assessment report.

The evidence considered as part of this early value assessment is not expected to be exhaustive and considers evidence most relevant to the decision problem. This approach is in line with the objectives and processes of an early value assessment. Prioritisation of studies was necessary due to the large volume of literature on robot assisted surgery to consider. As is standard in NICE guidance and guidelines, for the

original external assessment report, we limited prioritised studies to named technologies. This is because it is not clear if evidence for one robotic platform is generalisable to another, or if older iterations of robotic platforms have similar efficacy. However, for this addendum we have relaxed this criterion for new submitted evidence, as the robot model was not always referred to in the abstract or full text of articles, but could often be inferred from the date and company name, surgery type and geographic setting. Systematic reviews have also been considered in this addendum. Again, systematic reviews were less likely to refer to the robot model but to robotic surgery in general, and so were not considered in the original early value assessment. However, systematic reviews may give a more comprehensive overview of clinical effectiveness and the quality of the evidence and so a summary of recent reviews was included in this addendum. The generalisability of the new submitted evidence summarised in this addendum should be considered by the committee.

2 Overview of the technology

Included in this addendum are robotic-assisted surgical (RAS) platforms used in soft-tissue surgery. Technologies included in the addendum are technologies which were included in the original assessment report but have had further evidence provided. 5 technologies were included in the scope in total: Da Vinci Si/X/Xi robotic platforms (Intuitive Surgery), Da Vinci SP (Intuitive Surgery), Hugo Robotically Assisted Surgery System (Medtronic), Senhance (Asensus Surgical) and Versius (CMR Surgical). The Da Vinci Si robotic platform was not within the scope of the original assessment, but Intuitive confirmed that the Si and Xi models operate at an equivalent clinical and safety level as per regulatory clearances. Evidence on the Si model was therefore included in this addendum. The technologies are described further in the NICE Final Scope and the early value assessment report.

3 Clinical evidence selection

3.1 Evidence search strategy and study selection

Searches to identify evidence on the 5 scoped technologies were undertaken for the original early value assessment report. No further searches were undertaken for this addendum.

Companies were contacted and invited to submit further evidence. Evidence was received from CMR Surgical, Intuitive and Medtronic. Clinical experts were also consulted and 2 submitted evidence for consideration. 50 records were received from the companies and 79 from clinical experts.

Titles and abstracts were sifted by one reviewer based on the intervention and population. In the main review, studies were excluded if the technology was not named in the title and abstract, but this approach was not taken for this addendum. Otherwise, the same approach was used as reported in the original early value assessment report. Studies were prioritised if they were randomised controlled trials, other evidence was included if it was comparative and took place in the UK or Europe. Finding evidence from the UK setting which compared RAS with conventional minimally invasive surgery (MIS), or where the main comparator was open surgery was particularly important, as RAS is a type of MIS rather than a completely novel intervention. Studies from outside the UK or Europe were also included if they provided comparative evidence that addressed any of the outcomes with no evidence that were highlighted by the original assessment report.

A total of 32 full text papers were retrieved and examined by one reviewer to select those meeting the scope definition of an eligible technology.

This addendum also summarises the most recent systematic reviews in RAS. Systematic reviews were not an eligible study design for the original early value assessment. However, 17 systematic reviews were identified from the last 2 years for reference checking in the original assessment, and these reviews are summarised for this addendum. The reviews were identified from a combination of the searches undertaken for the original report and the company submissions. Full details of the search strategies used in the searches can be found in Appendix A of the original assessment report.

3.2 Included and excluded studies

A total of 12 relevant records were identified, reporting 10 new studies for inclusion. Clarification from the lead study author was sought on one of the studies as to the make and model of the RAS platform used in the study. It was confirmed that all 10 additional studies were on Intuitive's Da Vinci Si/X/Xi RAS platforms.

A list of studies excluded or de-prioritised at full text is provided in Appendix A

Table 3.1: Studies selected by the EAG as the evidence base

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Da Vinci Si				
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute	**Design:** RCT GREEN **Intervention:** Da Vinci Si **Comparator:** conventional MIS GREEN	**Indication:** Patients with adenocarcinoma of the rectum undergoing RAS (n=21) or conventional MIS (n=24) GREEN **Median (range) age**: **Da Vinci Si:** 53.4 (32 to 67) **conventional MIS:** 50.3 (36 to 64) **Male gender n (%):** **Da Vinci Si:** 11 (42.4) **conventional MIS:** 13 (54.2)	• Operative time • Conversion rate to open surgery • Days of hospital stay • Complications • Rate of readmission • 30-day mortality	28 patients were assigned to the Da Vinci Si group and 21 included in analyses. 7 patients excluded (2 withdrew consent, 5 had metastases). 29 patients were assigned to the conventional MIS group and 24 were included in the analyses. 5 patients excluded (1 withdrew consent. 3 had metastases, 1 had emergency surgery).
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals	**Design:** RCT GREEN **Intervention:** Da Vinci Si **Comparator:** conventional MIS GREEN	**Indication:** Patients with middle or low rectal cancer undergoing RAS (n=586) or conventional MIS (n=585) GREEN **Mean (SD) age**: **Da Vinci Si:** 59.1 (11) **conventional MIS:** 60.7 (9.8) **Male gender n (%):** **Da Vinci Si:** 356 (60.8)	• Cancer recurrence • Postoperative complications • Postoperative recovery	The main analysis populations are referred to as the mITT population because 6 patients allocated to Da Vinci Si refused and instead underwent conventional MIS. On the other hand, 7 patients refused conventional MIS and so had Da Vinci Si.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		conventional MIS: 354 (60.5)		
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Center	**Design:** RCT **GREEN** **Intervention:** Da Vinci Si **Comparator:** conventional MIS **GREEN**	**Indication:** Patients with mid or low lying rectal cancer undergoing RAS (n=66) or conventional MIS (n=73) **GREEN** **Mean (SD) age**: **Da Vinci Si:** 60.4 (9.7) **conventional MIS:** 59.7 (11.7) p=0.693 **Male gender n (%):** **Da Vinci Si:** 51 (77.3) **conventional MIS:** 52 (71.2)	• Assessment of laparoscopic skills (GOALS questionnaire) • Post-operative pain	ITT analysis used for all outcomes. Da Vinci Si and conventional MIS were carried out by the same surgical team which limits the impacts of surgeon skill.
Da Vinci (unspecified model)				
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019)	**Design:** RCT **GREEN** **Intervention:** Da Vinci (specific model not named) **Comparator:** conventional MIS **GREEN**	**Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection. **GREEN** 471 patients undergoing mesorectal resection for rectal cancer conducted by standard laparoscopic surgery (n= 234) or with robot-assistance (either	• Conversion to open surgery • HRQoL (SF-36v2) • Complications • Mortality	Target sample size based on power calculations was 400, which was achieved. Study describes primary analysis as ITT, however not all randomised patients are included; 4 patients in conventional MIS arm (1 complete response to chemotherapy and thus no surgery, 3 withdrew consent) and 1 in RAS

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Location: UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore **Setting:** Hospital		totally robotic or hybrid, n= 237). **GREEN** **Median (range) age**: **conventional MIS**: mean 65.5 (SD 11.93) **Da Vinci (unspecified)**: mean 64.4 (SD 10.98) **Male gender n (%): conventional MIS**: 159/234 (67.9%) **Da Vinci (unspecified)**: 161/237 (67.9%)		arm (withdrew as insurance required patient attend a non-study hospital for surgery). Complete case analysis. The anticipated conversion rate in the conventional laparoscopic group was 25%; authors note that the much lower than anticipated rate of conversion to open laparotomy limits the ability to provide conclusive evidence on how RAS laparoscopic surgery compares with conventional laparoscopic surgery in odds of conversion to open surgery.
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital	**Design:** Retrospective matched cohort study **GREEN** **Intervention:** Da Vinci (specific model not named)	**Indication:** 26 patients with head and neck squamous cell carcinoma undergoing transoral robotic surgery between December 18th 2008 and June 5th 2013, matched with a group of patients undergoing conventional surgery for the	• Operative time • Length of stay • Adjuvant therapy • Overall survival • Revision • Complications • Feeding tube dependency	Cohorts matched by age (withing 5 years), sex, TNM classification, tumour, location (oropharyngeal, hypopharyngeal, or supraglottic), neck dissection, and surgeon experience. Authors note

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
	Comparator: conventional MIS **GREEN**	same indication between July 19th 2005 and May 22nd 2008. **GREEN** **Mean age**: Da Vinci (specific model not named): 61 conventional MIS: 62 **Male gender n (%):** Da Vinci (specific model not named): 8/26 (30.8*%)		that study had a small sample size.
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia **Setting:** 40 centres	**Design:** RCT **GREEN** **Intervention:** Da Vinci (specific model not named) **Comparator:** Transoral laser microsurgery (TLM) **GREEN**	**Indication:** Patients with HIV-positive oropharyngeal carcinoma stage T1 to T3 N0 to N2b M0 with the primary tumour being considered resectable. **Median (IQR) age**: **RAS:** 58.8 (53.2 to 63.5) **TLM:** 57.7 (52.1 to 63.9) **Male to female gender ratio:** **RAS:** 235:78 **TLM:** 155:40	• Length of hospital stay • Patient reported outcomes (European Organization for Research and Treatment of Cancer Head and Neck Questionnaire (H&N35), and 30-item Quality of Life Questionnaire (QLQ C30))	Different numbers of patients used in the analysis of all outcomes. Unequal groups of patients, 195 in the comparator group and 313 in the RAS group.
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany	**Design:** Retrospective comparative cohort study **GREEN**	**Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma that were treated with either RAS (n=24) or	• Recurrence • Disease-free survival • Operative time • Blood loss • Length of stay	Comparison of baseline demographic and clinical characteristics for each cohort are reported, no

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Setting: University Hospital Elangen-Nuremberg	**Intervention:** Da Vinci (specific model not named) **Comparator:** conventional MIS GREEN	conventional MIS (N=30) between January 1st 2003 (Da Vinci first implemented in September 2012) and December 31st 2018. GREEN **Mean (SD) age**: **Da Vinci (specific model not named):** 60.8 (9.3) **conventional MIS:** 60.5 (10.3) **Male gender n (%):** Da Vinci (specific model not named): 22/30 (73.3%) conventional MIS: 17/24 (70.8%)	• Feeding tube requirement	significant differences. Small sample size.
Da Vinci (various models)				
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals	**Design:** Survey, case control GREEN **Intervention:** Da Vinci Xi and SP systems **Comparator 1:** MIS (endoscopic) **Comparator 2**: MIS (laparoscopic surgery)	**Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22 gynaecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric). 65 had a dominant surgical modality: 10 were dominantly	• Procedure-related pain • Career longevity (“burn-out”)	Comparisons are reported between surgeons with different “dominant” surgical modalities. Modality was considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than the other 3 modalities.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
	Comparator 3:Open surgery **GREEN**	endoscopic, 15 laparoscopic, 26 open and 14 robotic. **GREEN** **Mean (SD) age**: 46.6 (9.3) **Male gender n (%):** 48/79 (61%)		
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph's Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Design:** RCT **GREEN** **Intervention:** Da Vinci (various models) **Comparator:** MIS (video-assisted thoracoscopic surgery) **GREEN**	**Indication:** 164 patients indicated for minimally invasive pulmonary lobectomy for stage I to III NSCLC between January 2016 and July 2020. **Da Vinci (various models):** 81 **conventional MIS:** 83 **GREEN** **Median (IQR) age**: **Da Vinci (various models):** 68 (60 to 75) **conventional MIS**: 67 (60 to 74) **Male gender n (%):** **Da Vinci (various models):** 27/81 (33.33%) **conventional MIS:** 27/83 (32.53%)	• Conversion to open surgery • Complications • Mortality • Operative time • Length of stay • Adjuvant therapy	186 patients were randomised, of whom 22 were lost to follow up or excluded. 92 were randomised to Da Vinci, 5 did not receive intervention (3 due to robot being unavailable, 2 did not receive lobectomy), 2 withdrew, 3 were lost to follow-up, 1 was excluded to adjust for bias. 94 were randomised to VATs, 6 did not receive interventions (2 surgeon's decision, 4 did not receive lobectomy), 1 withdrew, 4 lost to follow-up. It is unclear why the patient excluded "to adjust for bias" was excluded.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
				A sample size of 166 patients, with 83 patients per arm was found to ensure detection of this difference with 80% power at a level of significance of 0.05. Authors note that differences in post-operative care between study centres could not be accounted for.
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database	**Design:** Large real-world database analysis GREEN **Intervention:** Da Vinci (various models) **Comparator 1:** conventional MIS **Comparator 2:** Open surgery GREEN	**Indication**: Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty. GREEN **Median (range) age**: **Da Vinci:** 67 (59 to 73) **conventional MIS:** 65 (59 to 71) **Open:** 65 (56 to 72) **Male gender n (%):** **Da Vinci:** 136, 524 (91)	• Mortality • Length of hospital stay	Predominantly male population, large sample size (total n = 993, 276). Retrospective analysis of a large hospital patient-level dataset. Due to the dataset containing data from 2005 to 2021, there is a difference in size between the different groups with the majority of patients being in the open surgery group (73.8%).

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		conventional MIS: 80,889 (74) **Open:** 570, 426 (78)		

Abbreviations: H&N35 - Head and Neck Questionnaire, HRQoL – Health related quality of life, IQR – Inter-Quartile range, ITT – Intention to treat, M0 – Cancer has not spread, MIS – Minimally invasive surgery, MITT – Modified intention to treat, N0 – No cancer in nearby lymph nodes, N2b - 1 lymph node contains cancer cells on the same side of the neck as the cancer, NR – Not reported, NSCLC - Non-small cell lung cancer, QLQ C30 - Quality of Life Questionnaire 30 item, RAS – Robot-assisted surgery, RCT – Randomised controlled trial, SD – Standard deviation, SP – Single port, T1 – Cancer is small and non-spreading, T3 – Cancer has grown into nearby tissues, TLM - Transoral laser microsurgery, TMN – Cancer staging system.

4 Clinical evidence review

4.1 Overview of methodologies of all included studies

10 primary studies were included in this addendum and all of the studies were comparative.

6 studies (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018, Jayne et al. 2017, O'Hara et al. 2024, Patel et al. 2023) were randomised controlled trials (RCTs), 2 of these (Jayne et al. 2017, O'Hara et al. 2024) were multi-centre studies which included centres based in the UK. 1 study (Patel et al. 2023) was a multi-centre study based in Canada, France and US. The other 3 RCTs were based in Egypt (Debakey et al. 2018), China (Feng et al. 2022) and South Korea (Kim et al. 2018).

1 study was a matched cohort study based in France (Hammoudi et al. 2015). 2 studies were based in Germany: a retrospective comparative cohort study (Sievert et al. 2021) and a large real-world database study (Pyrgidis et al. 2024). 1 study was a US-based case-controlled survey of surgeons with experience of using RAS platforms in soft-tissue surgery (Norasi et al. 2023).

8 of 10 studies compared RAS with a form of conventional MIS. The case-controlled survey on surgeon experiences compared RAS with open, conventional MIS and endoscopic surgery modalities (Norasi et al. 2023). The large database study included data on patients undergoing open surgery, conventional MIS and RAS (Pyrgidis et al. 2024).

Patients

The EAG considered all studies included in the addendum to fully meet this component of the decision scope. The evidence base evaluated the use of technologies in patients undergoing a variety of soft-tissue surgical procedures in different specialties.

In 4 studies, the patients were undergoing surgery for carcinoma or adenocarcinoma of the rectum (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018, Jayne et al. 2017). Other studies reported on surgery for oropharyngeal carcinoma (O'Hara et al. 2024,

Sievert et al. 2021) (n=2), head and neck squamous cell carcinoma (Hammoudi et al. 2015) (n=1), non-small cell lung cancer (Patel et al. 2023) (n=1) and urological procedures (Pyrgidis et al. 2024) (n=1). 1 study (Norasi et al. 2023) covered multiple specialties including urology, gynaecology, thoracic and general surgery.

8 studies addressed patients with cancer (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018, Jayne et al. 2017, Hammoudi et al. 2015, O'Hara et al. 2024, Patel et al. 2023, Sievert et al. 2021), 2 studies reported on populations with a mix of cancer and benign disease (Norasi et al. 2023, Pyrgidis et al. 2024). No studies reported on paediatric populations.

Interventions

All studies included in this addendum evaluated Intuitive's Da Vinci Si/X/Xi RAS platforms. 3 studies (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018) reported on the Si model. In 4 cases (Jayne et al. 2019, Hammoudi et al. 2015, O'Hara et al. 2024, Sievert et al. 2021), the model of Da Vinci RAS platform was not specified, and in 3 studies (Norasi et al. 2023, Patel et al. 2023, Pyrgidis et al. 2024) various Da Vinci models were used across participating centres. 1 of these studies (Patel et al. 2023) reports the use of an earlier Da Vinci model, the Da Vinci S, in the RAS arm, along with the Da Vinci Si and Da Vinci Xi. Results were not analysed by model type in this study. No evidence was included on the Hugo, Senhance or Versius RAS platforms.

4.2 Critical appraisal of studies

As specified by the NICE early value assessment interim guidance, no formal risk of bias assessment was conducted.

6 RCTs were prioritised, of which 4 were unblinded (Debakey et al. 2018, Feng et al. 2022, Jayne et al. 2017, O'Hara et al. 2024). In one study (Kim et al. 2018), the assessor was blinded. 1 study (Patel et al. 2023) reported that both participants and assessors were blinded. The other 4 studies (Hammoudi et al. 2015, Norasi et al. 2023, Pyrgidis et al. 2024, Sievert et al. 2021) were comparative but no information was provided on whether they were blinded or randomised. As noted in the original

assessment report, blinding was not possible for the surgeons due to the nature of the interventions. There is a particular risk of bias in the collection of subjective patient or surgeon-reported outcomes in unblinded studies, more so than objective outcomes such as operative time.

1 study (Norasi et al. 2023) was a survey with subjective surgeon-reported outcomes, and may be subject to recall bias. 3 studies were retrospective (Hammoudi et al. 2015, Pyrgidis et al. 2024, Sievert et al. 2021) and used a historical control.

In 1 of the RCTs (Feng et al. 2022), a modified intention-to-treat population was described, as 6 patients allocated to RAS refused treatment and were allocated to conventional MIS instead of RAS. A further 7 patients refused conventional MIS and were assigned to RAS instead.

There were some concerns over the generalisability of the 10 studies:

- Only 2 studies included a UK population (Jayne et al. 2017, O'Hara et al. 2024). Both were RCTs but were multi-centre studies across several countries. 1 of the studies (Jayne et al. 2017) compared robotic surgery to conventional MIS, and the other (O'Hara et al. 2024) compared RAS to transoral laser microsurgery in patients undergoing surgery for oropharyngeal carcinoma. It is possible that the results of the remaining studies may not be generalisable to the UK setting.
- 1 study (Feng et al. 2022) took place across 11 centres in China and reported issues with consistency of clinical protocols, as there were no standard perioperative protocols. This study also noted that there may be considerable differences between settings, as some patient characteristics (for example, body mass index) were significantly different in this study from those reported in other studies.
- Some studies reported small sample sizes. 4 studies (Debakey et al. 2018) (Hammoudi et al. 2015, Sievert et al. 2021, Norasi et al. 2023) had fewer than 30 participants in the RAS arm.
- Some studies noted a short follow-up time, with data only available for a limited time post-procedure (Hammoudi et al. 2015, O'Hara et al. 2024, Jayne et al. 2017, Patel et al. 2023). 4 studies reported a 30 day follow-up time (Debakey et al. 2018, Feng et al. 2022, O'Hara et al. 2024)with 1 study (Jayne et al. 2017) reporting a 6 month follow up and 2 studies (Kim et al. 2018, Patel et al. 2023) reporting a 12 month follow-up. Two retrospective studies reported an average follow-up time, based on patient records (Hammoudi et al. 2015, Sievert et al.

2021). 2 studies did not report a follow-up period as one was a survey (Norasi et al. 2023) and one was a large database study (Pyrgidis et al. 2024).

- As in the original assessment report, patient populations also varied across the studies. It is possible that the results for one type of surgery may not be generalisable to other types of surgery for certain outcomes.
- Again, as in the original assessment report, the EAG noted that results could differ for outcomes such as learning curve and operating time depending on surgeon experience and other factors such as the complexity of surgery. Therefore, the generalisability of these results is unclear. 2 studies commented that they had included surgeons who were still in their learning phase (Debakey et al. 2018, Jayne et al. 2017), and 1 study only included surgeons who had completed over 30 robotic surgeries (Kim et al. 2018). 2 studies included surgeons with experience of robotic surgeries, but did not give details as to how many surgeries were performed to constitute "experience" (Feng et al. 2022, Patel et al. 2023).

4.3 Results from the evidence base

Full outcome data are presented in Appendix B.

Clinical outcomes – primary outcomes (patient level)

Conversion rates

5 RCTs reported conversion to open surgery compared with conventional MIS (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018, Jayne et al. 2019, Patel et al. 2023). Conversion rates to open for Da Vinci Si/X/Xi RAS platforms ranged from 1.5% to 8.1%. 4 of these studies reported comparisons between treatment arms of which 3 (Kim et al. 2018, Jayne et al. 2017, Patel et al. 2023) reported no significant difference in the rates of conversion. 1 of the RCTs evaluating rectal surgery found a statistically significant difference in the rate of conversion to open surgery which was in favour of RAS (p=0.021) (Feng et al. 2022). However, this study took place in China using the Da Vinci Si RAS model and it is unclear how generalisable the results are to the UK setting.

Conversion to conventional MIS from RAS

None of the prioritised studies reported conversion to conventional MIS from RAS.

Length of hospital stay

8 of the 10 studies reported on the length of hospital stay (LoS), with only 2 studies (Norasi et al. 2023, Pyrgidis et al. 2024) not reporting this outcome. The median LoS was reported by 5 studies (Debakey et al. 2018, Feng et al. 2022, Kim et al. 2018, O'Hara et al. 2024, Patel et al. 2023), and the remaining 3 reported the mean LoS (Hammoudi et al. 2015, Jayne et al. 2017, Sievert et al. 2021). The median LoS ranged from 2 to 14 days in the robotic arm. 1 RCT (Feng et al. 2022) comparing RAS to conventional MIS in surgery for rectal carcinoma found a difference in favour of RAS (p=0.0001). A matched cohort study (Hammoudi et al. 2015) in patients with head and neck squamous cell carcinoma also found a mean difference of 8 days in favour of RAS (p=0.001). A multi-centre RCT on surgery for oropharyngeal carcinoma with some UK patients found a difference in LoS between patients treated with RAS and patients treated with transoral laser microsurgery (O'Hara et al. 2024). The median difference in this study was 2.6 days in favour of RAS (p=0.001). The other 5 studies (Debakey et al. 2018, Jayne et al. 2017, Kim et al. 2018, Patel et al. 2023, Sievert et al. 2021) found no difference in LoS between the RAS arm and the conventional MIS arm.

Intraoperative complications

4 studies, all in cancer patients, reported either overall, intraoperative or perioperative complications (Feng et al. 2022, Jayne et al. 2017, Kim et al. 2018, Patel et al. 2023). All 4 studies compared a Da Vinci RAS platform with conventional MIS. The proportion of patients experiencing complications varied from 5.5% to 34.8%. The study reporting the highest percentage of intraoperative complications was an RCT comparing conventional MIS to the Da Vinci Si RAS platform in patients undergoing surgery for rectal carcinoma (Kim et al. 2018). However, this study also found no difference between patients undergoing RAS and those undergoing conventional MIS. The lowest percentage of intraoperative complications was reported by an RCT in patients undergoing surgery for rectal carcinoma at 5.5% (Feng et al. 2022). This was also the only study to report a difference between the RAS arm and the conventional MIS arm in favour of RAS (p=0.030). This study took place in China and it is unclear whether the results are generalisable to a UK population.

Postoperative complications

5 studies (Debakey et al. 2018, Feng et al. 2022, Hammoudi et al. 2015, Jayne et al. 2017, Patel et al. 2023) reported on postoperative complications. All 5 studies compared the Da Vinci RAS platform with conventional MIS in cancer patients. The longest follow-up time reported for postoperative complications was 6 months, reported in 2 studies (Jayne et al. 2017, Patel et al. 2023). The other 3 studies did not report a follow up time. The percentage of patients experiencing postoperative complications ranged from 0.8% to 66.7%. By far the highest percentage of postoperative complications reported was in a multi-centre RCT which took place in Canada, France and the US (Patel et al. 2023). This study was in patients with non-small cell lung cancer. 66.7% of patients in the robotic arm reported an adverse event during hospital admission compared to 63.4% of patients receiving conventional MIS, which was not found to be statistically significant. The lowest proportion of postoperative complications (0.8%) was reported in the RAS arm of an RCT in patients undergoing surgery for rectal cancer (Feng et al. 2022). However, the studies measured this outcome at different time points, making it difficult to identify trends in the number of complications across the studies. All 5 studies found no significant differences between the RAS and the conventional MIS arm in terms of postoperative complications.

Clavien-Dindo score

2 studies reported Clavien-Dindo score (Feng et al. 2022, Kim et al. 2018). Both were RCTs in patients undergoing surgery for rectal carcinoma, and both compared the Da Vinci Si RAS platform to conventional MIS. 1 study reported a difference between patients undergoing RAS and those undergoing conventional MIS in favour of RAS ($p=0.003$) (Feng et al. 2022). 16.2% of patients in the RAS arm in this study had a Clavien-Dindo scored complication of grade 2 or higher within 30 days, as opposed to 23.1% in the conventional MIS arm. The second study reported the number of patients with a Clavien-Dindo score of grade 1 or higher, with 35.2% in the RIS arm and 23.2% in the conventional MIS arm having recorded a Clavien-Dindo score. The statistical significance of these results was not reported (Kim et al. 2018).

Health related quality of life (HRQoL)

2 studies reported HRQoL. A multi-centre study included patients undergoing robotic surgery for rectal carcinoma, some of the procedures were done in the UK. The study compared the Da Vinci RAS platform (model unspecified) with conventional MIS, and used SF-36v2 to measure HRQoL. It found no difference in HRQoL scores between the RAS arm and the conventional MIS arm at 30 days and 6 months post-surgery (Jayne et al. 2017), however the statistical significance was not reported. The other study to report this outcome found a statistically significant benefit for RAS at two timepoints (Patel et al. 2023). This study measured mean health utility scores using EQ-5D-5L at 3 weeks, 7 weeks, 12 weeks, 6 months and 12 months post-surgery. At 3 weeks, the mean score was 0.78 for the RAS group and 0.74 for the conventional MIS group (p=0.18). However, at 7 weeks, the mean scores were 0.84 for the RAS group and 0.78 for the conventional MIS group (p=0.04) and at 12 weeks the mean scores were 0.85 for the RAS group and 0.80 for the conventional MIS group (p=0.02). However, this statistically significant benefit was not observed in the longer term, with the RAS group reporting a mean score of 0.85 and the conventional MIS group reporting a mean score of 0.71 (p=0.68) at 6 months. At 12 months the scores were 0.84 for the RAS group and 0.79 for the conventional MIS group (p=0.16). This study therefore found that RAS may have benefits for HRQoL at 7 and 12 weeks post-surgery, but did not find a similar benefit at 3 weeks post-surgery, or in the long term.

Clinical outcomes – primary outcomes (surgeon level)

Procedure-related discomfort and ergonomics

1 study reported on procedure-related discomfort and ergonomics at surgeon-level (Norasi et al. 2023). This study took place across a range of surgical procedures and was a case-controlled survey of surgeons in the US. Comparisons were reported between surgeons with different “dominant” surgical modalities, where the modality was considered dominant if the proportion of procedural time the surgeon spent on the modality was at least 10% higher than the other modalities in the study. 4 modalities were included: RAS (using Da Vinci platforms), endoscopic surgery, laparoscopic

surgery and open surgery. The study found a statistically significant difference in favour of RAS for both outcomes examined: surgeons reporting ever having had or currently having neuromusculoskeletal pain (p=0.0057) and surgeons reporting any physical discomfort or pain in the upper extremity (p=0.0219). However, this study had a small sample size, with 14 surgeons in the robotic arm.

Clinical outcomes – primary outcomes (organisation level)

Rate of MIS compared with open surgery after RAS was introduced

No prioritised studies reported the rate of MIS compared with open surgery after RAS was introduced.

Volume of procedures

1 study reported on the volume of procedures (Pyrgidis et al. 2024). The large, real-world database study took place in Germany between 2005 and 2021 and included patients undergoing urological surgery using either RAS (utilising various Da Vinci RAS platforms), conventional MIS or open surgery. The number of patients undergoing a urological procedure with RAS was 14 in 2005 whereas 50,524 patients had an open procedure. In 2021, the number of patients undergoing a procedure with RAS had grown to 25,665, with a reduction in the number of patients undergoing open surgery to 29,230. There was a much smaller increase in the number of patients undergoing conventional MIS (4,571 in 2005 to 4,969 in 2021). The full year-by-year breakdown can be found in Appendix C.

Hospital capacity and wait-list reduction

No prioritised studies reported on hospital capacity and wait-list reduction.

Clinical outcomes – secondary outcomes (patient level)

Days alive and out of hospital at 30 days

2 studies reported on mortality at 30 days (Feng et al. 2022, Pyrgidis et al. 2024). 1 was conducted in patients undergoing surgery for rectal carcinoma and compared RAS to conventional MIS. 1 patient in each arm died within 30 days of the procedure, which was not found to be statistically different between the RAS arm and the conventional MIS arm (p=0.999) (Feng et al. 2022). A large database study conducted in Germany (Pyrgidis et al. 2024) compared RAS to open surgery and found that RAS resulted in less mortality at 30 days for patients undergoing radical cystectomy (p=0.04), radical nephrectomy (p=<0.001) and partial nephrectomy (p=<0.001). The statistical significance for differences between RAS and conventional MIS were not presented.

Post-operative pain

3 studies reported on post-operative pain (Kim et al. 2018, O'Hara et al. 2024, Patel et al. 2023). 1 RCT in patients undergoing surgery for rectal carcinoma reported on postoperative pain measured by a median present pain intensity index score and a visual-analog scale at days 1 to 5 (Kim et al. 2018). This study compared RAS using Da Vinci Si to conventional MIS and found no difference between the RAS arm and the conventional MIS arm. A multi-centre RCT on patients undergoing surgery for oropharyngeal carcinoma including some patients from the UK reported on postoperative pain using the Head and Neck 35 pain score, reported as a mean and as a median (O'Hara et al. 2024). At baseline, the mean score in the RAS arm was 17.5 (standard deviation (SD) 19.7) and it was 36.5 (SD 23.0) at 4 weeks following surgery. The comparator arm was transoral laser microsurgery (TLM) and reported a mean score of 14.6 (SD 18.0) at baseline and 34.0 (SD 25.6) at 4 weeks. This study also found no statistically significant difference between the RAS arm and the comparator arm (p=0.51).

A further RCT reported on postoperative pain, measured by EQ-5D as a median (Patel et al. 2023). This study was in patients undergoing lobectomy for non-small cell lung cancer and compared various models of the Da Vinci RAS platform to conventional

MIS. The median pain score reported in the Da Vinci arm was 2.82, and 2.84 in the conventional MIS arm. There was no statistically significant difference between the 2 arms (p=0.88).

Satisfaction with surgery

None of the prioritised studies reported on satisfaction with surgery.

Revision surgery for the same indication

2 studies, both comparing an unspecified model of Da Vinci RAS platform with conventional MIS (Hammoudi et al. 2015, Sievert et al. 2021) reported the proportion of patients who were reoperated on for the same indication. 1 of these studies was a matched cohort study in patients undergoing surgery for head and neck squamous cell carcinoma (Hammoudi et al. 2015). 2 patients in the RAS arm and 2 in the conventional MIS arm had a local recurrence of the tumour which led to further surgery. No patients in the RAS arm had nodal recurrence or metastasis leading to further surgery, compared to 1 patient in the comparator arm. The other study was a retrospective comparative study in patients undergoing surgery for oropharyngeal squamous cell carcinoma, which found that a relatively high proportion of patients in both arms required intraoperative resection (Sievert et al. 2021). 37.5% of patients in the RAS arm and 43.3% in the conventional MIS arm required further surgery. The statistical significance for differences between RAS and conventional MIS were not presented in either study.

Clinical outcomes – secondary outcomes (patient level- specific study designs)

Compared with open surgery – intraoperative blood loss

Only 1 study included patients undergoing open surgery (Pyrgidis et al. 2024), and this study did not report on intraoperative blood loss.

Cancer studies – survival rate

1 study on patients undergoing surgery for rectal carcinoma reported on both disease-free survival after 5 years and overall survival at 5 years (Jayne et al. 2017). 14.8% of patients in the RAS arm were alive and disease free at 5 years, compared with 16.8% in the conventional MIS arm (p=0.8736). Overall survival was 9.7% and 9.8% respectively (p=0.848). This study found no statistically significant differences in survival rate.

A matched cohort study on surgery for head and neck squamous cell carcinoma considered overall survival and disease-free survival at 3 years (Hammoudi et al. 2015). 81% of the patients who underwent RAS were alive at 3 years, compared with 95% of those in the conventional MIS arm (p=0.33). 89% of patients in the RAS arm were disease-free at 3 years compared with 85% in the conventional MIS arm (p=0.76). There was no statistical difference between the 2 arms.

A retrospective cohort study (Sievert et al. 2021) on patients undergoing surgery for oropharyngeal squamous cell carcinoma looked at disease-free survival at 125 months. 86.7% of patients who underwent surgery with the Da Vinci RAS platform (model unknown) were alive and disease-free at 125 months, compared to 87.5% who underwent conventional MIS (p=0.892). This study also found no statistical difference between RAS and conventional MIS for disease-free survival.

