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Supplementary Material for: A systematic review and in-depth analysis of outcome reporting in early phase studies of colorectal cancer surgical innovation

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1. Search strategy

An information specialist at the University of Bristol, Faculty of Health Sciences was involved in the development of a search strategy which was subsequently reviewed using the Peer Review for Electronic Search Strategies template. Search terms for 1) “colorectal cancer”, 2) “early phase studies” and 3) “invasive procedures”, were combined using the Boolean operators and limited to one year (January 2018 - 2019) and English language articles. All search terms (**Table S 1**) were entered into 3 databases (OvidSP, Web of Science, Cochrane Central Register of Controlled Trials) and search operators were adapted to the specifications of the relevant database.

Table S 1. Search terms used in OvidSP versions of Medline and Embase

Colorectal cancer
1. exp Rectal Neoplasms/ 2. (rect\$ adj3 (cancer\$ or tumor\$ or neoplasm\$ or carcinoma\$ or malignan\$)).tw. 3. (rect\$ adj3 adenocarcinoma).tw. 4. or/1-3
Early phase studies
1. (early adj phase).tw. 2. (phase adj I).tw. 3. (phase adj II).tw. 4. innovat*.tw. 5. transformative.tw. 6. new.tw. 7. novel.tw. 8. prototype.tw. 9. initial.tw. 10. experimental.tw. 11. emerging.tw. 12. IDEAL.tw. 13. Feasibility.tw. 14. (first adj case*).tw. 15. (initial adj case*).tw. 16. (investigation adj device adj exemption).tw. 17. IDE.tw. 18. (first adj in adj human).tw. 19. (1st adj in adj human).tw. 20. preliminary.tw. 21. (proof adj of adj principle).tw. 22. case reports/ 23. Medical Records/ 24. clinical trial, phase i/ 25. clinical trial, phase ii/ 26. observational study/ 27. comparative study/ 28. evaluation study/ 29. Feasibility Studies/ 30. Pilot Projects/

31. Cohort Studies/ 32. Therapies, Investigational/ 33. Device Approval/ 34. medical device recalls/ 35. safety-based medical device withdrawals/ 36. or/1-35
Invasive procedures
1. invasive.tw. 2. incision.tw. 3. cut.tw. 4. percutaneous.tw. 5. puncture.tw. 6. (natural adj1 orifice).tw. 7. endoscop*.tw. 8. colonoscop*.tw. 9. gastroscop*.tw. 10. thorascop*.tw. 11. laparoscop*.tw. 12. arthroscop*.tw. 13. bronchoscop*.tw. 14. catheter.tw. 15. scalpel.tw. 16. surgery.tw. 17. surgical.tw. 18. operat*.tw. 19. interventional.tw. 20. device*.tw. 21. implant*.tw. 22. prosth*.tw. 23. robotic*.tw. 24. exp Specialties, Surgical/ 25. exp Endoscopy/ 26. Radiology, Interventional/ 27. exp Surgical Procedures, Operative/ 28. exp "prostheses and implants"/ 29. or/1-28 30. humans/ 31. animals/ 32. 30 not 31 33. 29 and 32

A total of 8,373 unique records were identified through this search and underwent title and abstract screening. A detailed break-down of records retrieved per database can be found below.

Table S 2. Number of records identified through search strategy

Ovid	WoK	Cochrane	Total	Deduplicate 1 (Year, Author, Title)	Deduplicate 2 (Title only)	Total – Deduplicate 2 (% Total)
6,411	3,742	1,239	11,392	2,291	3,019	8,373 (73.4%)

2. Study selection and eligibility

Study selection criteria were initially defined using the PICO framework and contained the following criteria:

Population

Papers and abstracts reporting early phase studies, or protocols of early phase studies, of invasive procedures on adult patients (18 year or over) with primary colorectal cancer. Studies of patients with metastatic disease are included if the procedure under investigation treats the primary tumour. Early phase studies are defined as IDEAL (Idea, Development, Exploration, Assessment, Long-term follow up) phases 1-2 (Table S 2).

Table S 3. Characteristics associated with IDEAL stages

IDEAL stage	Characteristic
1 (First in Human)	Self-reports IDEAL 1, “first-in-human” or similar
2a (Prospective development study)	Self-reports IDEAL 2a, or prospective development study Sample size <30 Reports variation in the procedure in patients Reports modifications/improvements in the procedure
2b (Exploration study)	Self-reports IDEAL 2b Reports defined quality assurance measures Reports evaluation of learning curve Reports participant recruitment feasibility Reports outcome measure feasibility Report informs future sample size calculation

Interventions

All invasive procedures were included. An invasive procedure is one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed, and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, which include, but are not limited to, endoscopes, catheters, scalpels scissors, devices and tubes.

Where invasive procedures also involved the administration of a medicinal product, that could be categorised as being part of an ‘invasive procedure’ when operator skill is required for its administration within the body, i.e. when an internal action is performed to administer the product, or the product is administered to a targeted anatomical area. There are also procedures which involve operator skill to target something inside the body (e.g. electromagnetic radiation in the eye)

without an incision, percutaneous puncture, or instrumentation via a natural orifice. These types of procedures do not fall within the definition of an invasive procedure.

Comparator

There were no restrictions on comparators.

Outcomes

All outcomes were eligible for inclusion including clinical, patient reported and economic outcomes, adverse events, complications, reported criteria for modifying the technique, resource utilisation and reports of surgeon's experiences.

The systematic review excluded late phase studies (IDEAL stage 3-4), interventions targeting metastatic colorectal disease, non-English language papers, animal studies, and those published before January 2018.

Self-reported type of innovation

Studies were included in the review if authors reported the intervention as either 'entirely new' or 'modified' and were excluded if the intervention was considered 'adopted'. The categorisation of studies into these types of innovation was dependent on the authors' own descriptions and could be explicit and implicit. The terms below were used to aid categorisation.

Table S 4. Terms used to identify type of innovation

Type of innovation	Similar terms
'entirely new'	'(wholly) new', 'novel', 'used for the first time', 'first in human', 'innovative', 'reported for the first time', 'recently developed', 'not previously considered', for which 'outcomes remain unclear', 'IDEAL phase 1', 'phase 1'
'modified'	'changed', having undergone 'tinkering', 'adapted', 'improved', 'customised', 're-worked', 'tweaked', 'variation'
'adopted'	'stabilised', 'traditional', 'mainstream choice', 'preferred treatment', 'in common use', 'conventional', '(gold) standard', 'considered the management option', being aligned with 'broad consensus', 'typically'

3. Study screening

Title and abstract screening of all identified records (N = 8373) was performed independently by two authors (AM, CH). A customised inclusion/exclusion form was used to screen titles and abstracts to provide an audit trail. Further details on each authors' screening results can be found below.

Table S 5. Details of reviewers screening results

	AM	CH	Final
Included	851	857	816
Excluded	7523	7404	7557
Not colorectal cancer	3325	2580	
Not empirical study	181	373	
Not invasive procedure	4017	4451	
Unsure	19	111	

4. List of included studies

Table S 6. Studies included in the Systematic Review

1st author	Year	Title	Journal
A. Garcia-Granero	2018	Application of three-dimensional printing in laparoscopic dissection to facilitate D3-lymphadenectomy for right colon cancer	Techniques in Coloproctology
F. Feroci	2018	Barbed versus traditional suture for enterotomy closure after laparoscopic right colectomy with intracorporeal mechanical anastomosis: a case-control study	Updates in surgery
A. Schmidt	2018	Colonoscopic full-thickness resection using an over-the-scope device: a prospective multicentre study in various indications	Gut
T. Surya Suhardja	2018	Comparison of the Thunderbeat and Other Energy Devices in Laparoscopic Colorectal Resection: A Single-Center Experience	Journal of Laparoendoscopic and Advanced Surgical Techniques
S. Guadagni	2018	Control Comparison of the New EndoWrist and Traditional Laparoscopic Staplers for Anterior Rectal Resection with the Da Vinci Xi	Journal of Laparoendoscopic & Advanced Surgical Techniques
R. M. P. H. Crolla	2018	Does robotic rectal cancer surgery improve the results of experienced laparoscopic surgeons? An observational single institution study comparing 168 robotic assisted with 184 laparoscopic rectal resections	Surgical Endoscopy
K. Shen	2018	Double laparoscopy assisted cylindrical abdominal-perineal resection for low rectal cancer with 4 cases report	Medicine
T. Wada	2018	The effects of intraoperative ICG fluorescence angiography in laparoscopic low anterior resection: a propensity score-matched study	International Journal of Clinical Oncology.
B van der Spek	2018	Endoscopic full-thickness resection in the colorectum: a single-center case series evaluating indication, efficacy and safety	Endoscopy International Open
M. Chand	2018	Feasibility of fluorescence lymph node imaging in colon cancer: FLICC	Techniques in Coloproctology

H. O. Kim	2018	Hybrid Single-Incision Laparoscopic Colon Cancer Surgery Using One Additional 5 mm Trocar	Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A
H. T. Papaconstantinou	2018	Impact of a Novel Surgical Wound Protection Device on Observed versus Expected Surgical Site Infection Rates after Colectomy Using the National Surgical Quality Improvement Program Risk Calculator	Surgical Infections
Y. Fukui	2018	Laparoscopic intersphincteric resection of rectal cancer with posterior vaginal wall excision without hysterectomy	Techniques in Coloproctology
J. K. Shin	2018	Laparoscopic modified mesocolic excision with central vascular ligation in right-sided colon cancer shows better short- and long-term outcomes compared with the open approach in propensity score analysis	Surgical Endoscopy
S. G. Lee	2018	Laparoscopic transanal minimally invasive surgery (L-TAMIS) versus robotic TAMIS (R-TAMIS): short-term outcomes and costs of a comparative study	Surgical Endoscopy.
M. Yamamoto	2018	Left colic artery-preserving D3 lymphadenectomy using near-infrared spectroscopy was effective for double advanced cancers of the transverse colon and rectum: A case report	International Journal of Surgery Case Reports
S. Du	2018	A novel and safe approach: middle cranial approach for laparoscopic right hemicolon cancer surgery with complete mesocolic excision	Surgical Endoscopy
T. Sammour	2018	Oncological Outcomes After Robotic Proctectomy for Rectal Cancer Analysis of a Prospective Database	Annals of Surgery
A. Caycedo-Marulanda	2018	Outcomes of a Single Surgeon-Based Transanal-Total Mesorectal Excision (TATME) for Rectal Cancer	Journal of Gastrointestinal Cancer
L. Gu	2018	A Pilot Study for a Better Visibility in the 3D Laparoscopic Right Colectomy Surgery	World Journal of Surgery
A. d'Alessandro	2018	Preliminary experience with umbilical stoma in transumbilical single-port colorectal surgery	Techniques in Coloproctology
M. Rubinkiewicz	2018	A quest for sphincter-saving surgery in ultralow rectal tumours: a single-centre cohort study	World Journal of Surgical Oncology
M. J. Kim	2018	Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer A Phase II Open Label Prospective Randomized Controlled Trial	Annals of Surgery
D. D. Shaw	2018	Robotic Colorectal Surgery Learning Curve and Case Complexity	Journal of Laparoendoscopic &

			Advanced Surgical Techniques. Part A
B. Cui	2018	Robotic low anterior resection plus transanal natural orifice specimen extraction in a patient with situs inversus totalis	BMC Surgery
S. Arnott	2018	Robotic transanal microsurgery for high early rectal neoplasia (T0-T1, N0 lesions), case series of 10 patients	International Journal of Medical Robotics and Computer Assisted Surgery
P. Rouanet	2018	Robotic Versus Laparoscopic Total Mesorectal Excision for Sphincter-Saving Surgery: Results of a Single-Center Series of 400 Consecutive Patients and Perspectives	Annals of Surgical Oncology
K. U. Jung	2018	The Role of Hand-Assisted Laparoscopic Technique in the Age of Single-Incision Laparoscopy: An Effective Alternative to Avoid Open Conversion in Colorectal Surgery	Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A
T. W. A. Koedam	2018	Short-term outcomes of transanal completion total mesorectal excision (cTaTME) for rectal cancer: a case-matched analysis	Surgical Endoscopy
D. Kamali	2017	Short-term surgical outcomes and patient quality of life between robotic and laparoscopic extralevator abdominoperineal excision for adenocarcinoma of the rectum	Annals of the royal college of surgeons of england
U. Gibor	2018	Single Port and Conventional Laparoscopy in Colorectal Surgery: Comparison of Two Techniques	Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A
Y. Hirano	2018	Single-Incision Laparoscopic Colectomy for Colon Cancer: Experiences with 308 Consecutive Cases	American Surgeon
M. Rubinkiewicz	2018	Transanal total mesorectal excision for low rectal cancer: a case-matched study comparing TaTME versus standard laparoscopic TME	Cancer Management and Research
T. W. A. Koedam	2018	Transanal total mesorectal excision for rectal cancer: evaluation of the learning curve	Techniques in Coloproctology
R. Persiani	2018	Transanal Total Mesorectal Excision vs Laparoscopic Total Mesorectal Excision in the Treatment of Low and Middle Rectal Cancer: A Propensity Score Matching Analysis	Diseases of the Colon & Rectum
A, M, Mehta	2018	Transperineal retropubic approach in total pelvic exenteration for advanced and recurrent colorectal and anal cancer involving the penile base: technique and outcomes	Techniques in Coloproctology

