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. As is standard in NICE guidance and guidelines, for the original external assessment report, we limited prioritised studies to named technologies. Prioritisation of studies was necessary due to the large volume of literature on robot assisted surgery to consider in a limited time period. 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) **conventional MIS:** 354 (60.5)	• 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
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) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore	**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 totally robotic or hybrid, n= 237). GREEN	• 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 arm (withdrew as insurance required patient attend a non-study hospital for surgery). Complete case analysis.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
Setting: Hospital		**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%)		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) **Comparator:** conventional MIS **GREEN**	**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 same indication between July 19th 2005 and May 22nd 2008. **GREEN** **Mean age**: Da Vinci (specific model not named): 61 conventional MIS: 62	• 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 that study had a small sample size.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Male gender n (%): Da Vinci (specific model not named): 8/26 (30.8*%)		
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 **Setting:** University Hospital Elangen-Nuremberg	**Design:** Retrospective comparative cohort study **GREEN** **Intervention:** Da Vinci (specific model not named) **Comparator:** conventional MIS **GREEN**	**Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma that were treated with either RAS (n=24) or 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)	• Recurrence • Disease-free survival • Operative time • Blood loss • Length of stay • Feeding tube requirement	Comparison of baseline demographic and clinical characteristics for each cohort are reported, no significant differences. Small sample size.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
		Male gender n (%): Da Vinci (specific model not named): 22/30 (73.3%) conventional MIS: 17/24 (70.8%)		
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) **Comparator 3**:Open surgery **GREEN**	**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 endoscopic, 15 laparoscopic, 26 open and 14 robotic. **GREEN** **Mean (SD) age**: 46.6 (9.3) **Male gender n (%):** 48/79 (61%)	• 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.
Patel et al 2023 (NCT02617186) (Patel et al. 2023) **Location:** Canada, France and the US **Setting:** St. Joseph’s Healthcare, Hamilton; Toronto General Hospital;	**Design:** RCT **GREEN** **Intervention:** Da Vinci (various models)	**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**	• 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

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
UF Health Shands Hospital; and CHU-Hôpitaux de Rouen. **Indication:** Patients indicated for minimally invasive pulmonary lobectomy for stage I to III.	**Comparator:** MIS (video-assisted thoracoscopic surgery) **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%)		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. 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)	**Indication**: Patients undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty. **GREEN**	• Mortality • Length of hospital stay	Predominantly male population, large sample size (total n = 993, 276). Retrospective analysis of a large hospital patient-level dataset.

Study name and location	Design and intervention(s)	Participants	Outcomes	EAG comments
	Comparator 1: conventional MIS **Comparator 2:** Open surgery **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) **conventional MIS:** 80,889 (74) **Open:** 570, 426 (78)		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%).

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. 2 studies were 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.

(Teljeur et al. 2014) conducted a cost-minimisation analysis comparing robot-assisted hysterectomy using the da Vinci system (unspecified model) with traditional open and laparoscopic surgery for patients undergoing hysterectomy in the Republic of Ireland. Data from a mix of European and US trials, and existing analyses were used to estimate the incremental cost of RAS. Teljuer et al. estimated RAS to cost €3,291 higher per procedure compared with the existing mix of procedures. The study also estimated the impact of robot lifespan and patient volume on the incremental cost and concluded that, although RAS has higher upfront costs, these can be somewhat mitigated by increasing the volume of patients treated and ensuring maximum robot lifespan. As a cost-minimisation analysis, the study assumed equivalent clinical outcomes between robot-assisted, open, and laparoscopic hysterectomy and therefore did not include a comparison of health outcomes such as QALYs or conduct a full cost-effectiveness evaluation. Further to this, the study had a time horizon of 12 months and so long-term outcomes, such as re-intervention procedures and complications downstream, were not captured. The rapid advancements in RAS technologies since the data of publication (2014) may mean that the results of the analysis are somewhat outdated. Given the age of the publication, the mix of European and US data, and that the study used a non-UK healthcare perspective, the results should be interpreted with caution when applied to current UK healthcare settings.

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) **AMBER**
Primary – surgeon level	

Outcomes	Da Vinci Si/X/Xi
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**
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**

Outcomes	Da Vinci Si/X/Xi
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

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

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

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:

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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

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

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

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

Li K-P, Chen S-Y, Wang C-Y, et al. (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

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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Pyrgidis N, Volz Y, Ebner B, et al. (2024) Evolution of Robotic Urology in Clinical Practice from the Beginning to Now: Results from the GRAND Study Register. European Urology Focus

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

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

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

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

Teljeur C, O'Neill M, Moran PS, et al. (2014) Economic evaluation of robot-assisted hysterectomy: a cost-minimisation analysis. BJOG 121(12)**:** 1546-53

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
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