Cancer studies – need for adjuvant treatment

3 cancer studies reported on the need for adjuvant treatment (Hammoudi et al. 2015, Patel et al. 2023, Sievert et al. 2021). A matched cohort study comparing RAS with conventional MIS in patients undergoing surgery for head and neck squamous cell carcinoma found no statistically significant difference between the 2 groups in terms of the requirement for further treatment (p=0.49) and postoperative radiotherapy (p=0.17) or postoperative chemotherapy (p=0.48) (Hammoudi et al. 2015). An RCT with patients undergoing pulmonary lobectomy for non-small cell lung cancer compared RAS with video-assisted thoracic surgery and again found no statistically significant difference between the 2 groups in the need for adjuvant treatment (p=0.45) (Patel et al. 2023). A retrospective cohort study looked the need for adjuvant radiotherapy and radiochemotherapy in patients undergoing surgery for oropharyngeal squamous cell carcinoma (Sievert et al. 2021). This study also found no statistically significant difference between the RAS arm and the conventional MIS comparator arm (p=0.133).

Head and neck studies – feeding tube dependency

All 3 of the studies in head and neck cancer considered feeding tube dependency as an outcome (Hammoudi et al. 2015, O'Hara et al. 2024, Sievert et al. 2021). 1 study was a matched cohort study in patients undergoing surgery for head and neck squamous cell carcinoma (Hammoudi et al. 2015). This study found a difference between the RAS group and the conventional MIS control group in favour of RAS. In the RAS group, 65.4% of the patients required a feeding tube, compared with 100% of the conventional MIS group (p=0.004). The RAS group used a feeding tube for 9 days (SD 10) compared with 16 days (SD 10) for the conventional MIS group (p=0.01). The second study was an RCT in patients undergoing surgery for oropharyngeal carcinoma (O'Hara et al. 2024). Conversely, this study found no statistically significant difference between the RAS arm and the comparator arm, where the patients underwent transoral laser microsurgery (TLM). The Da Vinci RAS arm used the feeding tube for a median of 6 days and the TLM arm used the feeding tube for a median of 5 days (p=0.894). The third study which looked at the use of feeding tubes was a retrospective comparative cohort study (Sievert et al. 2021) in patients who were having surgery to treat

oropharyngeal squamous cell carcinoma. This study also found no statistically significant difference in the use of the feeding tube between the RAS group and the conventional MIS group. 54.2% of the RAS group required a feeding tube compared with 56.7% of the conventional MIS group (p=0.854). This study also looked at the duration of tracheal cannula, and also found no difference between the 2 groups. In the RAS arm, the duration of tracheal cannula was 5.4 months (SD 5.1) and in the conventional MIS group it was 3.0 (SD 5.8) (p=0.422).

Clinical outcomes – secondary outcomes (surgeon level)

Career longevity and musculoskeletal injury

1 study reported on career longevity and musculoskeletal injury (Norasi et al. 2023). This was a case-controlled survey of surgeons in the US, across a range of surgical specialties including urologic, gynaecologic, thoracic and general surgery. Surgeons working across open, laparoscopic, endoscopic and RAS modalities were included in the survey, with “dominant modality” being defined as the surgeon spending 10% or more of procedural time in a modality as compared with the other 3 modalities. This study looked at surgeon burnout and the number of surgeons reporting neuromusculoskeletal disorders. Surgeon burnout was based on the number of surgeons reporting “frequent burnout”, with frequent burnout being defined as experiencing burnout “a few times a month or more”. 20% of surgeons whose predominant modality was RAS reported frequent burnout, compared with 60% for laparoscopic (p=0.0042), 65% for open surgery (p=0.012) and 30% for endoscopic (p-value not reported). 7% of RAS surgeons reported having a neuromusculoskeletal disorder, compared with 67% of laparoscopic surgeons (p=0.0055), 62% of surgeons whose predominant modality was open surgery (p=0.0064) and 60% of endoscopic surgeons (p=0.0151). This study's findings were in favour of RAS. However, the sample sizes in this study was small, with only 14 surgeons in the RAS arm.

Human factors

None of the prioritised studies reported on additional human factors.

Learning curve

1 study in this addendum provided additional information on the surgeon learning curve (Kim et al. 2018). This study was an RCT reporting on surgery in patients with rectal carcinoma, using the Da Vinci Si RAS platform compared with conventional MIS. The Global Operative Assessment of Laparoscopic Skills (GOALS) scoring system was used to test autonomy, depth perception, bimanual dexterity, efficiency and tissue handling. There was no difference between the RAS group and the conventional MIS group in terms of depth perception, bimanual dexterity, efficiency or tissue handling, but there was a statistically significant difference between the RAS group and conventional MIS group in autonomy (i.e. the ability to complete tasks without guidance or with minimal guidance) (t-test p=0.002).

None of the studies included in the addendum provided additional information on the duration of surgeries over time, or information on docking or console time.

Clinical outcomes – secondary outcomes (organisation level)

Readmission at 30 days

2 studies assessed readmission at 30 days (Debakey et al. 2018, Feng et al. 2022). Both studies were RCTs in patients undergoing surgery for rectal carcinoma or adenocarcinoma, and both used the Da Vinci Si platform with a conventional MIS comparator group. 1 study found that 1 patient in each arm was readmitted within a 30-day period but did not report statistical significance (Debakey et al. 2018). The other study reported no statistically significant difference between the number of patients readmitted within 30 days after receiving RAS (17 patients) or conventional MIS (20 patients) (p=0.613). This study also found no statistically significant difference in reoperation within 30 days between the RAS and conventional MIS arms (p=0.098) (Feng et al. 2022).

Operating time

7 of the 10 studies reported on operating time (Debakey et al. 2018, Feng et al. 2022, Hammoudi et al. 2015, Jayne et al. 2017, Kim et al. 2018, Patel et al. 2023, Sievert et al. 2021).

Only 1 study found a statistically significant difference between the RAS arm and the conventional MIS arm and this was in favour of conventional MIS (Kim et al. 2018). This study was an RCT in patients undergoing surgery for rectal cancer. Mean operating time in the Da Vinci Si arm was 339.2 minutes (SD 80.1) and in the conventional MIS arm it was 227.8 minutes (SD 65.6) (p=<0.0001). However, this study did not report any data on learning curve and so it is unclear whether surgeon learning curve affected these results.

Results from 4 of the other studies found no difference between RAS and conventional MIS in terms of operating time. 1 RCT in patients undergoing surgery for rectal cancer found a mean operating time of 173 minutes (range 140 to 225 minutes) in the Da Vinci Si group and 170 minutes in the conventional MIS group (range 140 to 209 minutes) (Feng et al. 2022) (p=0.408). An RCT in patients undergoing minimally invasive pulmonary lobectomy for non-small cell lung cancer similarly found no difference in operating time between the RAS group and the video-assisted thoracoscopic surgery conventional MIS group (Patel et al. 2023). The Da Vinci group had a median operating time of 203 minutes (range 165 to 234 minutes) and the conventional MIS group had a median operating time of 193 minutes (range 171 to 225 minutes) (p=0.62).

2 other studies reported no statistically significant differences in operating time. A matched cohort study in patients undergoing surgery for head and neck squamous cell carcinoma reported mean operating time using an unspecified model of the Da Vinci platform to be 367 minutes (SD 101) compared with 343 minutes (SD 76) for conventional MIS (p=0.40) (Hammoudi et al. 2015). A retrospective comparative cohort study in patients having surgery for oropharyngeal carcinoma reported a mean operating time for tumour resection of 186 minutes (SD 54) using RAS arm and 140 minutes (SD 59) using conventional MIS (p=0.860) (Sievert et al. 2021).

2 studies presented data on operating time but did not calculate statistical significance. Both studies were RCTs in patients undergoing surgery for rectal cancer. In 1 study using the Da Vinci Si platform, the mean operating time was 201 minutes (range 140 to 280 minutes) in the RAS group and 134.5 minutes (range 110 to 190 minutes) in the conventional MIS group (Debakey et al. 2018). The other RCT assessed an unspecified model of the Da Vinci platform, reporting a mean operating time of 298.5 minutes (SD 88.71) compared with 261.0 minutes (SD 83.24) for conventional MIS (Jayne et al. 2017).

Staffing requirements

None of the prioritised studies reported staffing requirements.

4.4 Summary of systematic reviews

17 systematic reviews were identified for reference checking for the original assessment report. The systematic reviews were all in scope and published between 2022 and 2024. They therefore present recent evidence synthesis relevant to the decision problem. Full details of the systematic reviews can be found in Appendix D .

There was minimal overlap between the studies included in both the original early value assessment report and this addendum and the studies included in the 17 systematic reviews examined for this summary:

- 1 case control study from the original assessment report (Dixon et al. 2021) was included in a systematic review on the Versius RAS platform (Alkatout et al. 2022)
- 1 cohort study (Galata et al. 2019) was included in the largest systematic review that we examined (Leitao et al. 2023)
- a study on the Senhance RAS platform (Samalavicius et al. 2022) was included in a review of the newer robotic platforms (Leang et al. 2024).
- 1 RCT from this addendum (Feng et al. 2022) was included in a review of robot-assisted treatment for mid-and low-rectal cancer (Wu et al. 2023).

We did not check whether the systematic reviews overlapped with one another in terms of included studies.

Review characteristics

The systematic reviews were conducted across a range of surgeries including breast (Roy et al. 2023, Thornton et al. 2024), colorectal (Tschann et al. 2022, Wu et al. 2023), gynaecologic (Arcieri et al. 2023, Lenfant et al. 2023, Raffone et al. 2022), head and neck (Rogalska et al. 2023), thoracic (Wang et al. 2024) and urologic (Calpin et al. 2023, Fu S et al. 2024, Li et al. 2023, Lv et al. 2023). 1 review looked at colorectal, visceral, and gynaecological surgery in the same review (Alkatout et al. 2022). The largest review included 199 studies assessing the use of RAS in patients undergoing colorectal, urologic, endometrial, cervical, and thoracic surgery (Leitao et al. 2023). 1 review which considered ergonomics and cognitive load for surgeons included any type of soft tissue surgery (Shugaba et al. 2022), as did a head-to-head review on the newer robotic platforms (Leang et al. 2024).

Most reviews considered any type of RAS platform, with the exception of 1 review which specifically considered the Versius platform (Alkatout et al. 2022), a second review that considered the Da Vinci SP (Arcieri et al. 2023) and a third review that compared the Da Vinci robotic platforms with newer robotic platforms including Versius, Hugo and Senhance (Leang et al. 2024).

The majority sought to compare RAS with conventional MIS. 3 reviews looked at RAS versus open (Fu S et al. 2024, Lv et al. 2023, Roy et al. 2023) and 3 compared RAS with both open and conventional MIS (Calpin et al. 2023, Leitao et al. 2023, Lenfant et al. 2023). 3 reviews did not clearly state a comparator (Alkatout et al. 2022, Arcieri et al. 2023, Rogalska et al. 2023). Where geographic location was reported, 3 reviews included studies from a UK setting (Alkatout et al. 2022, Calpin et al. 2023, Fu S et al. 2024).

Review findings

The results of the systematic reviews were generally in line with the studies included in both the early value assessment report and this addendum. RAS was broadly comparable to conventional MIS across all of the reviews in terms of clinical effectiveness and safety. RAS may have benefits over open surgery including length of hospital stay, blood loss and rates of complications. RAS was reported to have longer operative time over both open surgery (Fu S et al. 2024, Lv et al. 2023, Roy et al. 2023) and conventional MIS (Leang et al. 2024, Tschann et al. 2022). However, no reviews contained data on the learning curve and so the results could be affected by surgeon capabilities and experience. Some reviews acknowledged this as a possible confounding factor (Lenfant et al. 2023, Thornton et al. 2024, Tschann et al. 2022).

The only review on ergonomics and the cognitive load on surgeons found that RAS appears to have less negative cognitive and musculoskeletal impact on surgeons compared to conventional MIS (Shugaba et al. 2022). However, 7 of 10 studies included in this systematic review were on simulations rather than patients, and the studies did not control for confounding factors such as surgeon handedness and surgeon experience. This study was included despite having a high number of studies on simulations because it covered an important evidence gap highlighted in the original early value assessment.

Quality of the evidence

The vast majority of the evidence included in the systematic reviews was retrospective. 2 reviews included preclinical studies, animal studies and case reports (Alkatout et al. 2022, Roy et al. 2023). The systematic reviews used varying tools to assess quality, and there was little consistency in the study designs included. Risk of bias was generally found to be high. Almost all the reviews stressed the lack of evidence from prospective comparative studies, recommending that further evidence should be provided by RCTs. Other limitations were commonly reported, including incomplete data, heterogenous data and a lack of data on economic costs. Small sample sizes and short follow-up times were also frequently identified as limitations.

This summary of systematic reviews has highlighted the need for further evidence from high quality, prospective studies which take place over at least 12 months. The data available was generally retrospective and not robust, and there was a lack of evidence from the UK setting.

4.5 Summary of the clinical evidence

20 primary studies were prioritised that provided clinical evidence for robotic surgery in the original assessment report, and a 10 further studies are included in this addendum with a summary of evidence from 17 recent systematic reviews. Further evidence from primary studies was included for the Da Vinci Si/X/Xi platforms and from 1 primary study for the Da Vinci SP, but further evidence from primary studies was not included for the Hugo, Versius or Senhance platforms. Some studies used a range of unspecified Da Vinci platforms, and we do not have any information as to whether the Da Vinci SP platform was included in any of the studies where the exact models used were not clearly identified.

The majority of the studies in this addendum used conventional MIS rather than open surgery as the comparator. The only exceptions to this were a case-controlled survey of surgeons in the US, which also included open and endoscopic arms in the study (Norasi et al. 2023) and a large database analysis of data from Germany, which included data on open, conventional MIS and RAS surgeries (Pyrgidis et al. 2024).

For the primary outcomes at a patient level (conversion rate, intraoperative complications, postoperative complications, Clavien-Dindo score and LoS), the studies from this addendum provided little evidence to suggest a difference between robotic surgery and conventional MIS. Only 1 study reported a significant difference in the rate of conversion to open surgery in favour of RAS (Feng et al. 2022), however this study took place in China and it is unclear how generalisable the results are to a UK setting. This study was also the only study to find a difference between the RAS arm and the conventional MIS arm in terms of intraoperative complications (Feng et al. 2022), where RAS led to fewer complications, and Clavien-Dindo score, with fewer patients in the RAS arm having a Clavien-Dindo score of 2 or above. The study was a large, multi-centre RCT with 1,240 participants undergoing surgery for rectal cancer. It concluded

that RAS resulted in better quality resections than conventional laparoscopic surgery with less surgical trauma and better postoperative recovery. However, some limitations were acknowledged, including a short-follow up time, the lack of data on the learning curve and the lack of consistent peri-operative protocols across the participating centres. The study authors also acknowledged that the participants may not be representative of those undergoing surgery for rectal cancer in other settings, as the body-mass index of participants in this study was lower than in other studies.

When compared with conventional MIS, the difference in LoS was significant in 3 studies and favoured the Da Vinci RAS platform (Feng et al. 2022, Hammoudi et al. 2015, O'Hara et al. 2024). None of the remaining studies reported a significant difference between robotic surgery and conventional MIS or open surgery in any patient-level primary outcome. Again, the summary of systematic reviews is generally aligned with this finding.

1 study found a statistically significant benefit in HRQoL, but only at specified timepoints, 7 and 12 weeks post-surgery (Patel et al. 2023). These benefits were not seen at 3 weeks post-surgery or in the long-term.

Only 1 study in this addendum considered surgeon-level primary outcomes (procedure-related discomfort and ergonomics) (Norasi et al. 2023). This study found a significantly reduced likelihood of surgeon neuromusculoskeletal pain and a reduction in surgeons reporting any physical discomfort or pain in the upper extremity compared with conventional MIS, open and endoscopic surgery across a range of specialties. This study also reported on the secondary outcome of career longevity and musculoskeletal injury, finding that the RAS surgeon arm experienced fewer episodes of burnout and fewer reported having a neuromusculoskeletal disorder. However, the sample sizes in this study were small, with only 14 surgeons in the RAS arm. A systematic review of surgeon ergonomics and cognitive load also found that RAS may be beneficial, but most of the studies included by this review were on simulations (Shugaba et al. 2022).

At an organisation-level, only 1 study reported on 1 of the outcomes, the volume of procedures undertaken (Pyrgidis et al. 2024). This was a large database study, which took place in Germany. The results showed that the number of RAS procedures undertaken across the participating centres had grown exponentially, alongside a significant reduction in the number of open surgeries performed from 2005 to 2021. The results of this study should be interpreted with caution, as the authors state that the data used was retrospective billing data, which may be prone to coding errors and misclassifications.

In terms of secondary outcomes at a patient-level, 3 studies were included in the addendum which reported on feeding tube dependency in patients having head and neck surgery (Hammoudi et al. 2015, O'Hara et al. 2024, Sievert et al. 2021). No studies on head and neck surgery were included in the original assessment report. 2 studies found no difference between RAS and conventional MIS in either the need for a feeding tube or the duration of feeding tube use (O'Hara et al. 2024, Sievert et al. 2021). 1 study found a significant difference in favour of RAS (Hammoudi et al. 2015). The other patient-level secondary outcomes with data reported were days alive and out of hospital at 30 days, postoperative pain, revision surgery for the same indication, cancer survival rate and the need for adjuvant cancer treatment. Studies reporting these outcomes reported no difference between the RAS and conventional MIS arms.

At a surgeon-level, 1 study provided some additional information on surgeon learning curve (Kim et al. 2018), finding that RAS surgeons scored higher on autonomy (i.e. the ability to complete tasks with no or minimal supervision) as opposed to conventional MIS surgeons. However, there was no difference between the RAS surgeons and the conventional MIS surgeons in terms of depth perception, bimanual dexterity, efficiency or tissue handling.

In the original assessment report, the only secondary outcome where studies consistently reported significant between-arm differences was operating time. The summary of systematic reviews aligned with this finding. Operative time was significantly longer for robotic surgery than conventional MIS. 7 of the 10 additional studies in this addendum also reported on operative time. However, only 1 of these

found a significant difference between RAS and conventional MIS, and this was in favour of conventional MIS (Kim et al. 2018). The other studies found no significant difference.

The EAG noted some concerns around the clinical evidence. Only 2 studies were conducted partly in the UK as part of large, multi-centre international studies (Jayne et al. 2017, O'Hara et al. 2024) and so it is unclear how generalisable the results are to a UK population. For example, in some countries, robotic surgery has been in use for a longer period and has more experienced surgeons as a result, and so it is likely that the learning curve involved in robotic surgery would have less impact on the results of a study. But as few of the studies report this data, including the systematic reviews considered for this addendum, it is difficult to generalise to the UK setting. As in the original assessment report, patient populations also varied across the studies, and different indications and types of surgery were evaluated. One of the systematic reviews which looked at a range of different surgery types concluded that the patients who participated in the studies in their review were generally not representative. Surgical cohorts were "carefully selected" and tended to have lower body-mass index scores and were less complex cases (Leang et al. 2024). Results for some outcomes (such as learning curve and operating time) were not widely reported and could be affected by surgeon experience and complexity of surgery. Study follow-up times were generally short, with some studies only following up for 30 days post-procedure. It is unclear whether results for one type of surgery are comparable with other types of surgery. However, our conclusions on the clinical evidence presented in this addendum remain the same as for the original assessment report. The summary of systematic reviews also found that RAS and conventional MIS were broadly comparable across a number of outcomes and types of surgery, which aligns with the results found from the primary studies.

5 Adverse events and clinical risk

Adverse events

The adverse events reported by the studies were perioperative and postoperative complications, Clavien-Dindo scores and rates of conversion to either conventional MIS or open surgery. The details are discussed in Section 4.3 and presented in Appendix B.

6 Economic evidence

6.1 Economic evidence

No further searches were conducted to identify economic evidence for the scoped technologies within this addendum.

Companies and experts were contacted and invited to submit further evidence. The studies identified and submitted by the companies and by clinical experts were assessed for economic evidence. Economic evaluations were considered eligible if they reported total costs, effectiveness, incremental analyses, other health economic evaluation outcomes, or measured any relevant cost or resource use associated with the use of the scoped technologies. 1 study was identified through the company submitted evidence.

Patel et al. (2023) was a trial-based cost-effectiveness analysis of da Vinci (various models) for robotic-assisted lobectomy (RPL-4) compared to video-assisted thoracic surgery lobectomy (VATS-lobectomy) in adults with early stage non-small cell lung cancer (Patel et al. 2023). The study authors used early data from the RAVAL Trial in Canada, the United States and France. The authors reported the incremental cost-effectiveness ratio (ICER) or da Vinci versus VATS-lobectomy as $14,925.62 per quality adjusted life year (QALY), which was determined to be cost-effective based on a willingness to pay threshold of $50,000 per QALY gained. However, the results did not include the costs of the da Vinci system, annual service costs, and other robot-related surgery costs. Therefore, the results do not account for all cost impacts to the

healthcare system. Furthermore, the time horizon of the economic analysis was 12 months, meaning longer term outcomes were not reflected in the analysis. Trial recruitment difficulties suggest a potential for selection bias as some interviewee patients preferred not to be randomised. The applicability of the outcomes should be considered, given this analysis is not from a UK perspective.

Table 6.1: Economic evaluations studies selected by the EAG

Study ID and location	Title	Study type	Narrative summary
Da Vinci (various models)			
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US	Robotic lobectomy is cost-effective and provides comparable health utility scores to video-assisted lobectomy Early results of the RAVAL trial	Cost-effectiveness analysis	RPL-4 (Da Vinci – various models) was compared to VATS-lobectomy in a trial-based cost-effectiveness analysis using early data from the RAVAL Trial in Canada, the United States and France, which is due to run until 2029. The population were adults with early-stage (clinical stage I, II, or IIIa) non-small cell lung cancer (RPL-4: n=81; VATS-lobectomy: n=83). The model captured clinical and oncological outcomes including adverse events, as well as utility data (EQ-5D-5L), all collected as part of RAVAL. The CI of the ICER were generated by bootstrap analysis (10,000 samples). At 12 months, the incremental cost of RPL-4 was reported as US$179.37 per person and the incremental QALY as 0.0120 per person. The ICER was $14,925.62 per QALY for RPL-4 compared with VATS lobectomy (95% CI: $6,843.69, $23,007.56), which was determined to be cost-effective by the authors based on a willingness to pay threshold of $50,000 per QALY gained. There were some major limitations of this publication. The publication (and referenced methods paper) did not include all relevant costs (such as the platform itself and maintenance costs, which are the largest cost burden of RAS). Since these costs were omitted, this would substantially skew the results in favour of robotic-assisted lobectomy. The time horizon of the economic analysis was 12 months and the authors recognised the potential impact longer term follow-up data may have. Trial recruitment difficulties suggest a potential for selection bias as some interviewee patients preferred not to be randomised. The applicability of the outcomes should be considered, given this analysis is not from a UK perspective. The publication did not state key information regarding the learning curve of surgeons, or the utilisation of the robot.

Abbreviations: CI – Confidence intervals, EQ-5D-5L - EuroQol 5 dimension 5 level, ICER – incremental cost-effectiveness ratio, QALY – quality-adjusted life year, RAS – robotic-assisted surgery, RPL-4 – robotic-assisted lobectomy, VATS- Video-assisted thoracic surgery lobectomy.

6.2 Implications for economic modelling

1 company submitted evidence that contained relevant economic evidence on the use of RAS (Patel et al. 2023). This assessed robotic-assisted lobectomy (RPL-4) against video-assisted thoracic surgery lobectomy (VATS) using preliminary trial data across Canada, the U.S., and France, for the use of Da Vinci (Si, X, and Xi models). The analysis omitted several key costs, including those for the da Vinci system, service costs, and other robot-specific expenses.

Although additional clinical evidence was considered in this addendum, the conclusions did not suggest anything substantially different to what was used to populate the EAG economic model. For instance, the EAG model reflects that RAS may lead to reductions in length of stay, readmissions and complications, with an uncertain impact on operative time when compared with both conventional MIS and open surgery. Larger benefits were estimated in open surgery than conventional MIS. Furthermore, a wide range of sensitivity and scenario analyses were conducted to estimate the uncertainty associated with estimated outcomes.

Therefore, no model updates are proposed in this addendum. The existing EAG model is likely representative, as the technology's features align with other scoped comparators and company trial data, primarily da Vinci, has been used to inform model parameters. Where additional inputs were identified in this addendum, they fall within the range of values already incorporated within the previous analysis and are therefore no more reflective than the existing inputs for an early evaluation.

The trial reported in the economic evidence reported a 12-month QALY gain of 0.05. For RAS to be cost-effective, a long-term QALY gain between 0.08 and 0.13 is needed (ranging from 0.01 to 0.14 in scenario analyses). This value falls within the scenario analysis, suggesting that RAS could plausibly be a cost-effective intervention to the NHS, if longer term benefits are also expected.

7 Interpretation of the evidence

7.1 Interpretation of the clinical and economic evidence

The EAG has considered evidence from 30 comparative primary studies and 17 recent systematic reviews for the original early value assessment and this addendum. Aside from one outlier based in China which found RAS was superior to conventional MIS for most of the outcomes they considered (Feng et al. 2022), the primary studies and the systematic reviews were broadly aligned in finding little evidence to suggest a difference between RAS and conventional MIS for most of the primary patient level outcomes. 4/30 studies reported that length of hospital stay may be shorter with RAS over conventional MIS, but the majority of the studies reported no statistically significant difference in this or any other patient-level outcome.

There was little evidence across primary studies and systematic reviews that addressed surgeon level outcomes or system level outcomes. 2/30 primary studies (Dixon et al. 2024, Norasi et al. 2023) and 1 systematic review (Shugaba et al. 2022) considered surgeon ergonomics and procedure-related discomfort, and all three found that RAS was associated with less cognitive and ergonomic strain than conventional MIS. However, the two primary studies had small sample sizes and the majority of the studies included in the systematic review were simulations. For system level outcomes, most of the studies provided data on operative time, with 18 studies from the original early value assessment and this addendum finding that conventional MIS had shorter operating time than RAS.

As in the original assessment report, the vast majority of the evidence was for the older models of Intuitive's Da Vinci robotic platform. Comparative, high-quality primary studies for the Hugo, Versius and Senhance platforms was not identified for this addendum. Only one of the additional primary studies included in the addendum had data on the newer Da Vinci SP robotic platform.

The available evidence was assessed at moderate-to-low quality, and data from the systematic reviews confirmed that there is a lack of comparative, high-quality studies and a lack of data from the UK setting.

1 cost-effectiveness analysis was included in this addendum. It assessed the cost-effectiveness of RAS (da Vinci systems) versus VATS-lobectomy in adults with early-stage non-small cell lung cancer in Canada, the US and France using early data from the RAVAL Trial. RAS was reported as being cost-effective at a willingness to pay threshold of $50,000 per QALY gained. However, the analysis was not from a UK perspective and did not consider a number of costs that impact the healthcare system: the system, service costs, and other robot-related surgery costs.

7.2 Ongoing studies

No ongoing studies were submitted, considered or assessed for this addendum.

8 Evidence gap analysis

This addendum mainly provides further evidence for 1 of the 5 scoped technologies: the Da Vinci Si/X/Xi RAS platform, although there was data from one study for the Da Vinci SP (Norasi et al. 2023). Additional evidence from RCTs was found for some primary outcomes: conversion to open surgery, LoS, intraoperative complications, postoperative complications, Clavien-Dindo scores and health-related quality of life. However, the RCTs primarily took place in Asia and only 2 included a UK population within much larger multinational studies. It is unclear whether the results of these studies are applicable to a UK setting.

The studies included in this addendum have provided evidence for 5 outcomes for which no evidence had been identified in the original assessment report. A small case-controlled survey reported on the surgeon level outcomes of surgeon-related discomfort and ergonomics and career longevity and musculoskeletal injury (Norasi et al. 2023). A database analysis study provided some data on the volume of RAS procedures compared to open and conventional MIS procedures (Pyrgidis et al. 2024). An RCT based in China (Feng et al. 2022) provided evidence on days alive and out of hospital in a cancer population. Finally, 3 studies on head and neck surgery reported data on

feeding tube dependency (Hammoudi et al. 2015, O'Hara et al. 2024, Sievert et al. 2021).

However, despite the inclusion of further studies in this addendum, we believe that the conclusions of the evidence gap analysis in the original early value assessment report are still valid. The evidence available is moderate to low quality comparative evidence for most outcomes, and studies are of too short a duration to understand the impact of the learning curve. Some of the studies had small sample sizes and statistically significant effects were not estimated. As in the original assessment, each study tended to focus on one specific type of surgery (e.g. colorectal resection). Organisational level outcomes were not well-reported. No studies included in this addendum addressed the key outcome of the rate of MIS compared with open surgery after RAS was introduced, and this remains a significant evidence gap. Hence, when considering all these limiting factors, the additional evidence was considered to be moderate to low quality.

The original assessment report concluded that there is a need for evidence from large multi-centre studies, across a range of indications or surgeries in settings where the robotic platform is being introduced and in settings where it is already established. At least a 12-month follow-up was recommended. None of the studies included in this addendum fulfilled these criteria. The systematic reviews summarised in this addendum similarly highlight the need for further evidence from high quality prospective studies with longer follow up and larger sample sizes. The EAG consider the existing summary of evidence gaps and recommendations for evidence generation reported in the EAG report to remain applicable.

Table 8.1: Summary and conclusions of evidence gap analysis

Outcomes	Da Vinci Si/X/Xi
Primary – patient level	
Conversion to open surgery	10 cohort studies (6 retrospective, 1 prospective; 3 historically controlled [9 Europe, 1 UK] 2 prospective non-randomised studies (Europe) (from main report) 5 RCTs (1 Egypt, 1 China, 1 South Korea, 2 multinational [1 including UK]) Canada]) **AMBER**
Conversion to conventional conventional MIS from RAS	1 prospective non-randomised study (Europe) 4 cohort studies (3 retrospective; 1 historically controlled [4 Europe]) (from main report) **AMBER**
Length of hospital stay	9 cohort studies (6 retrospective, 1 prospective, 2 historically controlled [1 UK; 8 Europe] 2 prospective non-randomised studies (Europe) (from main report) 6 RCTs (1 Egypt, 1 China, 1 South Korea, 3 multinational [2 including UK]) 2 cohort studies (retrospective) (Europe) **AMBER**
Intraoperative complications	6 cohort studies (4 retrospective; 1 prospective; 1 historically controlled [6 Europe]) (from main report) 4 RCTs (1 China, 2 multinational [1 including UK], 1 South Korea) **AMBER**
Postoperative complications	Overall complications: 4 cohort studies (2 retrospective studies; 1 historically controlled [4 Europe]) (from main report) 4 RCTs (1 Egypt, 1 China, 2 multinational [1 including UK]) 1 cohort study (retrospective) (Europe) **AMBER**
Clavien-Dindo score	8 cohort studies (5 retrospective, 1 prospective, 2 historically controlled [1 UK, 7 Europe] 2 prospective non-randomised studies (2 Europe) (from main report) 2 RCTs (1 China, 1 South Korea) **AMBER**
HRQoL	1 historically controlled cohort study (Europe) (from main report) 1 RCT (multinational, including UK)

Outcomes	Da Vinci Si/X/Xi
	AMBER
Primary – surgeon level	
Procedure-related discomfort and ergonomics	1 case-controlled survey (US) **AMBER**
Primary – organisation level	
Rate of MIS compared with open surgery after RAS was introduced	No studies **RED**
Volume of procedures	1 database analysis study (Europe) **AMBER**
Hospital capacity and wait-list reduction	No studies **RED**
Secondary – patient level	
Days alive and out of hospital	No studies (from main report) 1 RCT (China) 1 database analysis study (Europe) **AMBER**
Post-operative pain	4 cohort studies (1 prospective, 1 retrospective, 2 historically controlled [4 Europe] (from main report) 3 RCTs (1 South Korea, 2 multinational [1 including UK]) **AMBER**
Satisfaction	1 retrospective cohort study (Europe) (from main report) **AMBER**
Revision surgery for the same indication	2 prospective non-randomised studies (2 Europe) 5 cohort studies (4 retrospective; 1 prospective [1 UK; 4 Europe]) (from main report) 2 cohort studies (retrospective) (Europe) **AMBER**
Secondary – patient level (specific study types)	
Intraoperative blood loss (compared with open surgery)	1 prospective randomized study (Europe) (from main report) **AMBER**
Survival rate (in cancer studies)	3 retrospective cohort studies (1 UK; 2 Europe) (from main report) 1 RCT (multinational, including UK) 2 cohort studies (retrospective) (Europe) **AMBER**

Outcomes	Da Vinci Si/X/Xi
Need for adjuvant treatment (in cancer studies)	1 prospective non-randomized study (Europe) (from main report) 1 RCT (multinational) 2 cohort studies (retrospective) (Europe) **AMBER**
Feeding tube dependency (for head and neck studies)	No studies (from main report) 1 RCT (multinational including UK) 2 cohort studies (retrospective) (Europe) **AMBER**
Secondary outcomes – surgeon level	
Career longevity and musculoskeletal injury	1 case-controlled survey (US) **AMBER**

Abbreviations: RCT – Randomised controlled trial

Key: **RED** indicates no evidence for the scoped population; **AMBER** indicates weak evidence for the scoped population; **GREEN** indicates robust evidence for the scoped population.

9 Conclusions

The additional information presented to the EAG does not change the conclusions of the early value assessment report. The available clinical and economic evidence suggests that RAS is generally comparable with current standard of care for primary patient outcomes, for the procedures identified. However, only 1 of the scoped technologies had further evidence considered in this addendum. Evidence was moderate-to-low quality and there is limited evidence from a UK setting.