S. B. Ellebaek	2018	The value of contrast-enhanced laparoscopic ultrasound during robotic-assisted surgery for primary colorectal cancer	Journal of Clinical Ultrasound
D. Yasukawa	2018	Trans-perineal minimally invasive surgery during laparoscopic abdominoperineal resection for low rectal cancer	Surgical Endoscopy
P. Wang	2018	Surgical specimen extraction via a prophylactic ileostomy procedure: A minimally invasive technique for laparoscopic rectal cancer surgery	World Journal of Gastroenterology
J. B. van Praagh	2018	Stercoral perforation proximal to the stapled anastomosis after low anterior resection with an intraluminal device	International Journal of Colorectal Disease
G. M. Son	2018	Quantitative analysis of colon perfusion pattern using indocyanine green (ICG) angiography in laparoscopic colorectal surgery	Surgical Endoscopy.
J. Nijkamp	2018	Prospective study on image-guided navigation surgery for pelvic malignancies	Journal of Surgical Oncology.
B. Kawa	2018	Percutaneous Antegrade Colonic Stent Insertion Using a Proximal Trans-peritoneal Colopexy Technique	Cardiovascular & Interventional Radiology
T. Chen	2018	Long-term outcomes of endoscopic submucosal dissection for high-grade dysplasia and early-stage carcinoma in the colorectum	Cancer communications (London, England)
M. Wang	2018	Laparoscopic intersphincteric resection with intraoperative radiotherapy using low-energy X-rays for locally advanced ultra-low rectal cancer	World Journal of Surgical Oncology
S. Colak	2018	Evaluation of endoscopic mucosal resection and endoscopic submucosal dissection in submucosal lesions of the colon and rectum	Wideochirurgia I Inne Techniki Maloinwazyjne
C. Shem	2018	The effect of proctoring on the learning curve of transanal minimally invasive surgery for local excision of rectal neoplasms	Techniques in Coloproctology.
G. Andrisani	2018	Colo-rectal endoscopic full-thickness resection (EFTR) with the over-the-scope device (FTRD ^{}): A multicenter Italian experience	Digestive and Liver Disease.
R. A. Mitchell	2018	Characteristics of Patients with Colonic Polyps Requiring Segmental Resection	Canadian journal of gastroenterology & hepatology
J. K. M. Fan	2018	Application of transanal endoscopic operation device in laparoscopic assisted transanal total mesorectal excision for the treatment of ultra-low rectal carcinoma	Surgical Practice
Y. Wang	2018	Application of modified primary closure of the pelvic floor in laparoscopic extralevator abdominal perineal excision for low rectal cancer	World Journal of Gastroenterology

5. Data extraction

Data were extracted from eligible studies and included details of the study design and intervention characteristics. A detailed proforma can be viewed below and specifically, these were:

- 1) Publication characteristics (authors and investigators, date of publication, country and centre(s) of study, journal of publication and funding).
- 2) Study characteristics (study design and participant characteristics, sample size), interventions and comparators with any definitions extracted verbatim).
- 3) Intervention characteristic (type of surgical interventions and comparators with any definitions extracted verbatim. Innovative components of the operation were extracted and further classified using a framework by Blencowe et al.[14] which is illustrated in Figure S 1.
- 4) Governance (recorded approvals and informed consent, with details extracted verbatim.
- 5) Details on self-reported stage of innovation (verbatim justification and statements linked to self-reported novelty and/or modification of the procedure/device).
- 6) Specific characteristics that are associated with IDEAL stages 1-2b were extracted verbatim.

Figure S 1 Operative components (adapted from Blencowe et al. 2016)

Data Extraction Form A 2

Unique citation ID (assigned by project lead)

Assessor

- ☐ AM
☐ JMB
☐ CH
☐ Other

Add initials here

Section A: Citation details and eligibility. Complete for ALL PAPERS

Eligibility criterion: Invasive procedures

Included:

Studies where there is purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed, and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, which include, but are not limited to, endoscopes, catheters, scalpels scissors, devices and tubes.

Excluded are studies that

Report diagnostic invasive procedures (studies that aim to detect colorectal cancer)

Deliver an invasive procedure as a co-intervention e.g studies of multimodal therapies that include an invasive procedure, but where the invasive procedure is not the focus of investigation.

Report animal models, trends in treatment, training of surgeons

Report clinical presentations where the focus of the article is the presentation rather than treatment

A3: Does this paper meet the inclusion/exclusion criteria for invasive procedures

☐ Yes ☐ No ☐ Unsure

Eligibility criterion: Treatment of primary colorectal adenocarcinoma:

Included: Procedures that aim to cure, act as a bridge to curative treatment, or palliate the primary (within the colon or rectum) tumour. Studies of patients with metastatic disease are included if the procedure under investigation treats the primary tumour.

Excluded: Treatments of metastatic colorectal cancer such as liver, lung, brain or peritoneal disease; other histological disease types such as neuroendocrine or stromal tumours; benign polyps.

A4: Does this paper meet the inclusion/exclusion criteria for treatment of primary colorectal adenocarcinoma

☐ Yes ☐ No ☐ Unsure

Eligibility criterion: Empirical studies

Included: Full papers reporting studies that meet the above criteria that report primary empirical patient outcome data. This may include technical notes, case studies, case series, case-control, cohort and randomised trials.

Excluded:

Papers that do not include primary empirical patient outcome data such as reviews, letters, descriptions of techniques, and videos.

Conference abstracts

Full (not pilot/feasibility) multi-centre randomised controlled trials (IDEAL stage 3), long-term follow up data registries (IDEAL stage 4) and clinical audit/quality improvement studies.

A5: Does this paper meet the inclusion/exclusion criteria for empirical studies

☐ Yes ☐ No ☐ Unsure

SCREENING ELIGIBILITY CONFIRMED

DO NOT CONTINUE

A6: Title

A7: 1st author

A8: Journal

A9: Publication Year

A10: Date of data entry

A11: Record the corresponding author's email address here

Data Extraction Form B 2

Section B: Clinical studies - study design and rationale

B1 Does the article explicitly report study design

- ☐ Yes. Give reported study design in a)
☐ No. Give deduced study design using appendix 1 in a)

Appendix 1: Type of study

Use this algorithm to help determine the most appropriate study design for this paper. Indicate the study design by selecting the appropriate option below. If you are unsure about the study design, please discuss with the senior author.

B1a Study design

- ☐ Technical Note
☐ Case study
☐ Case series
☐ Cross-sectional study
☐ Case control study
☐ Retrospective cohort study
☐ Prospective cohort study
☐ Randomized trial
☐ Non-randomized trial

B2: Does the study include a comparator?

☐ Yes ☐ No

B3: Does the study use registry data?

☐ Yes ☐ No

Data Extraction Form C 2**Section C: Data about the centre and surgeons**

C1: Geography of study

- ☐ UK
- ☐ Europe (not UK)
- ☐ North America
- ☐ South America
- ☐ India
- ☐ Asia
- ☐ Australia/New Zealand
- ☐ Multiple
- ☐ Other

C1b Country Other:

C2: Centre

- ☐ single centre
- ☐ multi centre
- ☐ not reported

C3: Number of centres

C4: Is there any reporting of the expertise of those delivering the intervention(s)?
(for example, does the paper state the number of cases participating surgeons have performed previously?)

- ☐ Yes
- ☐ No
- ☐ Unclear

C4b: Please record here verbatim from paper

Data Extraction Form D 2**Section D: Data about the patient participants**

D1: Total number of participants

D2: Actual of average age of participant(s). For comparative studies select intervention group
(select mean/median/mode below as appropriate)

☐ mean ☐ median ☐ mode ☐ Not statedD3: Sex of participants % = male For comparative studies select intervention group
(calculate from paper if required)

D4: Did the authors include an a priori statement about inclusion and exclusion criteria for patients?

☐ Yes ☐ No ☐ Unclear

Inclusion criteria

Exclusion criteria

What cancer site was included?

- ☐ Exclusively colon
☐ Exclusively rectum
☐ Any colorectal
☐ Not reported/unclear

What cancer stage was included?

- ☐ Exclusively early (Stage 1-3)
☐ Exclusively late (Stage 4)
☐ Any stage
☐ Not reported/unclear

D5: Did the authors include a statement about what happened to patients who did not meet the inclusion criteria to receive the intervention (or to participate if it was a comparative study)?

☐ Yes ☐ No ☐ Unclear

D5b: Please record the statement here, verbatim from the paper

D6: Do the authors state that the study included consecutive patients?

☐ Yes ☐ No ☐ Unclear

D6b: Did the paper report outcomes for consecutive patients?

☐ Yes ☐ No ☐ Unclear

D7: Was information provided about the number of patients declining/dropping out of the intervention?

☐ Yes ☐ No ☐ Unclear

Data Extraction Form E 2**Section E: Data about governance and ethical factors**

E1: Does the article report any type of governance approvals?

☐ Yes ☐ No ☐ Unclear

E1b: Select from the following the type of governance approvals reported

- ☐ Research study governance approval
☐ Institutional/hospital review/ethics board
☐ Service evaluation or audit registration
☐ other

E1c: Record these statements here (verbatim from paper) including any governance approval number

E2: Was there a statement confirming individual patient consent?

☐ Yes ☐ No ☐ Unclear

E3: Was there a statement that patients were specifically informed about the innovative nature of the intervention?

☐ Yes ☐ No ☐ Unclear

E3b: Record this statement here (verbatim from paper)

E3c: Why is it unclear?

E4: Did the paper report any amendment to governance approval AFTER the study had started?

☐ Yes ☐ No ☐ Unclear

E4b: Include any statement here (including if the amendment was rejected, why the amendment was sought)

E5: Did the authors describe additional sources of information about the intervention(s) provided for patients such as information leaflets, web pages or other sources?

☐ Yes ☐ No ☐ Unclear

E5b: What were these sources?

E5d: Were links or references to these sources included in the paper?

☐ Yes ☐ No ☐ Unclear

E5e: Have these sources been obtained?

☐ Yes ☐ No ☐ Unclear

E6: Was information provided about FDA/NICE/CE marking/clinical effectiveness approval?

☐ Yes ☐ No ☐ Unclear

E6b: Record the statement verbatim here, including whether that approval was for the device in general (e.g. robot) or for a specific clinical indication (e.g. rectal cancer)

E7: Record any statement about conflict of interest (including declarations of no COI) including which author(s) it refers to and the precise nature of the COI here:

E8: Does the paper include a statement about sponsorship and/or funding?

☐ Yes ☐ No ☐ Unclear

E8b: What was the source of funding or sponsorship?

Data Extraction Form F 2

Section F: Data about the intervention

F1: Record the stated intervention verbatim

F2: What is the nature of the intervention under evaluation?
Select all that apply

- ☐ Operative technique
- ☐ Device
- ☐ Other

F3: Does the intervention involve any of the following
Select all that apply

- ☐ Robotic surgery
- ☐ Laparoscopic surgery
- ☐ Endoscopy
- ☐ Trans-anal/natural orifice surgery
- ☐ Implantable device
- ☐ Other

F3b: If other please state

F4: Does the article report the intervention as new in entirety?
e.g. all the components of the intervention are new

- ☐ Yes
- ☐ No
- ☐ Unclear

F5: Does the article report a component of the intervention as new?

- ☐ Yes
- ☐ No
- ☐ Unclear

F5b: What components of the intervention are reported as new?

- ☐ Technology set up/settings/positioning (not positioning of the patient)
- ☐ 'Pre-incision' (skin preparation, draping, positioning of patient)
- ☐ Incision
- ☐ Access
- ☐ Dissection
- ☐ Resection
- ☐ Haemostasis
- ☐ Insertion of adjuncts (e.g. drains)
- ☐ Closure
- ☐ Other

F5c: Other please state

F6: Record the stated comparator(s) verbatim

F7: What is the nature of the comparator(s) under evaluation?
Select all that apply

- ☐ Operative technique
- ☐ Device
- ☐ Other

F8: Is the study reporting an intervention in a new population?
e.g. new geographical location or disease?

☐ Yes ☐ No

F9: Is the study reporting new or different outcomes or types of outcome?
e.g. patient reported or health economic outcomes

☐ Yes ☐ No

F10: Is the study evaluating a combination of 2 or more invasive procedures?

☐ Yes ☐ No

F11: Are they combined in the same procedure or sequentially as part of a treatment plan?

- ☐ Combined within one procedure
- ☐ Delivered sequentially as part of a treatment plan

F12: Is there a statement about how surgeon performance/expertise was monitored?