Reference	Deprioritisation reason
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) Ileus (median days): 3 (12.5) Wound problems: 2 (8.3)	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 (%)	
					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) p = 0.123	**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):** -6.9 (-11.4 to -2.3) p = 0.003	NR
Kim et al 2018 (Kim et al. 2018)	**Intervention:** Da Vinci Si (n=66)	**Da Vinci Si:** 1 (1.5) **conventional MIS:** 0 (0)	NR	**Perioperative complications:**	NR	**CD I:** **Da Vinci Si:** 6 (9.1)	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 (%)	
Location: South Korea **Setting:** National Cancer Centre **Indication:** Middle or low rectal cancer	**Comparator:** conventional MIS (n=73)	p = 0.475		**Da Vinci Si:** 23 (34.8) **conventional MIS:** 17 (23.3) p = 0.133		**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) **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,	**Intervention:** Da Vinci	**Da Vinci (unspecified model)**:	NR	**Da Vinci (unspecified model)**:	**Within 30 days:** Da Vinci (unspecified	NR	**SF-36v2 Physical**

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 (%)	
NCT01736072) (Jayne et al. 2017) **Associated records:** (Corrigan et al. 2018) Jayne et al 2019 HRQoL data from: (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.	(unspecified model): (n=236) **Comparator:** conventional MIS: (n=230) Complete case	19/236 (8.1%) **conventional MIS**: 28/230 (12.2%) **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		36/236 (15.3%) **conventional MIS**: 34/230 (14.8%) **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	model): 78/236 (33.1%) conventional MIS: 73/230 (31.7%) <u>Unadjusted risk difference</u> −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%)		**component (mean, SD):** **Da Vinci (unspecified model):** Baseline (n=226): 51.4 (8.9) 30 days (n=213): 42.4 (8.55) 6 months (n=199): 48.7 (7.95) **conventional MIS:** Baseline (n=221): 51.6 (8.79) 30 days (n=198): 42.0 (8.42)

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 (%)	
					<u>Unadjusted risk difference</u> 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		6 months (n=195): 48.3 (8.9) p= n.s. at 6 months **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)

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: 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 squamous cell carcinoma	**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 (%)	
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 T3 stage oropharyngeal squamous cell carcinoma.	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	NR	NR	NR	NR	NR
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 (%)	
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 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	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 (%)	
	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 lobectomy for stage I to III.	**Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	**Conversion to thoracotomy:** Da Vinci (various models): 6/81 (7.41%) conventional MIS: 13/83 (15.66%) p=0.10	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%) 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%)	NR	**EQ-5D-5L Generated HU scores – mean (SD)** **HU score at 3 weeks: Da Vinci, various models:** 0.78 (SD 0.17) **Conventional MIS:** 0.74 (SD 0.19) p = 0.18

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: 28/67*(41.79%) p=0.86 **Patients with AE 3 to 7 weeks from 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		**HU score at 7 weeks:** **Da Vinci, various models:** 0.84 (SD 0.14) **Conventional MIS:** 0.78 (SD 0.18) p = 0.04 **HU score at 12 weeks:** **Da Vinci, various models:** 0.85 (SD 0.10)

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 (%)	
					models): 21/62* (33.87%) 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 discharge (n %):**		**Conventional MIS:** 0.80 (SD 0.19) p = 0.02 **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:**

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 (various models): 18/61* (29.51%) conventional MIS: 21/65* (32.31%) p=0.73		**Da Vinci, various models:** 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 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	NR	NR	NR

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)		
Jayne et al 2017 (ROLARR trial, NCT01736072) (Jayne et al. 2017) **Associated records:**	**Intervention:** Da Vinci (unspecified model): (n=236)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
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.	**Comparator:** conventional MIS: (n=230) **Complete case**	
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 **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Intervention:** Da Vinci (specific model not specified, n=313) **Comparator:** TLM (N=195)	NR
Sievert et al 2021 (Sievert et al. 2021) **Location:** Germany	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator: conventional MIS (n=30)**	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 Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.		
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 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.	**Intervention:** Da Vinci (various models, n=83) **Comparator:** conventional MIS (video-assisted thoracoscopic surgery, n=81)	NR

Study name and location	Technology name and number of patients	Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Score N (%)
Indication: Patients indicated for minimally invasive pulmonary 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)	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 **Indication:** Middle or low rectal cancer	**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
Da Vinci (unspecified model)				