10 References

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Calpin GG, Ryan FR, McHugh FT, et al. (2023) Comparing the outcomes of open, laparoscopic and robot-assisted partial nephrectomy: a network meta-analysis. BJU Int 132(4): 353-364

Corrigan N, Marshall H, Croft J, et al. (2018) Exploring and adjusting for potential learning effects in ROLARR: a randomised controlled trial comparing robotic-assisted vs. standard laparoscopic surgery for rectal cancer resection. Trials [Electronic Resource] 19(1): 339

Debakey Y, Zaghloul A, Farag A, et al. (2018) Robotic-Assisted versus Conventional Laparoscopic Approach for Rectal Cancer Surgery, First Egyptian Academic Center Experience, RCT. Minimally Invasive Surgery 2018(1): 5836562

Dixon F, Khanna A, Vitish-Sharma P, et al. (2021) Initiation and feasibility of a multi-specialty minimally invasive surgical programme using a novel robotic system: A case series. International Journal of Surgery 96: 106182

Dixon F, Vitish-Sharma P, Khanna A, et al. (2024) Robotic assisted surgery reduces ergonomic risk during minimally invasive colorectal resection: the VOLCANO randomised controlled trial. Langenbecks Archives of Surgery 409(1): 142

Feng Q, Yuan W, Li T, et al. (2022) Robotic versus laparoscopic surgery for middle and low rectal cancer (REAL): short-term outcomes of a multicentre randomised controlled trial. The Lancet Gastroenterology & Hepatology 7(11): 991-1004

Fu S, Shi H, Fan Z, et al. (2024) Robot-assisted radical cystectomy with intracorporeal urinary diversion: an updated systematic review and meta-analysis of its differential effect on effectiveness and safety. International Journal of Surgery 110(4): 2366 - 2380

Galata C, Vassilev G, Haas F, et al. (2019) Clinical, oncological, and functional outcomes of Da Vinci (Xi)-assisted versus conventional laparoscopic resection for rectal cancer: a prospective, controlled cohort study of 51 consecutive cases. International Journal of Colorectal Disease 34(11): 1907-1914

Hammoudi K, Pinlong E, Kim S, et al. (2015) Transoral robotic surgery versus conventional surgery in treatment for squamous cell carcinoma of the upper aerodigestive tract. Head Neck 37(9): 1304-9

Jayne D, Pigazzi A, Marshall H, et al. (2019) Robotic-assisted surgery compared with laparoscopic resection surgery for rectal cancer: the ROLARR RCT. Southampton UK:

Jayne D, Pigazzi A, Marshall H, et al. (2017) Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer: The ROLARR Randomized Clinical Trial. JAMA 318(16): 1569-1580

Kim MJ, Park SC, Park JW, et al. (2018) Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer: A Phase II Open Label Prospective Randomized Controlled Trial. Annals of Surgery 267(2): 243-251

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Leitao MM, Jr., Kreaden US, Laudone V, et al. (2023) The RECOURSE study: long-term oncologic outcomes associated with robotically assisted minimally invasive procedures for endometrial, cervical, colorectal, lung, or prostate cancer: a systematic review and meta-analysis. Annals of Surgery 277(3): 387-396

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Lv Z, Chen G, Chen X, et al. (2023) Open versus robot-assisted partial nephrectomy for highly complex renal masses: a meta-analysis of perioperitive and functional outcomes. Journal of Robotic Surgery 17(5): 1955-1965

Norasi H, Hallbeck MS, Elli EF, et al. (2023) Impact of preferred surgical modality on surgeon wellness: a survey of workload, physical pain/discomfort, and neuromusculoskeletal disorders. Surgical Endoscopy 37(12): 9244-9254

Norasi H, Kim J, Hallbeck MS, et al. (2024) Surgeons' dominant surgical modality: Impacts on wellbeing, burnout, and interventions for neuromusculoskeletal disorders. American Journal of Surgery 237: 115769

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Patel YS, Baste JM, Shargall Y, et al. (2023) Robotic Lobectomy Is Cost-effective and Provides Comparable Health Utility Scores to Video-assisted Lobectomy: Early Results of the RAVAL Trial. Annals of Surgery 278(6): 841-849

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Rogalska M, Antkowiak L, Kasperczuk A, et al. (2023) Transoral robotic surgery in the management of submandibular gland sialoliths: a systematic review. Journal of Clinical Medicine 12(8): 3007

Roy N, Alessandro CJ, Ibelli TJ, et al. (2023) The expanding utility of robotic-assisted flap harvest in autologous breast reconstruction: a systematic review. Journal of Clinical Medicine 12(15): 4951

Samalavicius NE, Kaminskas T, Zidonis Z, et al. (2022) Robotic cholecystectomy using Senhance robotic platform versus laparoscopic conventional cholecystectomy: a propensity score analysis. Acta Chirurgica Belgica 122(3): 160-163

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Sievert M, Goncalves M, Zbidat A, et al. (2021) Outcomes of transoral laser microsurgery and transoral robotic surgery in oropharyngeal squamous cell carcinoma. Auris, Nasus, Larynx 48(2)**:** 295-301

Thornton R, Davey MG and Kerin MJ (2024) Evaluating the utility of robotic axillary lymph node dissection in patients with invasive breast cancer: a systematic review. Irish Journal of Medical Science 193(3)**:** 1163-1170

Tschann P, Szeverinski P, Weigl MP, et al. (2022) Short- and long-term outcome of laparoscopic- versus robotic-assisted right colectomy: a systematic review and meta-analysis. Journal of Clinical Medicine 11(9)**:** 13

Wang P, Fu YH, Qi HF, et al. (2024) Evaluation of the efficacy and safety of robot-assisted and video assisted thoracic surgery for early non-small cell lung cancer: A meta-analysis. Technol Health Care 32(2)**:** 511-523

Wu H, Guo R and Li H (2023) Short-term and long-term efficacy in robot-assisted treatment for mid and low rectal cancer: a systematic review and meta-analysis. International Journal of Colorectal Disease 39(1)**:** 7

11 Appendices

Appendix A – List of studies excluded at full text assessment (n= 20)

Table 11.1: List of excluded studies (n=3)

Reference	Exclusion reason
Somashekhar SP, Ashwin KR, Rajashekhar J, Zaveri S. Prospective Randomized Study Comparing Robotic-Assisted Surgery with Traditional Laparotomy for Rectal Cancer-Indian Study. Indian J Surg. 2015 Dec;77(Suppl 3):788-94. doi: 10.1007/s12262-013-1003-4. Epub 2013 Nov 11. PMID: 27011458; PMCID: PMC4775566." Indian J Surg 77(Suppl 3): 788-794.	Pre 2014 study
2017 European Society of Coloproctology (ESCP) collaborating group. An international multicentre prospective audit of elective rectal cancer surgery; operative approach versus outcome, including transanal total mesorectal excision (TaTME). Colorectal Dis. 2018 Sep;20 Suppl 6:33-46. doi: 10.1111/codi.14376. PMID: 30255642.	Ineligible outcomes
Wang G, Wang Z, Jiang Z, Liu J, Zhao J, Li J. Male urinary and sexual function after robotic pelvic autonomic nerve-preserving surgery for rectal cancer. Int J Med Robot. 2017 Mar;13(1). doi: 10.1002/rcs.1725. Epub 2016 Jan 8. PMID: 26748601.	Ineligible outcomes

Table 11.2: List of deprioritised studies (n=17)

Reference	Deprioritisation reason
Bedrikovetski S, Dudi-Venkata NN, Kroon HM, Moore JW, Hunter RA, Sammour T. Outcomes of Minimally Invasive Versus Open Proctectomy for Rectal Cancer: A Propensity-Matched Analysis of Bi-National Colorectal Cancer Audit Data. Dis Colon Rectum. 2020 Jun;63(6):778-787. doi: 10.1097/DCR.0000000000001654. PMID: 32109916.	Not RCT, Australian setting
Chapman BC, Edgcomb M, Gleisner A, Vogel JD. Outcomes in rectal cancer patients undergoing laparoscopic or robotic low anterior resection compared to open: a propensity-matched analysis of the NCDB (2010-2015). Surg Endosc. 2020 Nov;34(11):4754-4771. doi: 10.1007/s00464-019-07252-5. Epub 2019 Nov 14. PMID: 31728754.	Not RCT, US setting
Chillakuru Y, Benito DA, Strum D, Mehta V, Saini P, Shim T, Darwish C, Joshi AS, Thakkar P, Goodman JF. Transoral robotic surgery versus nonrobotic resection of oropharyngeal squamous cell carcinoma. Head Neck. 2021 Jul;43(7):2259-2273. doi: 10.1002/hed.26724. Epub 2021 Apr 26. PMID: 33899949.	Not RCT, US setting
Dolejs SC, Waters JA, Ceppa EP, Zarzaur BL. Laparoscopic versus robotic colectomy: a national surgical quality improvement project analysis. Surg Endosc. 2017 Jun;31(6):2387-2396. doi: 10.1007/s00464-016-5239-5. Epub 2016 Sep 21. PMID: 27655383.	Not RCT, US setting
Gilmore B, Adam MA, Rhodin K, Turner MC, Ezekian B, Mantyh CR, Migaly J. Evolution of minimally invasive surgery for rectal cancer: update from the national cancer database. Surg Endosc. 2021 Jan;35(1):275-290. doi: 10.1007/s00464-020-07393-y. Epub 2020 Feb 28. PMID: 32112255.	Not RCT, US setting
Haskins IN, Ju T, Skancke M, Kuang X, Amdur RL, Brody F, Obias V, Agarwal S. Right Colon Resection for Colon Cancer: Does Surgical Approach Matter? J Laparoendosc Adv Surg Tech A. 2018 Oct;28(10):1202-1206. doi: 10.1089/lap.2018.0148. Epub 2018 May 18. PMID: 29775552.	Not RCT, US setting
Hu KY, Wu R, Szabo A, Ridolfi TJ, Ludwig KA, Peterson CY. Laparoscopic Versus Robotic Proctectomy Outcomes: An ACS-NSQIP Analysis. J Surg Res. 2020 Nov;255:495-501. doi: 10.1016/j.jss.2020.05.094. Epub 2020 Jul 1. PMID: 32622164.	Not RCT, US setting
Hyde LZ, Baser O, Mehendale S, Guo D, Shah M, Kiran RP. Impact of surgical approach on short-term oncological outcomes and recovery following low anterior resection for rectal cancer. Colorectal Dis. 2019 Aug;21(8):932-942. doi: 10.1111/codi.14677. Epub 2019 May 25. PMID: 31062521.	Not RCT, US setting
Khorgami Z, Li WT, Jackson TN, Howard CA, Sclabas GM. The cost of robotics: an analysis of the added costs of robotic-assisted versus laparoscopic surgery using the National Inpatient Sample. Surg Endosc. 2019 Jul;33(7):2217-2221. doi: 10.1007/s00464-018-6507-3. Epub 2018 Oct 16. PMID: 30327915.	Not RCT, US setting

Reference	Deprioritisation reason
Miller PE, Dao H, Paluvoi N, Bailey M, Margolin D, Shah N, Vargas HD. Comparison of 30-Day Postoperative Outcomes after Laparoscopic vs Robotic Colectomy. J Am Coll Surg. 2016 Aug;223(2):369-73. doi: 10.1016/j.jamcollsurg.2016.03.041. Epub 2016 Apr 19. PMID: 27109780.	Not RCT, US setting
Oliver JR, Persky MJ, Wang B, Duvvuri U, Gross ND, Vaezi AE, Morris LGT, Givi B. Transoral robotic surgery adoption and safety in treatment of oropharyngeal cancers. Cancer. 2022 Feb 15;128(4):685-696. doi: 10.1002/cncr.33995. Epub 2021 Nov 11. PMID: 34762303; PMCID: PMC9446338.	Not RCT, US setting
Parascandola SA, Hota S, Sparks AD, Boulos S, Cavallo K, Kim G, Obias V. Trends in utilization, conversion rates, and outcomes for minimally invasive approaches to non-metastatic rectal cancer: a national cancer database analysis. Surg Endosc. 2021 Jun;35(6):3154-3165. doi: 10.1007/s00464-020-07756-5. Epub 2020 Jun 29. PMID: 32601761.	Not RCT, US setting
Richards CR, Steele SR, Lustik MB, Gillern SM, Lim RB, Brady JT, Althans AR, Schlussel AT. Safe surgery in the elderly: A review of outcomes following robotic proctectomy from the Nationwide Inpatient Sample in a cross-sectional study. Ann Med Surg (Lond). 2019 Jun 20;44:39-45. doi: 10.1016/j.amsu.2019.06.004. PMID: 31312442; PMCID: PMC6610645.	Not RCT, US setting
Sujatha-Bhaskar S, Jafari MD, Gahagan JV, Inaba CS, Koh CY, Mills SD, Carmichael JC, Stamos MJ, Pigazzi A. Defining the Role of Minimally Invasive Proctectomy for Locally Advanced Rectal Adenocarcinoma. Ann Surg. 2017 Oct;266(4):574-581. doi: 10.1097/SLA.0000000000002357. PMID: 28650357.	Not RCT, US setting
Sun Z, Kim J, Adam MA, Nussbaum DP, Speicher PJ, Mantyh CR, Migaly J. Minimally Invasive Versus Open Low Anterior Resection: Equivalent Survival in a National Analysis of 14,033 Patients With Rectal Cancer. Ann Surg. 2016 Jun;263(6):1152-8. doi: 10.1097/SLA.0000000000001388. PMID: 26501702.	Not RCT, US setting
Sweigert PJ, Eguia E, Kothari AN, Ban KA, Nelson MH, Baker MS, Singer MA. Do prolonged operative times obviate the benefits associated with minimally invasive colectomy? Surgery. 2019 Sep;166(3):336-341. doi: 10.1016/j.surg.2019.05.006. Epub 2019 Jun 22. PMID: 31235244.	Not RCT, US setting
Taylor JP, Stem M, Althumairi AA, Gearhart SL, Safar B, Fang SH, Efron JE. Minimally Invasive Proctectomy for Rectal Cancer: A National Perspective on Short-term Outcomes and Morbidity. World J Surg. 2020 Sep;44(9):3130-3140. doi: 10.1007/s00268-020-05560-9. PMID: 32383054.	Not RCT, US setting

Appendix B – Clinical outcomes

11.1.1 Primary outcomes (patient level)

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Da Vinci Si							
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	**Da Vinci Si:** 1 (4.8) **conventional MIS:** 2 (8.3)	NR	NR	**Da Vinci Si:** Anastomotic leakage: 1 (4.8) Ileus (median days): 2 (9.5) Wound problems: 2 (9.5) Others: 1 **conventional MIS:** Anastomotic leakage: 1 (4.2)	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					Ileus (median days): 3 (12.5) Wound problems: 2 (8.3) Others: 1 p=0.965		
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	**Da Vinci Si:** 10 (1.7) **conventional MIS:** 23(3.9) **Difference between Da Vinci Si and conventional MIS (95% CI)**: -2.2 (04.3 to -0.4) p = 0.021	NR	**Da Vinci Si:** 32 (5.5) **conventional MIS:** 51 (8.7) **Difference between Da Vinci Si and conventional MIS (95% CI)**: –3·3 (–6·3 to –0·3) p = 0.030	**Anastomotic complications:** **Da Vinci Si (n=486):** 4 (0.8) **conventional MIS (n=449):** 9 (2) **Difference between Da Vinci Si and conventional MIS (95% CI)**: -1.2 (-3.p to 0.4)	**Patients with complications of CD grade II > within 30 days of operation:** **Da Vinci Si:** 95 (16.2) **conventional MIS:** 135 (23.1) **Difference between Da Vinci Si and conventional MIS (95% CI):** -	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					p = 0.123	6.9 (-11.4 to -2.3) p = 0.003	
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	**Da Vinci Si:** 1 (1.5) **conventional MIS:** 0 (0) p = 0.475	NR	**Perioperative complications:** **Da Vinci Si:** 23 (34.8) **conventional MIS:** 17 (23.3) p = 0.133	NR	**CD I:** **Da Vinci Si:** 6 (9.1) **conventional MIS:** 3 (4.1) **CD II:** **Da Vinci Si:** 11 (16.7) **conventional MIS:** 10 (13.7) **CD IIIa:** Da Vinci Si: 4 (6.4)	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
						conventional MIS: 2 (2.7) **CD IIIb:** **Da Vinci Si:** 2 (3) **conventional MIS:** 2 (2.7)	
Da Vinci (unspecified model)							
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** (Corrigan et al. 2018) Jayne et al 2019 HRQoL data from: (Jayne et al. 2019)	**Intervention:** Da Vinci (unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) Complete case	**Da Vinci (unspecified model)**: 19/236 (8.1%) **conventional MIS**: 28/230 (12.2%)	NR	**Da Vinci (unspecified model)**: 36/236 (15.3%) **conventional MIS**: 34/230 (14.8%)	**Within 30 days:** Da Vinci (unspecified model): 78/236 (33.1%) conventional MIS: 73/230 (31.7%) Unadjusted risk difference	NR	**SF-36v2 Physical component (mean, SD):** **Da Vinci (unspecified model):** Baseline (n=226): 51.4 (8.9)

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Location: UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.		**Unadjusted difference in proportions**: 4.1% (95% CI, −1.4% to 9.6%) **Adjusted OR (favouring RAS)**: 0.61 (95% CI, 0.31 to 1.21) p=0.16		**Unadjusted risk difference:** −0.5% (95% CI, −6.0% to 7.0%) **Adjusted OR**: 1.02 (95% CI, 0.60 to 1.74) p=0.94	−1.3% (95% CI, −9.8% to 7.2%) <u>Adjusted OR</u> 1.04 (95% CI, 0.69 to 1.58) p=0.84 **30 days to 6 months:** Da Vinci (unspecified model): 34/236 (14.4%) conventional MIS: 38/230 (16.5%) <u>Unadjusted risk difference</u>		30 days (n=213): 42.4 (8.55) 6 months (n=199): 48.7 (7.95) **convention al MIS:** Baseline (n=221): 51.6 (8.79) 30 days (n=198): 42.0 (8.42) 6 months (n=195): 48.3 (8.9) p= n.s. at 6 months

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					2.1% (95% CI, −4.5% to 8.7%) <u>Adjusted OR</u> 0.72 (95% CI, 0.41 to 1.26) p=0.25		**SF-36v2 Mental Component score (mean, SD)** **Da Vinci (unspecified model):** Baseline (n=226): 47.3 (11.82) 30 days (n=213): 45.6 (11.73) 6 months (n=199): 48.9 (11.62) **conventional MIS:**

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
							Baseline (n=221): 48.1 (11.48) 30 days (n=198): 44.1 (12.86) 6 months (n=196): 49.6 (10.04) p= n.s. at 6 months
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck	**Intervention:** Da Vinci (unspecified model): (n=26) **Comparator:** conventional MIS: (n=26)	NR	NR	NR	**Da Vinci (unspecified model)**: 1 **conventional MIS**: 2 p=0.45	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
squamous cell carcinoma							
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR	NR	NR	NR	NR	NR
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	NR	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
T3 stage oropharyngeal squamous cell carcinoma.							
Da Vinci (various models)							
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2023 **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10; dominant laparoscopic n=15) or open surgery (dominant open n=26)	NR	NR	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	*Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than the other 3 modalities.						
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph’s Healthcare, Hamilton; Toronto General	**Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted	**Conversion to thoracotomy:** Da Vinci (various models): 6/81 (7.41%) conventional MIS: 13/83 (15.66%)	NR	**Da Vinci (various models)**: 7/81 (8.64%) **conventional MIS**: 11/83 (13.25%) p=0.35	**Patients with AE during hospital admission (n %):** Da Vinci (various models): 54/81 (66.67%)	NR	**EQ-5D-5L Generated HU scores – mean (SD)** **HU score at 3 weeks:** **Da Vinci,**

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	thoracoscopic surgery, n=81)	p=0.10			conventional MIS: 52/82* (63.41%) p=0.66 **Patients with AE 3 weeks from discharge (n %):** Da Vinci (various models): 29/67* (43.28%) conventional MIS: 28/67*(41.79%) p=0.86 **Patients with AE 3 to 7 weeks from**		**various models:** 0.78 (SD 0.17) **Conventional MIS:** 0.74 (SD 0.19) p = 0.18 **HU score at 7 weeks:** **Da Vinci, various models:** 0.84 (SD 0.14)

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					discharge (n %): Da Vinci (various models): 22/60* (36.67%) conventional MIS: 26/60* (43.33%) p=0.46 **Patients with AE 7 to 12 weeks from discharge (n %):** Da Vinci (various models): 21/62* (33.87%)		**Conventional MIS:** 0.78 (SD 0.18) p = 0.04 **HU score at 12 weeks:** **Da Vinci, various models:** 0.85 (SD 0.10) **Conventional MIS:** 0.80 (SD 0.19) p = 0.02

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					conventional MIS: 22/63* (34.92%) p=0.90 **Patients with AE 12 weeks to 6 months from discharge (n %):** Da Vinci (various models): NR conventional MIS: 1/8* (12.5%) p=0.27 **Patients with AE 6 months to 12 weeks from**		**HU score at 6 months:** **Da Vinci, various models:** 0.85 (SD 0.12) **Conventional MIS:** 0.71 (SD 0.20) p = 0.68 **HU score at 12 months:** **Da Vinci, various models:**

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
					discharge (n %): Da Vinci (various models): 18/61* (29.51%) conventional MIS: 21/65* (32.31%) p=0.73		0.84 (SD 0.11) **Conventional MIS:** 0.79 (SD 0.22) p = 0.16
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428)	NR	NR	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Conversion to open surgery (for RAS compared with conventional MIS techniques) N (%)	Rate of conventional MIS compared with open surgery after RAS was introduced N (%)	Complications			HRQoL Score n (%)
				Intraoperative N (%)	Postoperative N (%)	Clavien-Dindo score N (%)	
nephrectomy, nephroureterectomy or pyeloplasty	**Comparator:** Open surgery (n=733,416)						

Abbreviations: AE – Accidence and emergency, CD – Clavien-Dindo, CI – Confidence intervals, HRQoL – Health related quality of life, conventional MIS – Minimally invasive surgery, N.S – Not significant, NR – Not reported, OR – Odds ratio, RAS – Robot-assisted surgery, RCT - Randomised controlled trial, SF-36v2 – Short Form questionnaire 36 items, TLM - Transoral laser microsurgery.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.2 Primary outcomes (surgeon level)

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Da Vinci Si		
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	NR
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR
Da Vinci (unspecified model)		

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.	**Intervention:** Da Vinci (unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) **Complete case**	NR
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck squamous cell carcinoma	**Da Vinci (unspecified model)**: (n=26) **conventional MIS**: (n=26)	NR
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Setting: 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage		
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator: conventional MIS (n=30)**	NR
Da Vinci (various models)		
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10; dominant laparoscopic n=15) or open surgery (dominant open n=26) *Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than the other 3 modalities.	**Surgeons reporting ever having had or currently having neuromusculoskeletal pain %, OR (95% CI) compared to Da Vinci (various models n=14, 21%)** Endoscopic (n=10): 80%, OR 0.068 (0.009 to 0.508), p=0.0087 Laparoscopic (n=15): 73%, OR 0.099 (0.018 to 0.551), p=0.0082 Open (n=26): 69%, OR 0.121 (0.026 to 0.557), p=0.0067 Model p-value (logistic regression; effect likelihood ratio test): p=0.0057 **Surgeons reporting any physical discomfort or pain in upper extremity %, OR (95% CI) compared to Da Vinci (various models n=14, 14%)** Laparoscopic (n=15): 67%, OR 0.083 (0.013 to 0.526), p=0.0082 Open (n=26): 54%, OR 0.143 (0.027 to 0.770), p=0.0235

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
		Model p-value (logistic regression; effect likelihood ratio test): p=0.0219
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph's Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	NR
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428)	NR

Abbreviations: CI – Confidence intervals, MIS – Minimally invasive surgery, NR – Not reported, OR – Odds ratio, RAS – Robot-assisted surgery, RCT - Randomised controlled trial, SP – Single port, TLM - Transoral laser microsurgery.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.3 Primary outcomes (organisation level)

Study name and location	Technology name and number of patients	Volume of procedures	Length of hospital stay median (range) days	Capacity and wait-list reduction
Da Vinci Si				
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	NR	**Da Vinci Si:** 3 (2 to 14) **conventional MIS:** 2 (2 to 11) p = 0.116	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	NR	**Da Vinci Si:** 7 (7 to 11) **conventional MIS:** 8 (7 to 12) **Difference between Da Vinci Si and conventional MIS (95% CI)**: -1 (-1 to 0) p = 0.0001	NR
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR	**Da Vinci Si:** 10.3 (3.4) **conventional MIS:** 10.8 (7.4) p = 0.621	NR

Study name and location	Technology name and number of patients	Volume of procedures	Length of hospital stay median (range) days	Capacity and wait-list reduction
Indication: Middle or low rectal cancer				
Da Vinci (unspecified model)				
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.	**Intervention:** Da Vinci (unspecified model): (n=223) **Comparator:** conventional MIS: (n=221) Complete case	NR	**Length of stay (days, mean SD)** Da Vinci (unspecified model, n=223): 8.0 (5.85) conventional MIS (n=221): 8.2 (6.03) p=n.s.	NR
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital	**Da Vinci (unspecified model)**: (n=26) **conventional MIS**: (n=26)	NR	**Length of hospitalisation (days, mean SD):** Da Vinci (unspecified model): 11 (6) conventional MIS: 19 (10)	NR

Study name and location	Technology name and number of patients	Volume of procedures	Length of hospital stay median (range) days	Capacity and wait-list reduction
Indication: Patients with head and neck squamous cell carcinoma			Mean difference (favouring RAS): -8, p=0.001	
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR	**Length of hospital stay n (%), median (95% CI)** **RAS:** 313 (61.6%), 5 (5 to 6) **TLM:** 195 (38.4%), 3 (2 to 4) **Median difference:** 2.6 (95% CI, 1.8 to 3.5) **Hazard ratio (univariable model):** 0.66 (95% CI 0.55 to 0.79) p<0.001 **Hazard ratio (univariable model):** 0.65 (95% CI 0.54 to 0.78) p<0.001	NR
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	**Length of hospitalisation, days (mean, SD)**: Da Vinci (specific model not named): 16.6 (10.7) conventional MIS: 15.1 (8.3) p=0.585	NR

Study name and location	Technology name and number of patients	Volume of procedures	Length of hospital stay median (range) days	Capacity and wait-list reduction
Da Vinci (various models)				
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10; dominant laparoscopic n=15) or open surgery (dominant open n=26) *Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than the other 3 modalities.	NR	NR	NR
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph’s Healthcare, Hamilton;	**Design:** RCT **Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted	NR	**Length of stay in days, median (IQR)** Da Vinci (various models): 3 (2 to 5) conventional MIS: 3 (2 to 5) p=0.85	NR

Study name and location	Technology name and number of patients	Volume of procedures	Length of hospital stay median (range) days	Capacity and wait-list reduction
Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	thoracoscopic surgery, n=81)			
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428) **Comparator:** Open surgery (n=733,416)	**Number of surgeries between 2005 and 2021:** **Da Vinci:** 150, 432 **conventional MIS:** 109, 428 **Open:** 733,416 A full breakdown of the surgeries per year, including the increase in RAS, can be found in Appendix A		NR

Abbreviations: CI – Confidence intervals, IQR – Inter-Quartile range, conventional MIS – Minimally invasive surgery, NR – Not reported, RAS – Robot-assisted surgery, RCT - Randomised controlled trial, SD – Standard deviation, TLM - Transoral laser microsurgery.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.4 Secondary outcomes (patient level)

Study name and location	Technology name and number of patients	Days alive and out of hospital at 30 days	Post-operative pain N (%)	Satisfaction N (%)	Revision surgery for the same indication N (%)
Da Vinci Si					
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	NR	NR	NR	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	**Mortality within 30 days after operation, n (%):** **Da Vinci Si:** 1 (0.2) **conventional MIS**: 1 (0.2) **Difference between Da Vinci Si and conventional MIS (95% CI)**: 0 (-0.8 to 0.8) p > 0.999	NR	NR	NR
Kim et al 2018 (Kim et al. 2018)	**Intervention:** Da Vinci Si (n=66)	NR	**Present pain intensity index**	NR	NR

Location: South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Comparator:** conventional MIS (n=73)		**score, median (range):** **Postoperative day 1:** Da Vinci Si: 2 (0 to 5) conventional MIS: 1 (0 to 5) p = - 0.072 **Postoperative day 2:** Da Vinci Si: 1 (0 to 4) conventional MIS: 1 (0 to 5) p = 0.998 **Postoperative day 3:** Da Vinci Si: 1 (0 to 5) conventional MIS: 1 (0 to 5) p = 0.852 **Postoperative day 4:** Da Vinci Si: 1 (0 to 5) conventional MIS: 1 (0 to 5) p = 0.938		

			Postoperative day 5: Da Vinci Si: 1 (0 to 4) conventional MIS: 1 (0 to 4) p = 0.347 **VAS pain score, median (range):** **Postoperative day 1:** Da Vinci Si: 5 (0 to 10) conventional MIS: 4 (0 to 10) p = 0.111 **Postoperative day 2:** Da Vinci Si: 4 (0 to 8) conventional MIS: 3 (0 to 10) p = 0.56 **Postoperative day 3:** Da Vinci Si: 4 (0 to 10) conventional MIS: 3 (1 to 9)		

			p = 0.312 **Postoperative day 4:** Da Vinci Si: 3 (0 to 10) conventional MIS: 3 (0 to 9) p = 0.899 **Postoperative day 5:** Da Vinci Si: 3 (1 to 9) conventional MIS: 2 (0 to 8) p = 0.386		
Da Vinci (unspecified model)					
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany,	**Intervention:** Da Vinci (unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) Complete case	NR	NR	NR	NR

France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.					
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck squamous cell carcinoma	**Intervention:** Da Vinci (unspecified model): (n=26) **Comparator:** conventional MIS: (n=26)	NR	NR	NR	**Local recurrence leading to further surgery**: Da Vinci (unspecified model): 2/26 (8%) conventional MIS: 2/26 (8%) **Nodal recurrence/metastasis leading to further surgery**: Da Vinci (unspecified model): 0/26 (0%) conventional MIS: 1/26 (5%)[1]
O'Hara et al 2024 (O'Hara et al. 2024)	**Intervention:** Da Vinci (specific model not specified, n=313)	NR	**H&N35 pain score, mean (SD) [median (IQR)]:** **RAS baseline (n=272):** 17.5 (19.7)	NR	NR

[1] Percentages are as-reported in text.