- ☐ Yes
- ☐ No
- ☐ Not stated

F13: Please record the statement verbatim from paper here

F14: When did patients receive the intervention?
(record month and year [MM/YY] or time period [MM/YYYY - MM/YYYY] of enrollment into the study, or enter 0000 if not reported)

Data Extraction Form G 2

G REPORTING STAGE OF INNOVATION

Please complete these questions based on information reported in the article only. Please note papers are not being categorised and articles may report conflicting information, e.g. articles may report that a procedure is 'new', however, previous studies evaluating the procedure may also be referenced

G1: Does the study describe the intervention as (wholly) 'new' (or similar term)?
This may include description of the intervention as 'new', 'novel', 'used for the first time', 'first in human', 'innovative', 'reported for the first time', 'recently developed', 'not previously considered', for which 'outcomes remain unclear', 'IDEAL phase 1', 'phase 1' (or similar implied term or phrase)

☐ Yes ☐ No

G1a: Copy and paste verbatim text relating to the concept of 'new'

G1b: Which section(s) of the paper does this text appear?

Tick all that apply

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

G1c: Field notes

G2: Does the study describe the intervention as 'modified' (or similar term)?

This may include descriptions of the intervention as 'changed, having undergone 'tinkering', 'adapted', 'improved', 'customised', 're-worked', 'tweaked', 'variation' (or similar implied term or phrase)

☐ Yes ☐ No

G2a: Copy and paste verbatim text relating to the concept of 'modified'

G2b: Which section(s) of the paper does this text appear?

Tick all that apply

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

G2c: Field notes

G3: Does the study describe the intervention as 'stabilised' or 'adopted' (or similar term)?

This may include description of the intervention as 'traditional', 'mainstream choice', 'preferred treatment', 'in common use', 'conventional', 'standard', 'considered the management option', being aligned with 'broad consensus', 'typically' (or similar implied term or phrase)

☐ Yes ☐ No

G3a: Copy and paste verbatim text relating to the concept of 'stabilised' or 'adopted'

G3b: Which section(s) of the paper does this text appear?

Tick all that apply

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

G3c: Field notes

G4 Does the study cite any previous studies where the exact same intervention has been used in the same way (i.e. as currently reported)

☐ Yes ☐ No

G4a How many previous studies are referenced?

G4b What are the study designs of the previous studies?

(Tick all that apply)

- ☐ Randomised controlled trial
☐ Non-randomised trial
☐ Prospective cohort study
☐ Retrospective cohort study
☐ Case control study
☐ Cross sectional study
☐ Case series
☐ Case study
☐ Technical note
☐ Animal study
☐ Unclear
☐ Other

G4c Other, please specify

G5 Does the study cite any previous studies where a similar (e.g. pre-modification) intervention has been used

☐ Yes ☐ No

G5a How many previous studies are referenced?

G5b What are the study designs of the previous studies?
(Tick all that apply)

- ☐ Randomised controlled trial
- ☐ Non-randomised trial
- ☐ Prospective cohort study
- ☐ Retrospective cohort study
- ☐ Case control study
- ☐ Cross sectional study
- ☐ Case series
- ☐ Case study
- ☐ Technical note
- ☐ Animal study
- ☐ Unclear
- ☐ Other

G5c Other, please specify

G6 Does the article report attempts to review relevant literature?

- ☐ Yes
☐ No

G7 Did the article report/reference that a systematic review was conducted?

- ☐ Yes
☐ No

G8 Did the article report any rationale for current evaluation of the intervention?

- ☐ Yes
☐ No

G8a What is the reported rationale for undertaking the current evaluation of the intervention?
(Tick all that apply)

- ☐ Inadequate previous study design
- ☐ Acquisition of new knowledge about outcomes
- ☐ Unresolved issue with the intervention
- ☐ Application of intervention to a different population
- ☐ Patient benefit
- ☐ Other

G8b Other, please specify

G8c Copy and paste text regarding the reported limitations of the literature or usual care

G8d Copy and paste text regarding the reported advantages of the study

G8e Is the reported rationale supported by citations?

☐ Yes ☐ No

G9 Concluding remarks about novelty of intervention/modification and assign category according to IDEAL framework (ideal-collaboration.net/framework/).
Give reasons for IDEAL classification and/or justification as to why categories do not represent the stage of surgical innovation reported in the study.

PROCEED TO OUTCOMES

Self reported early phase study

DO NOT PROCEED TO OUTCOMES

Self reported later phase study

Data Extraction Form O 2

Section O: Outcomes and further details- in depth

O 2. 1.1 Verbatim specific outcome (verbatim text)

O 2. 2.1 Where first stated in manuscript

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

O 2. 3.1 How was the outcome measured (include timing of assessment and follow-up periods if applicable)

O 2. 1.2 Verbatim specific outcome (verbatim text)

O 2. 2.2 Where first stated in manuscript

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

O 2. 3.2 How was the outcome measured (include timing of assessment and follow-up periods if applicable)

O 2. 1.3 Verbatim specific outcome (verbatim text)

O 2. 2.3 Where first stated in manuscript

☐ Title ☐ Abstract ☐ Introduction ☐ Methods ☐ Results ☐ Discussion

O 2. 3.3 How was the outcome measured (include timing of assessment and follow-up periods if applicable)

O 2. 1.4 Verbatim specific outcome (verbatim text)

O. 3. Were ANY outcomes in the study completely defined*? i.e. sufficient detail provided on how to measure the outcome and when.
*definition for a completely defined outcome is that 'the information provided is sufficient to allow others to use the same outcome' (CONSORT 2010 guidelines)

- ☐ Yes
☐ No
☐ Not stated

Confidential

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O. 4. 1. Do the authors classify any outcome(s) in relation to time? e.g. short/long term, early/late?

- ☐ Yes
☐ No
☐ Not stated

O. 4. 5. Was any rationale given for the time frame of the classification?

- ☐ Yes
☐ No
☐ Not stated

O. 4. 6. If yes, provide verbatim text describing the rationale for the time-frame of the classification

O. 5. 1. Is there any reports of surgeons' experiences? (e.g. ease of surgery)

- ☐ Yes
☐ No
☐ Unclear

O. 5. 2. If yes, provide any verbatim text of descriptions of surgeons' experiences

O. 5. 3. If unclear, please provide details

O. 6. 1. Is there any interpretation / conclusion for the study IN RELATION TO OUTCOMES?

- ☐ Yes
☐ No
☐ Not stated

O. 6. 2. If yes, provide verbatim text for the study interpretation / conclusion

O. 6. 3. Where in the paper was the interpretation / conclusion reported? (tick all that apply)

- ☐ Abstract
☐ Methods
☐ Discussion
☐ Conclusion
☐ Other

O. 6. 4. Other description

O. 7. Provide any verbatim text for limitations in interpretation/conclusions in relation to outcomes

O. 8. Provide any verbatim text relating to outcome assessment in future studies

O. 9. Provide any verbatim text relating to stopping the innovation/making changes to the procedure/device in future studies or applications of use

6. Further details on outcomes

Outcome reporting

Further details on outcome reporting are shown in Tables S 7 – S 8 and include analyses on outcome domains excluded from the manuscript.

Table S 7. Summary of outcome reporting per COHESIVE outcome domain

Outcome domains	Number of verbatim outcomes	%	Number of studies outcome domain is reported (N, %)	
Procedure completion success/failure	160	7.7	46	90.2
Modifications	43	2.1	22	43.1
Unanticipated advantages	0	-	0	-
Unanticipated disadvantages	7	0.3	4	7.8
Surgeon/operator's experience of the innovation	224	10.8	46	90.2
Patient's experience of the innovative procedure/device	2	0.1	2	3.9
Required resource use specific to the innovation	52	2.5	25	49
Details of operator training/expertise required in future	2	0.1	2	3.9
Details of patients suitable for the procedure in future	39	1.9	24	47.1
Mechanical/technical problems with device	83	4	25	49
Overall desired effect of procedure /device was achieved	258	12.5	47	92.2
Anticipated advantages	238	11.48	46	90.2
Anticipated disadvantages	660	31.8	50	98
Duration of procedure	72	3.5	41	80.4
Duration of hospital stay	49	2.4	35	68.6
Patient's physical/psychological experience after the procedure	184	8.9	38	74.5
Total	2168			
common data element	200	8.1	46	9.8
too broad to categorise	125	5	32	37.3
not an outcome	82	3.3	44	13.7
Grand Total	2,480			

Table S 8. Number of outcomes ‘measured’ and outcomes ‘mentioned but not measured’ per COHESIVE outcome domain

Outcome domain	‘measured’		‘mentioned but not measured’	
	n	%	n	%
Procedure completion success/failure	83	8.8	77	6.8
Modifications	8	0.8	35	3.1
Unanticipated advantages	0	-	0	-
Unanticipated disadvantages	1	0.1	6	0.5
Surgeon/operator’s experience of the innovation	17	1.8	207	18.3
Patient’s experience of the innovative procedure/device	0	-	2	0.2
Required resource use specific to the innovation	9	1	43	3.8
Details of patients suitable for the procedure	0	-	39	3.5
Details of operator training/expertise	0	-	2	0.2
Mechanical/technical problems with device	23	2.4	60	5.3
Overall desired effect of procedure /device was achieved	181	19.2	77	6.8
Anticipated advantages	20	2.1	218	19.3
Anticipated disadvantages	425	45	235	20.8
Duration of procedure	54	5.7	18	1.6
Duration of hospital stay	38	4	11	1
Patient’s physical/psychological experience after the procedure	85	9	99	8.8
Total	944		1,129	
common data elements	151	13.4	49	3.6
not an outcome	17	1.5	65	4.8
too broad to categorise	15	1.3	110	8.1
Grand total	1,127	100	1,353	100

Table S 9. Number of outcomes per COHESIVE outcome domain by self-reported type of innovation

Outcome domain	'entirely new' or similar term (N=17)		'modified' or similar term (N=34)	
	n	%	n	%
Procedure completion success/failure	51	8.2	109	7.5
Modifications	5	0.8	38	2.6
Unanticipated advantages	0	-	0	-
Unanticipated disadvantages	5	0.8	2	0.1
Surgeon/operator's experience of the innovative procedure/device	76	12.2	148	10.2
Patient's experience of the innovative procedure/device	1	0.2	1	0.1
Required resource use specific to the innovative procedure	18	2.9	34	2.3
Details of operator training/expertise required in future	0	0	2	0.1
Details of patients suitable for the procedure in future	12	1.9	27	1.9
Mechanical/technical problems with device	12	1.9	71	4.9
Overall desired effect of procedure /device achieved	80	12.9	178	12.3
Anticipated advantages	74	11.9	164	11.3
Anticipated disadvantages	205	33	455	31.3
Duration of procedure	27	4.3	45	3.1
Duration of hospital stay	19	3.1	30	2.1
Patient's physical/psychological experiences after the procedure	36	5.8	148	10.2
Total	621		1,452	
common data element	52	7	148	8.5
too broad to categorise	37	5	88	5.1
not an outcome	28	3.8	54	3.1
Grand total	738		1,742	

Extracted outcomes

A long list of all extracted outcomes per COHESIVE outcome domain are displayed below. A file with all outcomes per study is available on request.

Table S 9. Verbatim extracted ‘measured’ outcomes and ‘mentioned but not measured’ outcomes