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
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 **Indication:** Patients with head and neck squamous cell carcinoma	**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) Mean difference (favouring RAS): -8, p=0.001	NR
O'Hara et al 2024 (O'Hara et al. 2024)	**Intervention:** Da Vinci (specific model not specified, n=313)	NR	**Length of hospital stay n (%), median (95% CI)** **RAS:** 313 (61.6%), 5 (5 to 6)	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
Location: UK, Germany, France, US, Australia **Setting:** 40 centers **Indication:** HIV-positive oropharyngeal carcinoma stage	**Comparator:** TLM (N=195)		**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	
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
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	**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	NR	NR	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: 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).	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.			
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	**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
Pyrgidis et al 2024 (Pyrgidis et al. 2024) **Location:** Germany **Setting:** Hospital database	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428)	**Number of surgeries between 2005 and 2021:** **Da Vinci:** 150, 432 **conventional MIS:** 109, 428 **Open:** 733,416		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 undergoing radical prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Comparator:** Open surgery (n=733,416)	A full breakdown of the surgeries per year, including the increase in RAS, can be found in Appendix A		

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) **Location:** South Korea **Setting:** National Cancer Centre	**Intervention:** Da Vinci Si (n=66) **Comparator:** conventional MIS (n=73)	NR	**Present pain intensity index score, median (range):** **Postoperative day 1:**	NR	NR

Indication: Middle or low rectal cancer			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, 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	NR
Hammoudi et al 2015 (Hammoudi et al. 2015) **Location:** France **Setting:** Tours University Hospital	**Intervention:** Da Vinci (unspecified model): (n=26)	NR	NR	NR	**Local recurrence leading to further surgery**: Da Vinci (unspecified model): 2/26 (8%)

Indication: Patients with head and neck squamous cell carcinoma	**Comparator:** conventional MIS: (n=26)				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) **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	**H&N35 pain score, mean (SD) [median (IQR)]:** **RAS baseline (n=272):** 17.5 (19.7) [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**	NR	NR

[1] Percentages are as-reported in text.

			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 **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	NR	NR	**Intraoperative re-resection (n %):** Da Vinci (specific model not named): 9/24 (37.5%) 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	**Intervention:** Da Vinci Xi and SP systems **Comparator:** conventional MIS (endoscopic or laparoscopic surgery) or open surgery	NR	NR	NR	NR

(response rate 32.2%): 19 urologic, 22 gynecologic, 3 thoracic, and 35 general (including breast, colorectal, hepato-pancreato-biliary, and bariatric).					
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	**Postoperative pain during admission measured by EQ-5D, median (IQR):** Da Vinci (various models): 2.82 (1.69 to 4.40) conventional MIS: 2.84 (1.81 to 4.43) p=0.88	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 nephrectomy,	**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)	NR	NR	NR

nephroureterectomy or pyeloplasty		**Radical cystectomy mortality, n (%), Estimate (95% CI), p value:** **Da Vinci:** 84 (3.7), 0.8 (0.63 to 0.99), 0.04 **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
Kim et al 2018 (Kim et al. 2018) **Location:** South Korea	**Intervention:** Da Vinci Si (n=66)	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
Setting: National Cancer Centre **Indication:** Middle or low rectal cancer	**Comparator:** conventional MIS (n=73)					
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) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or	**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 **Overall survival** 5 year mortality: Da Vinci (unspecified model): 23/237 (9.7%) conventional MIS: 23/234 (9.8%)	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
abdominoperineal) mesorectal resection.				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% conventional MIS: 85% p=0.76	**No further treatment:** Da Vinci (unspecified model): 10/26 (38%) conventional MIS: 8/26 (29%) p=0.49 **Postoperative radiotherapy:** Da Vinci (unspecified model): 6/26 (24%) conventional MIS: 11/26 (43%) p=0.17 **Postoperative chemotherapy:** Da Vinci (unspecified	**Use of feeding tube (n, %)**: Da Vinci (unspecified model): 17/26 (65.4*%) conventional MIS: 26/26 (100%) p=0.004 **Duration of feeding tube use (days, mean SD)**: Da Vinci (unspecified model): 9 (10) conventional MIS: 16 (10) p=0.01

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**
					model): 10/26 (38%) conventional MIS: 7/26 (28%) p=0.48	
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	**Duration of feeding tube use in days, median (95% CI):** **Da Vinci (n=85):** 6 (4, 6) **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)	**Intervention:** Da Vinci (specific model not	NR	NR	**Disease-free survival at 125 months:**	**Da Vinci (specific model not named)**:	**Use of feeding tube (n, %)**:

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: Germany **Setting:** University Hospital Erlangen-Nuremberg **Indication:** Patients diagnosed with T1 to T3 stage oropharyngeal squamous cell carcinoma.	named, n=24) **Comparator:** conventional MIS (n=30)			Da Vinci (specific model not named): 86.7% conventional MIS: 87.5% p=0.892	Radiotherapy: 7/24 (29.2 %) Radiochemotherapy: 11/24 (45.8 %) **conventional MIS:** Radiotherapy: 9/30 (30 %) Radiochemotherapy: 8/30 (26.7 %) p=0.133	Da Vinci (specific model not named): 13/24 (54.2%) conventional MIS: 17 (56.7%) p=0.854 **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	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14)	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
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).	**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					