Location: UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Comparator:** TLM (N=195)		[8.3 (0 to 25.0)] **RAS 4 weeks post op (n=272):** 36.5 (23.0) [33. (19.4 to 50.0)] **TLM baseline (n=173)**: 14.6 (18.0) [8.3 (0 to 25.0)] **TLM 4 weeks post op (n=173)**: 34.0 (25.6) [33.3 (16.7 to 50.0)] **Effect of surgery, between-group difference (95% CI), p:** **Simple multivariable analysis:** 1.48 (−2.91 to 5.87), p=0.51 **Full multivariable analysis:** 4.58 (−0.90 to 9.96), p=0.01		
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany	**Intervention:** Da Vinci (specific model not named, n=24)	NR	NR	NR	**Intraoperative re-resection (n %):** Da Vinci (specific model not named): 9/24 (37.5%)

Setting: University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.	**Comparator:** conventional MIS (n=30)				conventional MIS: 13/30 (43.3%)
Da Vinci (various models)					
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	**Intervention:** Da Vinci Xi and SP systems **Comparator:** conventional MIS (endoscopic or laparoscopic surgery) or open surgery	NR	NR	NR	NR
Patel et al 2023 (NCT02617186) (Patel et al. 2023)	**Design:** RCT	NR	**Postoperative pain during admission measured by EQ-5D, median (IQR):**	NR	NR

Location: Canada, France and the US **Setting:** St. Joseph's Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)		Da Vinci (various models): 2.82 (1.69 to 4.40) conventional MIS: 2.84 (1.81 to 4.43) p=0.88		
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428)	**n (%), estimate (95% CI), p-value v open surgery** **Radical prostatectomy mortality** **Da Vinci:** 44 (<0.1), 0.63 (0.41 to 0.94), 0.03 **conventional MIS:** 6 (0.1), 0.9 (0.34 to 1.9), 0.8 **Open:** 52 (0.2) **Radical cystectomy mortality, n (%), Estimate (95% CI), p value:** **Da Vinci:** 84 (3.7), 0.8 (0.63 to 0.99), 0.04	NR	NR	NR

		conventional MIS: 20 (2.9), 0.63 (0.38 to 0.96), 0.04 **Open:** 1,057 (5.0) **Radical nephrectomy mortality** **Da Vinci:** 21 (0.9), 0.28 (0.18 to 0.43), <0.001 **conventional MIS:** 36 (0.7), 0.21 (0.15 to 0.29), <0.001 **Open:** 660 (3.5) **Partial nephrectomy mortality** **Da Vinci:** 21 (0.2), 0.43 (0.26 to 0.68), <0.001 **conventional MIS:** 10 (0.3), 0.62 (0.3 to 1.1), 0.2 **Open**: 96 (0.6) **Nephroureterectomy mortality** **Da Vinci:**17 (1.3), 0.47 (0.28 to 0.76), 0.004 **conventional MIS:** 16 (1.2), 0.45 (0.26 to 0.73), 0.002 **Open:** 193 (2.6) **Pyeloplasty mortality:**			

		Da Vinci: 0 (0) **conventional MIS:** 0 (0) **Open:** 4 (0.1)			

Abbreviations: CI – Confidence intervals, EQ-5D – EuroQol 5 dimension, IQR – Inter-Quartile range, MIS – Minimally invasive surgery, NR – Not reported, RAS – Robot-assisted surgery, SD – Standard deviation, TLM - Transoral laser microsurgery, VAS – Visual analogue scale.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.5 Secondary outcomes (patient level) - specific study types

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Da Vinci Si						
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	NR	NR	NR	NR	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	NR	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR	NR	NR	NR	NR
Da Vinci (unspecified model)						
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Survival data from Jayne et al 2019 (Jayne et al. 2019)	**Intervention:** Da Vinci (unspecified model): (n=237) **Comparator:** conventional MIS: (n=234) ITT	NR	NR	**Disease free survival** 5-year recurrence rate: Da Vinci (unspecified model): 35/237 (14.8%) conventional MIS: 38/234 (16.2%) Adjusted hazard ratio (favouring conventional MIS): 1.030 (95% CI 0.713 to 1.489) p=0.8736	NR	NA

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.				**Overall survival** 5 year mortality: Da Vinci (unspecified model): 23/237 (9.7%) conventional MIS: 23/234 (9.8%) Adjusted hazard ratio (favouring RAS): 0.945 (95% CI 0.530 to 1.686) p=0.848		
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck squamous cell carcinoma	**Intervention:** Da Vinci (unspecified model): (n=26) **Comparator:** conventional MIS: (n=26)	NA	NA	**Overall survival at 3 years:** Da Vinci (unspecified model): 81% conventional MIS: 95% p=0.33 **Disease-free survival at 3 years:** Da Vinci (unspecified model): 89%	**No further treatment:** Da Vinci (unspecified model): 10/26 (38%) conventional MIS: 8/26 (29%) p=0.49	**Use of feeding tube (n, %)**: Da Vinci (unspecified model): 17/26 (65.4*%) conventional MIS: 26/26 (100%) p=0.004

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
				conventional MIS: 85% p=0.76	**Postoperative radiotherapy:** Da Vinci (unspecified model): 6/26 (24%) conventional MIS: 11/26 (43%) p=0.17 **Postoperative chemotherapy:** Da Vinci (unspecified model): 10/26 (38%) conventional MIS: 7/26 (28%) p=0.48	**Duration of feeding tube use (days, mean SD)**: Da Vinci (unspecified model): 9 (10) conventional MIS: 16 (10) p=0.01
O'Hara et al 2024 (O'Hara et al. 2024)	**Intervention:** Da Vinci (specific model not	NR	NR	NR	NR	**Duration of feeding tube use in days, median (95% CI):** **Da Vinci (n=85):** 6 (4, 6)

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Location: UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	specified, n=313) **Comparator:** TLM (N=195)					**TLM (n=10):** 5 (0.5, 12) **Hazard ratio, univariable model (95% CI):** 0.96 (0.50, 1.85) p = 0.894 **Hazard ratio, multivariable model (95% CI):** 1.05 (0.52, 2.12) p=0.897
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	NR	**Disease-free survival at 125 months:** Da Vinci (specific model not named): 86.7% conventional MIS: 87.5% p=0.892	**Da Vinci (specific model not named)**: Radiotherapy: 7/24 (29.2 %) Radiochemotherapy: 11/24 (45.8 %) **conventional MIS:** Radiotherapy: 9/30 (30 %)	**Use of feeding tube (n, %)**: Da Vinci (specific model not named): 13/24 (54.2%) conventional MIS: 17 (56.7%) p=0.854

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
T3 stage oropharyngeal squamous cell carcinoma.					Radiochemotherapy: 8/30 (26.7 %) p=0.133	**Duration of tracheal cannula, months (mean, SD):** Da Vinci (specific model not named): 5.4 (5.1) conventional MIS: 3 (5.8) p=0.422
Da Vinci (various models)						
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant	NR	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
the survey (response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	endoscopic n=10; dominant laparoscopic n=15) or open surgery (dominant open n=26) *Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than					

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
	the other 3 modalities.					
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph's Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Design:** RCT **Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	NA	NA	NR	**Da Vinci (various models):** 14/81 (17.28%) **conventional MIS:** 18/83 (21.69%) p=0.45	NA
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany	**Intervention:** Da Vinci (n=150, 432)	**Length of hospital stay cases, median (range), estimate**	NR	NR	NR	NR

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
Setting: Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Comparator:** conventional MIS (n=109, 428) **Comparator:** Open surgery (n=733,416)	**(95% CI), p-value v open surgery** **Radical prostatectomy:** **Da Vinci:** 7 (6 to 8), -2.5 (-2.6 to -2.5), <0.001 **conventional MIS:** 9 (7 to 10), -0.7 (-0.8 to -0.5), <0.001 **Open:** 9 (8-11) **Radical cystectomy:** **Da Vinci:** 15 (12 to 22), -3.9 (-4.7 to -3.2), <0.001 **conventional MIS:** 16 (11 to 24), -3.8 (-5 to -2.5), <0.001				

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
		Open: 18 (15 to 26) **Radical nephrectomy:** **Da Vinci:** 6 (5 to 8), -5.6 (-6.1 to -5.1), <0.001 **conventional MIS:** 7 (5 to 8), -5.2 (-5.5 to -4.8), <0.001 **Open**: 9 (7 to 15) **Partial nephrectomy:** **Da Vinci:** 6 (4 to 7), -3.3 (-3.5 to -3.2), <0.001 **conventional MIS:** 6 (5 to 8), -2.8 (-3 to -2.5), <0.001 **Open:** 8 (7 to 10)				

Study name and location	Technology name and number of patients	Compared with open surgery		For cancer studies		For head and neck studies
		Length of hospital stay Days	Intraoperative blood loss g/dl, mean (SD)	For cancer studies: Survival rate	Need for adjuvant treatment	Feeding tube dependency
		Nephroureterectomy: **Da Vinci:** 8 (6 to 11), -4 (-4.8 to -3.3), <0.001 **conventional MIS:** 9 (7 to 11), -3.7 (-4.4 to -3), <0.001 **Open:** 11 (8 to 16) **Pyeloplasty:** **Da Vinci:** 6 (5 to 7), -3.4 (-3.7 to -3.1), <0.001 **conventional MIS:** 7 (5 to 9), -1.9 (-2.2 to -1.6), <0.001 **Open:** 8 (6 to 11)				

Abbreviations: CI – Confidence intervals, MIS – Minimally invasive surgery, NR – Not reported, SD – Standard deviation, SP – Single port, TLM - Transoral laser microsurgery.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.6 Secondary outcomes (surgeon level)

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Da Vinci Si				
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	NR	NR	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	NR	NR	NR
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR	NR	The GOALS scoring system showed that Da Vinci Si and conventional MIS performed similarly in depth perception, bimanual dexterity, efficiency and tissue handling. Da Vinci Si procedures scored

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Indication: Middle or low rectal cancer				higher in autonomy (t test p=0.002).
Da Vinci (unspecified model)				
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.	**Intervention:** Da Vinci (unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) Complete case	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck squamous cell carcinoma	**Intervention:** Da Vinci (unspecified model): (n=26) **Comparator:** conventional MIS: (n=26)	NR	NR	NR
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR	NR	NR
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
stage oropharyngeal squamous cell carcinoma.				
Da Vinci (various models)				
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Surgeon "burn-out" data from Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey (response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10; dominant laparoscopic n=15) or open surgery (dominant open n=26) *Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was "at least 10% higher" than the other 3 modalities.	**Surgeons reporting feeling "burned out" from their work as "more frequent" (a few times a month or more) %, OR (95% CI) vs Da Vinci Xi/SP (n=14, 20%)** Laparoscopic: 60%, OR 5.5 (1.06 to 28.42) p=0.0042 Open: 65%, OR 6.93 (1.53 to 31.38) p=0.012 Endoscopic: 30%, OR NR **Surgeons reporting any neuromusculoskeletal disorders %, OR (95% CI) compared to Da Vinci Xi/SP (n=14, 7%)** Endoscopic (n=10): 60%, OR 0.051 (0.005 to 0.563), p=0.0151 Laparoscopic (n=15): 67%, OR 0.038 (0.004 to 0.384), p=0.0055 Open (n=26): 62%, OR 0.048 (0.005 to 0.426), p=0.0064 Model p-value (logistic regression; effect likelihood ratio test): p=0.0013	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph's Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Design:** RCT **Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	NR	NR	NR
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428) **Comparator:** Open surgery (n=733,416)	NR	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
nephrectomy, nephroureterectomy or pyeloplasty				

Abbreviations: CI – Confidence intervals, GOALS - Global operative assessment of laparoscopic skills, conventional MIS – Minimally invasive surgery, NR – Not reported, OR – Odds ratio, SP – Single port, LM - Transoral laser microsurgery.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

11.1.7 Secondary outcomes (organisation level)

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Da Vinci Si				
Debakey et al 2018 (Debakey et al. 2018) **Location:** Egypt **Setting:** National Cancer Institute **Indication:** Adenocarcinoma, rectal surgery	**Intervention:** Da Vinci Si (n=21) **Comparator:** conventional MIS (n=24)	**Da Vinci Si**: 1 (4.8) **conventional MIS:** 1 (4.2)	**Da Vinci Si**: 201 (140 to 280) **conventional MIS:** 134.5 (110 to 190)	NR
Feng et al 2022 (Feng et al. 2022) **Location:** China **Setting:** 11 hospitals **Indication:** Middle or low rectal cancer, rectal surgery	**Intervention:** Da Vinci Si (n=586) **Comparator:** conventional MIS (n=585)	**Readmission within 30 days:** **Da Vinci Si:** 17 (2.9) **conventional MIS:** 20 (3.4) **Difference between Da Vinci Si and conventional MIS (95% CI)**: -0.5 (-2.6 to 1.6) p = 0.613 **Reoperation within 30 days:** **Da Vinci Si:** 14 (2.4) **conventional MIS:** 24 (4.1)	**Operating time in minutes:** **Da Vinci Si:** 173 (140 to 225) **conventional MIS:** 170 (140 to 209) **Difference between Da Vinci Si and conventional MIS (95% CI)**: 2 (-4 to 10) p = 0.408	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
		Difference between Da Vinci Si and conventional MIS (95% CI): -1.7 (-3.9 to 0.3) p = 0.098		
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR	**Da Vinci Si:** 339.2 (80.1) **conventional MIS:** 227.8 (65.6) p < 0.0001	NR
Da Vinci (unspecified model)				
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:** Corrigan et al 2018 (Corrigan et al. 2018) Jayne et al 2019 (Jayne et al. 2019)	**Intervention:** Da Vinci (unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) Complete case	NR	**Da Vinci (unspecified model) (n=236):** 298.5 (88.71) **conventional MIS (n=230)**: 261.0 (83.24)	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
Location: UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or abdominoperineal) mesorectal resection.				
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital **Indication:** Patients with head and neck squamous cell carcinoma	**Intervention:** Da Vinci (unspecified model): (n=26) **Comparator:** conventional MIS: (n=26)	NR	**Operating time, minutes (mean, SD)**: Da Vinci (unspecified model): 367 (101) conventional MIS: 343 (76) p=0.40	NR
O'Hara et al 2024 (O'Hara et al. 2024) **Location:** UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR	NR	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
oropharyngeal carcinoma stage				
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	**Operating time for tumour resection, minutes (mean, SD)**: Da Vinci (unspecified model, n=9): 186 (54) conventional MIS (n=10): 140 (59) p=0.860	NR
Da Vinci (various models)				
Norasi et al 2023 (Norasi et al. 2023) **Associated records:** Norasi et al 2024 (Norasi et al. 2024) **Location:** US **Setting:** Academic hospitals **Indication:** 79 surgeons completed the survey	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10; dominant laparoscopic n=15) or open surgery	NR	NR	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
(response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).	(dominant open n=26) *Modality considered dominant for a surgeon if the percentage of the procedural time they spent on performing a surgical modality was “at least 10% higher” than the other 3 modalities.			
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph’s Healthcare, Hamilton; Toronto General Hospital; UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary	**Design:** RCT **Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	NR	**Total time in operating room (minutes, median IQR)** Da Vinci (various models): 203 (165 to 234) conventional MIS: 193 (171 to 225) p=0.62	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
lobectomy for stage I to III.				
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database **Indication:** Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428) **Comparator:** Open surgery (n=733,416)	NR	NR	NR

Abbreviations: CI – Confidence intervals, IRQ – Interquartile range, LM - Transoral laser microsurgery, MIS – Minimally invasive surgery, NR – Not reported, SD – Standard deviation.

No significant difference; significant difference in favour of RAS; significant difference in favour of comparator

Appendix C - Increase in rates of RAS since 2005

Characteristic	Overall (n = 993 276)	Open (n = 733 416)	Laparoscopic (n = 109 428)	Robot assisted (n = 150 432)	p value
Year of surgery, n (%)					**<0.001**
2005	55 109 (5.5)	50 524 (6.9)	4571 (4.2)	14 (<0.1)	
2006	58 043 (5.8)	52 530 (7.2)	5321 (4.9)	192 (0.1)	
2007	62 566 (6.3)	55 482 (7.6)	6514 (6.0)	570 (0.4)	
2008	61 871 (6.2)	53 671 (7.3)	6988 (6.4)	1212 (0.8)	
2009	60 187 (6.1)	50 305 (6.9)	7244 (6.6)	2638 (1.8)	
2010	60 214 (6.1)	48 526 (6.6)	7459 (6.8)	4229 (2.8)	
2011	60 540 (6.1)	47 052 (6.4)	7297 (6.7)	6191 (4.1)	
2012	58 384 (5.9)	44 627 (6.1)	6919 (6.3)	6838 (4.5)	
2013	54 975 (5.5)	41 657 (5.7)	6493 (5.9)	6825 (4.5)	
2014	54 218 (5.5)	40 325 (5.5)	6457 (5.9)	7436 (4.9)	
2015	54 156 (5.5)	39 241 (5.4)	6541 (6.0)	8374 (5.6)	
2016	56 681 (5.7)	39 156 (5.3)	7255 (6.6)	10 270 (6.8)	
2017	57 767 (5.8)	38 097 (5.2)	6866 (6.3)	12 804 (8.5)	
2018	58 434 (5.9)	36 490 (5.0)	6681 (6.1)	15 263 (10)	
2019	61 056 (6.1)	34 892 (4.8)	6310 (5.8)	19 854 (13)	
2020	59 211 (6.0)	31 611 (4.3)	5543 (5.1)	22 057 (15)	
2021	59 864 (6.0)	29 230 (4.0)	4969 (4.5)	25 665 (17)	

Appendix D – Summary of systematic reviews

11.1.8 Characteristics and key findings of recent systematic reviews

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Alkatout et al 2022 (Alkatout et al. 2022) **Number of included studies**: 17 **Of which conducted in the UK**: 9	**Aim:** To determine the feasibility, clinical safety, and effectiveness of the Versius system in conventional MIS. **Population:** Colorectal, visceral, and gynaecological surgery **Intervention:** RAS (Versius) **Comparator**: Not reported **Outcomes:** Not reported **Study designs included:** 6 pilot studies, 3 clinical trials, 3 case series, 1 observational study, 4 unknown.	• Postoperative and major complications within 30 days varied from 7.4% to 39%. • No major complications and no readmissions or reoperations were reported in visceral and gynecological surgeries. • Readmission and reoperation rates in colorectal surgeries were 0–9%. • Some procedures required conversion to conventional laparoscopic surgery or open surgery, and all procedures were completed successfully. • Based on the studies reviewed in the present report, it was concluded that the Versius robot can be used safely and effectively in conventional MIS.	Of the 17 studies identified, only 3 were clinical trials (2 in humans) and other designs included preclinical studies. 16 studies were considered at high risk of bias (1 cadaver and animal study was assessed as at low risk of bias). Limitations included: small sample sizes, short follow-up times, lack of high quality RCT evidence.
Arcieri et al 2023 (Arcieri et al. 2023) **Number of included studies:** 6 **Of which conducted in the UK**: 0	**Aim:** To provide a comprehensive overview of the status and applications of da Vinci SP in gynaecologic surgery. **Population:** Gynaecologic surgery. **Intervention**: RAS (da Vinci SP) **Comparator:** Not reported. **Outcomes**: Feasibility of da Vinci SP1098 in gynecologic surgery, evaluating the rate of conversion to multi-port laparoscopy or	• There was no conversion to multi-port laparoscopy or laparotomy and no major complications related to SP surgery. • The preliminary and limited data available regarding the da Vinci SP1098 Surgical System suggest the technical feasibility and safety for its use in gynecologic surgery, with minimal alteration of the surgical technique.	Only 1 of the 6 included studies was prospective, and 1 retrospective was comparative. No risk of bias assessment was undertaken. No studies from a UK setting. Limitations included: lack of RCT evidence, small sample sizes.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
	laparotomy and complications related to single port surgery, post-operative data. **Study designs:** 5 retrospective (1 comparative), 1 prospective. No further data reported.		
Calpin et al 2023 (Calpin et al. 2023) **Number of included studies:** 31 **Of which conducted in the UK**: 1	**Aim:** To perform a comprehensive review of the literature encompassing all available data regarding open surgery, laparoscopic and robotic surgery and to subsequently perform a network meta-analysis of these data to determine the advantages and disadvantages of the various management techniques for renal cell carcinoma, with particular attention to intraoperative, immediate postoperative, as well as longer term functional and oncological outcomes. **Population:** Surgery for renal cell carcinoma (partial nephrectomy) **Intervention:** RAS (any platform/model) **Comparator(s):** Open surgery or conventional MIS **Outcome(s):** Ischaemia time, intraoperative complications, positive surgical margins and trifecta rate, operative time, estimated blood loss, transfusion rate, postoperative complications (<30 days), postoperative estimated glomerular filtration rate, length of stay and conversion to open surgery among patients who had conventional MIS or RAS.	• There was no difference for either conventional MIS or RAS as compared to open in ischaemia time, intraoperative complications, positive surgical margins, operative time or trifecta rate. • The estimated blood loss, postoperative complications and length of stay were all significantly reduced in RAS compared with open. • The outcomes of RAS and conventional MIS were largely similar except the significantly reduced estimated blood loss in RAS.	Only 1 RCT was included, the majority of studies were retrospective (n=26). Newcastle-Ottawa scale was used to assess study quality, with all included studies scoring between 7 and 9 (high quality). Limitations included: lack of RCT evidence, significant heterogeneity between studies.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
	Study designs: 1 RCT, 4 prospective studies, 26 retrospective studies, study designs unclear.		
Fu et al 2024 (Fu S et al. 2024) **Number of included studies:** 22 **Of which conducted in the UK**: 3	**Aim:** Systematic review and meta-analysis on the efficacy and safety of robot-assisted laparoscopic cystectomy with intracorporeal urinary diversion and open radical cystectomy in the treatment of bladder cancer to provide a better reference for clinical practice. **Population:** Cystectomy for bladder cancer. Intervention: RAS (any platform/model) **Comparator(s):** Open surgery **Outcome(s):** Operative time, estimated blood loss, length of hospital stay, transfusion rate, positive surgical margins, ureteroenteric stricture, readmission rate, intraoperative complications and complications occurring within 30 days and 90 days after surgery were included measured by Clavien-Dindo score. **Study designs**: 4 RCTs, and a further 9 prospective studies, 9 retrospective studies. Study designs unclear.	• Compared to open surgery, RAS was superior for: estimated blood loss, blood transfusion rate, length of hospital stay, Clavien–Dindo grades ≥III complication rate, positive surgical margin. • RAS had a longer operative time and a higher rate of ureteroenteric stricture. • Robot-assisted laparoscopic cystectomy with intracorporeal urinary diversion appears to be superior to open radical cystectomy in terms of effectiveness and safety. Attention should be paid to the occurrence of ureteroenteric stricture during follow-up.	4 RCTs included, 2 were assessed as high risk of bias. 9 retrospective studies were included. The non-randomised studies were assessed with Newcastle Ottawa and all but 2 scored between 7 and 9 (high quality). Limitations included: high level of heterogeneity in studies for some outcome measures, differences in surgical protocols/treatment options may have influenced perioperative outcomes. Data was lacking on surgical volume, adjuvant therapy and tumour staging.
Leang et al 2024 (Leang et al. 2024) **Number of included studies:** 12	**Aim:** To systematically review the existing literature on the clinical outcomes of new robotic surgical systems. **Population:** Any soft-tissue surgery **Intervention:** Multiport robot systems	• 6 new robotic systems (Micro Hand S, Senhance, Revo-i MSR-5000, KangDuo, Versius, and Hugo RAS) were compared against Da Vinci Si or conventional MIS. • The clinical outcomes achieved by these new robotic systems were comparable to	Lack of RCT evidence highlighted as a limitation. The 10 observational studies were assessed using Newcastle Ottawa scale, scoring 6 or

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Of which conducted in the UK: 0	**Comparator(s):** Da Vinci systems or conventional MIS **Outcome(s):** Surgical complication rate: Clavien–Dindo grading, length of stay, estimated blood loss, conversion rate being defined as conversion from the intended robotic approach to any other approaches or a different robotic platform and standard outcomes in cancer resection studies. **Study designs:** 2 RCTs, 5 prospective studies, and 5 retrospective studies.	the established da Vinci robotic system in selected cases. • When compared against conventional laparoscopic approaches, the robotic platforms demonstrated lower volume of blood loss, shorter length of stay but longer operative time.	above (good to high quality). The 2 RCTs were assessed using the Jadad scale and were assessed at moderate and good quality.
Leitao et al 2023 (Leitao et al. 2023) **Number of included studies:** 199 **Of which conducted in the UK:** Not reported	**Aim:** To assess long-term outcomes with robotic versus laparoscopic/thoracoscopic and open surgery for colorectal, urologic, endometrial, cervical, and thoracic cancers **Population:** Colorectal, urologic, endometrial, cervical, and thoracic surgery **Intervention:** RAS (any platform/model) **Comparator(s):** Open, conventional MIS **Outcome(s):** Long-term [≥12 months] recurrence, disease-free/recurrence-free survival, biochemical recurrence-free/progression-free survival or overall survival. **Study designs:** 7 RCTs, 15 prospective studies, 154 retrospective studies, 23 database studies	• Cervical cancer: overall survival and disease-free survival were similar between robotic and laparoscopic or open. • Endometrial cancer: the only significant result favoured robotic over open surgery • Lobectomy: disease-free survival favoured robotic over thoracoscopic surgery, overall survival favoured robotic over open surgery • Low-anterior resection: Overall survival significantly favoured robotic over laparoscopic and open surgery. • Long-term outcomes were similar for robotic versus laparoscopic/thoracoscopic and open surgery, with no safety signal or indication requiring further research	Vast amount of the data is from retrospective studies. Unclear how much evidence is applicable to the UK context. The 7 RCTs showed high bias in the measurement of the outcomes due to shorter than ideal follow-up time for survival outcomes. The non-randomized studies showed moderate-to-critical bias for confounding and selection of participants domains, as well as low-to-moderate bias for the majority of procedures, comparisons, and outcomes for the remaining domains.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Lenfant et al 2023 (Lenfant et al. 2023) **Number of included studies:** 24 **Of which conducted in the UK:** 0	**Aim:** To provide a comprehensive and updated systematic review and meta-analysis of the available evidence to compare perioperative outcomes of the robotic approach to other existing surgical approaches to treat benign uterine pathology. **Population:** Benign hysterectomy **Intervention:** RAS (any platform/model). **Comparator(s):** conventional MIS (laparoscopy or vaginal) or open. **Outcome(s):** Conversions, intraoperative complications, blood transfusions and/or estimated blood loss, operative time, postoperative complications, length of hospital stay, readmissions, mortality. **Study designs:** 4 RCTs, 5 prospective comparative studies, 15 database studies.	• The robotic approach was associated with a shorter hospital stay, less blood loss, and fewer complications when compared to the open approach. • The main benefit compared to the laparoscopic and vaginal approaches was a shorter hospital stay. • While the robotic approach was mainly comparable to the laparoscopic approach, this meta-analysis confirms the benefits of minimally invasive surgery when comparing robotic hysterectomy to open surgery.	Study highlighted heterogeneity in outcomes, a lack of RCTs for robotic vs. open comparisons, learning curve issues, and limited robotic vs. vaginal publications are limitations. Some concerns were reported on risk of bias for the RCTs because of deviations from the intended interventions. For the database and prospective cohort studies, the Newcastle-Ottawa scores ranged between 6 and 9 (good or high quality) for the included cohort studies, with a lack of specifying whether patients were lost to follow-up being the most common reason for a lower score. Limitations: majority of the studies were retrospective, studies had high levels of heterogeneity. No data on costs.
Li et al 2023 (Li et al. 2023) **Number of included studies:** 6	**Aim:** To summarize the available clinical studies on single-port robotic-assisted partial nephrectomies and compare its reported results to those of the conventional robotic-assisted partial nephrectomy to guide clinicians in clinical decision-making.	• There were no significant differences in operative time, transfusion rates, off-clamp, total perioperative milligram morphine equivalents, intraoperative complications, major complications, overall complications, positive surgical	Study designs were not reported, although the ROBINS-I tool was used to assess the quality of all 6 included studies, suggesting that they were non-RCT studies. The overall risk of

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Of which conducted in the UK: 0	**Population:** Nephrectomy **Intervention:** Single-port robotic-assisted partial nephrectomies **Comparator(s):** Conventional robotic-assisted partial nephrectomy **Outcome(s):** Perioperative outcomes, complication and oncologic outcomes **Study designs:** Not reported	margins and local recurrence between single-port robotic-assisted surgery and conventional robotic surgery. • The marginal results were recorded in length of hospital stay subgroup and blood loss. Single-port robotic-assisted surgery had longer warm ischemia time compared to conventional robotic surgery. Single-port robotic-assisted surgery provided similar effectiveness and safety to conventional robotic surgery, while single-port robotic-assisted surgery might be associated with a marginally shorter length of hospital stay and less blood loss.	bias for all studies was assessed as moderate. Limitations included: all included studies were retrospective and of intermediate quality. Short follow-up times, missing data.
Lv et al 2023 (Lv et al. 2023) **Number of included studies:** 5 **Of which conducted in the UK:** 0	**Aim:** To summarise recent research on the differences in perioperative and functional outcomes between open and RAS for complex renal masses **Population:** Partial nephrectomy **Intervention:** RAS (any platform/model) **Comparator(s):** Open surgery **Outcome(s):** Perioperative outcomes, functional outcomes **Study designs:** 5 retrospective comparative studies	• There were no significant differences in blood loss, minor complication rate, glomerular filtration rate decline from baseline, positive surgical margin, and ischemia time between open surgery and RAS. • RAS was associated with a shorter hospital stay, lower overall complication rate, lower transfusion rate and lower major complication rate compared to open surgery. • The operation time for open surgery was shorter than that for RAS.	All included studies were retrospective. Quality assessment was via Newcastle-Ottawa scale, and all studies were rated at moderate risk of bias. There was moderate to high heterogeneity across the studies. Limitations: studies are retrospective and of intermediate quality. Some studies included more patients with only 1 kidney and higher preoperative chronic renal

Study name	Aim, PICO and included study designs	Key findings	EAG comments
			disease (CKD) stage (≥ 3), which had a potential impact on the postoperative renal function. Short follow-up times, lack of standard definitions of functional or oncologic outcomes.
Raffone et al 2022 (Raffone et al. 2022) **Number of included studies:** 5 **Of which conducted in the UK:** 0	**Aim:** To compare robotic and laparotomic surgery in the treatment and staging of elderly endometrial carcinoma patients **Population:** Surgery for endometrial carcinoma **Intervention:** RAS (any platform/model) **Comparator(s):** conventional MIS **Outcome(s):** Rates of overall complications, intra-operative complications, the rate of peri-operative complications, mean length of stay in hospital **Study designs:** 5 retrospective cohort studies	• Robotic surgery significantly decreases the risk of overall and peri-operative complications (mainly major complications) and the length of stay when compared with conventional MIS. • The decrease in risk of overall complications is greater with increasing patient age.	All included studies were retrospective. The Methodological Index for Non-Randomized Studies (MINORS) tool was used to assess quality. All included studies were judged at low risk of bias in 6 of 8 domains, and at unclear risk of bias in the other 2 domains, except for 1 study which was assessed as low risk of bias in the "Inclusion of consecutive patients" domain. Limitations included: retrospective data, lack of data on survival outcomes.
Rogalska et al 2023 (Rogalska et al. 2023) **Number of included studies**: 9	**Aim:** The purpose of the present study was to systematically review the literature to determine the efficacy and safety of transoral robotic surgery (TORS) in the management of submandibular gland sialolithiasis. **Population:** Surgery submandibular gland sialolithiasis.	• TORS is a safe and effective management modality for hilar and intraparenchymal submandibular gland sialoliths, with high procedural success in terms of successful sialolith removal, submandibular gland preservation, and reduced risk of permanent postoperative lingual nerve damage.	No quality assessment or risk of bias assessment of the included studies was performed. Characteristics of included studies table does not include study designs or geographic location.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Of which conducted in the UK: Not reported	**Intervention:** TORS (any platform/model) **Comparator(s):** Not reported **Outcome(s):** Not reported **Study designs:** Not reported		Limitations included: lack of high quality RCT evidence, limited sample sizes, short follow up times.
Roy et al 2023 (Roy et al. 2023) **Number of included studies:** 17 **Of which conducted in the UK:** 0	**Aim:** To characterize the current trends in robotic autologous breast reconstruction and provide insight on the current advantages and areas for improvement for each flap described in the literature. **Population:** Surgery for breast reconstruction following mastectomy **Intervention:** RAS (any platform/model) **Comparator(s):** Data from the National Surgical Quality Improvement Program (NSQIP) on open surgery **Outcome(s):** Postoperative complications, operative time, robotic-assisted flap harvest time, robotic technique and number of reconstruction stages. **Study designs:** 5 retrospective cohort studies, 5 case reports, 4 retrospective case series, 1 case series, 1 retrospective review, and 1 retrospective comparative study	• Complication rates were comparable to NSQIP data on open surgery. • Operative times compared to NSQIP data on open techniques were higher (although downward trends in operative time with consecutive procedures were reported). • The available data in the literature confirms that robotic surgery is a promising alternative to traditional open methods of breast reconstruction following mastectomy.	No RCTs were included, all data was from retrospective studies or case reports/case series. No quality assessment of the included studies was undertaken. Limitations included: lack of high quality RCTs and other comparative data, Majority of studies did not differentiate between total operative and robotic time, making it difficult to determine if the robotic component influences operative time or financial costs. Lack of consistent reporting of patient demographics and comorbidities. NSQIP data has limitations with coding not being granular enough to capture enough detail.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Shugaba et al 2022 (Shugaba et al. 2022) **Number of included studies:** 10 **Of which conducted in the UK:** 0	**Aim:** To comprehensively review the available scientific literature and report on the musculoskeletal demands in surgeons performing RAS as compared to conventional MIS, and the associated cognitive fatigue. **Population:** Surgeons undertaking any type of surgery **Intervention:** RAS (any platform/model) **Comparator(s):** conventional MIS **Outcome(s):** Electromyographic activity for musculoskeletal fatigue and questionnaires (NASA-TLX, SMEQ, or Borg CR-10) for cognitive fatigue. **Study designs:**10 observational, prospective studies.	• Electromyographic activity was consistently lower in robotic than in laparoscopic surgery in the erector spinae and flexor digitorum muscles but higher in the trapezius muscle. • Significantly lower cognitive load in robotic than laparoscopic surgery in 7 of 10 studies. • Evidence suggests a reduction in musculoskeletal demands during robotic surgery in muscles excluding the trapezius. • Robotic surgery appears to have less negative cognitive and musculoskeletal impact on surgeons compared to laparoscopic surgery.	Of the 10 included studies, 7 were on simulated tasks, 3 on live surgeries. Quality assessment was via GRADE. All studies were considered to at least be of 'fair' quality. Limitations included: heterogeneous data, studies used varying methods and were of varying quality. Confounders (surgeons' handedness, BMI, diet, physical activity levels and experience) were not controlled in most of the studies.
Thornton et al 2024 (Thornton et al. 2024) **Number of included studies:** 2 **Of which conducted in the UK:** Not reported	**Aim:** To evaluate the literature pertaining to the use of RAS in patients with invasive breast cancer and determine if outcomes are comparable to conventional surgery **Population:** Axillary lymph node dissection for breast cancer **Intervention**: RAS (Da Vinci platforms) **Comparator(s):** Conventional surgery **Outcome(s):** Operative time, intra-operative blood loss, size of surgical incision, postoperative complications rate, number of positive lymph nodes, overall nodal harvest	• There was no significant difference observed with respect to intra-operative blood loss or operative time. • 1 study reported a significant difference in lymphoedema rates in support of RAS. • Data in relation to postoperative fat necrosis, wound infection rates, and wound ≤ 40 mm in length supported RAS. • Oncological outcomes were only reported in 1 of the studies, which concluded that there was no local or metastatic recurrence in either group at 3-month follow-up.	2 studies included, 1 was an RCT. No risk of bias or quality assessment was undertaken. Limitations included: lack of studies matching the eligibility criteria, duration of study follow-up, lack of data on costs and the learning curve.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
	Study designs: 1 RCT, 1 retrospective cohort study	• These provisional results support RAS as a safe alternative to conventional surgery. • The paucity of data limits the robustness of conclusions. Further high-quality studies are required to ratify these findings.	
Tschann et al 2022 (Tschann et al. 2022) **Number of included studies:** 25 **Of which conducted in the UK**: 0	**Aim:** To undertake a systematic review and a meta-analysis of literature which compares laparoscopic and robotic rightsided colorectal resections. **Population:** Right colectomy In**tervention:** RAS (any platform/model) **Comparator(s):** conventional MIS **Outcome(s):** Intraoperative blood loss, type of anastomosis, operative time, conversion to open surgery and number of harvested lymph nodes and postoperative variables (hospital mortality, overall morbidity, anastomotic leak, postoperative hemorrhage, abdominal abscess, time to first flatus, postoperative ileus, wound infections, length of hospital stay, incisional hernia, quality of surgery, local recurrency and oncological 3 and 5 years disease free and overall survival rates). **Study designs:** 1 RCT, 2 prospective cohort studies, 23 retrospective studies	• Operative time was significantly shorter in the conventional MIS arm. • Blood loss, conversion rate and hospital stay was significantly lower in the RAS group • Oncological long-term results did not differ between both groups. • The advantages of robotic colorectal • procedures were clearly demonstrated and RAS can be regarded as safe and feasible. • Most of the included studies were retrospective with a limited level of evidence. Further randomized trials are needed.	1 RCT included, but 23/25 studies were retrospective. The Methodological index for non-randomized studies (MINORS) scale was used to evaluate the quality for cohort studies, while the Jadad scoring was used for randomized controlled trials. The cohort studies were all assessed as moderate quality. The RCT was assessed as high quality. Limitations included: lack of RCT evidence, lack of data on tumour localisation which could bias outcome data, data heterogeneity, missing data on the measurement of outcomes, lack of data on the learning curve and its role in perioperative findings, postoperative outcomes and

Study name	Aim, PICO and included study designs	Key findings	EAG comments
			costs, short-term follow up in all but 4 studies.
Wang et al 2024 (Wang et al. 2024) **Number of included studies:** 18 **Of which conducted in the UK:** 0	**Aim:** To use meta-analysis to analyse and compare the real clinical effects of video assisted thoracic surgery (VATS) and RAS in the treatment of non-small cell lung cancer, in order to make a more objective evaluation of the efficacy and safety of the 2 procedures. **Population:** Thoracic surgery for non-small cell lung cancer **Intervention**: RAS (any platform/model) **Comparator(s):** VATS **Outcome(s):** Operation time, intraoperative conversion rate, intraoperative blood loss, number of lymph nodes dissected, postoperative mortality, postoperative recurrence rate, postoperative complication rate, postoperative chest drainage time, postoperative hospital stay. **Study designs:** 4 prospective cohort studies, 14 retrospective cohort studies	• Intraoperative blood loss of RAS was significantly less than that of VATS, and the difference was statistically significant. • Compared with VATS, the number of lymph nodes dissected in RAS was significantly higher. • The rate of conversion to thoracotomy in RAS was lower, and the difference was statistically significant. • There was no significant difference • between RAS and VATS in operation time, postoperative thoracic drainage • time, postoperative hospital stay, postoperative mortality and postoperative complications.	Majority of included data was retrospective (14/18 studies). No further information was given on study design. Newcastle-Ottawa scale was used to assess quality. 17/18 studies scored 7 or more and were assessed as high quality. Limitations noted included lack of data on tumour diameter and stage, the variation in surgical methods used across the studies, the small sample sizes in some of the studies and the lack of data on the difference in cost between VATS and RAS.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Wu et al 2023 (Wu et al. 2023) **Number of included studies:** 11 **Of which conducted in the UK:** Not reported	**Aim:** To provide a more comprehensive understanding of the relative effectiveness of these 2 surgical approaches [RAS and conventional MIS], offering clearer guidance for treatment decisions in patients with rectal cancer. **Population:** Surgery for mid- and low-rectal cancer **Intervention:** RAS (any platform/model) **Comparator(s):** conventional MIS **Outcome(s):** Conversion to open surgery rate, total hospital stay, postoperative complications, circumferential resection margin positive rate, operation time, operative blood loss, protective stoma rate, time to flatus, time to liquid diet, occurrence rate of complications with Clavien–Dindo grade ≥ 3, harvested lymph nodes, proximal resection margin, distal resection margin, 3-year overall survival rate, 3-year disease-free survival rate. **Study designs:** 3 RCTs, 8 non-RCTs	• The RAS group exhibited less intraoperative bleeding, a lower conversion rate to open surgery, a higher number of harvested lymph nodes and a lower circumferential resection margin positive rate, lower postoperative morbidity rate and a lower occurrence rate of complications with Clavien–Dindo grade ≥ 3. • Further subgroup analysis revealed a lower anastomotic leakage rate in the RAS group. • No significant differences were observed between the 2 groups in the analysis of operation time, occurrence rates of protective stoma, proximal resection margin and distal resection margin, time to flatus, time to liquid diet, total hospital stay, 3-year overall survival rate and 3-year disease-free survival rate. • Robot-assisted laparoscopic treatment for mid and low rectal cancer yields favourable outcomes, demonstrating both efficacy and safety. • The method achieves comparable short-term and long-term treatment results to those of conventional laparoscopic surgery.	8/11 studies were non-randomised. Cochrane's risk of bias tool was used to assess the quality of the RCT evidence. 1 RCT had an unclear risk of bias in random sequence generation, 1 RCT had a higher risk of bias, and another RCT had an unclear risk of bias in the blinding of outcome assessment. 2 RCTs had an unclear risk of bias in incomplete outcome data. ROBINS-I was used to assess the non-RCTs. 1 study was at moderate risk of bias, while the rest of the studies were assessed to be at low risk. Limitations noted included: relatively small sample sizes, short observation periods, the lack of high quality RCTs in the area.