Outcome domain	Verbatim outcome ‘measured’	Verbatim outcome ‘mentioned but not measured’
Procedure completion success/failure	<p>[Additional port insertion] For transection of the rectum</p> <p>Additional port insertion</p> <p>adenocarcinoma detected by polypectomy prior to surgery</p> <p>Adenocarcinoma diagnosed (%)</p> <p>attempted polypectomy which was abandoned and not reattempted</p> <p>changes to the incision or insertion of an additional trocar</p> <p>Complete resection of the primary rectal lesions (R0)</p> <p>completed successfully</p> <p>Conversion</p> <p>conversion [to laparoscopy]</p> <p>conversion rate</p> <p>conversion rate</p> <p>Conversion rate</p> <p>conversion rate</p> <p>conversion rate to open surgery</p> <p>conversion to an open procedure</p> <p>Conversion to laparotomy</p> <p>conversion to open surgery</p> <p>conversion to open surgery</p> <p>conversion to open surgery</p> <p>conversion to open surgery</p> <p>conversion to open surgery</p> <p>conversions</p> <p>conversions to an open approach</p> <p>conversions to laparoscopy</p> <p>conversions to laparotomy</p> <p>converted to open surgery</p> <p>converted to open surgery</p> <p>curative resection (= lateral and deep R0 resection)</p> <p>Diverting ileostomy, no.</p> <p>drainage to the sentinel node</p> <p>Effectiveness: complications</p> <p>Effectiveness: resection margins</p> <p>Effectiveness: survival</p>	<p>ability of eFTR to completely resect scar tissue</p> <p>accurate irradiation</p> <p>acute load to failure strength</p> <p>additional trocar was inserted for adhesiolysis</p> <p>adequately performed by a single surgeon</p> <p>anus preservation outcome</p> <p>anus preserving probability</p> <p>Better Visibility</p> <p>competence by the different surgeons</p> <p>complete robot assistance</p> <p>conversion during laparoscopic surgery</p> <p>conversion from the laparoscopic to open approach would have been expected</p> <p>conversion required robotic abdominal access to repair a proctotomy</p> <p>Conversion risk</p> <p>converted to robotic abdominal repair for optimal closure</p> <p>could not dissect through the exact plane and it was impossible</p> <p>to locate the right ureter</p> <p>definition of video images</p> <p>demanding a conversion to a permanent stoma due to severe faecal incontinence</p> <p>designed radiation dosage</p> <p>direct referral for surgical resection</p> <p>effective</p> <p>effective for the resection of colorectal lesions</p> <p>effective locoregional treatment</p> <p>efficient</p> <p>eFTR did not seem feasible</p> <p>facilitate laparoscopic suturing</p> <p>failed cases</p> <p>failed for technical reasons</p> <p>functional outcome</p> <p>impossible to measure StO₂ before the mesenteric dissection</p> <p>improve planning of laparoscopic right hemicolectomy</p> <p>inability to advance in laparoscopic mode</p> <p>inaccuracy of the navigation system [due to] setup difference</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>Efficiency: localisation of tumor</p> <p>Efficiency: total duration of procedure</p> <p>EFTR rate: proportion of patients with histologically confirmed full-thickness resection (mucosal, submucosal and muscle layers)</p> <p>eFTR-specimens [...] free of residual carcinoma</p> <p>en bloc resection</p> <p>en-bloc resection</p> <p>endoscopic failure and subsequent surgical resection</p> <p>endoscopic residual/recurrent adenoma after ER</p> <p>evidence of residual/recurrent lesion after 3?months</p> <p>failure rate</p> <p>frequently needed one or more trocars for safe dissection and distal division</p> <p>ICG angiography (Yes, No)</p> <p>incidence of LLND</p> <p>incomplete resection at histology (R1 resection)</p> <p>incomplete specimens</p> <p>intestinal viability</p> <p>intraoperative conversion</p> <p>intraoperative image clarity</p> <p>Lateral lymph node dissection</p> <p>macroscopically radical resection</p> <p>margins free of scar tissue</p> <p>Median time from local excision to completion surgery/Interval TAMIS to TaTME (weeks)</p> <p>necessity of surgical therapy</p> <p>need for open conversion</p> <p>need to convert</p> <p>No. of conversions to open surgery</p> <p>numbers and size of incisions</p> <p>operation was uneventful</p> <p>Operative stoma-related morbidity</p> <p>overall conversion to open laparotomy rate</p> <p>pigtail drain and suture anchors were subsequently removed without complications</p> <p>polyps deemed to be unresectable</p> <p>polyps that were successfully resected by colonoscopy</p> <p>primary anastomosis</p> <p>primary resection of malignant lesion</p>	<p>incompletion rate of TME</p> <p>intraoperative conversions to open laparotomy</p> <p>judged that the colorectal anastomosis could be performed safely</p> <p>lateral margins of the lesion cannot be seen circumferentially</p> <p>lesion could not be removed endoscopically due to severe scarring and size of lesion</p> <p>lesion could not be successfully cannulated due to tortuosity</p> <p>lymph node was successfully localized</p> <p>lymphatic map was seen</p> <p>met the Z6051 trial criteria for the composite outcome of successful resection</p> <p>missed lymph nodes</p> <p>necessary to evaluate the colo-rectal wall mobility</p> <p>necessity for definitive stoma formation</p> <p>need for further surgery</p> <p>no need to perform a more proximal ligation of the vessel</p> <p>number of incisions</p> <p>operation was successfully performed</p> <p>probability of fogged lens</p> <p>procedure was performed successfully</p> <p>quality of the dehazed image</p> <p>rate of segmental resection</p> <p>reasons for conversion to laparotomy</p> <p>referred to surgical resection due to unsuccessful EFTR</p> <p>required transection line changes</p> <p>rupture of the SILS system</p> <p>safe performance of the procedure</p> <p>stent patency</p> <p>strength of the suture</p> <p>success rates</p> <p>successful</p> <p>successful cases</p> <p>successful in performing oncologic resection</p> <p>Successful incorporation of the lesion into the cap</p> <p>successfully treated</p> <p>surgeon's ability to obtain a high-quality oncologic resection</p> <p>surgery to be considered a success</p> <p>surgical learning curve</p> <p>suspicion of mesorectal fascia infiltration</p> <p>suture breakage</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>procedure could not be carried out due to major peritoneal adhesions</p> <p>proficiency [composite outcome, expressed in cases]</p> <p>Resection</p> <p>splenic flexure mobilization (%)</p> <p>stapled anastomosis</p> <p>Target lesion reached with FTRD, n (%)</p> <p>"Technical success (macroscopically complete & en-bloc), number (% of total) [composite] (macroscopic incomplete resection, no specimen obtained)"</p> <p>Technical success rate (TS: lesion reached and resected)</p> <p>the presence of lymph nodes outside the proposed mesenteric resection</p> <p>type of anastomosis</p> <p>Unsuccessful procedure</p> <p>**not verbatim** lesions deemed difficult to reach</p> <p>**not verbatim** lesions deemed difficult to resect</p> <p>*not verbatim* reason for conversion</p>	<p>TaTME patients seem to control defecation better than patients undergoing intersphincteric resection</p> <p>technical failure of eFTR</p> <p>technically feasible</p> <p>vertical or horizontal incision in the lower abdomen</p> <p>was technically completed</p> <p>would not have been visualized without ICG FI</p>
Modifications	<p>clipping was revealed to be useless</p> <p>creation of defunctioning stoma</p> <p>end colostomy</p> <p>para-aortic lymph node dissection</p> <p>Patients with lymph nodes identified with ICG outside of the proposed mesenteric resection margin?</p> <p>severe peritoneal adhesion</p> <p>started to adopt an early ileostomy closure</p> <p>Transition to a two-team approach</p>	<p>a change was made in the protocol of the C-seal trial</p> <p>a specific mattress was designed</p> <p>a switch was made to the AirSeal insufflator</p> <p>additional 12-mm trocar was required</p> <p>additional operating ports</p> <p>additional trocars</p> <p>alternative resection strategy may be considered</p> <p>appropriate cut-off value for the perfusion factors predicting anastomotic complications</p> <p>change of surgeon performing the transanal approach</p> <p>equipment malfunction</p> <p>exploring the use of a footswitch to change program settings</p> <p>extra incision</p> <p>failure to progress</p> <p>have made improvement in our techniques</p> <p>improvements which were made</p> <p>in danger of being under tension</p> <p>manual calibration of the navigation system</p> <p>mesenteric resection was extended to safely include the node</p> <p>necessary to change the surgical strategy</p> <p>not included in the planned resection or routine lymphadenectomy</p> <p>not sufficient to guide a lymphadenectomy</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>patient setup needs to be adapted to fit the scanner</p> <p>protocol of treatment, including chemoradiotherapy and perioperative care, did not change during the study duration.</p> <p>recommend a gentle snare closure</p> <p>robotic port locations, robotic arm positions, and assistant and nursing positions need to be modified</p> <p>R-TAMIS platform makes access for endoluminal surgery of the rectum straightforward</p> <p>simplification of navigation software</p> <p>standardize the protocol for future work</p> <p>taking additional mesenteric tissue at this margin</p> <p>target organ cannot be reached with instruments or the camera</p> <p>assistance is poor</p> <p>The TAMIS platform though designed for local excision can be adapted to performing TME</p> <p>transition to a two-team approach</p> <p>two further percutaneous colonic stents using a mild variation in technique</p> <p>using a red inversion mode with a light sky blue color after the midpoint of the study</p> <p>were repaired intraoperatively</p>
Unanticipated advantages	-	-
Unanticipated disadvantages	inadvertent peritoneal entry	<p>inadvertently tear the marginal artery causing ischemia at the anastomosis</p> <p>mistakenly dissect the tissue alongside the prostate</p> <p>unexpected disasters</p> <p>unexpected injuries of irrelevant organs</p> <p>unexpected perforation with exposure of the tumor</p> <p>unexpected post-operative cardiac event</p>
Surgeon/operator's experience of the innovative procedure/device	<p>case complexity</p> <p>Decisiveness</p> <p>Difficult case reported by surgeon</p> <p>difficult incorporation of lesion into cap</p> <p>difficulties encountered at the previous TAMIS-site</p> <p>easy to perform</p> <p>eFTR learning curve [not measured]</p> <p>feasible procedure for the operative team</p> <p>Global Operative Assessment of Laparoscopic Skills (GOALS)</p>	<p>variations in surgeon experience</p> <p>additional surgeons progressively transitioning from open to robotic</p> <p>change point in the CUSUM curve</p> <p>occurred within the first learning phase</p> <p>rapid adoption of this technique by surgeons all over the world</p> <p>rapidly adopted by many colorectal surgeons</p> <p>transitions to phase II learning</p> <p>controlled ligation of the dorsal venous plexus</p> <p>2-week familiarization period</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>learning curve (CUSUM)</p> <p>Procedures without documented difficulties</p> <p>Resection reported to be difficult</p> <p>robotic learning Curve</p> <p>simple to perform</p> <p>surgeon's anxiety</p> <p>surgical experience</p> <p>usability [System Usability Scale]</p>	<p>ability of the robot to perform low rectal dissection more easily</p> <p>ability of the surgeon to control the surgical field</p> <p>acceptance of a new operative technique</p> <p>acceptance of the use of laparoscopic surgery</p> <p>access</p> <p>access to the plane of dissection</p> <p>adequate competency</p> <p>advancing of the FTRD to the target lesion can be difficult</p> <p>agreement on the proper training</p> <p>allowing trainee surgeons to develop competency in the technique within a relatively short period of time</p> <p>allows seated surgeons with optimized ergonomic position</p> <p>anatomically and technically demanding cases</p> <p>anatomically difficult to anastomose</p> <p>barrier to utilization</p> <p>better visualization</p> <p>bimanual dexterity</p> <p>brings the surgeons the operation practice closer to naked eyes</p> <p>Cadaver training</p> <p>cadaver training</p> <p>can be carried out competently without the need for extensive prior laparoscopic experience</p> <p>can display 3D surgical field same as in human eyes</p> <p>can perform hybrid SILS without a learning curve</p> <p>case load</p> <p>cases are required for a surgeon to become proficient</p> <p>challenging due to the narrow pelvic space and vital surrounding structures</p> <p>changeover points</p> <p>changes in surgical techniques</p> <p>comfort for surgeons</p> <p>complexity of the case</p> <p>considered a challenge for the colorectal surgeon</p> <p>considered more difficult technically</p> <p>conversion to CML is easy and feasible without additional complications</p> <p>critical surgical points</p> <p>crowding of surgical instruments</p> <p>cumbersome nature of traditional transanal instruments</p> <p>degree of ease of operation by surgeons</p> <p>degree of self-teaching</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>depth perception</p> <p>did not require a steep learning curve</p> <p>difficult operation to master</p> <p>difficult to acquire a stable video during the operation</p> <p>difficult to conduct LRH</p> <p>difficult to perform</p> <p>difficult to remove en bloc with piecemeal EMR</p> <p>difficulties with the laparoscopic platform</p> <p>difficulty in achieving negative circumferential resection margins</p> <p>difficulty maintaining an adequate seal for insufflation</p> <p>difficulty significantly increases when anastomosis is performed intracorporeally</p> <p>difficulty with maintaining stable pneumorectum</p> <p>discontinuity in the learning curve</p> <p>ease and quality of proctectomy</p> <p>ease in performing anastomosis in morbidly obese patients</p> <p>ease of defect closure</p> <p>ease of laparoscopic suturing</p> <p>ease of suturing</p> <p>easy</p> <p>easy introduction of instruments and gauzes without significant interference to the transanal platform</p> <p>easy retrograde ascending dissection</p> <p>easy to perform</p> <p>easy to perform</p> <p>easy to perform</p> <p>eFTR learning curve</p> <p>enables the surgeon to focus on the quality of surgery</p> <p>entails advanced laparoscopic skills</p> <p>ere trained in the procedure</p> <p>ergonomics</p> <p>experience of the minimally invasive team</p> <p>experience of the observer</p> <p>experience of the operating team</p> <p>expert skills in laparoscopic surgery</p> <p>facilitate demanding operations</p> <p>Factors related to the surgeon</p> <p>fatigue</p> <p>fatigue of the surgical team</p> <p>fitness of the surgeons</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		flexibility and versatility with port placement gaining sufficient experience hand tremor amplification has led some surgeons to adopt alternative approaches have innate limitations for the surgical excision hazard because of the lack of a precise definition of the surgical training required to safely perform a TaTME procedure hinders the accurate space perception of the chief surgeon during the operation improved visualization inconvenience of using different robotic platforms and surgical techniques integration of the system in the clinical workflow interest and acceptance among surgeons intracorporeal suturing to be performed without extensive training involves the most difficult techniques it is difficult for the surgeon to operate, such as grasping, puncturing, suturing and cutting during the operation lack of triangulation laparoscopic technical skills learning curve learning curve learning curve learning curve learning curve for robotic-assisted interventions learning curve of the robotic technique learning curve of the surgical procedure learning curve with respect to reducing conversion risk during robotic surgery learning effects level of competence for the participating surgeons likely to find favor with surgeons limited range of motion limited visualization local control loss of dexterity major features and difficulties during TpMIS were examined from a surgical viewpoint make laparoscopic suturing easier mental and physical stress of operating surgeons