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 **Setting:** Hospital database **Indication:** Patients undergoing radical	**Intervention:** Da Vinci (n=150, 432) **Comparator:** conventional MIS (n=109, 428)	**Length of hospital stay cases, median (range), estimate (95% CI), p-value v open surgery** **Radical prostatectomy:**	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
prostatectomy, radical cystectomy, radical nephrectomy, partial nephrectomy, nephroureterectomy or pyeloplasty	**Comparator:** Open surgery (n=733,416)	**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 **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), -				

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
		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) **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:**				

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: 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 **Indication:** Middle or low rectal cancer	**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 higher in autonomy (t test p=0.002).
Da Vinci (unspecified model)				

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
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
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

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
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 stage oropharyngeal squamous cell carcinoma.	**Intervention:** Da Vinci (specific model not named, n=24) **Comparator:** conventional MIS (n=30)	NR	NR	NR
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	**Intervention:** Da Vinci Xi and SP systems (surgeon with dominant robotic modality* n=14) **Comparator:** conventional MIS (dominant endoscopic n=10;	**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	NR	NR

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
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).	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 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		
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

Study name and location	Technology name and number of patients	Career longevity and musculoskeletal injury	Human factors	Learning curve
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, 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) **Difference between Da Vinci Si and conventional MIS (95% CI)**: -1.7 (-3.9 to 0.3)	**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
		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) **Location:** UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore. **Setting:** Hospital **Indication:** Rectal cancer, (high or low anterior resection or	**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
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 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	**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

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
stage oropharyngeal squamous cell carcinoma.				
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)	**Design:** RCT	NR	**Total time in operating room (minutes, median IQR)**	NR

Study name and location	Technology name and number of patients	Readmission at 30 days N (%)	Operating time Mean (SD)	Staffing requirements
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): 203 (165 to 234) conventional MIS: 193 (171 to 225) p=0.62	
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 laparotomy and complications related to single port surgery, post-operative data. **Study designs:** 5 retrospective (1 comparative), 1 prospective. No further data reported.	• 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
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. **Study designs:** 1 RCT, 4 prospective studies, 26 retrospective studies, study designs unclear.	• 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.
Fu et al 2024 (Fu S et al. 2024) **Number of included studies:** 22	**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.	• 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	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).

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Of which conducted in the UK: 3	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.	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.	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 **Of which conducted in the UK:** 0	**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 **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.	• 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 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.	Lack of RCT evidence highlighted as a limitation. The 10 observational studies were assessed using Newcastle Ottawa scale, scoring 6 or 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)	**Aim:** To assess long-term outcomes with robotic versus laparoscopic/thoracoscopic and open surgery for colorectal, urologic, endometrial, cervical, and thoracic cancers	• Cervical cancer: overall survival and disease-free survival were similar between robotic and laparoscopic or open.	Vast amount of the data is from retrospective studies. Unclear how much evidence is applicable to the UK context.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Number of included studies: 199 **Of which conducted in the UK:** Not reported	**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	• 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	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.
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.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
			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 **Of which conducted in the UK:** 0	**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. **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	• 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 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.	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 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	• 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	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.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
	Study designs: 5 retrospective comparative studies	major complication rate compared to open surgery. • The operation time for open surgery was shorter than that for RAS.	Limitations: studies are retrospective and of intermediate quality. Some studies included more patients with only 1 kidney and higher preoperative chronic renal 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)	**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	• 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,	No quality assessment or risk of bias assessment of the included studies was performed.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Number of included studies: 9 **Of which conducted in the UK**: Not reported	management of submandibular gland sialolithiasis. **Population:** Surgery submandibular gland sialolithiasis. **Intervention:** TORS (any platform/model) **Comparator(s):** Not reported **Outcome(s):** Not reported **Study designs:** Not reported	submandibular gland preservation, and reduced risk of permanent postoperative lingual nerve damage.	Characteristics of included studies table does not include study designs or geographic location. 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 **Study designs:** 1 RCT, 1 retrospective cohort study	• 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. • These provisional results support RAS as a safe alternative to conventional surgery. • The paucity of data limits the robustness of conclusions. Further high-quality	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
		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 costs, short-term follow up in all but 4 studies.
Wang et al 2024 (Wang et al. 2024)	**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	• Intraoperative blood loss of RAS was significantly less than that of VATS, and the difference was statistically significant.	Majority of included data was retrospective (14/18 studies). No further information was given on study design.

Study name	Aim, PICO and included study designs	Key findings	EAG comments
Number of included studies: 18 **Of which conducted in the UK:** 0	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	• 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.	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.
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-	• 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.	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

Study name	Aim, PICO and included study designs	Key findings	EAG comments
	year overall survival rate, 3-year disease-free survival rate. **Study designs:** 3 RCTs, 8 non-RCTs	• 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.	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.