Abbreviations: BMI – Body mass index, GRADE – Grading of recommendations assessment, development and evaluation, MINORS – Methodological index for non-randomized studies, MIS – Minimally invasive surgery, NASA-TLX – NASA task load index, NSQIP – National Surgical Quality Improvement Program,

ROBINS-I – Risk Of Bias In Non-randomised Studies - of Interventions, RAS – Robot-assisted surgery, RCT – Randomised controlled trial, SMEQ – Subjective Mental Effort Questionnaire, TORS – Transoral robotic surgery, VATS – Video-assisted thoracic surgery.

NICE National Institute for Health and Care Excellence

Health Technologies Assessment Programme

Robot-assisted surgery for soft-tissue procedures: early value assessment

Early Value Assessment Consultation (before committee 1) – Comments

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
Overall comments on the report				
1	13	Section 1 Decision problem	The use of RAS has several unique challenges that complicate the health technology assessment process, such as incremental development (i.e. different surgical platform models), context dependency (i.e. organisational impact), quality variation (i.e. evidence uncertainties) and physical mode of action (i.e. device-operator interaction). I appreciate it the report concerned all this factors and the outcome scope included patient level and surgeon level and organisational level.	Thank you for your comment. n/a
2	Overall Report		After reviewing this draft report, we are quite surprised and overall disappointed in how the report was developed and the subsequent conclusions that were reached. We feel that it is important to call out this feedback given that this will be a publicly available document produced by a globally influential agency that is often seen as a gold-standard for producing value assessments. Much of the report, including the methods and conclusions, are confusing, lack transparency, and are misrepresentative of the da Vinci system, which has been used in the UK for more than 2 decades.	Thank you for your comment. N/a- responses to concerns are in the individual comments relating to specific issues that were submitted.
3	Overall Report		Main Concerns • The decision problem was very broad with over 10 different surgical specialities and 20+ outcomes of interest. It is difficult to expect that a limited evidence review of a handful of small studies would be sufficient to address multiple outcomes across a broad range of surgical specialities.	Thank you for your comment. Search strategies can be discussed at committee. The search and selection approach used reflects the pragmatic approach to identifying evidence. The searches were designed to

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			• There are concerns with the search strategy and biases with selecting studies. Some of the methods for study selection lacked transparency and it is unclear why some studies were excluded in certain scenarios and for certain procedures. It also seems inequitable that different search strategies are applied for difference robotic platforms, but the recommendations apply to all robotic systems. • The approaches taken in this report do not seem appropriate. It is confusing that a proper evidence gap assessment was attempted without considering the available body of evidence that exist. This leads to conclusions that are based on a small subset of studies that may not accurately reflect the existing evidence base of the technology. Particularly for a technology that has been commercially available and used in clinical settings across the world for 20+ years. • This report has lumped all robotic platforms together and came to broad conclusions based on a limited review of the evidence. The robotic platforms reviewed, all have different levels of evidence and have been commercially available in the UK for different lengths of time. This report depicts all robotic platforms as new technologies without any existing evidence. This is an inaccurate representation of the da Vinci platform. A point that was made by several of the subject matter expert surgeons (including the lead of the specialist advisor committee) was that that evidence is not transferable across RAS platforms. The EAG seem to have completely ignored this advice.	identify studies of the eligible technologies. During study selection, studies had to specify the robot in the title or abstract to be included. While the EAG appreciate that this approach may have missed some eligible studies, it was considered to be an appropriate approach in the context of a pragmatic review. The same approach was taken for all eligible technologies. The EAG have added clarification to section 2.1 about the availability differing between technologies.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
4	1-336		Medtronic would like to thank NICE for the opportunity to review and respond to the external assessment report (EAR) and economic model for Robot-assisted surgery: soft-tissue procedures. Medtronic welcomes the evaluation. While we acknowledge the thoroughness of the report and the economic model, we would like to address several key points: 1. Generalisability 2. Uncertainty in evidence 3. Cost considerations 4. Unidentified evidence due to restrictive search strategy	Thank you for your comment. n/a- responses to concerns are in the individual comments relating to specific issues that were submitted.
Comments on formatting errors and fact-checking				
5	16	2.1 Included technologies	Reference says Error!	Thank you for your comment. Fixed in updated report
6	16	Section 2.1 Included technologies	There is reference link cannot be found. 'Details relevant to this EVA are summarised in **Error! Reference source not found.**, summarised from the company submitted documents.'	Thank you for your comment. Fixed in updated report
7	64	5.3 Revision surgery for the same indication	Can you please check the p value of 1.000? – seems strange	Thank you for your comment. This has been checked and the p-value is accurate as is reported in the study
8	57	5.3 Results from the evidence base	Section on intraoperative complications States: 'The two studies assessing Versius did not report intraoperative or perioperative complications (Dixon et al. 2024, Kakkilaya et al. 2023).' This is incorrect and complications being reported is correctly listed in the NICE document in Table 4.1 on pages 46 and 47.	Thank you for your comment and flagging these additional complications.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			In Dixon et al. 2024, peri-operative and 30 day Clavien Dindo complications are reported in Table 2. This is not reported in the relevant sections of the NICE document. Also note 4a complication in lap group not reported, but 3a complication in robotic group reported in NICE doc. Better to include the complications reported in both groups. Complications reported as not significantly different In Kakkilaya et al. 2023 publication, peri-op complications and pain at post-op day 1 are reported with follow-up of all patients to 60 days post-operatively. All patients were discharged at POD1 and no readmissions, recurrences or re-operations at 60 days. These findings are not currently reported in the sections on complications, readmissions at 30 days or re-operations.	Re. Dixon 2024, the EAG will update the report to include these data. Re Kakkilaya 2023, the EAG could not locate any peri-operative complications, or any data reported at 60 days.
9		Section 8,1	Economic Model Ref says Error!	Thank you for your comment. Fixed in updated report
10	70	Section 8.1 Economic evidence	There is reference link cannot be found. 'Three costing studies were identified through the searches and company submitted evidence and are summarised below and in Table 8.1. **Error! Reference source not found.'**	Thank you for your comment. Fixed in updated report
11		Section 8.3.2	Economic Model Error in reference for the DSA.	Thank you for your comment. Fixed in updated report
12	131	Table 10.1 Summary and	Table 10.1 states no reported intra-operative complications for Versius.	Thank you, this is addressed above.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
		conclusions of evidence gap analysis	Please see comment 5 above which reports the intra-operative complications in the two papers selected	
13		Table 2.1	Please check with the company if Intuitive Xi has the license for nipple sparing mastectomy and reconstruction. The robot has been used in multiple countries to perform the procedure under the CE mark. In the UK we have not support from Intuitive to use Xi for breast procedures. The SP has the License to be used for breast procedures. This procedure has not yet been performed in the UK.	Thank you for your comment. Fixed in updated report
14	11 and 12	Scope of practice – linked to section 1, page 13	Spotted an error in the July Scope of practice document which is linked to section 1, Decision problem – appendicectomy is part of colorectal surgery not HPB	Thank you for your comment. No correction needed for EAG report
15	12	Scope of practice – linked to section 1, page 13	Spotted an error in the July Scope of practice document which is linked to section 1, Decision problem – Cholecystectomy should be part of HPB	Thank you for your comment. No correction needed for EAG report
16	13	Section 1 - intervention	Senhance is due to be taken over by another medtech company and will no longer be Asensus Surgical. The system is not widely used in the UK and its use in Europe has also diminished.	Thank you for your comment. The EAG have added clarification into the text about the recent acquisition on Senhance. They have also reiterated they failed to respond to NICEs invite to participate.
17	19	Table 2.1 Included technologies	Intuitive x/xi – are HpB and UGI classed as general surgery procedures here?	Thank you for your comment. The EAG have listed these separately based on the way the

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				information is provided. Unless confirmation can be provided, suggest leaving as is.
18	21	Table 2.1 Included technologies	Right hemicolectomy is not a urological procedure – HUGO system info.	Thank you for your comment. The EAG have corrected this.
19	22	Table 2.1 Included technologies	Senhance has 4 separate robotic arms and an open platform for the surgeon to sit on using 3D glasses and joy-sticks. It uses eye and head movements and tracking to control the robotic camera arm. (from personal experience)	Thank you for your comment. The EAG have adjusted the wording of descriptions
20	18	Table 2.1 Included technologies	Why is the *'Portable between surgical theatres'* column included in this table? It implies the same weighting as important (and documented) facts such as 'Regulatory status' and 'Indications for use'. NICE must have evidence to support claims that one particular system is *'Transportable across existing surgical theatres'* whereas the others are 'Not easily transportable' We would ask NICE to be transparent with this data. All systems are transportable. This column seems to be based on circumstantial and anecdotal information given by the manufacturer. Transportation between theatres happens rarely and therefore this column is of little relevance. What is relevant is the physical footprint of the technology within an operating theatre. This is factual and can have an impact on the performance of the surgical team. This point was made during the scoping meeting and has been ignored.	Thank you for your comment. The EAG has removed this from the feature table. This can be discussed at committee.
21	18	Table 2.1 Included technologies	Why does the description of the surgeon console include a mention of 3D video feed for one manufacturer and not the other systems, even though the description of 3DHD capabilities was provided in the RFI and company submission. There is also no mention of availability of advanced instrumentation for each platform. Advanced energy systems and staplers are key technological features that	Thank you for your comment. The EAG have adjusted this for each platform on the video feed. They have added the availability of advanced

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			allow for certain procedures to even be performed on a given platform.	instrumentation in the text, given it is common to each platform.
22	102	Table 8.8	Summary of Deterministic results are not as same as provided modelling in excel. Table 8.8 showed the average cost per procedure for SoC is £7,453 and for RAS is £7,744. However, the modelling results (in excel) are £7,432 for SoC and £7,254 for RAS.	Thank you for your comment. The EAG have checked against the model, and the reported costs match the stated model. They believe this is due to this expert having the redacted model. They are happy to explore this further though with the expert if needed.
23	81	Figure 8.1	Remove “and children” in the blue box; it’s stated the scoped population are adult patients.	Thank you for your comment. EAG have actioned this change.
24	92	Table 8.2	Typo “Average LoS may have dropped since 20212…”	Thank you for your comment. The EAG acknowledge length of stay is likely to differ on a range of factors and may be lower now than 2012. However, the key aspect for the model is the relative difference between open and MIS (which is 2 days) and they think is still generalisable currently. They are happy for this to be discussed further with clinical experts.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
25	93	Table 8.6	Readmission rates of open seems low. Checked the reference (Gavriilidis et al. 2020) and could not verify the inputs.	Thank you for your comment. EAG have provided more detail, as contained in the model. This is taken from a meta-analysis, and a risk ratio applied to MIS
26	97	8.2.1	Training for the da Vinci platforms are included by the company at no extra cost. This clarification needs to be edited as the current text makes it seem that training is not provided by the company.	Thank you for your comment. The EAG have updated to acknowledge this is included in the robot cost.
27	16	2. Overview of the technologies > 2.1 Included technologies	Medtronic kindly request that the following error statement be resolved within the report: “Error! Reference source not found”	Thank you for your comment. This has been fixed in the report.
28	70	8. Economic evidence > 8.1 Economic evidence	Medtronic kindly request that the following error statement be resolved within the report: “Error! Reference source not found”	Thank you for your comment. This has been fixed in the report.
29	104	8. Economic evidence > 8.3 Results from the economic modelling > 8.3.1 Scenario analysis	Medtronic kindly request that the following error statement be resolved within the report: “Error! Reference source not found	Thank you for your comment. This has been fixed in the report.
30	107	8. Economic evidence > 8.3 Results from the economic modelling >	Medtronic kindly request that the following error statement be resolved within the report: “Error! Reference source not found	Thank you for your comment. This has been fixed in the report.

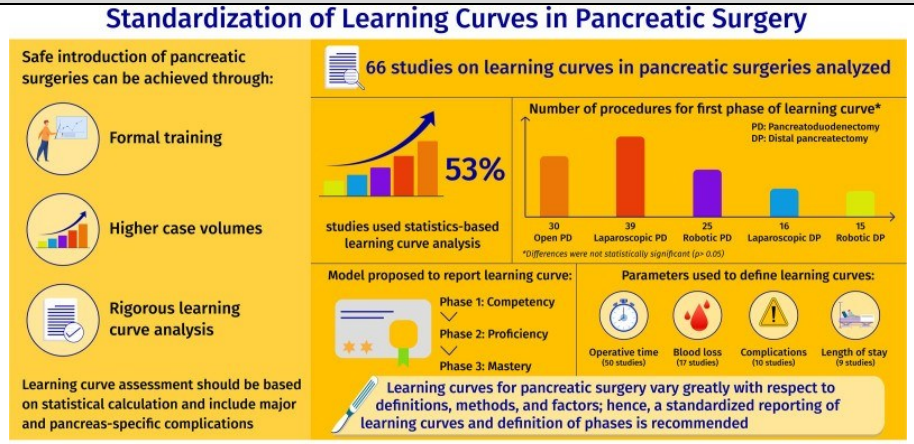
Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
		8.3.2 Deterministic sensitivity analysis		
Comments on terminology used				
31	54	5.3 Conversion to manual MIS from RAS	Manual MIS is not a commonly used term; why not “standard laparoscopic surgery”?	Thank you for your comment. EAG have now updated to conventional MIS throughout.
32	24	3 Clinical context	Would use the term “non-intuitive” handling in the context of this EVA. Would proposed “unnatural”	Thank you for your comment. EAG have changed this to unnatural.
Comments on the impact of learning curve on other outcomes and findings (see also some comments in relation to Table 8.2 Assumptions and limitations of the current model)				
33	54	5.3 Conversion outcomes	I don’t think conversions should be a primary level outcome- it is a function of learning curve almost entirely.	Thank you for your comment. This needs to be included as a discussion at committee as part of the evidence gap analysis and recommendations- how to measure learning curve (including what are the key measurable parameters that define learning curve, e.g. operative time, complications), how to adjust for learning curve in associated variables that we also want to capture because of resource

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
34	55	5.3 LoS	Comparing LOS between robot and lap surgery seems meaningless as it's the same operation- one with robot assistance and one without but with the same approach. Hence there is no rationale for a LOS difference unless related to learning curve.	Thank you for your comment. Committee may need a discussion sense checking this- is this based purely on a prostatectomy perspective (high volume, ?low complexity procedure)? Would clinical experts always expect a surgeon to reach the same level if it's a low volume high complexity procedure?
35	55-58	5.3 Intraoperative/ postoperative complications	Complications are also related to learning curve but there are other modality specific factors. These are highly operation-specific and one of the EVA outputs should be to recommend registry collection of procedure-specific data for open, lap, and robot cases.	Thank you for your comment. Same as above.
36	67		Operating time is mostly a function of learning curve not the modality used per se.	Thank you for your comment. The EAG believe we have responded to this comment within responses to other learning curve comments. Other clinical experts have indicated even after the learning curve is complete, the RAS procedure can still take longer.
37		Table 8.2 Assumptions and limitations of current model	Economic Model- where did you get 3 months as the learning curve? This is clearly surgeon, procedure, and volume variable. I would estimate 6-12 months as a crude figure rather than 3.	Thank you for your comment. This was based on previous clinical feedback (and should say 4

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				months). The EAG have detailed this in the correspondence log, but have varied this within sensitivity analysis, and have acknowledged that in some cases, could be much higher. This would depend on a variety of factors.
38		Table 8.2 Assumptions and limitations of current model	Economic Model converting from robot to lap is almost entirely only done by surgeons still in their learning curve, as robot malfunction is extremely rare.	Thank you for this context. The EAG have stated they believe this is a rare event but have added it is likely to be surgeons on the learning curve for future context within the table.
39		Table 8.3 Set-up parameters	Economic Model again I think time to proficiency of 4 months is too short.	Thank you for your comment. The EAG received feedback from a range of clinical experts indicating that for some procedures, this may take anywhere from 1 to 6 months based on a range of factors. They have used this as a base case but have varied this in sensitivity analysis. They believe this will be heterogenous, and the uncertainty should be reflected in the parameter.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				Learning curves may be impossible to disentangle from the clinical data, so may still be implicitly captured within other parameters, such as complication rates.
40	Page 116	8.4 Summary and interpretation of the economic modelling	Economic Model - when talking about learning curves, it is also important to understand that the learning curve for lap surgery is typically longer than for robotic surgery. Hence, for surgeons learning an operation from scratch it will be a long-term cost saving for them to learn robotics than lap in this regard.	Thank you for your comment. The EAG have added further clarification to this section to acknowledge this impact.
41	Page 122	Section 9.1 Interpretation of the (clinical and) economic evidence	Economic Model - Hugo robot is generally used by experienced robotic surgeons who are already expert with da Vinci robots, and this is likely why the operating times are shorter than for laparoscopy. Operating times are a function mostly of learning curve when comparing modalities across the same procedure.	Thank you for this information. This is not something the EAG believe they can conclude from the study, although if this is the case, should be discussed at committee.
42	Page 124	Section 9.2 Integration into the NHS	Economic Model you state the learning curve is up to 6 months and yet the economic modelling uses 3 – unless I'm misunderstanding?	Thank you for your comment. The learning curve is applied for 4 months in the model (as stated in Table 8.3). Feedback from clinical experts indicated this process could take between 1 month and 6 months depending on a range of factors.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				Therefore, the EAG assumed it would be approximately 1 third of a year. We acknowledge this is only a base case input, and is likely to vary, with the upper boundary being around 6 months to complete the learning curve.
43	Page 124	Section 9.2 Integration into the NHS	Economic Model - you mention the longer training time but not the shorter training time for novice surgeons cf. lap- I think this is important to note for a balanced argument.	Thank you for your comment. EAG agree this is a fair comment and have noted this in the report in section 8.4. It is important to note that training costs are not a key driver of the model, so any impact on training is unlikely to change the conclusions of the analysis.
44	124	9.2 Integration into the NHS (Learning Curve considerations)	**Learning Curve:** Importance and impact of 'learning curve' on the surgical outcomes in robotic assisted surgery (RAS) is an extremely important point discussed in the review. It is commonly accepted to be around 50 cases. There are two systematic reviews on learning curve in robotic assisted surgery worth considering https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996634/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10431463/	Thank you for your comment. The EAG have discussed in section 8.2 and 8.4. They acknowledge that many studies likely implicitly capture the learning curve period with respect to key clinical outcomes. This is something that they cannot disentangle from the

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			 Patients' metrics commonly associated with learning curve are operating time, LOS, conversion, complications (intra/post operative). All studies included in the evaluation, reported longer operating time and comparable LOS, conversion and complications of RAS compared to either open or MIS, which clearly suggests **these operations were undertaken by surgeons who were in the early phase of their learning curve in RAS**. For the reason stated above reliance on these studies and metrics in providing clinical analyses and economic evaluation cannot be safe.	available evidence and should be considered when interpreting the model. They believe the systematic review aligns with the conclusions made in 9.2, that it is highly heterogenous dependent on a range of factors. The systematic reviews provided do not suggest 50 as a common metric, but show how this can range from 15 procedures, to over 150 depending on the metric used to measure the learning curve. We have added these references to support our conclusions in the integration to the NHS.
45	152	11.3 Conclusions on the gap analysis	Comment on: *'It would be beneficial to do this in settings where robotic surgery is already established and also where it is in the process of being introduced.'*	Thank you for your comment. See comments above in response to

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			Whilst this is a pragmatic recommendation, the evidence for this approach is poor as new technologies being evaluated (with a less experienced surgeon) against established treatment approaches (with experienced surgeon), usually fail to identify the advantages of the novel technology due to learning curve effects. The first RCT in RARP vs open surgery concluded no advantages to RARP, yet no patients in that institution currently undergo open surgery. If the centre has established robotic surgery/MAS it is also difficult to go back to open surgery for the same reasons but also because it is felt to offer the patient a worse option.	learning curve recommendations for evidence generation- learning curve should probably be captured in some form in every study going forward as at the moment it cannot (easily or consistently) be disentangled. This can be discussed at committee.
46	85	8.2 Conceptual model (assumptions and limitations)	Learning curve – the impact should be measured in the number of cases done for specific surgeons on an RAS list compared to their own and their peer's surgical lists during and after the defined initial number of cases specified as a learning curve.	Thank you for your comment. See responses to previous comments. This can be discussed at committee.
47			**Economic Model** **Description of problem:** Time-to-proficiency will be very heterogenous depending on surgeon RAS experience and annual cases. **Description of proposed amendment:** The model used additional 30 minutes to reflect the learning curve time. However, the learning curve might also impact on other clinical outcomes.	Thank you for this comment. The EAG have acknowledged this is likely to be very heterogenous and have varied this as part of sensitivity analysis. It is also important to note that the learning curve cannot be disentangled from the study data. The available studies are likely to have the learning curve impacting the outcomes of the study. The EAG have

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				acknowledged this as a limitation of the report. The EAGs learning curve implementation also removes the benefit of reduced length of stay from RAS, but again, they acknowledge it may impact other outcomes, which may or may not already be reflected in the parameters.
48	88	8. Economic evidence > 8.2. Conceptual Model > 8.2.1 Model inputs > Set up parameters	"Table 8.3: Set-up parameters - Time to proficiency" The report highlights a lack of data regarding the impact of the learning curve associated with Robotic-Assisted Surgery (RAS). As a result, it is not reasonable to assume that there is no improvement in outcomes during this phase.	Thank you for your comment. EAG believe that it is important to test this assumption and have provided scenarios with this not included. As stated in the report, we believe the emphasis should not be on the base case, but the whole range of results, given the early nature of the analysis.
Comments on search strategy and evidence selection, and notification of missing studies				
49	64	5.3	The reason you haven't got enough data is that the studies were selected at the start and not selected on a per-outcome basis. You could use different studies to assess different outcomes and then would get far more data which would be meaningful.	Thank you for your comment however, in the context of this review, the eligibility criteria were prespecified in order to avoid any selection bias

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				and ensures that each technology is addressed systematically.
50	1		"The search was designed only to retrieve studies where the named eligible technologies were mentioned in the title, abstract, keyword heading word or original title" I feel this a **major flaw** in this report. The recommendations are based on 19-20 studies. Many research papers do not state the manufacturer in the title or abstract, instead using the more generic term "robot". Within my own field of oesophagogastric cancer, for example, a major RCT (the ROBOT trial: van der Sluis PC, van der Horst S, May AM, Schippers C, Brosens LAA, Joore HCA, Kroese CC, Haj Mohammad N, Mook S, Vleggaar FP, Borel Rinkes IHM, Ruurda JP, van Hillegersberg R. Robot-assisted Minimally Invasive Thoracolaparoscopic Esophagectomy Versus Open Transthoracic Esophagectomy for Resectable Esophageal Cancer: A Randomized Controlled Trial. Ann Surg. 2019 Apr;269(4):621-630. doi: 10.1097/SLA.0000000000003031. PMID: 30308612) has been omitted from this analysis. This study compared da vinci oesophagectomy versus open and showed significant benefit. It also included a financial impact. I feel that unless the search terms are altered, this assessment may misrepresents the available data.	Thank you for your comment. The EAG's selection process and rationale is outlined above. This study did not name the technology in the title or abstract and the model is not specified in the full text.
51	25	4 Clinical evidence selection	**<u>Process of selection of studies:</u>** I would like to make submission on the EAG review submitted. I would like to raise concerns that the process of selection of studies for the review was not robust as the most important variable (minimum number of robotic cases in the study was not defined). Impact of learning curve (early phase of competency) of the selected (20) studies on clinical outcomes was not considered. In the absence of this vital component, I would submit the any	Thank you for your comment. The rationale for the review approach is addressed above. 1. We were interested in identifying evidence for the 5 scoped technologies so studies of "robot

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			interpretation and recommendation on clinical and economic impact would not be safe. My detailed reasons are given below 1. *A total of 492 full texts were retrieved and examined. A total of 110 studies were considered to meet the scope because they evaluated a named technology in the relevant population*. I am concerned that the process of selection of studies for this review on the face of it seems to be narrow and misdirected. It is sated that 'studies considered as they evaluated the named technology'. I am not clear if all studies which had the word 'robotic assisted surgery' were included in this review. As there are 30, 334 full text studies in PubMed when one types 'robotic assisted surgery'. I am concerned that most of these studies were probably not considered in this review 2. *20 comparative studies were prioritised and included, 19 of these studies were either cohort or non-randomised.* The only RCT included this review (Dixon et al 2024) has primary focus on surgeon related stress in RAS. Patient outcomes were not a primary focus of this study. *Robotic assisted surgery reduces ergonomic risk during minimally invasive colorectal resection: the VOLCANO randomised controlled trial.* This needs to be highlighted and inference on surgical outcomes should be taken with some caution.	assisted surgery" were not eligible unless they specifically named one of the eligible technologies in the title or abstract. 2. Thank you for highlighting this. Both patient level and surgeon level outcomes were eligible for this review. 3. The IROC trial was not included because it did not mention a specific robot in the title and abstract.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			3. Did the review panel considered IROC trial, which is an RCT https://pubmed.ncbi.nlm.nih.gov/35569079/ Effect of Robot-Assisted Radical Cystectomy with Intracorporeal Urinary Diversion vs Open Radical Cystectomy on 90-Day Morbidity and Mortality Among Patients With Bladder Cancer: A Randomized Clinical Trial	
52	26	4.2 Included and excluded studies	**Speciality/procedure selection:** 12/20 studies had a focus on cancer (unlike 6 stated in the report) Upper GI/HpB: 4 Colorectal: 7 Urology: 2 (Kidney cancer + RPLND) Inguinal Hernia: 2 Hysterectomy: 2 Cholecystectomy: 2 Nissen fundoplication:1 It is very surprising that not one study of robotic radical prostatectomy (RARP) was included in this review. This is despite the fact that it is the most common robotic operation undertaken since 2000. It has the biggest patient numbers and most mature outcomes, if one were to evaluate clinical outcome and cost effectiveness. Upper GI/ HPB/RPLND are relatively complex procedures and have been done in fewer numbers across the world, most surgeons undertaking these procedures will therefore be in their early phases on learning curve.	Thank you for your comment. The EAG has rechecked these studies and confirm that there are six with a focus on cancer. These are the following studies: Aktas et al - adenocarcinoma (cancer) Bergdhal et al - metastatic germ cell cancer (cancer) Butnari et al - Colorectal cancer (cancer) Di Lascia - Colorectal cancer (cancer) Galata et al - Rectal adenocarcinoma (cancer) Rattenborg - Colon cancer (cancer) Other studies do contain patients with cancer but are not exclusively focused on malignant disease. These studies have been placed in