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p> mental strain in robotic surgery mentorship methods are inconvenient and invasive need specific training and education need to resect skin at the stoma site need to tie a knot in a confined space new technical difficulties related to rigid instruments with a limited degree of freedom number of patients needed to reach competency observed 20 TaTME-cases performed by a colleague prior to performing their first procedure participated in TAMIS training courses participation of new surgeons performance in autonomy performed by a surgeon considered to still be in his/her learning curve for the robotic approach physical [strain in robotic surgery] poor visibility popularity precise and complex performance in quite confined spaces of the pelvis preference for the innovative setting proctoring or training was available prolonged learning curve or inexperienced endoscopists protracted learning curve (>10 cases) was required provides the chief surgeon and assistant more accurate spatial positioning quality of life scores reasons for colonoscopists not involving therapeutic gastroenterologists recognition of the important structures require training and the technical skill of passing the needle/suture through the tissues requires more experience and attention requires more technical skills requires proper training requires substantial expertise rigidity of the TEO system shift to hybrid SILS without a learning curve shown the greatest change with increased experience specific challenges </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p> stability stable operative platform stood on the right [/left] of the patient Structural training of surgeons sufficient experience with laparoscopic TME sufficient knowledge of this procedure suitable for surgeons, who were still on the right-half of the colon learning curve surgeon can comfortably perform the transanal procedure in a highly ergonomic manner surgeon could clearly see the projection of the gauze and safely dissect the tissue at the lower edge of the pancreas surgeon needs to adapt to the abnormal anatomy surgeon operative performance (GOALS) surgeon well-being surgeon[-]report[ed] technical difficulties related to OTSC presence surgeon-related factors (e.g., learning curve, experience, and technical ability) surgeons being at the early stages of their learning curve surgeons have become familiar with a laparoscopic technique and confident in performing it surgeons have now completed their own learning curve surgeons' strong preference towards one technique or the other surgical difficulty score surgical experience surgical experience SUS scores technical challenges endoscopically technical complexity of TAMIS technical difficulty technical guidance during TpAPR technical independence technical tips technically and ergonomically demanding technically challenging technically challenging technically demanding technically demanding technically demanding surgical technique </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>technique that is relatively difficult to master</p> <p>techniques required for effective use of TB appeared to be transferable from other energy devices</p> <p>technology that is already familiar and available</p> <p>the level of stress, to the robotic technique itself, and to hardware</p> <p>tissue handling</p> <p>trained in the recently introduced robotic surgery</p> <p>training or mentoring programs were available at that time</p> <p>training quality</p> <p>transitioned to utilizing prone positioning</p> <p>translational skills learnt from this technique</p> <p>triangulation</p> <p>uncomfortable ergonomic positions for surgeons</p> <p>uncontrolled assistants' traction</p> <p>useful to implement surgical training of colorectal surgeons</p> <p>vibration and shaking of a transmitted video</p> <p>visibility</p> <p>visualisation of the operative field</p> <p>visualization</p> <p>we were inclined to follow the traditional direction</p> <p>widely considered one of the most difficult and time-consuming</p> <p>working in a limited space</p>
Patient's experience of the innovative procedure/device		<p>comfort level</p> <p>satisfied with the result</p>
Required resource use specific to the innovative procedure	<p>cost constraints</p> <p>involvement of therapeutic gastroenterologists</p> <p>total procedure time</p> <p>cost of robotic surgery</p> <p>secondary suturing (d after daily dressing change)</p> <p>Use of analgesic drugs (pod)</p> <p>Follow-up colonoscopy</p> <p>laparoscopic exploration [as a result of intestinal obstruction]</p> <p>successfully retreated endoscopically</p>	<p>access to the robotic platform</p> <p>additional time was needed to position the scanner, perform a prerotation to assess possible collisions and for the acquisition itself</p> <p>amount of extra time needed to use the system</p> <p>camera holder and assistant are needed in laparoscopic surgery</p> <p>changes will make it possible to operate the navigation system without additional staff during surgery</p> <p>cost of the procedure</p> <p>costs the instrument nurses more time to swab the laparoscopic lens with iodine cotton ball</p> <p>dedicated technical assistants are involved in the patient setup and the imaging in the OR</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>During surgery, one technical assistant remains present to monitor performance and for troubleshooting</p> <p>employ this technique only when surgeons and instruments are available at our hospital</p> <p>expense</p> <p>increases the workload of the nurses</p> <p>initial costs</p> <p>Initially, this process added 10 to 20?minutes of OR time, but towards the end of the study, scans were consistently performed within 8?minutes</p> <p>limitation of laparoscopic/endoscopic apparatus</p> <p>price of equipment</p> <p>requires at least two surgical teams and two sets of laparoscopic/endoscopic apparatus</p> <p>shortage of surgeons</p> <p>stuff energy saved</p> <p>surgeon can operate on his or her own self without the need of an assistant surgeon</p> <p>surgeon solely controls the camera and assist arm in the robotic system</p> <p>suture length to complete the procedure</p> <p>use of expensive consumables</p> <p>24 h monitoring</p> <p>additional cost of the robot</p> <p>Additional procedures (VRAM perineal reconstruction, Intra-operative radiotherapy)</p> <p>cost associated with the equipment</p> <p>cost of robotic surgery</p> <p>cost of robotic surgery</p> <p>cost-savings associated with reduced hospitalization in patients who might have otherwise required an open approach</p> <p>extra costs to the health-care system</p> <p>required anorectal dilation secondary to severe stenosis within a 2?month postoperative period</p> <p>requires a specific procedural surgeon and institutional experience</p> <p>requires careful patient scheduling and planning</p> <p>requires more personnel and more surgical equipment</p> <p>requires plastic surgeons</p> <p>restoration of ileostomy without any treatment</p> <p>time-consuming</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>economical restrictions of the hospital</p> <p>expensive</p> <p>health-care-associated cost</p> <p>impact on hospital finances and reimbursement</p> <p>Repeat endoscopy</p>
Details of operator training/expertise required in future		<p>experienced surgeon who has performed more than 260 robotic colorectal surgeries</p> <p>procedure must be carried out by a highly skilled endoscopist</p>
Details of patients suitable for the procedure in future		<p>adequate standardization of the procedure and experiences</p> <p>alternative to surgery in selected cases</p> <p>annual changes in the numbers of patients</p> <p>avoided in the early stages of the learning process</p> <p>cannot be recommended</p> <p>casts doubts on the relevance of the >?1?mm margin requirement and the necessity for eFTR</p> <p>confounding factors that limit the application</p> <p>contraindications to performing this approach</p> <p>contraindications to u-stomas</p> <p>cut-off size of the lesion</p> <p>early rectal cancers amenable to local resection</p> <p>effective for difficult-to-resect colorectal lesions</p> <p>Eligibility for eFTR in selected patients</p> <p>endorsed by renowned colorectal experts worldwide for several indications</p> <p>generalizability of TAMIS for rectal neoplasms</p> <p>Indication for EFTR</p> <p>Indications for intended-to-be temporary stomas</p> <p>limits its use to relatively small lesions</p> <p>limits its use to relatively small lesions</p> <p>mandatory before the surgeon may commence to learn or implement TAMIS</p> <p>mandatory when (relatively) novice surgeons learn novel surgical techniques</p> <p>maximum size of the lesions, which can be successfully resected, is limited</p> <p>no definitive treatment recommendations</p> <p>not suitable for surgery due to medical comorbidities</p> <p>not widely used in the surgical field</p> <p>operability</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>patients suitable to this new surgical technique</p> <p>patients themselves selected the surgical procedure</p> <p>patients were deemed resectable</p> <p>possibility to be an alternative to the treatment of locally advanced rectal cancer</p> <p>procedure may not be eligible</p> <p>R0 resection of higher rectal cancers is possible using transanal robotic microsurgery</p> <p>reasons for non-enrolment</p> <p>recommend its widespread use</p> <p>routinely performed</p> <p>threshold for local therapy</p> <p>transferability of our results of robotic TME to western people</p> <p>useful technique in a cohort of patients in whom conventional stenting has failed/is unsuitable</p>
Mechanical/technical problems with device	<p>unable to measure the StO₂</p> <p>incomplete OTSC deployment</p> <p>mean target registration errors</p> <p>snare malfunction</p> <p>technical difficulty with colonoscopy and concerns for surveillance</p> <p>technical issues with the laparoscopic approach</p> <p>Tracker registration error (range, mm)</p> <p>clip presence at surveillance endoscopy</p> <p>ICG localization consistent with preoperative imaging?</p> <p>ICG lymphatic mapping timing</p> <p>injection site</p> <p>intact C-seals in situ</p> <p>median proximal change distance of the transection line</p> <p>median time from ICG injection to the first visible fluorescence signal</p> <p>no specimen obtained [...] due to inability to mobilize the lesion into the cap</p> <p>optimal protocol for dose</p> <p>OTSC to spontaneously dislocate unnoticed</p> <p>rate of device failure</p> <p>snare dysfunction after clip deployment</p> <p>Target lesion reached with FTRD, n (%)</p> <p>Technical success (macroscopically complete and en bloc), n (%)</p> <p>Tumour localized with ICG</p>	<p>10-Fr pigtail catheter was exchanged for the sheath, capped and left in place along with the colopexy suture anchors</p> <p>colonic gas explosion caused by the resection snare</p> <p>degree of maladjustment was experienced at the beginning of surgery</p> <p>deployment of an uncovered colonic stent</p> <p>fogging time</p> <p>fulcrum effect of straight laparoscopic instruments</p> <p>inaccessibility of the target lesion</p> <p>insufficiency of OTSC closure</p> <p>Laparoscopic lens fogging</p> <p>line of sight system employed by the current robotic platforms</p> <p>lumen closure could be due to excessive suction applied during the traction phase</p> <p>need of technical support</p> <p>obstruction of the gut lumen</p> <p>patient-specific three-dimensional (3D) roadmap</p> <p>performance of this tool</p> <p>snare dysfunction with rupture</p> <p>stiffness of the endoscope</p> <p>technical difficulty in ESD</p> <p>Technical innovations in the robotic approach</p> <p>technological superiority provided by the robotic system</p> <p>unstable 2-D (two-dimensional) view</p> <p>[knot tying] to have a high rate of failure</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Visualization of lymphatic drainage	a single-use incision protector should be used to protect incision from pollution or cancer cell implantation when taking out the surgical specimen via the incision absence of peristalsis in the C-seal air pressure of the perineal surgery area change in fluorescence intensity distance between the target colon and the laparoscopic camera lens Due to clip geometry, the snare often cannot be placed close enough to the pseudopolyp base fluorescence intensity fluorescence intensity of the intestine at the initially planned transection site fluorescence slope hypoperfusion appearance image conditions information suitable for a tailored, patient-specific laparoscopic approach Knot integrity less to no bowel movements distal to the anastomosis because of the C-seal lighting conditions of the surgical field location of video shooting Lymphatic drainage was variably demonstrated maintaining adequate traction of the suture maintaining stable peritoneum no further spread 10 min after injection node was not readily palpable but clearly visible optimal concentration of ICG poor perfusion of the proximal colon judged by ICG angiography real-time evaluation of intestinal perfusion reliability in function of the device revision of the transection site sensitivity rates specificity specificity rates surgeon's visual interpretation for ICG fluorescence surgical difficulties technical difficulties technical limitations

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		technical problems tissue tearing transmural resection (muscularis propria fully present, including serosal layer) utility of quantitative evaluation visibility during resection is impaired by the long cap
Overall desired effect of procedure /device achieved	the presence of positive resection margins histological complete resection Histologically confirmed full-thickness resection histologically negative margins Histopathology confirmed full-thickness resection R0 resection R0 resection R0 resection R0 resection (negative lateral and deep margins) R0, sm invasion >1000 um radical/ complete resection (R0) rate recurrent lesion after eFTR Resection classified as curative, n (%) "Resection classified as incurative, n (%)" resection en bloc resection macroscopically complete residual adenocarcinoma detected residual disease Endoscopic surveillance [...] 3 months after eFTR Endoscopic surveillance [...] 9 months after eFTR Five-year disease-free survival Five-year overall survival High risk of lymph node metastasis after resection of T1-CRC lateral and basal margins free of carcinoma lateral and basal margins free of scar tissue No residual or recurrent lesion Disease free survival, months disease-free survival distal metastasis local recurrence loco-regional recurrence during the follow-up period Locoregional tumor recurrences lymph node recurrence in peri-pancreatic region overall survival rates	additional colon resection adequate local control with good-quality surgery alone local disease control need additional surgery recurrence free survival surgical integrity of the specimen local recurrence rate recurrence after surgery 5-year survival 5-year survival rates accuracy of the TME dissection accurate and precise transanal dissection additional morbidity adequate local control adequate lymphadenectomy blood pressure of marginal artery cancer-free survival circumferential and deep margins circumferential resection margin (CRM) clip removed endoscopically clip spontaneously detached from the colonic wall colorectal surgeon's ability to address early rectal cancer CRM was negative curative curative R0 laparoscopic right hemicolectomy death disease-free survival documented reasons for failure frequency of local recurrence inconclusive radicality Involvement of the lateral compartment structures life expectancy local disease recurrence local radical resection was plausible after eFTR (lateral and basal margins free of carcinoma)