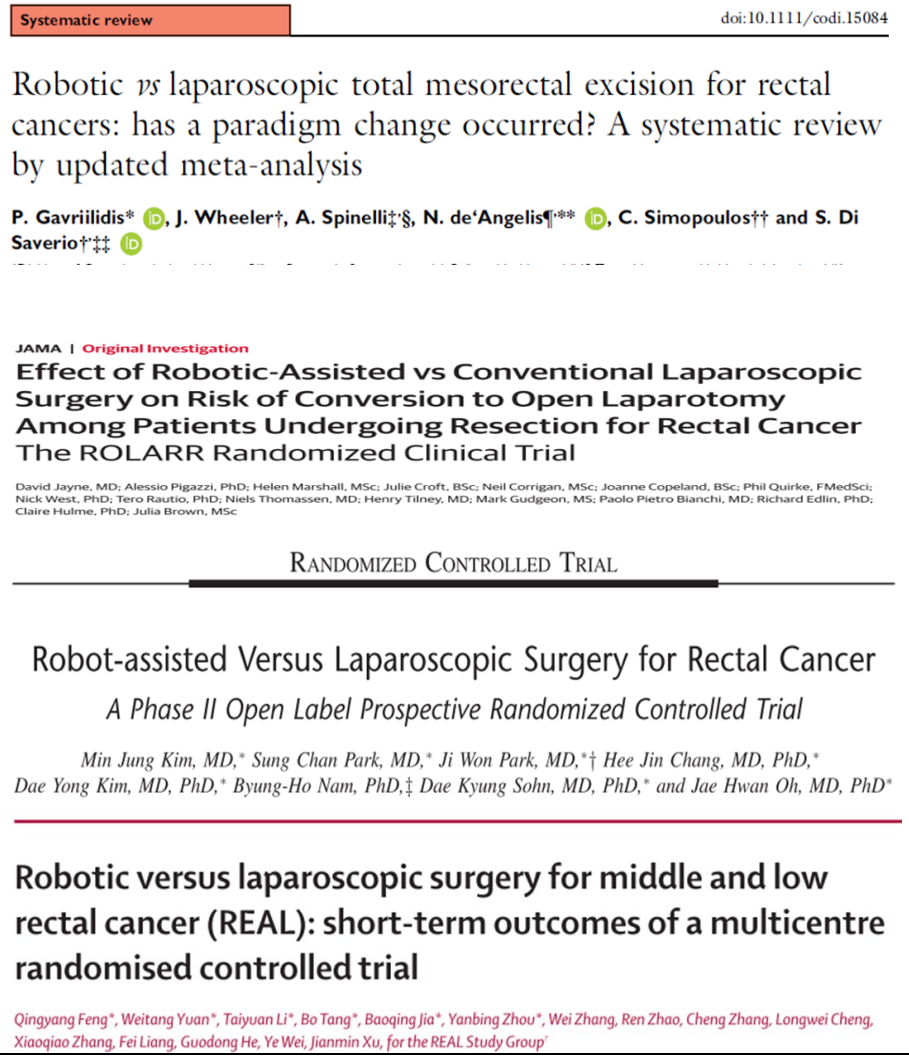
Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			The EAG needs to consider that various surgical specialties are at different stages of maturity in robotic assisted surgery. Their clinical outcomes, cost effectiveness and work force development/requirement would also vary. An overarching statement will therefore miss out on this extremely important point	the mixed population category. EVA is designed for technologies that are early in the life cycle, new applications of technologies. This is to better support adoption and evidence generation of promising technologies and applications, whilst they become more established. The highest level of recommendation is for a technology to be conditionally recommended for use while further evidence is generated. So, prostatectomy was excluded form the scope of this assessment because it is an established procedure with existing NICE Guidelines and national policy. Evidence from studies of prostatectomy was therefore excluded.
53	Table 4.1	Table 4.1 Studies selected by the EAG as	**Very low number of robotic cases reported in the studies:**	Thank you, rationale for prioritising comparative evidence is provided above.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
		the evidence base	The biggest flaw in the review is that the study selection process sole consideration has been given to RCT/cohort studies. Due consideration has not been given to the number of robotic cases included in each study. 18 of the twenty studies considered, had < 50 robotic cases each, among these 7 had <20 patients and one study had only 7 patient in the robotic arm. This is completely opposite to the reason for rejection of single arm prospective studies in the document, which is stated that they had <50 (robotic) cases. Why this rule was not been applied to cohort studies included for evaluation. It will be striking and extremely unfortunate that despite the fact the over 10,000,0000 patients have undergone robotic assisted surgery so far and each year additional 1.25 million patients undergo RAS worldwide. NICE guidance would be based a very small number of low volume studies which only have 700 patients who have undergone RAS. Aktas et al 2020: Retrospective: robotic (n=30) or laparoscopic (n=64) gastrectomy Alvarez et al 2023: Prospective: MIS (n=35) or robotic (n=22) pancreatectomy Bergdhal et al 2022: Prospective: 29 robotic 58 open surgery RPLND Bilgin et al 2019: Retrospective: MIS (n=22) or robotic (n=20) colectomy, Diverticulitis Butnari et al 2024: Retrospective: robotic (n=100) MIS (n=112) Colorectal cancer Di Franco et al 2022: Retrospective: robotic (n=20) or open surgery (n=40) Whipple	

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			Di Lascia et al 2020: Retrospective: laparoscopic (n=15) or robotic (n=7) Colorectal cancer Galata et al 2019: Prospective: laparoscopic(n=33) or robotic(n=18) Ant resection Gitas et al 2022: Retrospective: Robotic (n=42) MIS (n=97: hysterectomy Muysoms et al 2018: Retrospective: robotic unilateral (n=34) or bilateral (n=16) Laparoscopic unilaterally (n=22) or bilaterally (n=42) Ozben et al 2019: Retrospective: robotic (n=26) or MIS (n=56) Colorectal cancer Rattenborg 2021: Retrospective: robotic 35 Laparoscopic 40 Right hemi colectomy Schmelzle et al 2022: Retrospective: robotic (n=129) Laparoscopic (n=471) Hepatic resection Lee et al 2023: Prospective: MIS (n=48) or robotic surgery (n=31) hysterectomy Prata et al 2024: Retrospective: robotic (n=27) laparoscopic (n=62) partial nephrectomy. Aggarwal 2020: Retrospective: robotic (n=20) or laparoscopic (n=20) cholecystectomy Killaars et al 2024: Retrospective: robotic (n=20) laparoscopic (n=20). nissen fundoplication Samalavicius et al 2022: Retrospective: robotic (n=20) MIS (n=20) cholecystectomy Dixon et al 2024: RCT: robotic (n=40) or MIS (n=20) Surgeon ergonomic risk (REBA tool) • Surgeon cognitive strain: *Robotic assisted surgery reduces ergonomic risk during minimally invasive colorectal resection: the VOLCANO randomised controlled trial* Kakkilaya et al 2023: Prospective: robotic (n=44) or laparoscopic(n=440): Inguinal hernia	

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
54	140	10.1 Key areas for evidence generation	I wonder if the EAG is aware of the following study which is looking at system level impact of wider role out of RAS in the NHS **REINFORCE:** A real world in-situ, evaluation of Introduction and Scale up of Robotic assisted surgical services in the NHS- Evaluating its impact on clinical and service delivery, effectiveness and cost (study is currently recruiting) https://w3.abdn.ac.uk/hsru/REINFORCE/Public/Public/index.cshtml I think it will be important for NICE to reflect as to why quality of surgical research in robotic assisted surgery is poor. It would become quite evident that NIHR and CRUK have historically spent a very low percentage of their research grant into surgical research. It is hoped that this report will reinvigorate funding into areas of research gap identified by the review.	Thank you for your comment. This is an ongoing UK evaluation but there is no indication of the eligible platforms (it may not be robot specific and it's unclear whether findings will be available for specific technologies).
55	152	11.3 Conclusions on the gap analysis	Document states: '*Future evidence should therefore be generated across a longer timeframe to understand the learning curve. This should be done in large multi-centre prospective studies across a range of surgeries with at least twelve-month follow-up.'* CMR Surgical submitted a registry paper that was declined and registry data is a good solution for this and includes multiple surgeries that can be grouped and analysed in this proposed way. This is real world data which will also evaluate safe implementation and will give valuable information on the learning curve. CMR surgical and other RAS companies have built a registry to collect this data. CMR submitted this paper as published evidence and it was removed from the evidence. Given that it addresses some of the main recommendations by this NICE document, we would advocate that this registry paper is included to highlight an important	Thank you. The study that you mention is non-comparative. The EAG prioritised comparative evidence for this EVA and the rationale for this is provided above.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			approach to collect real world surgical data [Soumpasis I, Nashef S, Dunning J, Moran P, Slack M. Safe Implementation of a Next-Generation Surgical Robot: First Analysis of 2,083 Cases in the Versius Surgical Registry. Ann Surg. 2023 Oct 1;278(4):e903-e910. doi: 10.1097/SLA.0000000000005871. Epub 2023 Apr 10.PMID: 37036097].	
56			The document is well written and comprehensive. Most of the comparison is between MIS and Robot assisted procedures. In Breast surgery MIS procedures are not used. We will be comparing Open breast procedures to Robot assisted. Some of the findings discussed may not be relevant. Although there is paucity of data from plastic surgery procedures, there is a wealth of information for breast procedure from all around the world, for both benign (risk reducing) and cancer procedures, including an RCT (Toesca 2022). Overall, excellent work covering a heterogenous group of surgeries with meaningful and useful conclusions.	Thank you for your comment. This study was not identified because there is no indication of what robot was used in the title/abstract or clinical trial record.
57	48	Table 4.1 Studies selected by the EAG as the evidence base	Very important seminal papers missing for colorectal cancer evidence Ann Surg. 2018 Jun;267(6):1034-1046. doi: 10.1097/SLA.0000000000002523. **Robotic Versus Laparoscopic Minimally Invasive Surgery for Rectal Cancer: A Systematic Review and Meta-analysis of Randomized Controlled Trials.** Prete FP[1,2], Pezzolla A[1], Prete F[3], Testini M[4], Marzaioli R[1], Patriti A[5], Jimenez-Rodriguez RM[6], Gurrado A[4], Strippoli GFM[3,7,8].	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG have taken.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				

Systematic review

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Robotic *vs* laparoscopic total mesorectal excision for rectal cancers: has a paradigm change occurred? A systematic review by updated meta-analysis

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JAMA | Original Investigation

Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer
The ROLARR Randomized Clinical Trial

David Jayne, MD; Alessio Pigazzi, PhD; Helen Marshall, MSc; Julie Croft, BSc; Neil Corrigan, MSc; Joanne Copeland, BSc; Phil Quirke, FMedSci; Nick West, PhD; Tero Rautio, PhD; Niels Thomassen, MD; Henry Tilney, MD; Mark Gudgeon, MS; Paolo Pietro Bianchi, MD; Richard Edlin, PhD; Claire Hulme, PhD; Julia Brown, MSc

RANDOMIZED CONTROLLED TRIAL

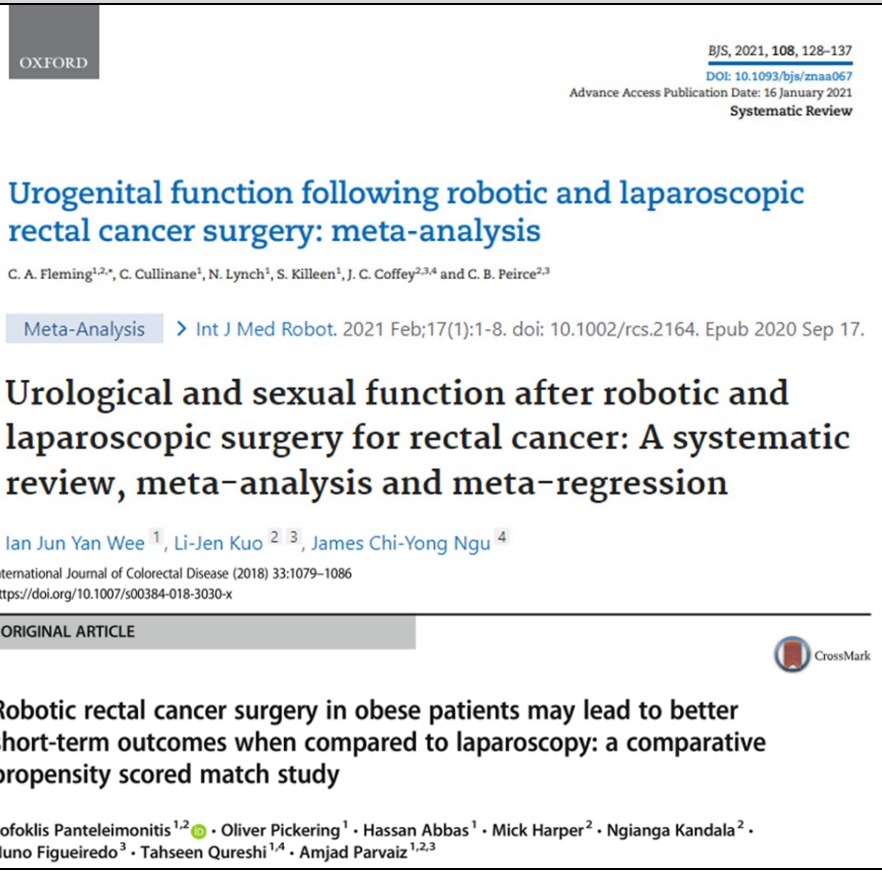
Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer

A Phase II Open Label Prospective Randomized Controlled Trial

Min Jung Kim, MD, Sung Chan Park, MD,* Ji Won Park, MD,*† Hee Jin Chang, MD, PhD,* Dae Yong Kim, MD, PhD,* Byung-Ho Nam, PhD,‡ Dae Kyung Sohn, MD, PhD,* and Jae Hwan Oh, MD, PhD**

Robotic versus laparoscopic surgery for middle and low rectal cancer (REAL): short-term outcomes of a multicentre randomised controlled trial

Qingyang Feng, Weitang Yuan*, Taiyuan Li*, Bo Tang*, Baoqing Jia*, Yanbing Zhou*, Wei Zhang, Ren Zhao, Cheng Zhang, Longwei Cheng, Xiaoqiao Zhang, Fei Liang, Guodong He, Ye Wei, Jianmin Xu, for the REAL Study Group†*

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				

OXFORD

BJS, 2021, 108, 128–137
DOI: 10.1093/bjs/znaa067
Advance Access Publication Date: 16 January 2021
Systematic Review

Urogenital function following robotic and laparoscopic rectal cancer surgery: meta-analysis

C. A. Fleming[1,2,*], C. Cullinane[1], N. Lynch[1], S. Killeen[1], J. C. Coffey[2,3,4] and C. B. Peirce[2,3]

Meta-Analysis > Int J Med Robot. 2021 Feb;17(1):1-8. doi: 10.1002/rcs.2164. Epub 2020 Sep 17.

Urological and sexual function after robotic and laparoscopic surgery for rectal cancer: A systematic review, meta-analysis and meta-regression

Ian Jun Yan Wee [1], Li-Jen Kuo [2] [3], James Chi-Yong Ngu [4]

International Journal of Colorectal Disease (2018) 33:1079–1086
https://doi.org/10.1007/s00384-018-3030-x

ORIGINAL ARTICLE

CrossMark

Robotic rectal cancer surgery in obese patients may lead to better short-term outcomes when compared to laparoscopy: a comparative propensity scored match study

Sofoklis Panteleimonitis[1,2] · Oliver Pickering[1] · Hassan Abbas[1] · Mick Harper[2] · Ngianga Kandala[2] · Nuno Figueiredo[3] · Tahseen Qureshi[1,4] · Amjad Parvaiz[1,2,3]

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			Review Article | Published: 25 July 2019 **The impact of robotic colorectal surgery in obese patients: a systematic review, meta-analysis, and meta-regression** Ian Jun Yan Wee, Li-Jen Kuo & James Chi-Yong Ngu *Surgical Endoscopy* **33**, 3558–3566 (2019) | Cite this article **642** Accesses | **10** Citations | **7** Altmetric | Metrics Surg Endosc. 2021; 35(12): 6796–6806. PMCID: PMC8599412 Published online 2020 Dec 7. doi: 10.1007/s00464-020-08184-1 PMID: 33289055 **Short-term clinical outcomes of a European training programme for robotic colorectal surgery** Sofoklis Panteleimonitis,[1] Danilo Miskovic,[2] Rachelle Bissett-Amess,[3] Nuno Figueiredo,[3] Matthias Turina,[4] Giuseppe Spinoglio,[5] Richard J. Heald,[3,6] Amjad Parvaiz,[✉1,3,7] and On behalf of the EARCS Collaborative JOURNAL ARTICLE **Minimally Invasive Surgery for Inflammatory Bowel Disease: A Systematic Review and Meta-analysis of Robotic Versus Laparoscopic Surgical Techniques** Get access Shafquat Zaman ✉, Ali Yasen Y Mohamedahmed, Nuha A Yassin *Journal of Crohn's and Colitis*, Volume 18, Issue 9, September 2024, Pages 1522–1523, https://doi.org/10.1093/ecco-jcc/jjae065 **Published:** 23 May 2024 **Article history**	
58	10	Executive summary	*"The included studies were prioritized for synthesis on the basis of relevance to the decision problem, study quality, and geo-location"*	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			There are arguably thousands of higher quality studies that provide data on most of the primary and secondary outcomes listed in the decision problem. Concluding that there is no, or limited evidence is misleading.	
59	26	4.1 Evidence search strategy and study selection	*"Due to the volume of literature identified, studies which did not name one of the 5 technologies in the title or abstract were excluded"* The majority of publications on RAS do not specify the technology in the title or abstract. This is a major limitation in the search strategy. The authors state that this was done to strike an appropriate balance of sensitivity and precision to meet the project resources and timelines, but in doing so, have severely limited the information for review and subsequently the conclusions and recommendations of the report. 3,874 is a very low number of studies to retrieve for RAS. Over 3,000 peer-reviewed papers were published on soft-tissue RAS in 2023 alone.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.
60	26	4.2 Included and excluded studies	*"Some higher-level evidence de-prioritised if there was a high volume of literature for a particular technology"* This approach does not seem to make sense for a gap assessment or the purpose of an EVA. It seems strange that this would be the approach taken in an assessment where higher levels of evidence exist to answer questions and provide information on outcomes in the decision problem, but instead lower levels of evidence are prioritized.	Thank you for your comment. All European, comparative evidence was prioritised. For technologies that did not have any European data, the EAG included comparative studies from other countries in order to

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				include evidence for all technologies. Evidence for DaVinci was de-prioritised from countries outside of Europe (regardless of study design), because of concerns regarding generalisability and only included for other technologies due to a lack of more relevant data.
61	27	4.2 Included and excluded studies	*"Studies of Da Vinci X/Xi in a non-EU setting were deprioritised"* This approach also does not seem appropriate if non-EU studies were accepted for other robotic platforms. This implies that non-EU studies would be acceptable to address the decision problem for other robotic platforms but not for da Vinci. Inconsistencies in methods lead to biases in the report and take away from the validity of recommendations or conclusions.	Thank you for your comment. All European, comparative evidence was prioritised. For technologies that did not have any European data, the EAG included comparative studies from other countries in order to include evidence for all technologies.
62	28	4.2 Included and excluded studies	From this report it sounds like dV RAS has only 14 publications. The scope is very broad and in the end the report is lacking scientific rigor with the evidence gap recommendations not supported by the true state of the evidence.	Thank you for your comment. The EAG have tried to make it clear that this EVA is informed by a pragmatic

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
				(rather than systematic) review
63	49	5 Clinical evidence review	This report tells the audience that there are no RCTs for dV RAS – that is deceiving and incorrect. Overall there are more than 50 relevant RCTs on the da Vinci platform, many of them which include European population (N=22). Studies such as iROC, CORAL, BORARC and ROLARR have UK population and were not included, mainly because they included prior generations of the da Vinci platform. The Si and X/Xi models operate at an equivalent clinical and safety level as per regulatory clearances. These excluded studies address outcomes within the decision problem and would be relevant to the recommendations made within the gap assessment. If this current approach will continue to be taken in the future, then every time a new generation of platforms come to market, the recommendations in this report no longer apply and the process will need start over again. This will create more work for a process that was already done rapidly to account for lack of bandwidth. As noted in the RFI, the 5th generation of the da Vinci platform has already been approved by the FDA in the US. This approach would imply that all X/Xi studies and recommendations are also not applicable to dV5 and an additional assessment would now need to be conducted in the near future. This comment is also applicable to comment number 25 below.	Thank you for your comment. For this EVA, both the X and the Xi platforms were eligible. However, the reason that these studies were not included is that they did not specify the robot in the title and abstract (and in some cases it is not clear in the full text either). The EAG applied the same criteria to all the technologies. Studies of the Si platform would not have been eligible. The scope of the review was limited to the technologies named in the NICE scope.
64	49	5 Clinical evidence review	The scope in the decision problem covers more than 10 surgical specialities, yet the evidence was restricted to a handful of small studies for a few indications. Several of which are not primary	Thank you for your comment. The EAG did not select evidence based on

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			procedures for most RAS platforms in the NHS or represent rapidly growing procedures in the NHS. It would seem more appropriate to make recommendations based on a gap assessment for procedures that are most relevant to the current environment in the NHS.	indication- these are the indications for which there was evidence (based on the approach).
65	53	5.3 Results from the evidence base	There is a substantial amount of literature available on da Vinci RAS and conversion rates, both for individual procedures and across specialities. The numbers presented in this report based on the included studies may not be an accurate representation of the literature on conversion rates.	Thank you for your comment. The data reported are based on the evidence identified in the pragmatic review. However, within the model, the EAG have conducted sensitivity analyses around these values which captures a range of variability.
66	60	5.3 Results from the evidence base	There are several pertinent studies available on procedure-related discomfort and ergonomics that were not included in the review, particularly the study from Norasi et al. 2023.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.
67	60	5.3 Results from the evidence base	It is likely that a separate search strategy would be needed to address outcomes at the organization level such as rate of MIS compared with open and volume of procedures. NICE may be interested in a recent RWE study out of Germany that evaluated the growth of RAS since its adoption in Urology. N. Pyrgidis, Y. Volz, B. Ebner et al., Evolution of Robotic Urology in Clinical Practice from the Beginning to Now: Results from the	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. The reference provided is for a retrospective analysis of a large non-UK database

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			GRAND Study Register, Eur Urol Focus (2024), https://doi.org/10.1016/j.euf.2024.08.004	which would not have been eligible for the review.
68	61	5.3 Results from the evidence base	Similar to the comment above, it is likely that a separate search strategy would be needed to address outcomes at the organization level, or that the existing strategy is too narrow to capture relevant studies related to capacity and wait-list. NICE may be interested in a recent study looking at efficacy and productivity gains related to RAS in the NHS. Maynou L, McGuire A, Serra-Sastre V. Efficiency and productivity gains of robotic surgery: The case of the English National Health Service. *Health Econ*. 2024;33(8):1831-1856. doi:10.1002/hec.4838	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. The reference provided is for prostatectomy which is not eligible for the EVA.
69	64	5.3 Results from the evidence base	Evidence on long-term data, cancer outcomes, and various measurements of mortality are available for many procedures. Concluding that there is no evidence for these outcomes is misleading.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.
70	121	9.1	There is available evidence to address many of the outcomes of interest within the decision problem. The evidence search and gap analysis recommendations do not accurately reflect a review of the topic that this EVA was intended to assess, “robotic-assisted surgery for soft-tissue procedures”.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.
71	Table B2	Appendix B	Many of the excluded studies state “model not specified”, however it can be assumed given the timeframe and geography of these studies, that a da Vinci platform was used. Other excluded studies state “ineligible intervention” based on the platform being an Si system.	Thank you for your comment. For this EVA, both the X and the Xi platforms were eligible. However, the reason that these studies were not

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			The Si and X/Xi models operate at an equivalent clinical and safety level as per regulatory clearances. These excluded studies address outcomes within the decision problem and would be relevant to the recommendations made within the gap assessment. Furthermore, a study that provided economic outcomes for da Vinci Si was prioritized in the economic review, but all other relevant studies excluded from other parts of the report. The issue around excluding relevant studies based on prior generations is also discussed above in comment number 10, and how this would apply for future generations of robotic platforms.	included is that they did not specify the robot in the title and abstract (and in some cases it is not clear in the full text either). The EAG applied the same criteria to all the technologies. Studies of the Si platform would not have been eligible. The scope of the review was limited to the technologies named in the NICE scope. The da Vinci Si study included for economic outcomes has been edited to focus on the da Vinci Xi outcomes only.
72	217	Appendix B	The report states there is no long-term data available on RAS. The Leitao study was included as part of the company submission to address this question. Stating that there is no long-term evidence is inaccurate.	Thank you, the reference you refer to is a systematic review which the EAG identified and checked for additional references.
73	223	Appendix B	Why is the Norasi 2023 paper excluded based on an ineligible intervention? The paper states the platforms used were da Vinci Xi or SP systems. Inclusion of this study also addresses several	Thank you. Results were not reported for each intervention but

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			ergonomic and surgeon-related outcomes within the decision problem.	reported overall. This was a US study.
74	26	4. Clinical Evidence Selection > 4.1. Evidence search strategy and study selection	Medtronic acknowledge the comprehensive search strategy employed. However, the EAR states that "Due to the volume of literature identified, studies which did not name one of the 5 technologies in the title or abstract were excluded", which indicates the limitation on the breadth of data considered in the evaluation. In summary, Medtronic kindly request the EAG to consider the additional studies which were not identified during this literature search. 1. Bracale U, Corcione F, Neola D, et al. Transversus abdominis release (TAR) for ventral hernia repair: open or robotic? Short-term outcomes from a systematic review with meta-analysis. Hernia. 2021;25(6):1471-1480. doi:10.1007/s10029-021- 02487-5 2. Cuk P, Kjær MD, Mogensen CB, Nielsen MF, Pedersen AK, Ellebæk MB. Short-term outcomes in robot-assisted compared to laparoscopic colon cancer resections: a systematic review and meta-analysis. Surgical endoscopy. 2022;36(1):32-46. doi:10.1007/s00464-021-08782-7 3. Dixit R, Prajapati OP, Krishna A, Rai SK, Prasad M, Bansal VK. Patient-reported outcomes of laparoscopic versus robotic primary ventral and incisional hernia repair: a systematic review and meta-analysis. Hernia. 2023/01/06 2023;27(2):245-257. doi:10.1007/s10029-022-02733-4 4. Giuliani G, Guerra F, Coletta D, et al. Robotic versus conventional laparoscopic technique for the treatment of left-sided colonic diverticular disease: a systematic review with meta-analysis. International Journal of Colorectal Disease. 2021/10/01 2021;37(1):101-109. doi:10.1007/s00384-021-04038-x 5. Guerrini GP, Esposito G, Magistri P, et al. Robotic versus laparoscopic gastrectomy for gastric cancer: The largest meta-analysis. International Journal of Surgery. 2020/10 2020;82:210-228. doi:10.1016/j.ijsu.2020.07.053 6. Henriksen NA, Jensen KK, Muysoms F. Robot-assisted abdominal	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG have taken. Identified systematic reviews were used for reference checking only.

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			wall surgery: a systematic review of the literature and meta-analysis. Hernia. 2018/12/06 2018;23(1):17-27. doi:10.1007/s10029-018-1872-3 7. Lim, P. et al. Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 133, 359–64 (2016).)Luciano, A., Luciano, D., Gabbert, J. & Seshadri-Kreaden, U. The impact of robotics on the mode of benign hysterectomy and clinical outcomes. The international journal of medical robotics + computer assisted surgery : MRCAS 12, 114–24 (2016). 8. Ma S, Chen Y, Chen Y, et al. Short-term outcomes of robotic-assisted right colectomy compared with laparoscopic surgery: A systematic review and metaanalysis. Asian Journal of Surgery. 2019/05 2019;42(5):589-598. doi:10.1016/j.asjsur.2018.11.002 9. Park, D., Lee, D., Kim, S. & Lee, S. Comparative safety and effectiveness of robotassisted laparoscopic hysterectomy versus conventional laparoscopy and laparotomy for endometrial cancer: A systematic review and meta-analysis. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology 42, 1303–14 (2016). gRudiman R, Hanafi RV, Almawijaya A. Single-site robotic cholecystectomy versus single-incision laparoscopic cholecystectomy: A systematic review and metaanalysis. Ann Gastroenterol Surg. 2023;7(5):709-718. doi:10.1002/ags3.12688 10. Solaini L, Bocchino A, Avanzolini A, Annunziata D, Cavaliere D, Ercolani G. Robotic versus laparoscopic left colectomy: a systematic review and meta-analysis. International journal of colorectal disease. 2022;37(7):1497-1507. doi:10.1007/s00384-022-04194-8 11. Wang, T., Tang, H., Xie, Z. & Deng, S. Robotic-assisted vs. laparoscopic and abdominal myomectomy for treatment of uterine fibroids: a meta-analysis. Minimally invasive therapy & allied	

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			technologies : MITAT : official journal of the Society for Minimally Invasive Therapy 27, 249–264 (2018). yYang Y, Wang G, He J, Wu F, Ren S. Robotic gastrectomy versus open gastrectomy in the treatment of gastric cancer. Journal of Cancer Research and Clinical Oncology. 2016/09/20 2016;143(1):105-114. doi:10.1007/s00432-016-2240-2 12. Zhang Z, Zhang X, Liu Y, et al. Meta-analysis of the efficacy of Da Vinci robotic or laparoscopic distal subtotal gastrectomy in patients with gastric cancer. Medicine (Baltimore). 2021;100(34):e27012-e27012. doi:10.1097/MD.0000000000027012 13. Zhu QL, Xu X, Pan ZJ. Comparison of clinical efficacy of robotic right colectomy and laparoscopic right colectomy for right colon tumor: A systematic review and metaanalysis. Medicine (Baltimore). 2021;100(33):e27002-e27002. doi:10.1097/MD.0000000000027002	
75	26	4. Clinical Evidence Selection > 4.2. Included and excluded studies	The EAR states “Prioritisation was conducted per technology, with some higher-level evidence de- prioritised if there was a high volume of literature for a particular technology”, implying that evidence that could provide robust outcomes and appropriately demonstrate the use of RAS may not have utilised. Medtronic kindly request the EAG to provide the following: 1. Clear definition of “higher-level evidence” 2. Provide the methodology for the de-prioritisation of “higher-level evidence” 3. Reassurance that the data published within the literature categorised as “higher level evidence” but deprioritised has been reviewed. Medtronic kindly requests that NICE provide further details of the algorithm/method used to prioritise particular studies and clarify their definition of ‘higher-level evidence’.	Thank you for your comment. The prioritisation process was such that all European, comparative evidence was prioritised. For technologies that did not have any European data, we included comparative studies from other countries in order to include evidence for all technologies. Evidence for DaVinci was de-prioritised from countries outside of Europe (regardless of study

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				design), because of concerns regarding generalisability and only included for other technologies due to a lack of more relevant data.
76	130	10. Evidence gap analysis	"Table 10.1. Summary and conclusions of evidence gap analysis: Primary -patient level: Conversion to open surgery" Medtronic kindly request the EAG to review of the additional publications identified below to support the evidence analysis for "conversion to open surgery". 1. Luciano, A., Luciano, D., Gabbert, J. & Seshadri-Kreaden, U. The impact of robotics on the mode of benign hysterectomy and clinical outcomes. The international journal of medical robotics + computer assisted surgery : MRCAS 12, 114–24 (2016). 2. Park, D., Lee, D., Kim, S. & Lee, S. Comparative safety and effectiveness of robotassisted laparoscopic hysterectomy versus conventional laparoscopy and laparotomy for endometrial cancer: A systematic review and meta-analysis. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology 42, 1303–14 (2016). 3. Wang, T., Tang, H., Xie, Z. & Deng, S. Robotic-assisted vs. laparoscopic and abdominal myomectomy for treatment of uterine fibroids: a meta-analysis. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy 27, 249–264 (2018). 4. Cuk P, Kjær MD, Mogensen CB, Nielsen MF, Pedersen AK, Ellebæk MB. Shortterm outcomes in robot-assisted compared to laparoscopic colon cancer resections: a systematic review and meta-analysis. Surgical	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG has have taken (see comment 116)

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			endoscopy. 2022;36(1):32-46. doi:10.1007/s00464-021-08782-7 Giuliani G, Guerra F, Coletta D, et al. Robotic versus conventional laparoscopic technique for the treatment of left-sided colonic diverticular disease: a systematic review with meta-analysis. International Journal of Colorectal Disease. 2021/10/01 2021;37(1):101-109. doi:10.1007/s00384-021-04038-x 6. Zhu QL, Xu X, Pan ZJ. Comparison of clinical efficacy of robotic right colectomy and laparoscopic right colectomy for right colon tumor: A systematic review and meta-analysis. Medicine (Baltimore). 2021;100(33):e27002-e27002. doi:10.1097/MD.0000000000027002	
77	130	10. Evidence gap analysis	"Table 10.1. Summary and conclusions of evidence gap analysis: Primary -patient level: Length of stay hospital" Medtronic kindly request the EAG to review of the additional publications identified to support the evidence analysis for RAS and "length of hospital stay": 1. Park, D., Lee, D., Kim, S. & Lee, S. Comparative safety and effectiveness of robotassisted laparoscopic hysterectomy versus conventional laparoscopy and laparotomy for endometrial cancer: A systematic review and meta-analysis. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology 42, 1303–14 (2016). 2. Lim, P. et al. Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 133, 359–64 (2016). 3. Ma S, Chen Y, Chen Y, et al. Short-term outcomes of robotic-assisted right colectomy compared with laparoscopic surgery: A systematic review and metaanalysis. Asian Journal of Surgery. 2019/05 2019;42(5):589-598. doi:10.1016/j.asjsur.2018.11.002	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG have taken (see comment 116)

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			4. Yang Y, Wang G, He J, Wu F, Ren S. Robotic gastrectomy versus open gastrectomy in the treatment of gastric cancer. Journal of Cancer Research and Clinical Oncology. 2016/09/20 2016;143(1):105-114. doi:10.1007/s00432-016- 2240-2 5. Zhang Z, Zhang X, Liu Y, et al. Meta-analysis of the efficacy of Da Vinci robotic or laparoscopic distal subtotal gastrectomy in patients with gastric cancer. Medicine (Baltimore). 2021;100(34):e27012-e27012. doi:10.1097/MD.0000000000027012 6. Giuliani G, Guerra F, Coletta D, et al. Robotic versus conventional laparoscopic technique for the treatment of left-sided colonic diverticular disease: a systematic review with meta-analysis. International Journal of Colorectal Disease. 2021/10/01 2021;37(1):101-109. doi:10.1007/s00384-021-04038-x 7. Bracale U, Corcione F, Neola D, et al. Transversus abdominis release (TAR) for ventral hernia repair: open or robotic? Short-term outcomes from a systematic review with meta-analysis. Hernia. 2021;25(6):1471-1480. doi:10.1007/s10029- 021-02487-5 8. Dixit R, Prajapati OP, Krishna A, Rai SK, Prasad M, Bansal VK. Patient-reported outcomes of laparoscopic versus robotic primary ventral and incisional hernia repair: a systematic review and meta-analysis. Hernia. 2023/01/06 2023;27(2):245- 257. doi:10.1007/s10029-022-02733-4Di	
78	131	10. Evidence gap analysis	“Table 10.1. Summary and conclusions of evidence gap analysis: Primary -patient level: Intraoperative complications” Medtronic kindly request the EAG to review of the additional publications identified to support the evidence analysis for RAS and “intraoperative complications”: 1. Park, D., Lee, D., Kim, S. & Lee, S. Comparative safety and effectiveness of robotassisted laparoscopic hysterectomy versus conventional laparoscopy and laparotomy for endometrial cancer: A systematic review and meta-analysis. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology 42, 1303–14 (2016). 2. Rudiman R, Hanafi RV,	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG have taken (see comment 116)

Comment number	Page number	Section number	Comment	NICE Response/EAG considerations
			Almawijaya A. Single-site robotic cholecystectomy versus single-incision laparoscopic cholecystectomy: A systematic review and metaanalysis. Ann Gastroenterol Surg. 2023;7(5):709-718. doi:10.1002/ags3.12688	

79	131	10. Evidence gap analysis	"Table 10.1. Summary and conclusions of evidence gap analysis: Primary -patient level: Postoperative complications" Medtronic kindly request the EAG to review of the additional publications identified to support the evidence analysis for RAS "postoperative complications" and overall complications: 1. Luciano, A., Luciano, D., Gabbert, J. & Seshadri-Kreaden, U. The impact of robotics on the mode of benign hysterectomy and clinical outcomes. The international journal of medical robotics + computer assisted surgery : MRCAS 12, 114–24 (2016). 2. Wang, T., Tang, H., Xie, Z. & Deng, S. Robotic-assisted vs. laparoscopic and abdominal myomectomy for treatment of uterine fibroids: a meta-analysis. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy 27, 249–264 (2018). 3. Lim, P. et al. Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 133, 359–64 (2016). 4. Ma S, Chen Y, Chen Y, et al. Short-term outcomes of robotic-assisted right colectomy compared with laparoscopic surgery: A systematic review and meta- analysis. Asian Journal of Surgery. 2019/05 2019;42(5):589-598. doi:10.1016/j.asjsur.2018.11.002 5. Henriksen NA, Jensen KK, Muysoms F. Robot-assisted abdominal wall surgery: a systematic review of the literature and meta-analysis. Hernia. 2018/12/06 2018;23(1):17-27. doi:10.1007/s10029-018-1872-3 6. Guerrini GP, Esposito G, Magistri P, et al. Robotic versus laparoscopic gastrectomy for gastric cancer: The largest meta-analysis. International Journal of Surgery. 2020/10 2020;82:210-228. doi:10.1016/j.ijsu.2020.07.053 7. Solaini L, Bocchino A, Avanzolini A, Annunziata D, Cavaliere D, Ercolani G. Robotic versus laparoscopic left colectomy: a systematic review and meta-analysis. International journal of colorectal disease. 2022;37(7):1497-1507. doi:10.1007/s00384-022-04194-8 8. Cuk P, Kjær MD, Mogensen CB, Nielsen MF, Pedersen AK, Ellebæk MB. Short-term outcomes in robot-assisted compared to laparoscopic colon	Thank you for your comment. The pragmatic approach and rationale adopted for this EVA is provided above. None of these studies are eligible based on the approach the EAG have taken (see comment 116)

			cancer resections: a systematic review and meta-analysis. Surgical endoscopy. 2022;36(1):32-46. doi:10.1007/s00464-021-08782-7 9. Bracale U, Corcione F, Neola D, et al. Transversus abdominis release (TAR) for ventral hernia repair: open or robotic? Short-term outcomes from a systematic review with meta-analysis. Hernia. 2021;25(6):1471-1480. doi:10.1007/s10029-021- 02487-5	
80	169 – 181	13. Appendices > Search strategies	While the initial search strategy was comprehensive, it was also restrictive. The strategy employed may have inadvertently excluded studies that could have been valuable for this evaluation by focusing on publications that explicitly named the specific RAS systems in their titles and abstract. In light of this Medtronic believe that the search criteria should be broadened to include agnostic terms. This include the following: 1. “RAS*” 2. “surgical-system*” 3. “Surgical robot*” 4. “Minimally invasive robotic system* Although the “search limitations” (p.164-165) have been identified within the external assessment report, primary searches should align with the additional searches conducted for newly identified technologies ensuring a more comprehensive capture of relevant studies and strengthening the robustness of the overall assessment.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above.
81	169-181	13. Appendices > Search strategies	Medtronic noted that the key words in the search criteria for Senhance differed to those utilised in the primary literature search for Hugo RAS system, Verisus, da Vinci X / Xi Surgical System and da Vinci SP Surgical System. The additional key word “surgical system” was added. Medtronic believe that this additional key word should have been used in the primary search to capture additional relevant studies which could have been utilised to produce key inputs in the model.	Thank you for your comment. The approach and rationale adopted for this EVA is provided above. Please note that the study selection still would have required the technology to be named in the title or abstract to be considered eligible.

Comments on the scope, outcome definitions and changes to the scope				
82	Page 78	Section 8.2	Economic Model Cost effectiveness analysis limited to adults – due to lack of data in children	Thank you for your comment. The NICE EVA programme is a multi-technology guidance output. The aim is to identify and evaluate all available and appropriate technologies that have the potential to address an unmet need in the system.. Given some technologies are indicated for use in children, and this group are part of the unmet need, they are included in this assessment. For the economic analysis, the EAG have outlined the limitation that this is only considering adults, due to available evidence. They have discussed in section 8.1 and 8.4 the implications this may have for children.
83	23	Section 3 Clinical context	I agree that soft-tissue procedures and or wider musculoskeletal conditions should be assessed separately.	Thank you for your comment.

84	60	Section 5.3 Results from the evidence base	I appreciate that the report aimed to address a broad scope of clinical outcomes, including at the surgeon, organisation, and patient levels. These aspects should be considered for evaluation, particularly in the context of economic analysis. For instance, increased utilisation of surgical robots could lead to better cost-efficiency, as the cost per procedure may decrease with higher surgical volumes. Given that platforms have limited capacity, developing a shared scheduling framework is crucial, as it can enhance operational efficiency. However, in the prioritised studies, there was no evidence found of procedure-related discomfort, ergonomics, procedure volume, or capacity and wait-list reduction. I recommend clarifying the term 'capacity' to specify whether it refers to platform capacity or hospital capacity. I believe this report refers to the latter, aiming to capture the positive benefit of shorter hospital stays associated with using RAS.	Thank you for your comment. EAG have updated this wording in the report.
85	65	Section 5.3 Results from the evidence base	The secondary clinical outcomes at the surgeon level discussed the human factors and the learning curve, among other aspects. In terms of proficiency, it’s important to note that it relates not only to the surgeon but also to the entire surgical team. One contributing factor to the longer operative time in RAS is the docking time (preparation). The evidence presented here in this report is unclear on whether the total operative time includes docking time or how 'operative time' is defined.	Thank you. The EAG have revisited these studies and, in some cases, definitions weren’t reported. In other cases definitions varied between studies (some including docking in overall operative time and some not specifying this information). Where other elements of surgery such as docking or console time were reported these have been extracted and are available in the

				appendix. In the narrative results section for operating time, the EAG have focused on reporting the outcome with the closest definition to an overall operating time. The EAG have clarified this in the report.
86	13	Table 1.1 Summary of decision problem (Comparators)	This will (I am afraid) not capture the true cost as in some cancer groups, radiotherapy is either the only or one of the comparators (posterior tongue and prostate Ca) As most of the robotic assisted surgery will be focused on cancer surgery, in the cost effectiveness analysis, cost of additional/differential rates of radiotherapy or chemotherapy required or in case of prostatectomy and need for artificial sphincters for urinary incontinence or penile implants for erectile dysfunction has not been considered or captured. These are substantial secondary costs associated with cancer surgery. There will be similar examples in other specialities. RAS seems to decrease this need for this additional cost due to its precision.	Thank you for your comment. The EAG have discussed in Section 8.2 that the model is limited to comparison of standard surgical care. They accept this is a limitation, for some procedures where surgery may not be an option for standard of care. Given the scope of an EVA, and the range of conditions covered in the scope, it is not feasible to conduct analysis for every procedure. Prostatectomy is out of scope; therefore, this has not been considered within the core

				modelling parameters. The EAG accept long-term benefits, such as different rates of radiotherapy may not be captured in the model. This is not a generalisable outcome, hence, is not captured within the flexible model structure. If RAS can reduce the need for radiotherapy, this would be an unquantified benefit. The EAG have discussed the required benefit for RAS to be cost-effective from what is not captured, so this point should be considered within committee discussion.
87	13	Table 1.1 Decision problem (outcomes)	Length of Hospital stay is dependent on several factors (social, stoma, ERAS to name a few)	Thank you for your comment. The EAG have added to report as a discussion point.
Comments on the executive summary				
88	11	0	Medtronic kindly ask for further clarification regarding the following statement: “The results of RAS replacing open surgeries would incur less costs than RAS replacing standard MIS, £135-£354 per procedure compared with £408-£704 per procedure respectively”. Specifically, we would like to confirm whether this statement is referring to the	Thank you for this comment, this has been amended within the report to reflect this clearer.

			incremental costs per procedure. If so, we would kindly like to offer alternative wording to ensure a clearer understanding of this comparison. Please see wording suggestion below: “The results show that replacing open surgeries with RAS incurs lower costs than replacing standard MIS with RAS, with the estimated cost difference of £135-354 per procedure for open surgeries compared to £408-£704 per procedure for MIS” We believe this wording allows for a straightforward interpretation of the cost estimates and is crucial in supporting informed decision making.	
89	11	0. Executive summary > Quality and relevance of the economic evidence	Given that the results of the model are derived from limited data across a range of different soft tissue procedures and carry a high level of uncertainty, the conclusions and assumptions should not be relied upon as the basis for considerations on further investment in RAS and purchasing decisions. The variability in procedures and the associated uncertainty weakens the reliability of the model for guiding such decisions. As previously stated, it is crucial that NICE communicates these limitations when publishing their recommendations, ensuring that decision makers are aware of the model’s constraints, uncertainties in the data and the potential risks of making decisions based on these findings.	Thank you for your comment. The limitations of the economic modelling will be discussed during the committee meeting. The EAG have discussed the limitations of the model in other comments and the report, and the impact this may have on the results. They believe the model is still a useful tool for consideration of RAS at this early stage.
Comments on Section 3 Clinical context				
90	25	3 Clinical context	Equality issues – should mention that access to RAS for patients depends on which surgeon they see in clinic and if they are robotically trained in addition to the trust having a robotic platform. Some patients in neighbouring post-codes may benefit from RAS compared to others, with learning curves also affecting the outcomes and perceived benefits.	Thank you for your comment. They believe this is an important point. This was raised in the NICE scope, and have also discussed this

				further in section 9.2. The impact on health inequalities is an important point to consider.
Comments on Section 5.3 Results from the evidence base				
91	54	5.3 Results from the evidence base	This section summarises conversion rates from the 20 evaluated publications. This is an important indicator of safe implementation related to both training and functionality of the robot. Each company has results that are reported. Currently Hugo (1 study) and Versius (2 studies) are summarised in one sentence. *'One study evaluating Hugo (Prata et al. 2024) and two assessing Versius (Dixon et al. 2024, Kakkilaya et al. 2023) vs. MIS reported no conversions in either arm.'* Due to the significance of this outcome data we would advise that Hugo and Versius findings are separated into two separate sentences.	Thank you for your comment. This has been updated in the report.
92	63	5.3 Results from the evidence base (Revision surgery)	Is this captured in clavien-dindo >III – need to clarify if this is a re-operation within 30 days or revisional surgery beyond that time frame.	Thank you for your comment. Revision surgery was extracted separately to Clavien-Dindo >III). The EAG revisited these studies and only one that reported this outcome defined that this was reoperation within 30 days. The remaining studies did not specify a timeframe.
General comments on the modelling approach				
93			Economic Model	This comment is really useful. The EAG have already discussed in

			A couple of general points- consider the alternative to robotics- that surgeons learning a procedure learn it lap- without the advantages of dexterity and vision the robot provides this means a longer learning curve- also without the screens and consoles used to train it will take even longer. Fewer and fewer novice surgeons are learning lap for these reasons- they are all going robotic. Secondly, for future economic modelling based on groupings I would suggest these grouping are not by specialty per se but rather by anatomy- pelvic procedures all together, abdominal, chest, etc.	detail the length of the learning curve, and the impact of removing it (even though it may still be implicitly captured in the underlying data). They have added a sentence in the integration to NHS to reflect how this may be changing over time (newer surgeons with shorter learning curves). They have added that groupings could also be done by anatomy, but would welcome further discussion on this at committee, or in future research if a positive EVA recommendation is provided.
94			**Economic Model** **Description of problem:** The report/ model aimed to highlight the key short-term factors that influence the range of outcomes in which the technology may operate. The base case assumption sets the annual utilisation of RAS at 400 cases. However, in real-world settings, this might be under-utilised or more than expected.	Thank you for your comment. The EAG agree that this is an important consideration. Scenario analysis is section 8.3.1 demonstrates the impact of lower and higher utilisation, setting cases to 300 and 1,000 per year.

			As we know, the annual case volume can impact clinical outcomes due to the volume-outcome relationship. Higher-volume centres are able to overcome the learning curve faster and maintain proficiency more effectively. **Description of proposed amendment:** If possible, it would be beneficial to include scenarios with varying annual case volumes and present a threshold analysis.	Section 8.3.2 also highlights the relative importance of this, showing to be one of the key drivers of the results. The EAG don't believe that threshold analysis on this input is worthwhile, as even at 10,000 surgeries per year, it is still cost incurring (£251 in the base case). Therefore, this input alone will not lead to it crossing the threshold.
95			**Economic Model** **Description of problem:** The model adopted parameters from various procedures, grouping them together to generate estimated results. However, these parameters can vary significantly across different specialties and hospitals. For instance, the proportion of MIS was estimated based on colorectal procedures, but this may differ in other specialties or hospitals where laparoscopic methods are less commonly used. The proportion of MIS (63.7%) was adopted from colorectal; it may have difference in HPB.	Thank you for your comment. EAG agree that the case mix is likely to vary across all soft tissue procedures. They believe the range of sensitivity analysis, including scenarios, DSA and PSA, reflects how the case mix may differ across use in the healthcare system.

			Therefore, the proportion of MIS can be seen as a strategic combination (case-mix) rather than a fixed value. For example, the focus should be on procedures with low laparoscopic surgery rates and high rates of conversion from open to RAS. **Description of proposed amendment:** If possible, it would be beneficial to see how different case-mixes impact the results and would be valuable for operational management.	The EAG have also demonstrated the added value of reducing open surgeries from the use of RAS, compared with RAS replacing standard MIS, which also helps inform case mix. This is discussed further across sections 8.3 and 8.4
96			**Economic Model** **Description of problem:** One of the main barriers in the uptake of robotic assisted surgery have been the hidden costs that impact the wider healthcare organisation, such as additional required equipment and operating costs. Robotic systems such as Versius were designed and built to integrate seamlessly in the existing operating theatres and flow, eliminating the need for: - expensive additional equipment (dedicated operating table for 'table motion', low temperature sterilisation machine such as STERRAD or similar); - significant and expensive theatre remodelling, installation of additional independent electrical circuits, floor reinforcement; - the transparent actual cost-per-case that CMR Surgical provides transfers the risk to the robotic supplier, and has been different from the theoretical "average" cost-per-case commercial modelling provided by the supplier that in reality translates into unpredictable costs during the programme and transfers the risk to the healthcare institution.	Thank you for your comment. EAG have discussed the limitations of theatre re-modelling in section 8.2. They acknowledge that some systems may require theatre remodelling, however, there are no clear costs of what this will be. Furthermore, even though this may be an expensive upfront cost, per procedure, over the lifespan on the theatre use, this may not impact the results. The EAG has been transparent about including costs, which

			Description of proposed amendment: It is important that the cost components and wider implications of the lifetime cost of RAS during the duration of the program, and its variability across suppliers, is captured in a transparent way. **Result of amended model or expected impact on the result (if applicable)** With a transparent commercial approach and the avoidance of hidden costs, the utilisation can be maximised, the learning curve shortened, while the risk of basing the clinical decision on cost - regarding which robotic instrument to use or how many robotic instruments during a case-, is eliminated.	are based on available evidence. Any potential additional costs not reflected in the model, which may increase the cost of RAS should be discussed by the committee.
97			**Economic Model** **Description of problem:** The safe implementation of surgical robotic systems, low conversion rates and complications have not been taken into consideration in the economic model. **Description of proposed amendment:** We would suggest that the positive impact on the economic model following the safe implementation of surgical robotic systems, low conversion rates and complications be taken into consideration in the analysis of the economic model. CMR Surgical submitted a registry paper that was declined and registry data is a good solution for this and includes multiple surgeries that can be grouped and analysed in this proposed way. This is real world data which will also evaluate safe implementation and will give valuable information on the learning curve. CMR surgical and other RAS companies have built a registry to collect this data. CMR	Thank you for your comment. This described problem has been captured in the model. The EAG have accounted for lower potential complication rates, and lower conversion rates in the model (as detailed in section 8.2.1). The literature used to populate parameters indicates similar outcomes to other papers raised during

			submitted this paper as published evidence and it was removed from the evidence. Given that it addresses some of the main recommendations by this NICE document, we would advocate that this registry paper is included to highlight an important approach to collect real world surgical data [Soumpasis I, Nashef S, Dunning J, Moran P, Slack M. Safe Implementation of a Next-Generation Surgical Robot: First Analysis of 2,083 Cases in the Versius Surgical Registry. Ann Surg. 2023 Oct 1;278(4):e903-e910. doi: 10.1097/SLA.0000000000005871. Epub 2023 Apr 10.PMID: 37036097].	consultation. Therefore, they do not feel the model requires updating, given the wide range of sensitivity analysis.
98			**Economic model** **Description of problem:** Outcomes are based on different procedures. **Description of proposed amendment:** Case mixes on proportion of the procedures being compared/evaluated with the weighted outcomes relevant to each procedure type. You will always need to associate **a specific procedure to the outcomes**. Outcomes/complications are highly procedure, system dependent. **Result of amended model or expected impact on the result:** A scenario for each procedure on each RAS system should be run using the most appropriate published data for that system.	Thank you for your comment. The EAG believe the evidence generation recommendations go some way to answering why this can't (feasibly) be done- it's infeasible to do it for every procedure and to group it you need expert consensus on how to group- as per PS comment, it's not even as simple as 'per specialty', it might make more sense to do it on anatomy. There are common outcomes to all procedures, of which the EAG have captured.

				They believe we have reflected a sensible range of scenarios, to cover potential outcomes. The suggestion by the company would lead to over 500 scenarios at least, which would not be useful for the committee to inform a decision. Furthermore, this also assumes that there is data available for every scoped procedure, and appropriate time to synthesise all of this data. This would not match the purposes of an EVA.
99			**Economic model** **Description of problem:** Why is the free loan scenario yielding higher cost? **Description of proposed amendment:**	Thank you for your comment. The free loan scenario is yielding a higher cost because of the disposable component cost, which is increased greater than the robotic platform, averaged over all procedures. Hence, it is a higher cost scenario.

			Data inputs may have been masked, but clarification of the difference of this costing system vs outright purchase would be helpful; the report did mention such free-loan structure isn't a popular approach. **Result of amended model or expected impact on the result:** Having this as a standalone scenario, rather than one of the base case scenarios would be more appropriate as it's not representative of the majority of situations within the NHS.	The EAG have clarified this is a less popular approach but given these were the three different types of costing structures raised by companies when asked, the EAG thought it would still be useful to keep in the report for each result. It may not be the most common costing scenario, but it is a potential costing scenario, so the EAG would advocate leaving the results as presented, so that the difference can be seen between each. They have detailed that it is less common as part of the report.
100			**Economic model** **Description of problem:** In general, the cost model does not lend itself well for use with the SP system **Description of proposed amendment:**	Thank you for your comment. The EAG have discussed throughout the heterogeneity across procedures. They have also engaged the company on the cost of the technology, of which

			As a company we requested for the SP system to be assessed separately from the MP systems however this was denied. **Result of amended model or expected impact on the result:** The SP has specific indications in particular surgical disciplines that includes different costings yielding different values.	they said they could not provide any further details for SP, which also makes the consideration for SP more difficult. If the company provide details on the differences, it is likely we can run scenarios to accommodate this in part 2 of the meeting if required.
101	General Responses	Economic Model	In general, the cost model does not lend itself well for use with the SP system. As a company we requested for the SP system to be assessed separately from the MP systems however this was denied. The SP has specific indications in particular surgical disciplines that includes different costing structures for both capital and instruments. Therefore, scenarios for SP within the cost model do not show the true value of this RAS system.	Thank you for your comment. The cost model is intended to capture use of RAS in a wide range of indications. This was considered to be the most helpful approach to support the decision problem.
102	General Response	Economic Model	The report states that given the wide scope of procedures assessed, only a 1-year time horizon was used and an annual volume of soft tissue procedures of 400 was assumed. We can appreciate the attempted approach to account for multiple procedures in a single model, but the outcomes will be dependent on procedure mix, system dependent conversion rates, and procedure dependent complication rates. Although directional, this model is not useful when trying to determine actual impacts for a given procedure.	Thank you for your comment. The EAG have responded to this in other comments and throughout the report, including a range of sensitivity analysis, and rationale for the approach, including detailed limitations.

103	1-336	Executive summary (Quality and relevance of the economic evidence)	It should be clearly stated in the report that the economic analysis conducted by the External Assessment Group (EAG) along with the information resulting from this assessment in the final NICE early value assessment (EVA) publication, should not be used as a basis for considerations of further investment in RAS and purchasing decisions. This is due to the high-level of uncertainty associated with the methodology, model outcomes and sensitivity analysis. This uncertainty is partly due to the methodology used by the EAG to generate results, where data from patients undergoing a variety of procedures across different specialties are combined to estimate model parameters. In several instances, data points for the model have been drawn from single publications related to specific procedures and indications, limiting their generalisability across the wide range of procedures for which RAS is employed. For example, MIS → open conversion rate 7.3% (Table 8.4) the data point is taken from a study on rectal resection. Rectal resection is more complex than many other procedures due to the confined operating space. This may be an overestimate when applied more broadly across procedures and generalised within the model. Given that the value of robot-assisted surgery (RAS) platforms is expected to differ depending on the procedure and speciality, it is inappropriate to base purchasing decisions on a model that does not adequately account the procedure- and speciality-specific benefits that RAS platforms provide. Medtronic kindly request that NICE include a statement within the executive summary clarifying that the model results described in both the EAR and NICE EVA final publication should not be used as a basis for further investment in soft tissue RAS platforms or associated purchasing decisions, due to the high level of uncertainty in the results. Medtronic kindly request that the generalisability of datapoints derived from single studies from specific procedures should be subject to scrutiny by the EVA committee's clinical experts.	Thank you for your comment. The EAG will agree that this model was an exploratory model but also feel that it may be a useful tool to inform future modelling and purchase decisions. It is also important to raise that the figures used in the model reflect similar outcomes in other available studies, therefore, they believe the direction of the results and scenarios conducted are a useful tool for decision makers. The EAG have acknowledged throughout the limitations of this type of approach. It's important to note the limitations also reflect potentially underestimating the costs of RAS. This includes the potential for double counting, and the omission of costs where there is no evidence

				(such as difference in energy or IT software). These limitations are reflected in the report.
104	14	1. Decision problem > Table 1.1: Summary of decision problem > Time horizon	Medtronic agree that the 1-year time horizon is insufficient to capture meaningful long-term outcomes, especially when evaluating the full clinical and economic impact of RAS. The limited timeframe fails to account for significant differences in the costs between the surgical approaches being compared. Much of the cost reducing impact of RAS, compared to surgical standard of care, occurs beyond the 1-year period. For instance, in colorectal cancer, the use of RAS platforms enables a higher proportion of patients to undergo surgical resection, leading to an improvement in progression-free survival and ultimately reduces the requirement for anticancer therapies in the future. Given these limitations, the 1-year time frame should not be used as a basis for decisionmaking regarding the adoption of RAS. A longer time horizon is necessary to reflect the benefits, costs and long-term value of technology, particularly in term of patient outcomes and resource utilisation over time.	Thank you for your comment. EAG have discussed in the report the limitations of using a shorter time horizon. They believe that longer-term time horizons should be conducted in future models. However, given the available evidence, and wide range of long-term outcomes across all included procedures, it was not feasible to include long-term outcomes in the model at this stage. The EAG believe the committee should consider the plausibility of long-term benefits, if these are likely to be realised, and if there are any surgeries which are unlikely to see long-term benefits.
105			**Economic Model** **Description of problem;**	Thank you for your comment. EAG have reflected the annutised

			Costing of robot-assisted surgery platforms The cost-comparison model appears to assume that all robots have an operational lifespan of 1-year when annuitising the cost of the platforms. By not annuitising the cost of each platform over its platform-specific operational life span, model results will not flect the true cost of introducing robotassisted surgery platforms. Please also refer to comment number 13. **Description of proposed amendment;** The model should be adapted that such cell E30 in the 'Set up' sheet allows for platform-specific operational lifespans to factor into the annuitisation calculation in cell E35 of the 'Costs' sheet. **Result of amended model or expected impact on the result;** By using platform-specific figures rather than an assumed figure of 1-year for consistency with the model time horizon, the annuitised cost of robot-assisted surgery platforms will reduce, reducing the incremental cost per cohort/procedure for robot-assisted surgery.	cost over the lifespan of the technology. They believe the confusion from this comes from the dummy model, where this figure on the set-up page is set to 1. This is because we used company provided feedback on the lifespan, which was considered CiC. The EAG are annuitizing the cost as they describe, based on the lifespan.
Comments on Section 8.1 Economic evidence				
106	72	Section 8.1 Economic evidence	The report discussed the economic evidence for the scoped technologies. I appreciate that it consistently used the term 'robotic platforms,' emphasising their potential as tools that can be shared across specialties in hospital settings. However, the economic evidence identified in Table 8.1 focuses only on specific procedures in the cost-comparison analysis. It is important to note that the cost per procedure may decrease with higher surgical volumes, meaning that the value-for-money of RAS becomes more significant in high-volume surgeries. Therefore, economic evaluations of robotic platforms should take a system-wide approach, considering multiple procedures.	Thank you for your comment. Table 8.1 summarises the literature evidence including that this evidence relates to specific studies in focused settings. In the summary (Section 8.4) the EAG have reiterated that these previous economic evaluations consider specific procedures

				which is different to the EAG model.
107	70	8.1 Economic evidence	**Quality and relevance of the economic evidence** *A total of 3 economic costing studies were identified.* It is stated that the quality of evidence for economic evaluation is of low quality. I wonder if following cost effectiveness studies were considered for this evaluation OBJ OBJ OBJ **1. Systematic review and economic modelling of the relative clinical benefit and cost-effectiveness of laparoscopic surgery and robotic surgery for removal of the prostate in men with localised prostate cancer** National Institutes of Health (NIH) (.gov) https://pubmed.ncbi.nlm.nih.gov › ... **Cost-effectiveness of Robotic-Assisted Radical Prostatectomy for localised prostate cancer in the UK. National Institutes of Health (NIH) (.gov)** https://www.ncbi.nlm.nih.gov › articles › PMC8980901	Thank you for your comment. The EAG acknowledge these costing studies, however, these are out of scope of the evaluation given they are for prostatectomy. RAS prostatectomy is already recommended in NICE guidelines, so has not been included here. No further changes.
108	74	Table 8.1 Narrative summary of economic studies	NICE has correctly recognised that the “Intuitive costing model does not account for the cost of the robotic platform, maintenance or additional instruments”. In addition to this, we would ask that the following implementation, additional equipment and operating costs associated with the deployment of some robotic systems, are also included in the statement.	Thank you for your comment. The EAG believe that the statement is clear that important costs are omitted from the

			- Implementation Costs
			  o Robot Related
			  ▪ Additional endoscopes, cameras and light guide cables (CMR Surgical delivers these included in the first package)
			  ▪ Second operating console (required for robots with periscope-style surgeon consoles)
			  ▪ Cost of freight (shipping robot to the hospital) (CMR Surgical as UK based supplier does not charge for shipping)
			  ▪ Virtual reality trainer
			  o Theatre Installation costs for some providers (CMR Surgical was designed to integrate with existing theatre equipment and hospitals do not incur in the significant costs listed below)
			  ▪ Theatre remodelling
			  ▪ Installation of additional independent electrical circuits
			  ▪ Floor reinforcement
			  ▪ Dedicated operating table (for 'table motion')
			  o Additional Sterilisation Equipment Implementation
			  ▪ Larger height sinks
			  ▪ Containers and baskets
			  ▪ Low temperature sterilisation machine (Sterrad or similar)
			  ▪ Additional ultrasonic washer disinfector
			  o Training and support
			  ▪ Surgeon and Theatre Staff training, device training/technical training is the legal responsibility for industry
			  ▪ Procedural training is guided by societies and ultimately the responsibility for the surgeon to be adequately trained in procedural surgery, lies with the hospital/organisation that has
				analysis. The EAG do not feel the detail of every possible cost that is omitted should be listed, to be concise. They think the largest, such as the robotic platform, and maintenance are the key ones to mention here. The EAG have tweaked the wording to say 'such as'

			responsibility for the patient. Costs for procedural training should be considered in the business plan for the robotic service ▪ Sterilisation team training - Operating Costs o Case related instruments and disposables ▪ Instruments – the costs associated with establishing a significant stock of instruments (usually enough for 6-months of procedures prior to implementation) - these costs are born by the manufacturer in true ‘pay-per-case' contracts. ▪ Instruments – the additional costs associated with replacing instruments early (i.e. an instrument with 10 ‘lives’ or ‘uses’, becoming unusable after 5 due to failures/breakages attributed to user error) - these costs are born by the manufacturer in true ‘pay-per-case' contracts, where the hospital is only invoiced for the procedures they do, rather than paying to maintain a stock of instruments ▪ Reusable trocars ▪ Single-use seals for the reusable trocars o IT, Software & Licenses ▪ Annual Simulator Licence fees ▪ Robot software updates ▪ Digital networking – to enable storage of data on hospital servers o Additional Sterilisation Equipment Use and Maintenance ▪ Cost per use of additional washer disinfectors/sterilisers ▪ Annual service contracts for those machines o Energy costs	

			▪ Energy consumed during normal use ▪ Energy consumed when in standby (some machines need to be left connected to the mains constantly to charge batteries) It is important that the cost components of the lifetime cost of RAS (and its variability across suppliers) is made clear to stakeholders involved in this EVA.	
109	70	8. Economic evidence > 8.1 Economic evidence	Medtronic kindly ask the EAG to consider the following economic publications in addition to the economic evidence analysed within this evaluation: 1. Sadri H, Fung-Kee-Fung M, Shayegan B, Garneau PY, Pezeshki P. A systematic review of full economic evaluations of robotic-assisted surgery in thoracic and abdominopelvic procedures. J Robot Surg. 2023 Dec;17(6):2671-2685. doi: 10.1007/s11701-023-01731-7. Epub 2023 Oct 16. PMID: 37843673; PMCID: PMC10678817.	Thank you. The EAG acknowledge these costing studies included in the Sadri 2023 review, however, these studies were either ineligible for this review (prostatectomy was out of scope) or were not retrieved due to the search approach adopted. See the detailed response to comment 80 for how the search for this pragmatic review was designed to identify studies of the eligible technologies and the eligibility criteria used meant studies had to specify the robot in the title or abstract to be included.

Comments on Figure 8.1 Conceptual model and Table 8.2 Assumptions and limitations of the current model				
110	81	Figure 8.1 Cost-comparison model structure	Fig 8.1 summarises some the cost considerations. I think it is important to recognise/incorporate the increasing cost of MIS surgery (compared to open). Integrated theatres are still commissioned with multiple high resolution 4K (sometimes 3D) monitors, expensive endoscopes and management/service contracts. The cost of RAS is indeed higher, but MIS and open should not be considered as financially equivalent and it would be advisable to make a clear distinction.	Thank you, this is a useful comment. The EAG have covered a range of different costs for MIS and open in the analysis, including maker open surgeries more expensive and cheaper than RAS (such as through PSA). We have made it clear in input tables that MIS and open have different costs, and in the discussion said this will vary between procedures. They have added some extra words into the structure description part to accommodate for this.
111		Table 8.2 Assumptions and limitations of current model	Economic Model The reasons for potentially increasing the number of surgeries may be due to the reduced burden of RAS. This is true but also may be because RASD means that surgeries which could not be done laparoscopically can now be done robotically.	Thank you for your comment. The EAG agree and have discussed there may be multiple reasons later on in the text, but that the primary feedback has been the reduced burden.
112		Table 8.2 Assumptions and	Economic Model	Thank you for your comment. This is an

		limitations of current model	Its' not just the physical health of the staff that RAS can improve cf. lap. A robot is a flagship for a hospital. Surgeons and theatre staff will be more likely to want to work in a hospital with the robot and thus it has a well-being benefit beyond just the physical.	interesting article. If the use of RAS impacts recruitment, and recruitment impacts waiting time for surgery, then this could impact the economics. However, quantifying this impact with the available evidence is not feasible. It's also not clear if this impacts staff recruitment or retention. The paper referenced does not actually link to retention, just that RAS adoption is important. The EAG have extended 9.2 to discuss this on patient and clinician acceptability. They have also added to 10.3 to talk about how you may be able to quantify this effect, if there is available evidence.
113	84	Table 8.2 Assumptions and limitations of the current model	In the assumptions and limitations section the impact of physician's health is correctly noted. Currently this is a non-quantifiable component. An additional non-quantifiable component of RAS is Institutional reputation (this is a major driver as shown in a published Pucher PH, Maynard N, Body S, Bowling K, Chaudry MA, Forshaw M, Hornby S, Markar SR, Mercer SJ, Preston SR, Sgromo B, van Boxel	Thank you for your comment. The EAG have added this to their discussion.