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>Overall survival, months</p> <p>2-year overall survival rates</p> <p>2-year relapse-free survival rates</p> <p>30-day mortality</p> <p>30-day readmission rate</p> <p>3-year overall survival rate</p> <p>3-year survival rate</p> <p>5-year disease-free survival</p> <p>5-year disease-free survival rate</p> <p>5-year disease-specific survival rate</p> <p>5-year local recurrence rate for curative resection</p> <p>5-year overall survival rate</p> <p>5-year survival rate</p> <p>90-day postoperative mortality</p> <p>anal function (Anorectal manometry results)</p> <p>anastomotic blood supply</p> <p>anastomotic recurrences</p> <p>blood flow</p> <p>cancer recurrence</p> <p>cancer recurrences</p> <p>Change of transection line (Yes/No)</p> <p>circumferential and distal resection margins</p> <p>circumferential distal margins</p> <p>circumferential radial margins</p> <p>circumferential resection margin</p> <p>Circumferential resection margin</p> <p>circumferential resection margin</p> <p>circumferential resection margin (CRM)</p> <p>Circumferential resection margin (positive, negative)</p> <p>circumferential resection margin involvement</p> <p>clear resection margins</p> <p>Complete mesorectal excision (intact mesorectal fascia)</p> <p>complete TME</p> <p>Complete TME samples</p> <p>completeness of mesorectal excision (complete, nearly complete, incomplete - Quirke et al.)</p> <p>Curability</p> <p>Dead</p> <p>death in the peri-operative period</p> <p>deaths</p> <p>disease-free survival</p>	<p>local recurrence</p> <p>local recurrence</p> <p>local recurrences</p> <p>long-term survival</p> <p>margin involvement</p> <p>marginal arterial stump pressure</p> <p>misdiagnosis of the perfusion status by novice surgeons</p> <p>morbidity</p> <p>morbidity</p> <p>mortality</p> <p>nodes were removed by lymph node picking</p> <p>of no clinical consequence to the patients</p> <p>oncological local control</p> <p>oncological radicality</p> <p>optimal TME</p> <p>poor prognosis</p> <p>prognosis of patients</p> <p>quality of pathological specimens</p> <p>quality of resected oncological specimens</p> <p>quality of specimen</p> <p>quality of surgery</p> <p>quality of surgery</p> <p>quality of the mesorectum</p> <p>quality of the resection</p> <p>quality of the specimen</p> <p>R0 resection rate</p> <p>radicality of the resection</p> <p>recurrence rate</p> <p>requiring repeated colonoscopies</p> <p>resection margin</p> <p>satisfactory oncologic results</p> <p>specimen quality</p> <p>specimen quality</p> <p>substantial morbidity</p> <p>successful oncologic resection</p> <p>surgical quality of robotic TME</p> <p>survival outcomes after surgery</p> <p>survival rate</p> <p>the FTRD clip was not in place any more</p> <p>TME quality</p> <p>traditionally considered irresectable</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>disease-free survival (1-year-follow-up)</p> <p>distal and circumferential margin</p> <p>distal margin</p> <p>Distal margin (mm), mean- SD</p> <p>distal resection margin</p> <p>distal resection margin</p> <p>distal resection margin</p> <p>Distal resection margin (cm; mean $\pm$ SD)</p> <p>distal resection margin (positive, negative)</p> <p>distal resection margins</p> <p>Distant metastases</p> <p>distant metastases</p> <p>Distant recurrence</p> <p>Distant recurrence</p> <p>distant recurrence rate</p> <p>distant recurrences</p> <p>Efficacy for tumor targeting</p> <p>endoscopic cure rate</p> <p>evidence of lymph node metastasis</p> <p>Fate of OTSC, n (%) (Spontaneously fallen off, In place, Removed endoscopically)</p> <p>Intraoperative blood loss (ml)</p> <p>involvement of circumferential resection margins</p> <p>Involvement of circumferential resection margins</p> <p>ircumferential margin</p> <p>lateral node recurrences</p> <p>local pelvic recurrences</p> <p>Local recurrence</p> <p>local recurrence</p> <p>Local recurrence</p> <p>local recurrence</p> <p>local recurrence</p> <p>local recurrence in the specimen extraction sites</p> <p>local recurrences</p> <p>local recurrences</p> <p>Long-term outcomes</p> <p>Margin positivity</p> <p>margin status</p> <p>margin status</p> <p>Margin status</p> <p>margins</p>	<p>tumor remnant</p> <p>unclear margins due to fragmentation</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>Median circumferential resection margin</p> <p>median distal resection margin</p> <p>median time to recurrence (local and/or distant)</p> <p>mesorectal integrity (complete, near complete, incomplete)</p> <p>metastasis to distant organs</p> <p>metastasis to the lymph nodes</p> <p>morbidity</p> <p>morbidity</p> <p>mortalities</p> <p>mortality</p> <p>mortality</p> <p>Mortality (n) (%)</p> <p>Nearly complete TME samples</p> <p>negative circumferential resection margin</p> <p>negative margins</p> <p>No. of positive LNs, mean??SD</p> <p>Nodal status</p> <p>Number of patients with tumor-free resection margins</p> <p>One-year overall survival</p> <p>Overall survival</p> <p>overall survival rate</p> <p>pelvic recurrences</p> <p>positive circumferential margin</p> <p>positive circumferential margin (CRM)</p> <p>Positive CRM</p> <p>Positive distal margin</p> <p>Positive LNN count</p> <p>positive lymph nodes</p> <p>Positivity of resection margins</p> <p>Postoperative death (12 mo)</p> <p>postoperative deaths</p> <p>Postoperative liver/lung metastasis (12 mo)</p> <p>Postoperative local recurrence (12 mo)</p> <p>proximal and distal resection margins</p> <p>Proximal resection margin (cm; mean $\pm$ SD)</p> <p>proximal resection margins</p> <p>proximal, distal, radial, and circumferential margins</p> <p>Quality of specimen</p> <p>quality of the mesorectum, according to Quirke's criteria</p>	

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Quality of the mesorectum, n (%) (good, intermediate, poor) quality of total mesorectal excision (TME) specimen R0 resection R0 resection radial margin Radial margin positive (RM1) Radical resection margin, n (%) recurrence recurrence recurrence for 3 months recurrence for 48 months recurrence rate recurrences [at 6-month follow-up] regional nodal recurrences Resection margin status resection status residual tumour stoma reversal Successful ICG fluorescence imaging surgical margin Survival target lymph nodes successfully removed the number of positive lymph nodes tissue oxygen saturation (StO2) TME completeness rates tumor recurrence tumor recurrences or metastases occurred widespread multivisceral recurrence	
Anticipated advantages	clinical value [defined as the number of additional liver metastases found by CE-LUS cysts detection rate of occult liver metastasis eFTR of lesions at the appendix base focal fatty sparing hemangioma number of lymph nodes that can be harvested perform the surgery safely performed by a single surgeon R0 resection Surgical Efficiency tactile feedback	ability to move the patient quickly during robotic surgery advantage in using TB over other alternatives allowing the surgeon to adjust the resection margins and ensure all oncologically relevant tissue is removed with precise mesocolic margins avoids the need to reposition the endoscope before snaring benefit of laparoscopic surgery better access due to a higher degree of freedom of motion with robotic instruments Better and stable vision boundary of the removed tissue could be clearly identified change the operative course