			GI, Gossage JA. Association of Upper GI Surgery of Great Britain and Ireland (AUGIS) Delphi consensus recommendations on the adoption of robotic upper GI surgery. Ann R Coll Surg Engl. 2024 Mar 6. doi: 10.1308/rcsann.2024.0014. Epub ahead of print. PMID: 38445587.) and has a likely/possible impact on staff recruitment and retention. I wonder whether it is worth adding this to the table	This point can be discussed at committee.
114	83	Table 8.2 Assumptions and limitations	In table on assumptions and limitations under physicians health the table says: *'It is reported that improving the physical burden on surgical staff is one benefit of RAS (Cole et al. 2018). At a per surgery impact, it is not feasible to quantify the potential impact of reducing physical burden on surgical staff with respect to economic outcomes. However, the EAG notes this is a valuable potential impact of RAS, as this may also lead to increased workforce retention or less absenteeism among surgical staff. This is discussed further in section 8.4.'* I do not see further discussion in the section 8.4 but there is further discussion in section 9.2 Retainment and longevity are important considerations. Whilst there is currently limited evidence for the cost analysis, there is good evidence for the ergonomic effects of laparoscopy and RAS in a closed console, which indicates significant workload on the surgeon. Overall RAS is superior to Laparoscopy and is likely to positively impact the surgeon's productivity and longevity [Yu, D., Dural, C., Morrow, M.M.B. et al. Intraoperative workload in robotic surgery assessed by wearable motion tracking sensors and questionnaires. Surg Endosc 31, 877–886 (2017). https://doi.org/10.1007/s00464-016-5047-y].	Thank you for your comment. The EAG believe this should say 9.2, so have amended this in the report, where this is discussed further. They have referred to evidence of the positive impact this may have on surgeons, including a range of studies. The EAG believe this study also supports the same conclusions as the studies referenced in the report. As stated in the report, although not quantified in the economic analysis, we do believe this is an important consideration.
115	79	8.2	Why was a threshold of 20k per QALY adopted when the conventional WTP in UK is typically between 20-30K GBP?	Thank you for your comment. The EAG believe given the high uncertainty in an early value assessment, the upper £30k threshold should not be

				considered at this stage. They have therefore only considered the results with respect to £20k. The manual is cited in the report, and we believe this aligns with the NICE reference case.
116	77-78	8. Economic evidence > 8.2 Conceptual model	Medtronic do agree with the EAR that the generalisability of the model is limited, and therefore should not be relied upon as a basis for determining further investment in RAS and purchasing decisions. Given the variations between clinical settings, patient populations and procedural outcomes, the economic model assumptions may not completely capture the subtleties required to inform procurement strategies. Medtronic believe that, for purchasing assessments, a detailed and tailored economic evaluation accounting for the difference in relevant outcomes for specific indications would be necessary to ensure that the decisions are well aligned with clinical settings and financial ability.	Thank you for your comment. The generalisability may have some limitations, but in nearly all scenarios and iterations, it suggests the short-term impact will lead to cost-incursions. The EAG believe this is useful for decision makers, to determine if long-term benefit is feasible, and if this can offset short-term cost impacts. The aim of the early value assessment is to determine the plausibility of cost-effectiveness, not to make a final decision if something is cost-effective or not. The EAG believe no further changes are required.

117	78	8. Economic evidence > 8.2 Conceptual model > Model structure	Medtronic agree that the 1-year time horizon is insufficient to capture meaningful long-term outcomes, especially when evaluating the full clinical and economic impact of RAS. The limited timeframe fails to account for significant differences in the costs between the surgical approaches being compared. Much of the cost reducing impact of RAS, compared to surgical standard of care, occurs beyond the 1-year period. For instance, in colorectal cancer, the use of RAS platforms enables a higher proportion of patients to undergo surgical resection, leading to an improvement in progression-free survival and ultimately reduces the requirement for anticancer therapies in the future. Medtronic kindly request the EAG to provide a statement at the beginning of Section 8.2 of the EVA, acknowledging that certain cost savings associated with RAS platforms are not captured in the EAG's model due to the limitations of its 1-year time horizon.	Thank you for your comment. The EAG believe this is already reflected in the text, where they discuss long-term benefits. The EAG acknowledges this early evaluation does not capture all potential benefits, due to a lack of evidence. However, the long-term benefits are currently unclear, such as improving progression-free survival. They have characterised this required benefit in QALYs, but have also stated in the report this could come from future cost savings. The EAG believe no further changes are required.
118	82	8. Economic evidence > 8.2 Conceptual model > Model structure	The use of probabilistic sensitivity analysis (PSA) to assess the impact of uncertainty in model parameters on incremental cost estimates is not suitable, given the diverse range of procedures across different specialties included in the population. Each procedure and specialty is associated with unique healthcare resource use and costs, making it highly uncertain to assign accurate probability distributions to these parameters across all softtissue procedures. The application of probability distributions that fail to adequately represent the uncertainty in model parameters risks producing biased estimates of the likelihood that RAS is costsaving. Medtronic, therefore, believe that the	Thank you for your comment. EAG agree there are limitations to PSA at this early stage. Assumptions have been made on some standard errors for parameters in the PSA. The EAG has provided PSA in line with NICEs guidelines

			deterministic analysis, which avoids these complexities, provides a clearer and more reasonable assessment.	for economic evaluation. However, we do believe that all sensitivity analysis should be considered. They agree that the DSA and scenario analysis is more useful than the PSA at this stage. However, the EAG believe that both are useful in the report.
119	85	8. Economic evidence > 8.2 Conceptual model > Assumptions and limitations	The assumption in the EAG model that patients undergoing RAS who require a change in surgical approach can automatically convert to open surgery is inappropriate. As noted in Table 8.2, evidence suggests that RAS can be converted to traditional laparoscopic minimally invasive surgery (MIS) during a procedure, which was not accounted for in the model. Open surgery is associated with a longer length of stay and higher complication rates compared to MIS; therefore, assuming all conversions lead to open surgery likely overestimates the costs associated with RAS, resulting in a biased estimate of incremental costs. As a result of this, Medtronic respectfully requests that the EAG request clinical experts review the reasonableness of this assumption. Following this the clinical experts within the NICE EVA committee will also have to review to review the reasonableness of this same assumption.	Thank you for your comment. The data we have used is specifically from studies which report conversion to open surgery, not just conversion rates in general. Clinical responses have indicated that conversions to conventional MIS are rare, but we admit not capturing this may underestimate the cost of RAS. The EAG believe the values used reflect the costs of conversion to open surgery, and have used values favourable

				to robotic platforms, with evidence suggesting they are less likely to lead to conversions that conventional MIS. They have made no further changes.
120	86	8. Economic evidence > 8.2. Conceptual Model > 8.2.1 Model inputs > Set up parameters	Medtronic kindly suggest the use of straight-line depreciation over a particular period for capital investments, such as the RAS platform. This may be more appropriate than the annuitisation approach with a 3.5% rate used in the current model (commonly used by NICE). Straight-line depreciation is commonly applied in NHS practice, ensuring that the cost of capital is evenly spread over the asset's useful life. This method could provide a clearer representation of the actual costs associated with the use of the RAS platform in practice. Using annuitisation at 3.5% instead of straight-line depreciation may inadvertently overestimate the costs in the economic model, as it introduces additional cost factors that may not typically reflected in the NHS. Medtronic, therefore, kindly ask the committee to consider this adjustment as it may better reflect the true financial impact over time.	Thank you for your comment. Company responses have indicated that interest rates are often applied to purchases spread over time. Hence, straight line depreciation is less likely to be representative of the true cost. Furthermore, we have varied the cost of robotic platforms across a range of sensitivity analysis to account for a range of different costs. Therefore, the EAG think plausible ranges for robotic platforms are already reflected within the report.
121	87	8. Economic evidence > 8.2. Conceptual Model > 8.2.1	Medtronic kindly request the associating reference for this statement “Standard surgical procedure costs were sourced from a cost-comparison study.”	Thank you for your comment. This cost is provided in Table 8.7 with its associated reference.

		Model inputs > Costs		
122	93	8. Economic evidence > 8.2. Conceptual Model > 8.2.1 Model inputs > Types of surgery > Table 8.6: Rates of Complications	Medtronic believes that an additional study could have been incorporated to better inform the economic model, particularly in representing the MIS complication rates, in addition to the company submission. The study by Guerini et al (2020), a large meta-analysis of twenty-one studies, assessed the frequency of surgical complications according to the Clavien-Dindo classification system. The meta-analysis specifically focused on the complications classified as Grade III or higher (Clavien-Dindo Grade ≥ III) between the RAS (RG) and laparoscopic surgery (LG) groups. This rate was lower in the RG group than the LG group: 4.13% (150/3631) and 6.44% (498/7727), [OR 0.66, (95%CI 0.49, 0.88) p = 0.005]" Medtronic kindly request the EAG to consider the inclusion of this study to Guerini et al (2020) in the economic evaluation: 1. Guerrini GP, Esposito G, Magistri P, et al. Robotic versus laparoscopic gastrectomy for gastric cancer: The largest meta-analysis. International Journal of Surgery. 2020/10 2020;82:210-228. doi:10.1016/j.ijsu.2020.07.053	Thank you for your comment. The EAG believe this is a useful study but does suggest anything significantly different to the existing evidence used. For instance, if this is used in the base case version of the model, it would only reduce the costs by approximately £14 per procedure (£460 per procedure). Furthermore, it is difficult to determine if this is more generalisable to all of soft tissue procedures than the current evidence used. Therefore, at the stage of an early evaluation, the EAG do not think it is necessary to update the model with additional data, given it will have minimal impact on the results.
123	88	8.3 Set-up parameters	The section discusses costs but does not consider operational inefficiencies. Potential hospital inefficiencies and downtime during the	Thank you for your comment. The EAG have included

			early adoption phase of RAS are not considered, which could lead to underestimating indirect costs.	differences in staff time, such as training, which may account for inefficiencies in procedure. However, they are not clear what other hospital inefficiencies, include at the early adoption, and has not been raised by other clinical experts. The EAG are happy for this to be discussed in more detail at the committee meeting. If there are other inefficiencies created by RAS, then the EAG would agree the model would underestimate the cost. They have added a statement in section 8.2.1 on the costs to clarify the impact of potential omissions.
124	95	8.3 Set-up parameters	The report does not address the potential additional costs of conversions from RAS to open surgery or MIS, even though conversions could incur significant costs. The report refers to cost differences but does not highlight conversions to other types of surgeries explicitly.	Thank you for your comment. Section 8.2.1 provides details on the inputs. Table 8.4 highlights the difference in conversions to open surgery and their associated costs. Different costs are

				applied for converted surgeries, as well as differences in length of stay and complications. The EAG have not included conversions from RAS to conventional MIS, given they did not locate any suitable evidence on this. Furthermore, clinical experts suggests this only really occurs in the learning curve, and is rare, so is unlikely to significantly impact the results.
Comments on Section 8.4 Summary and interpretation of the economic modelling				
125	118	8. Economic Evidence > 8.4 Summary and interpretation of the economic modelling > Key drivers of the economic result	Medtronic would like to request further clarification and rationale on the estimate of £2000 - £3000 in the statement “Depending on the values and scenarios selected, current estimates suggest that RAS will cost an additional £2,000 to £3,000 to conduct the surgery per person.”? Is this the annuatised cost for the technology?	Thank you for your comment. This estimated range is based on all the estimate scenarios conducted in the model. In the up front purchase model, the EAG have annuitised the cost based on the estimated life cycle of the robot, and then scaled this cost to a per procedure cost, based on utilisation

				in a year. This range includes all other costs stated in the report, such as maintenance and disposable components.
Comments on Table 8.7 Costs				
126	Page 97	Table 8.7 Costs	Economic Model why do we not have the maintenance cost for the SP when it is currently used in two NHS hospitals?	Thank you for your comment. Intuitive did not provide the maintenance cost for SP. Correspondence in the RFI and the correspondence log confirms they did not wish to provide any more costing information.
127	95	Table 8.7 Costs	Table 8.7. Specific cost comparisons are made in van Boxel GI, Carter NC, Fajksova V. Three-arm robotic cholecystectomy: a novel, cost-effective method of delivering and learning robotic surgery in upper GI surgery. J Robot Surg. 2024 Apr 23;18(1):180. doi: 10.1007/s11701-024-01919-5. PMID: 38653914. This publication compares the consumable cost of robotics in the NHS for cholecystectomy.	Thank you for providing this paper. The EAG have opted to continue to use the company provided costs for consumables/disposable equipment. They believe this is more reflective given they were provided directly from companies. They have conducted scenarios with no disposable costs, as well as included the impact of

				reducing disposable costs in the tornado. Therefore, they believe a range of different consumable costs are reflected in the results.
128	95-96	Table 8.7 Costs	It is incorrect to assume leasing costs are half of the up-front annuitised purchase costs for any of the robotic systems in scope. Depending on the structure of the lease, some RAS suppliers who fund leasing from within their organisations typically amortise the up-front cost of capital plus the cost of financing (an interest rate) over a 5-7 year term with no residual value guarantees at the end of the term. Conversely, CMR works with a finance partner who can offer a variety of finance solutions, some of which allow the hospital to pay less than the cost of capital over 5-7 years (based on a guaranteed residual value model). Though typically this is still around 90% of the up-front purchase cost over the term.	Thank you for your comment. The available literature and suggestions from companies is that leasing costs would be lower than a full upfront purchase. Companies have not provided these details when asked, therefore, we made an assumption of how this may impact the cost. We have varied the costs over a wide range. If the cost is closer to the upfront purchase, than a 50% reduction in most cases, this should be reflected in the committee discussion, that upfront purchase is the most likely cost option and results representative of purchasing for the NHS.
129	99	8.7 Costs	For NHS RAS Costs, NICE has correctly included the cost of training, staff time, robotic system, RAS maintenance, and RAS disposable	Thank you for your comment. The EAG

			components. In addition to this, CMR Surgical would ask that the following implementation and operating costs associated with the deployment of some robotic systems, should also have been included in the analysis.
			- Implementation Costs
			  o Robot Related
			  ▪ Additional endoscopes, cameras and light guide cables
			  ▪ Second operating console (required for robots with periscope-style surgeon consoles)
			  ▪ Cost of freight (shipping robot to the hospital)
			  ▪ Virtual reality trainer
			  o Theatre Installation
			  ▪ Theatre remodelling
			  ▪ Installation of additional independent electrical circuits
			  ▪ Floor reinforcement
			  ▪ Dedicated operating table (for 'table motion')
			  o Additional Sterilisation Equipment Implementation
			  ▪ Larger height sinks
			  ▪ Containers and baskets
			  ▪ Low temperature sterilisation machine (Sterrad or similar)
			  ▪ Additional ultrasonic washer disinfector
			  o Training and support
			  ▪ Surgeon and Theatre Staff training, device training/technical training is the legal responsibility for industry
			  ▪ Procedural training is guided by societies and ultimately the responsibility for the surgeon to be adequately trained in procedural surgery, lies with the hospital/organisation that has responsibility for the patient. Costs for
				have included many of the different costs on this list including training, disposable components, maintenance.
				
				Companies have specified that the robot-related are often included in the overall platform costs, therefore, we cannot disentangle these costs.
				
				There is some costs we have not included from this list including sterilisation, which we have explained that the evidence to cost this is very poor, given the heterogeneity across NHS trusts, and the fact this may be a substitute of existing equipment with robotic platform equipment.
				
				The stock of instruments would not impact the cost per procedure, only the up front costs, which we have discussed in

			procedural training should be considered in the business plan for the robotic service ▪ Sterilisation team training - Operating Costs o Case related instruments and disposables ▪ Instruments – the costs associated with establishing a significant stock of instruments (usually enough for 6-months of procedures prior to implementation) - these costs are born by the manufacturer in true ‘pay-per-case' contracts. ▪ Instruments – the additional costs associated with replacing instruments early (i.e. an instrument with 10 ‘lives’ or ‘uses’, becoming unusable after 5 due to failures/breakages attributed to user error) - these costs are born by the manufacturer in true ‘pay-per-case' contracts, where the hospital is only invoiced for the procedures they do, rather than paying to maintain a stock of instruments ▪ Reusable trocars ▪ Single-use seals for the reusable trocars o IT, Software & Licenses ▪ Annual Simulator Licence fees ▪ Robot software updates ▪ Digital networking – to enable storage of data on hospital servers o Additional Sterilisation Equipment Use and Maintenance ▪ Cost per use of additional washer disinfectors/sterilisers ▪ Annual service contracts for those machines o Energy costs ▪ Energy consumed during normal use	section 8.4 and 9.2 as an important consideration. Energy costs IT software, and theatre installation costs were not included, given the lack of evidence to populate these costs. The EAG have added further wording to the report, to clarify this may underestimate the cost of RAS from not including them.

			▪ Energy consumed when in standby (some machines need to be left connected to the mains constantly to charge batteries) It is important that the cost components of the lifetime cost of RAS (and its variability across suppliers) properly assessed by the EAG. The above costs are required for the deployment of some robotic systems but not others and they play a major role in the affordability. A retrospective analysis of spend on robots in the field in the UK would be a sensible approach to understanding the real-world costs.	
Comments on Table 8.10				
130	103	Table 8.10	Why is the free loan scenario yielding higher cost? Data inputs may have been masked, but clarification of the difference of this costing system vs outright purchase would be helpful; the report did mention such free-loan structure isn't a popular approach. Having this as a standalone scenario, rather than one of the base case scenarios would be more appropriate as it's not representative of the majority of situations within the NHS. The free loan scenario often happens when a manufacturer wishes to conduct a study but then the system can be used on patients not meeting the study inclusion criteria.	Thank you for your comment. Please see comment 99 for this response.
131	106	Table 8.11	The first two rows (on page 106) are a little confusing, i.e., why would costs go the opposite directions with halve/double MIS cost? Also for the free loan scenario, the costs would increase either way?	Thank you for your comment. This is because the cost of open surgeries will also change, and the absolute cost difference between open and conventional MIS will be higher. Therefore, a higher overall surgery cost of MIS and Open

				(and a greater absolute difference) means that converting an open surgery to RAS has a higher capacity to benefit. These results do not significantly change from the base case results. The EAG have also corrected a typo in the 'free loan' subgroup for the doubled procedures.
Comments on Section 9.2 Integration into the NHS				
132	126	9.2 Integration into the NHS	The section discusses the general reduction in physical strain on surgeons but does not go into quantifiable impacts such as longer working careers. While the physical impact of RAS on reducing surgeon fatigue is acknowledged, there is no detailed quantification of potential long-term benefits like increased career longevity.	Thank you for your comment. As stated in the report, the EAG believe this is an important consideration for the committee. At this stage, it is not possible to quantify how much longer someone may work due to RAS. Furthermore, scaling the economic benefits of this down to a per procedure benefit is not feasible. Therefore, the EAG have not provided any detailed

				quantification, because of available evidence and the practicalities of quantification. They still believe this potential benefit should be considered by the committee, even if not considered by the committee.
Comments on Section 10 Evidence gap analysis				
133	141	Section 10 Evidence gap analysis	I agree that, in real-world settings, hospitals typically use a mix of RAS, laparoscopic surgery, and open surgery. In many cases, the robotic platform is initially acquired for a urology department (often through purchase or donation). However, for operational reasons, such as maintaining annual case volume, the robotic platform may be shared across multiple specialties to maximise its utilisation. This may lead to indication creep that the use of RAS extends to the indications where the clinical benefit gains are marginal. Therefore, it's crucial to consider the system as a whole when evaluating its impact.	Thank you for your comment. The EAG believe this is an important consideration. They have reiterated throughout the report how different procedures are likely to have different overall outcomes. The EAG believe that prospective studies should limit indication creep, and only capture indicated populations. Scenarios in the modelling can be used to capture the potential impact of indication creep, using threshold analysis to understand the acceptable level of

				creep, which would change the cost-effectiveness results (assuming no difference in clinical outcomes).
134	142	Table 10.2 Evidence gap analysis for key economic outcomes	The section touches on procedure-specific grouping but does not delve into generalisability limitations. The report does not fully address the limitations in generalising outcomes across different types of soft-tissue procedures, even though it acknowledges that different procedures have different complexities.	Thank you for your comment. This is documented in section 8.4 and 8.2. The EAG acknowledges the key generalisability limitations, that the results may underestimate or overestimate the cost impact of RAS for specific procedures. The EAG have expanded the text in Table 8.2 to make sure this is explicitly reflected.
Comments on Table 10.3 Evidence generation recommendations				
135	143	Table 10.3 Evidence generation recommendations	This section mentions the need for future studies but does not quantify the impact on cost-effectiveness. The report does touch on the importance of patient acceptability of RAS but does not explore the potential cost-effectiveness impacts of patient preferences on the adoption of RAS.	Thank you for your comment. The EAG have added a sentence that all the listed evidence gaps will help inform the cost-effectiveness. They believe better understanding patient uptake will inform the utilisation of RAS, which

				is likely to be an important driver of cost-effectiveness.
136	143	Table 10.3 Evidence generation recommendations	Training (trainees) is totally missing	Thank you for your comment. This is a sensible recommendation as an evidence gap. The EAG have therefore added this into the table. The EAG believe it was covered within the understanding learning curve outcomes, although, happy to make this more specific.
Comments on Section 11.3 Conclusions on the gap analysis				
137	151	11.3 Conclusions on the gap analysis	If NICE recommendations were accepted then one can envisage **multi-speciality and multiplatform robotic assisted surgery programme** in many big Trusts which will introduce its own complexity around governance, risk management, co-ordination around workforce and productivity. These risks will need to be identified and manged. RCS Eng. has produced a document about developing a robust governance mechanism around robotic assisted surgery programme. https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/robotic-assisted-surgery/	Thank you for your comment. The EAG have added this at the end of the evidence gap section as a consideration, as well as sentence in the conclusion.

NICE National Institute for Health and Care Excellence

Medical Technologies Advisory Committee Interests Register

Topic: Robot-assisted surgery for soft-tissue 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
Michael Kolovetsios	Committee member	Financial interest	Medtronic company employee	Ongoing	18.09.2024	Ongoing	Declaration prevents participation
Katherine Boylan	Committee Member	Financial Interests	Leading on the negotiation of a research, development and innovation master agreement between my employing organisation (Manchester University NHS Foundation Trust) 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 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	Ongoing	16.09.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Katherine Boylan	Committee Member	Financial Interests	Received payment from 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	16.09.2024	One off	No further action
Katherine Boylan	Committee Member	Non - Financial professional & personal interests	CMR and Intuitive are suppliers to my employing organistion. I have not been involved in these supplier relationships. I understand my employing organisation is speaking to both companies around the local ambitions to expand the robotic surgery programme, but I haven't been directly involved to date.	Ongoing	16.09.2024	Ongoing	No further action
Jason Fleming	Specialist Committee Member	Financial Interests	One off consultancy discussion regarding ENT instrument requirements for TORS (CMR Surgical)	26.01.2024	26.01.2024	Ongoing	No further action
Jason Fleming	Specialist Committee Member	Non-Financial professional & personal interests	Member of TORS Medical Advisory Board for CMR Surgical (concerned developing clinical hazard guidelines; no financial compensation)	1/8/2023	25/9/2023	Ongoing	No further action
Jason Fleming	Specialist Committee Member	Non-Financial professional	PI for Prospective Clinical Study to Assess the Safety and Efficacy of Versius, in Transoral Robotic	13.12.2023	23.08.2024	Ongoing	**Declare and participate**

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		& personal interests	Surgery (**https://clinicaltrials.gov/study/NCT06112535)**				
Liviu Titu	Specialist Committee Member	N/A	NIL	N/A	05.2024	N/A	No Further action
Toby Page	Specialist Committee Member	N/A	NIL	N/A	05.2024	N/A	No Further action
Prasanna Sooriakumaran	Specialist Committee Member	N/A	NIL	N/A	05.2024	N/A	No Further action
Declan Dunne	Specialist Committee Member	Financial Interests	Applying to become specialist trainer in robotic surgery	Not yet completed application form but intending to pursue over next 6 months.	09.07.2024	Not yet applied	No further action
Declan Dunne	Specialist Committee Member	Financial Interests	Considering Private practice	Not yet completed application form but may start during next 6 months	09.07.2024	Not yet applied	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Declan Dunne	Specialist Committee Member	Non-Financial professional & personal interests	Robotic surgery has led to an improvement in my own physical health as I have had multiple spinal fractures and suffer with chronic back pain.	01.12.2022	09.07.2024	ongoing	No further action
Declan Dunne	Specialist Committee Member	Non-Financial professional & personal interests	Paper under submission relating to the outcomes of robotic gallbladder surgery	Currently under review by Journal	09.07.2024	Ongoing	No further action
David Van Dellen	Specialist Committee Member	Financial Interests	Gore - speaking on behalf and arranging immersion courses in hernia surgery and mesh (not relevant to this committee)	11.2020	09.07.2024	Ongoing	No further action
David Van Dellen	Specialist Committee Member	Financial Interests	Allergan - speaking on behalf and arranging immersion courses in hernia surgery and mesh (not relevant to this committee)	11.2016	09.07.2024	05.2023	No further action
David Van Dellen	Specialist Committee Member	Financial Interest	Egis - speaking on behalf and arranging immersion courses in hernia surgery and mesh (not relevant to this committee)	02.2022	09.07.2024	07.2023	No further action
David Van Dellen	Specialist Committee Member	Financial Interest	Chiesi - arranging educational courses for Transplant trainees (not relevant to this committee)	11.2023	09.07.2024	Ongoing	No further action
Sheraz Marker	Specialist Committee Member	Non-Financial professional & personal interests	Robotic assisted publications from US NCDB datasets	2022	07.2024	2023	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
David Chuter	Lay Specialist Committee Member	Non-Financial professional & personal interests	ICPV, Charity Chair	07.2023	07.2024	Ongoing	No further action
David Chuter	Lay Specialist Committee Member	Non-Financial professional & personal interests	Digestive Cancer Europe, Board member (Volunteer role)	05.2022	07.2024	Ongoing	No further action
David Chuter	Lay Specialist Committee Member	Non-Financial professional & personal interests	use MY data, Unpaid Director	02.2023	07.2024	Ongoing	No further action
John Organ	Lay Specialist Committee Member	Financial Interests	Royal marsden ppi panels paid for meetings	01.2024	07.2024	Ongoing	No further action
John Organ	Lay Specialist Committee Member	Non-Financial professional & personal interests	Ambassador throat cancer foundation. Founder life after lary no financial gain	05.2023	07.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Carmine Civille	Expert	Non-Financial professional & personal interests	BIARGS Nursing representative	2023	07.2024	Ongoing	No further action
Debashis Ghosh	Expert	Financial Interests	Private Practice		28.08.2024	Ongoing	No further action
Debashis Ghosh	Expert	Financial Interests	Medicolegal Expert		28.08.2024	Ongoing	No further action
Deena Harji	Expert	Financial Interests	Private Robotic Practice - HCA Manchester	17.07.2023	07.2024	Ongoing	No further action
Deena Harji	Expert	Financial Interests	Intuitive Surgical Educational Workshop Renumeration	14.04.2024	07.2024	Ongoing	No further action
Deena Harji	Expert	Non-Financial professional & personal interests	Executive member of Royal College of Surgeons Robotic and Digital Initiative	1.10.2020	07.2024	Ongoing	No further action
Deena Harji	Expert	Non-Financial professional	NiHR HS&DR. REINFORCE Project - Real-World, In-Situ, Evaluation of The Introduction And Scale-Up Of Robot Assisted	05.2021	07.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		& personal interests	Surgical Services In The NHS: Evaluating Its Impact On Clinical And Service Delivery, Effectiveness And Cost. £1.3 million. May 2021. Co-Applicant				
George Mochlolis	Expert	N/A	NIL	N/A	06.2024	N/A	N/A
Gijs Van Boxel	Expert	Financial Interests	Proctor for Intuitive Surgical	1.11.2021	06.2024	Ongoing	No further action
Gijs Van Boxel	Expert	Non-Financial professional & personal interests	Chief Investigator for STARLING Trial (Robotic-assisted cholecystectomy vs Laparoscopic cholecystectomy. Trial in planning phase, with a likely start date of Spring 2025	01.01.2024	06.2024	Ongoing	No further action
Gijs Van Boxel	Expert	Non-Financial professional & personal interests	Committee Member RCS RADAR	01.01.2023	06.2024	Ongoing	No further action
Jajini Vargese	Expert	N/A	NIL	N/A	28.08.2024	N/A	N/A
James Tibbott	Expert	Financial Interests	Paid presentation on behalf of Gideon Richter on our experience of using their new drug RYEQO for fibroids	04.2024	06.2024	06.2024	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
James Tibbott	Expert	Financial Interests	I am the local TPD for the delivery of gynaecology training in Yorkshire and humber. How we could deliver the SITIM on robotic surgery and simulation for that is something I am looking at	09.2022	06.2024	09.2025	No further action
James Tibbott	Expert	Non-Financial professional & personal interests	I will be the PI for the REINFORCE study looking at the benefits of robotic surgery	01.2024	06.2024	Ongoing	No further action
Joshua Burke	Expert	Indirect Interest	Charity Trustee - The Association of Surgeons in Training	12.2023	06.2024	Ongoing	No further action
Joshua Burke	Expert	Indirect Interest	Charity Trustee - CORESS Patient Safety Chairty	12.2023	06.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Karen Redmond	Expert	Financial Interests	Work part-time in clinical private practice. Otherwise nothing to declare.	2011	05.09.2024	Ongoing	No further action
Karen Redmond	Expert	Non-Financial professional & personal interests	Co-chair Thoracic Surgery Subcommittee and Trustee SCTS UK & Ireland	2023	05.09.2024	Ongoing	No further action
Karen Redmond	Expert	Non-Financial professional & personal interests	ITS Council Member, Ireland	2022	05.09.2024	Ongoing	No further action

Karen Redmond	Expert	Non-Financial professional & personal interests	Publications: Lung volume reduction surgery: a micro-costing analysis from a national tertiary referral centre. Mulryan K, Sorensen J, Waller D, **Redmond K.**Eur J Cardiothorac Surg. 2024 Jun 3;65(6):ezae222. doi: 10.1093/ejcts/ezae222.PMID: 38833683 METHODS: Three pathways were defined by their surgical procedures: bronchoscopic endobronchial valve insertion (EBV-LVRS), video-assisted thoracic surgery LVRS and **robotic**-assisted thoracic surgery LVRS. The costing model considered use of hospital resources from the LVRS … Is **robotic** lobectomy cheaper? A micro-cost analysis. Shanahan B, Kreaden US, Sorensen J, Stamenkovic S, **Redmond KC.**J Robot Surg. 2022 Dec;16(6):1441-1450. doi:		05.09.2024		No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			10.1007/s11701-022-01377-x. Epub 2022 Feb 28.PMID: 35226288 **Free PMC article.** Higher capital costs and operating room costs associated with Lobectomy via **Robot** Assisted Thoracic Surgery (RATS) have previously been suggested as the principal contributors to the elevated overall cost. This study uses a micro-costing approach to a previous analysis of … **Robotic** sleeve lobectomy-recent advances. Shanahan B, O'Sullivan KE, **Redmond KC.**J Thorac Dis. 2019 Apr;11(4):1074-1075. doi: 10.21037/jtd.2019.02.103.PMID: 31179042 **Free PMC article.** No abstract available. A systematic review and meta-analysis of **robotic** versus open and video-assisted thoracoscopic				

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			surgery approaches for lobectomy. O'Sullivan KE, Kreaden US, Hebert AE, Eaton D, **Redmond KC.**Interact Cardiovasc Thorac Surg. 2019 Apr 1;28(4):526-534. doi: 10.1093/icvts/ivy315.PMID: 30496420 It is inferior to both VATS and open with respect to operative duration (**robotic** vs. VATS; WMD 4.98, 95% CI 2.61-7.36, P < 0.001, **robotic** vs. open WMD 65.56, 95% CI 53.66-77.46, P < 0.00001). ...CONCLUSIONS: This is the largest published systematic review and… A systematic review of **robotic** versus open and video assisted thoracoscopic surgery (VATS) approaches for thymectomy. O'Sullivan KE, Kreaden US, Hebert AE, Eaton D, **Redmond**				

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			KC. Ann Cardiothorac Surg. 2019 Mar;8(2):174-193. doi: 10.21037/acs.2019.02.04.PMID: 31032201 **Free PMC article.** Review. Original research articles comparing **robotic** to VATS or to open thymectomy for myasthenia gravis, anterior mediastinal masses, or thymomas were included. ...**Robotic** thymectomy was comparable with the VATS approach; both have the advantage of avoiding median sternoto …				
Karen Redmond	Expert	Indirect interests	Co-chair Thoracic Surgery Subcommittee and Trustee SCTS UK & Ireland	2023	05.09.2024	Ongoing	No further action
Leanne Ashrafian	Expert	Financial Interests	Bristol Myers Squibb – Advisory board /speaking engagements	03.2024	31.07.2024	03.2024	No further action
Leanne Ashrafian	Expert	Financial Interests	Astra Zeneca –Speaking engagements	06.2024	31.07.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Leanne Ashrafian	Expert	Non-Financial professional & personal interests	Robotic representative for Society of Cardiothoracic Surgeons Thoracic Surgery Subcomittee	2022	31.07.2024	Ongoing	No further action
Leanne Ashrafian	Expert	Non-Financial professional & personal interests	Participation in Health Technology Wales (HTW) Evidence Appraisal Report Robot-assisted thoracic surgery	03.2024	31.07.2024	01.2024	No further action
Marrielle Nobbenhuis	Expert	Financial Interests	Proctor Intuitive Surgical	2015	05.2024	Ongoing	No further action
Marrielle Nobbenhuis	Expert	Non-Financial professional & personal interests	Past president of BIARGS	06.2021	05.2024	11.2023	No further action
Marrielle Nobbenhuis	Expert	Non-Financial professional & personal interests	council member SERGS	06.2022	05.2024	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Nuha Yassin	Expert	Financial Interest	Robotic proctor/trainer for DaVinci	08.2022	05.2024	Ongoing	No further action
Nuha Yassin	Expert	Non-Financial professional & personal interests	IRCSEng council member and lead for future of surgery, robotics and digital surgery (a device agnostic college and programme)	07.2023	05.2024	Ongoing	No further action
Timothy Pencavel	Expert	Financial Interest	Proctor in HPB Robotics - Intuitive Europe	02.2024	05.2024	Ongoing	No further action
Neil Hawkins	Committee Member	Financial interests	Alongside my academic role, I have provided advice and undertaken analysis for a number of pharmaceutical and biotech companies related to HTA activities and am listed as a director of a company providing HTA services. I have not provided consultancy to any of the stakeholders listed for this appraisal.	Ongoing	20.09.2024	Ongoing	No further action