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>accuracy</p> <p>Abdominal laparoscopic closure of defect, n (%)</p> <p>No complication, n (%)</p> <p>Penile viability</p> <p>potential prevention of permanent stoma formation</p> <p>referred to/ need for additional oncologic surgery</p> <p>better preserve normal voiding and sexual function</p> <p>**not verbatim** time to perform the CE-LUS procedure</p>	<p>coverage of a wide surgical area was required</p> <p>direct visual access to the perineal operative field</p> <p>ease and precision of distal transection</p> <p>functional advantages over laparoscopic approaches</p> <p>identify the anatomical layer</p> <p>improves the quality of TME in CAPR</p> <p>intraoperative advantages</p> <p>limited range of motion</p> <p>offers considerable leverage</p> <p>operation quality of cylindrical resection</p> <p>performed under direct vision</p> <p>plane of surgery</p> <p>possible to make this change without needing to perform a more complex dissection</p> <p>potential to guide mesenteric lymphadenectomy</p> <p>precision of dissection</p> <p>preferable to vaginal preservation</p> <p>prevents extraluminal fluid leakage</p> <p>problems related to the need for one-handed manual firing</p> <p>provides skills and senses a human being lacks</p> <p>quality of surgical resection</p> <p>reducing the need for instrument changes</p> <p>safety margin can be more easily obtained</p> <p>secure stump formation</p> <p>self-control of the camera and a third instrument</p> <p>simplified intestinal reconstruction</p> <p>surgery could be avoided</p> <p>tension-free anastomosis during da Vinci Xi rectal resection</p> <p>the magnified laparoscopic view allows the surgeon a new view angle to observe perineal topography</p> <p>the surgeon could easily achieve R0 resection</p> <p>theoretical advantages like better 3D vision and more precise dissection</p> <p>unfavorable entry angle from the assistant port</p> <p>use of more than three cartridges for distal rectal transection</p> <p>well suited for multiquadrant surgery</p> <p>width and limited range of motion</p> <p>a step ahead in customized image-guided surgery</p> <p>accommodating a larger amount of tissue</p> <p>adequate exposure of the distal urethra</p> <p>advantages of flexible operative platform</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p> advantages of robotic surgical systems advantages related to minimally invasive surgery advantages to performing LE allowing for a more aggressive resection with a stable platform beneficial effect of ICG angiography beneficial in the technically challenging area of low rectal cancer surgery benefit of robotic-assisted laparoscopy compared with conventional laparoscopy benefits of D3-lymphadenectomy benefits of intracorporeal anastomosis after laparoscopic right colectomy benefits of robotic surgery benefits of SILS better angulation and firing of stapler insertion better preservation of the abdominal wall better visualized using the TaTME technique can minimize physical invasion changing places of working instruments and camera clear operative vision clinical value of CE-LUS common pitfall complexity of procedures confer an advantage considered an alternative to open conversion consistent results constrained by the anatomy of the pelvis control of distal resection margin designed to be reusable after sterilization differences of operator and team setting difficulty in achieving adequate traction of the rectum direct visualization of the inferior edge of the tumor easier to learn effects of other technical factors related to AL endowristed instrumentation enhanced ability enhanced dexterity enhanced image resolution with 3D visualization excellent sealing effects excellent vision exposure of the deep pelvis from the abdominal cavity </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p> exposure to surrounding structures good supply of the anastomosis grossly intact circumferential mesorectal specimens holds great value identification of pelvic autonomic nerves improve our knowledge of anatomy as applied to laparoscopic surgery improved bleeding control compared to conventional laparoscopy improved motion scaling and filtering improvements in surgical hardware and technique increased rotation movements increased surgeon's proximal reach individualized preoperative planning for complex operations inhibits regional fluid collection insufficient blood perfusion intestine adhesion to the pelvic floor Intraoperative ICG fluorescence imaging is beneficial in several surgical fields lesion accessibility less handling of the tumor limited angulation of laparoscopic instruments local quality effects magnified three-dimensional view controlled by the surgeon Magnified visualization via endoscopy major benefits maneuverability minimal toxicity need for extreme traction on the specimen newer robotic systems offer flexible access number of stapler firings oncological appropriateness of the retrieved specimen operations were successfully performed operative stress outside triangulation parietal trauma pelvic insight poor visualization possibility to improve postoperative outcomes postural changes potential superiority </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>potentially promising method</p> <p>precise tissue handling</p> <p>preserving advantages of minimally invasive surgery</p> <p>preventing damage to vital surrounding structures</p> <p>procedures more uneventful</p> <p>provided better exposure with reduced intraluminal smoke</p> <p>proximal change of the initially planned transection site</p> <p>quality of surgical care</p> <p>quick to perform</p> <p>R0 negative distal margin</p> <p>ransanal robotic surgery gives the colorectal surgeon additional tools to address pathology farther from the anal verge than was previously possible</p> <p>reduce the technical difficulties</p> <p>requires a large skin incision to create an adequate surgical field</p> <p>retain the advantages of minimally invasive surgery while minimizing the limitations of SILS</p> <p>retraction to improve the view and dissection</p> <p>Robotic approach provides some advantages over conventional laparoscopic approach</p> <p>robotic assisted approach affords several technical advantages over standard laparoscopy</p> <p>robotic procedures may enable more meticulous TMEs</p> <p>safe anesthesia</p> <p>safe laparoscopic surgical field</p> <p>short-term recovery profiles</p> <p>small surgical wound surface</p> <p>specially designed to facilitate complex surgery</p> <p>speed of dissection</p> <p>stable image-transmission environment</p> <p>stable surgical platform</p> <p>successfully managed</p> <p>sufficient surgical field</p> <p>superior to conventional completion TME</p> <p>surgical precision</p> <p>surgical stress</p> <p>technical advantages</p> <p>technical advantages of the da Vinci Xi system's thinner arms, longer instrument shafts, and increased joint dexterity</p> <p>technical difficulties</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p>technical difficulties associated with standard laparoscopy</p> <p>technical difficulties that are encountered during LAR and ISR</p> <p>technically difficult</p> <p>theoretical benefits of the robotic approach</p> <p>tissue trauma</p> <p>translate the surgeon's hand movements to smaller and more precise movements of the instruments inside the patient</p> <p>usefulness</p> <p>uses fewer and or smaller trocars</p> <p>view of the resection margins</p> <p>visual magnification of the resection field</p> <p>visualisation of the perianal region</p> <p>visualization</p> <p>visualization</p> <p>visualization of the distal margin</p> <p>working space inside the abdomen</p> <p>air-sealing quality</p> <p>appropriate use of insufflation devices</p> <p>benefit is likely related to the robot's magnified view</p> <p>different viewing modes</p> <p>flexibility of current single-use transanal ports</p> <p>mechanic arm flexibility</p> <p>seven degrees of wrist-like motion</p> <p>three-dimensional vision</p> <p>tremor filtering</p> <p>allows real-time monitoring and quantifying of StO2 in various organs and tissues</p> <p>burst pressure in arteries up to 7mm in diameter using TB</p> <p>improved instrument design</p> <p>is easily reproducible</p> <p>prevent major surgery</p> <p>faster anastomosis times</p> <p>clear benefits of the laparoscopic approach</p> <p>effects of the use of rectal tubes</p> <p>immune function after surgery</p> <p>improvements in short-term post-operative results</p> <p>lower leak rate after these technical modifications</p> <p>lower postoperative infection rate</p> <p>offer better results than laparoscopic TME</p> <p>pain</p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
		<p> patient avoided transportation and great risks to lose heart beat and get infected patient safety perioperative outcomes postoperative recovery preservation of immune function procedure-related factors rate of constructing a protective ileostomy recovery recovery times reduced the need for surgery risk reduction in relapse satisfactory healing without stricture or defect satisfied cosmetology short-term benefits sphincter preservation stent to have opened nicely with free flow of contrast to the transverse colon stoma site was clean and healthy stress superior cosmetic effect trauma potential added value for future clinical application improved quality of life incremental patient and provider benefits </p>
Anticipated disadvantages	<p> [intraoperative] complications [occurrence of] perforation of the rectum [total number of] Complications Acute appendicitis with requirement of laparoscopic appendectomy acute inflammation adverse events Bleeding bleeding Bleeding (ml) bleeding / Major bleeding (Hb drop >2 g/l) bleeding control bleeding from small bowel mesentery bleeding from the inferior mesenteric vein pedicle after using the vessel sealer blood loss </p>	<p> adhesions adhesions bleeding blockage of the blood flow blood flow to the mucosa and submucosa may be deficient blood loss blood loss blood loss from the dorsal venous plexus burns can expose patients to peculiar and terrifying complications collision between instruments collision of instruments complications related to the barbed suture material Complications suspected to be device-related conflicts between the camera scope and instruments contamination of the operating field </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	blood loss Blood loss (mL) blood transfusion blood transfusion bowel perforation colo-rectal wall trauma/ Traumatic wall lesions concomitant colitis requiring resection concurrent diverticulosis defect of the bladder wall dense adhesions diffuse bloody oozing from the cut surface of the mesocolon dilated small intestine distal stapler misfire requiring anastomosis revision ESD-related complications Estimated blood loss (%) fragmentation of a 12-cm mass during resection increase in surgery complications injuries Injury to organs intestinal perfusion Intraoperative adverse event, n (%) Intraoperative adverse events intraoperative bleeding intraoperative bleeding Intraoperative bleeding (mL, median) intraoperative bleeding volume intraoperative blood loss Intraoperative blood loss Intraoperative complication intraoperative complication (bowel wall perforation with intestinal content spillage) Intra-operative complications (%) intraoperative complications or any adverse events related to ICG administration Intraoperative injury Intraoperative morbidity Intraoperative perforation Intraperitoneal adhesion ischemia of the transverse colon Major bleeding (transfusion needed)	contamination with feces or cancer cells crowding in the small single incision decrease in the StO2 is expected to be extensive difficulties during the operation easily proceed toward the anterior-lateral side of the prostate fibrosis at the previous excision site fibrosis of the wall fragmentation of a 12-cm mass during resection gut injury hemodynamic instability high procedural complication rate inadequate countertraction incorrect plane dissection inflammatory change injuries injury or resection of the surrounding tissues or organs injury to adjacent organs injury to the anterior tissues injury to the mesorectal fascia Injury to the pelvic autonomic nerves injury to the ureter integrity of the rectal wall interference of intraoperative factors on the operation intra-abdominal injury during resection intraoperative difficulties mist from exudates oedema perforation of the rectal tube perforation of the rectum perforation risk perioperative trauma peritoneal perforation poor visibility problems related to multifiring of the stapler problems with correct dissection plane identification pulsation and bleeding from the marginal arteries purse-string suture failure right gastroepiploic artery bleeding risk for peritoneal entry associated with the TAMIS access platform risk of bleeding during laparoscopy

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	major complications major intra-operative complication major peritoneal adhesions massive venous bleeding Minor bleeding Minor bleeding paroxysmal atrial fibrillation penetrated the whole layer of the bowel perforation perforation Perforation (1primary, 1secondary) Perforation of the rectum Perioperative complications [composite] Peritoneal violation poor polyp visualization due to patient factors procedure-related adverse events rate of intraoperative complications rectal disruption during insertion of a stapler device Rectal perforation (%) serious complications serious intraoperative complications significant anastomotic bleeding after stapling small injury on its wall specimen fragmentation stenosis after the deployment of the clip surgical site complications Surgical site infection tracheostomy Transfusion during operation tumour perforations tension on the anastomosis Adverse events irrigation of the incision [number of] adverse events [number of] post-surgical patients 30 day post-operative complications 30-day morbidity [composite] 30-day mortality 30-Day Postoperative Outcomes (Clavien-Dindo classification) [composite] 30-day readmission	risk of failure to progress in the pelvis. risk of inadvertent injury risk of insufficient margins risk of urethral injury severe adhesions specimen fragmentation surgical wound complications tearing of the superior mesenteric vein technical concerns technical limitations technical problems tissue damage tissue fibrosis Transfusion trocar-related potential complications of abdominal trauma unclear anatomical planes unclear anatomy vesical trigone injury vessel injury violation of the intraperitoneal cavity will most likely injure the autonomic nerve plexus restricted ranges of instrument movement within the confines of the pelvic space robotic arm collision robotic arm collision blood supply of the rectal stump bowel contents are not pushed through the C-seal patient convalesced nicely without any complications 30-day mortality abdominal abscess abdominal wall trauma Acute appendicitis Acute ischemia additional complication risks additional surgery was recommended additional treatment After this protocol change, we did not see any perforations proximal to the anastomosis anastomotic bleeding anastomotic complications were suspected within 30 days after surgery

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	30-day reoperation rate 30-Days complications (Clavien-Dindo) 30-Days mortality abdominal pain abdominal sepsis due to various reasons abdominal wound dehiscence Abscess (%) acute urinary retention Acute voiding difficulty additional eFTR of scar tissue after endoscopic resection Adverse event rate adverse events caused by the use of the system AL (Emergent surgery) Anal incontinence anastomotic complication anastomotic complications Anastomotic dehiscence anastomotic fistula / anastomotic leakage (%) anastomotic leak Anastomotic leak Anastomotic leakage Anastomotic leakage anastomotic leakage anastomotic leakage Anastomotic leakage anastomotic leakage Anastomotic leakage anastomotic leakage Anastomotic leakage Anastomotic leakage (conservative treatment) Anastomotic leakage (operative treatment) Anastomotic leakage (percutaneous drainage of the near-anastomotic abscess) Anastomotic leakage [Grade II] Anastomotic leakage [Grade III] Anastomotic leakage with concomitant sepsis (operative treatment) anastomotic leaks anastomotic leaks anastomotic stenosis antibiotics	anastomotic leak rate anastomotic leakage anastomotic leakage anastomotic leakage with fatal outcome anastomotic stenosis Anastomotic stricture, through which it was difficult to pass the endoscope anticipated risk of stenosis asymptomatic anastomotic fistulas avoiding harm to the patient Biopsies if there was evidence of residual/recurrent lesion blowout in the already vulnerable proximal bowel wall bowel obstruction carcinomatosis from pelvic seeding after peritoneal entry chronic perineal sinus clinical sequelae of AL clinically relevant stenosis clip was deeply ingrown into the colonic wall and could not be removed colonic hypomobility colonic ischemia colonic lumen diameter [...] directly after eFTR colonic necrosis complication in the learning phase compromised blood flow at the site of the anastomosis could impair genitourinary function damage to surrounding organs dehiscence delayed bleeding delays subsequent therapy did not completely prevent AL died of other diseases or old age discharged without complication elevated infection parameters emergency surgery was necessary endoscopic clip removal endoscopically untreatable adenoma recurrence at surveillance estimated toxicity faecal incontinence fecal contents might congest in the C-seal while the content is distally propelled

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p> appendicitis Appendicitis (mild symptoms), conservatively treated Aspiration pneumonia asymptomatic anastomotic leak rates Bleed Bleeding Bleeding bleeding Bleeding at anastomotic site Bleeding at anastomotic site [Grade III] bowel distension bowel necrosis bowel occlusion bowel perforations proximal of the anastomoses C difficile Cardiac problems Cardiopulmonary Clavien-Dindo classification Clavien-Dindo classification Clavien-Dindo complications type (n) (%) (I, II, III, IV) Clear or haemoserous discharge from the perineal wound Colitis [Grade II] complication Complication complication complication rate (acceptable, unacceptable) complications Complications Complications complications (Clavien-Dindo classification) complications (Clavien-Dindo grade) complications (SSI and anastomotic leakage excluded) Complications were graded using the Clavien-Dindo (CD) classification congestive heart failure death deaths related to AL Debridement (d after daily dressing change) Deep infection with or without tissue breakdown deep surgical site infection [following u-stoma reversal] </p>	<p> fecal discharge from the pelvic drain fecal impaction fecal spill fistula formation free intraperitoneal air good safety profile hard fecal mass high intraluminal pressures in the denervated part Hospital readmissions incidence rate insufficient collateral circulation intra-abdominal fluid intractable perineal complications ischaemic cerebral stroke at day 8 after resection leak rate [...] due to technical aspects likelihood that patients will experience complications within 30-days after operation major complications managed successfully with intravenous antibiotics minimal morbidity morbidity morbidity morbidity mortality mortality mucosal leak due to incomplete closure of the OTSC necessitating blood transfusion need for a permanent stoma needed a minor surgical procedure needed-to-treat and significant morbidity/mortality negative impact on the long-term prognosis of patients nerve injuries not associated with any complications NSQIP Risk Calculator rate for the population enrolled in the study overtreatment for cases without invasion to the vagina patients lost patients underwent a relaparotomy pelvic abscess pelvic abscess pelvic abscess formation </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p> deep surgical site infection at the wound site deep vein thrombosis defecatory dysfunction Delayed bleeding delayed healing delirium diarrhea died after several readmissions dilations for rectal stenosis [at two follow-up visits] drainage Early postoperative surgery (60 days) Emergency surgery after eFTR Endoscopic exam for leak Enterocolonic fistula after EFTR of an adenoma at appendiceal orifice evidence of infection fecal incontinence Fecal peritonitis, sepsis Fever (%) Fever with unknown cause Haemorrhage (%) Hematoma High output ileostomy High output ileostomy with readmission High output stoma Histological incomplete resection ileal volvulu Ileus Ileus Ileus Ileus ileus Ileus Ileus Ileus Ileus [Grade II] Ileus [Grade III] incision infection in the perineal region incisional hernia incisional hernia 22 months after surgery incisional hernia during the study period infection grade </p>	<p> pelvic dysfunction pelvic sepsis percutaneous catheter drainage was performed perioperative morbidity perioperative mortality peritonitis persistent severe diarrhoea after successful resection persistent symptoms physical trauma pneumonia port site and umbilical hernias port-recurrences possibility wound infection postoperative complicated course rates post-operative complication postoperative morbidity rate postoperative mortality potential adverse outcomes predicted rate of SSI probability of anastomotic complications prolonged wound care psychological trauma pus R1 resection after EMR/ESD/polypectomy raised intraluminal pressure readmissions re-admissions readmitted to an external facility rectovaginal fistula re-operation rate required antibiotics required further surgical treatment required surgical intervention requiring discharge with a urinary catheter requiring re-intervention requiring re-intervention residual rectal defect risk of anastomotic leakage risk of intra-abdominal tumour cell seeding risk of permanent stoma risks of surgery </p>

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	infection rate in-hospital deaths Internal hernia Intestinal obstruction Intestinal obstruction Intra-abdominal abscess Intraabdominal abscess [Grade II] Intra-abdominal bleeding intra-abdominal bleeding that did not require surgical intervention Intra-abdominal fluid collection Intraluminal bleeding ischemia ischemia ischemia of the ileal conduit Leak with abscess Leak with sepsis Leak without abscess Leak without sepsis Leakage leakage of stoma leakage rate line sepsis Lymphocele infection major (Clavien-Dindo grade 3-4) postoperative morbidity Major 30-day morbidity (Clavien-Dindo??III) major adverse events rate (within 30 days) major postoperative complications metastasis Mild adverse events Minor (CD I-II), n (%) Moderate adverse events morbidity Morbidity Mortality mortality Mortality mortality mortality Mortality (30-day or in-hospital mortality)	safe safety serious health care problems serious malfunction of the neorectal short-term prognosis signs of clinical leakage signs of peritonitis sinus formation specific pitfalls and complications Stercoral perforation stoma-related problems stricture requiring endoscopic dilatation or surgical treatment subsequent bleeding surgery-related anastomotic failure surgical morbidities surgical risk Surgical site infection rate suspected bowel ischemia trocar site hernia wound complications wound infection wounds healed by secondary intention during the course of follow-up

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Mortality (CD V) mortality rates Mucosal prolapse myocardial infarct needed reoperation needed repeated dressing and repair under general anesthesia Non surgical site complications-NSSC (%) Normal perineal wound healing (10, 30, 60 d 10 d postoperatively) Number of complications (Clavien-Dindo) observed/expected ratio Operation-related [morbidity] Operation-unrelated [morbidity] organ space SSI Overall complications Overall morbidity overall observed SSI rate (superficial, deep, or organ space) Overall rate of postoperative morbidity overall rate of symptomatic AL (grades B and C) Pancreatic fistula Parastomal hernia parastomal hernias [during stoma reversal] Patients readmitted (n) (%) Pelvic abscess Perforation/leak perfusion perineal fistula Perineal wound breakdown perineal wound infection Perineal wound infection perioperative morbidity perioperative complications Perioperative morbidity Perioperative mortality perioperative mortality peritonitis like fever Platzbauch Pneumonia pneumonia	

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Pneumonia Pneumonia (%) Pneumonia [Grade II] Postop mortality (<?POD30) Postoperative bleeding Postoperative bleeding postoperative complication rate associated with the operation Postoperative complications postoperative complications postoperative complications Postoperative complications postoperative complications Postoperative complications (Clavien Dindo, per event) postoperative complications (Clavien-Dindo classification) Postoperative complications (Clavien-dindo) Postoperative complications (Clavien-Dindo) postoperative complications (grade III or higher) Postoperative complications after the TAMIS operation postoperative complications Grade II n (%) postoperative complications Grade III n (%) Postoperative fever of unknown origin postoperative ileus Postoperative ileus (conservative treatment) Postoperative ileus (operative treatment) Postoperative minor surgical complications (%) postoperative morbidity postoperative morbidity postoperative morbidity postoperative morbidity postoperative morbidity postoperative mortality Postoperative perineal hernia (12 mo) postoperative sepsis Postpolypectomy syndrome post-polypectomy syndrome Postprocedural cardiac event pouchitis after total abdominal colectomy Presacral abscess Presacral abscess	

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p> presacral abscess presacral fistula pubic bone osteomyelitis pulmonary complications Pulmonary embolus Pulmonary infections Pulmonary problems Pus/purulent discharge Radial nerve paresis (due to prolonged compression on the operating table) rate of postoperative anastomotic leakage Rate of re-operation rates of postoperative surgical complications Readmission readmission readmission rate readmissions recovered without complications rectal or pelvic dysfunction relaparotomy reoperation Re-operation reoperation for incisional hernia reoperation for intestinal obstruction (i.e., Clavien-Dindo IIIb) Reoperation for leak reoperation rates reoperation within 30 days after surgery Reoperations reoperations Retention of urine separation of the suture line [at first follow-up] serious complications Severe adverse events severe perineal wound infection (Clavien-Dindo grade 3) short-term complications short-term complications short-term morbidity site-specific NSQIP reported rates for SSI skin excoriations "Skin inflammation around the stoma " </p>	

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	<p>small bowel obstructions</p> <p>Specific postoperative surgical complications</p> <p>SSI</p> <p>SSI</p> <p>SSI deep</p> <p>SSI superficial</p> <p>stenosis</p> <p>Stoma bleeding</p> <p>Stoma edema</p> <p>Stoma fistula</p> <p>Stoma infection</p> <p>Stoma necrosis</p> <p>Stoma necrosis</p> <p>Stoma retraction</p> <p>Stoma stenosis</p> <p>stoma-related problems</p> <p>stoma-related problems</p> <p>Stoma-related problems (major CD III-IV)</p> <p>Stoma-related problems (Minor (CD I-II)</p> <p>superficial incisional SSI</p> <p>superficial surgical site infection [following u-stoma reversal]</p> <p>surgical site infection</p> <p>Surgical Site Infection</p> <p>surgical site infections</p> <p>Surgical site infections (SSI)</p> <p>surgical wound dehiscence</p> <p>symptom of acute radiation injury</p> <p>symptomatic AL</p> <p>Symptomatic AL needing reoperation (grade C)</p> <p>symptomatic anastomotic leak rates</p> <p>symptomatic anastomotic leakage rate</p> <p>systemic recurrence</p> <p>TPN requirement</p> <p>treatment-related deaths</p> <p>uncontrolled ascites</p> <p>Urethral stricture [Grade III]</p> <p>Urinary infection</p> <p>Urinary infection [Grade II]</p> <p>Urinary infections</p> <p>Urinary problems</p>	

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Urinary retention Urinary retention urinary retention Urinary retention Urinary retention (%) Urine retention UTI Vaginal stenosis Wound discharge Wound infection Wound infection Wound infection Wound infection [Grade II] Wound infections wound infections Rate of readmission Readmission Readmission readmission rate readmissions	
Duration of procedure	Adjusted mean operation time average operative time bowel reconstruction time Docking time (minutes), mean- SD Lap ISR time Mean operating time Mean operating time mean operation time Mean operative time mean operative time mean operative time Mean surgery time Mean theatre time median console time median docking time Median operative time Median operative time Median operative time, minutes (IQR) Median total operating time operating time operating time for u-stoma construction	anesthesia time console time docking time duration of the procedures duration to find the tumor four or five-port technique was used in their hands operation time long operation time mean operation time mean operative times non-console operating time operative duration optimal dissection line radiation time takes little time time needed to segment the target volumes and normal structures time of the surgeon to explore the space time spent operating on the robot

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	operation time operation time Operation time (min) Operation time (min) Operation time (min, median) Operation time (minutes) Operation time, min, mean (SD) operative time operative time operative time operative time operative time operative time operative time Operative time (minutes), mean pelvic reconstruction time Planned procedure time radiation time surgery [duration] time for resection time needed to reach the lesion with the device mounted on the tip of the scope time of dehumidification time of fog nursing time of operation time spent on the console total duration (min) total operating time Total operation time (min) Total operative time total operative time total procedure time total procedure time whole operative time	
Duration of hospital stay	discharge discharge discharge (POD) discharge on postoperative day discharged (POD) Duration of hospital stay, days, mean (SD) End of case to discharge (h)	discharge discharge discharged from hospital to home duration of stay hospital stay hospital stay hospitalization time

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Hospital stay hospital stay hospital stays hospitalized length of hospital stay length of hospital stay Length of hospital stay (days), mean $\pm$ SD [range] length of stay Length of stay (days) LOS LOS mean admission duration Median duration of hospital stay median hospital stay (IQR), d median hospitalization, Length of stay (days) median length of stay, days (IQR) Median postoperative hospital stay Median postoperative hospital stay Median postoperative hospital stay Postoperative hospital stay (day) Postoperative hospital stay (days), mean - SD "Postoperative hospitalization (d; mean $\pm$ SD)" Postoperative LOS, days Postoperative stay (days) [Time of] discharge Admit to discharge (h) Length of postoperative hospital stay mean length of hospital stay Median length of stay hospital stay "Postoperative hospital stay (d) "	length of hospital stay patients' charge time in-hospital costs length of hospital stay
Patient's physical/psychological experiences after the procedure	[ease of visualisation of the] u-stoma [by patients] during stoma care Abdominal pain (QLQ-C29) Abdominal pain with readmission able to drink water after emergence from anesthesia Adjustment to the stoma Anxiety (QLQ-C29) bladder dysfunction Body image (QLQ-C29) bowel function recovered and eating	Abdominal pain anal function anal sphincter function autonomic functional outcomes benefits to patients bladder dysfunction bladder function bowel function bowel function recovery bowel movement

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	bowel function recovered rapidly bowel function recovery Bowel movement (pod) Cognitive (QLQ-C30) duration of indwelling urinary catheter Emotional (QLQ-C30) fasting after the procedure and resuming a normal diet at 24?h Fatigue (QLQ-C30) fecal incontinence first defecation functional outcome 6 months after defunctioning ileostomy closure functioning functioning score (QLQ-C29) functioning score (QLQ-C30) general condition of the patient global health status, Impotence (QLQ-C29) increased stool frequency Jorge-Wexner scale Korean version of the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire (version 3.0) learning curve for managing the u-stoma life quality liquid diet [d after operation] major low anterior resection syndrome (LARS score) mean global health scores mean impotence score minor low anterior resection syndrome (LARS score) Nausea and vomiting (QLQ-C30) non-specific abdominal pain Off-bed activity time, hours Oral intake, days, median (range) outpatient procedures, resuming a normal diet after 12h Pain score on the first day after surgery (VAS) patient satisfied with the outcome patient's postoperative course was uneventful PCA usage	Change of functional outcome constipation cosmesis cosmesis cosmesis cosmesis cosmetic results cosmetics could sleep on either side easily defecatory disorders demand among patients difficulty in hiding the stoma bag under their clothes Dysmotility of the colon erectile function and sexual desire (International Index of Erectile Function (IIEF)) faster recovery fecal dysfunction fecal incontinence Fecal Incontinence Severity Index Female Sexual Function Index fever functional outcome functional outcomes functional outcomes functional results high chance on acceptance by the end users inability to accept LARS syndrome International Prostate Symptom Score liquid diet meal ingestion mean interval from primary surgery to ileostomy opioids were used for the pain management pain pain pain patient could easily visualize, reach, and manage a u-stoma patient health and wellbeing patient quality of life patient reported outcomes patient satisfied and acceptable Patient-controlled analgesia

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Physical (QLQ-C30) Postoperative anal function postoperative bowel movement recovery (time to the first flatus and time to the first defecation) Postoperative feeling of bulge (12 mo) Postoperative LARS Postoperative pain score (mean $\pm$ SD) (VAS , first day, second day, third day) postoperative pain scores Postoperative Wexner Present Pain Intensity (PPI) index QLQ-CR38 quality of life quality of life (European Organisation for Research and Treatment of Cancer QLC-CR30 and QLC-CR29 questionnaires) quality of life (global quality of life questionnaire (EORTC QLQ-C30)) quality of life (QOL) after surgery Recovery of bowel function (h) Recurrent abdominal pain of unknown cause resumption of diet Role (QLQ-C30) sexual dysfunction sexual function 12 months postoperatively Social (QLQ-C30) stoma exhaust time [hours after operation] Symptom score (QLQ-C29) symptom score (QLQ-C30) symptom subscale scores temporary anal incontinence after low anterior resection tenesmus tenesmus and perineal pain urinary dysfunction Urinary retention, n (%) Urine frequency (QLQ-C29) Visual Analog Scale (VAS) Weight (QLQ-C29) evaluation of residual/recurrent lesion and treatment number of postoperative visits for stoma care	perioperative pain peristaltic recovery postoperative analgesia postoperative pain postoperative pain postoperative pain postoperative pain postoperative pain postoperative recovery postoperative recovery prolonged colonic transit time propulsion of fecal mass psychological problems QOL quality of life quality of life quality of life recovery recovery recovery of intestinal function recovery of sexual function recovery time refused colostomy require more time for proper adaptation return of bowel function return to work sexual dysfunction sexual function sexual function sexual function Sips of water soiling solid diet straightforward well-tolerated procedure superior patient-reported outcomes symptom-based outcomes urinary function urinary function urinary function urogenital function various degrees of incontinence

Outcome domain	Verbatim outcome 'measured'	Verbatim outcome 'mentioned but not measured'
	Postoperative chemotherapy Postoperative hospital stay, days, median (range) Postoperative radiotherapy postoperative stay Preoperative chemoradiation	acceptance of repeated operations for recurrence admitted for postoperative observation arranging efficient logistics Endoscopic examination was repeated patient accepted an intensive follow-up patient transferred to the fluoroscopy suite patients visited the outpatient clinic every 3 months for the first 2 years, every 6 months for the subsequent 3 years, and annually thereafter period of acquisition