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**To cite this article:** Diya Shah, Freweini Martha Tesfai, Matthew Boal, Alberto Arezzo & Nader Francis (2025) Evaluation of current and emerging endoluminal robotic platforms using the IDEAL framework, *Minimally Invasive Therapy & Allied Technologies*, 34:4, 253-266, DOI: [10.1080/13645706.2025.2467805](https://doi.org/10.1080/13645706.2025.2467805)

**To link to this article:** <https://doi.org/10.1080/13645706.2025.2467805>



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Published online: 21 Feb 2025.



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## Evaluation of current and emerging endoluminal robotic platforms using the IDEAL framework

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### ABSTRACT

**Background:** Robotic-assisted endoluminal systems are rapidly evolving within the field of minimally invasive surgery. The IDEAL framework (Idea, Development, Exploration, Assessment, and Surveillance) can be used to evaluate novel technologies. This review provides a summary of current and emerging endoluminal systems using the IDEAL framework.

**Methods:** A scoping review was conducted to include all existing and developing robotic-assisted endoluminal systems. Data was collected *via* virtual interviews, questionnaires, biomedical databases, company websites, and peer-reviewed articles. Key metrics were reported, enabling the assignment of each system to an IDEAL stage.

**Results:** The review identified 17 distinct systems from 16 companies. Nine systems received regulatory approval in their respective countries. Our evaluation showed that two systems were at the pre-IDEAL Stage 0. Seven systems were in the Idea stage (Stage 1), six systems were in the Development stage (Stage 2) and two systems completed Stage 3. No system underwent long-term study evaluation (Stage 4).

**Conclusions:** There is a gap in long-term clinical data of robotic-assisted endoluminal systems, indicated by the absence of systems at Stage 4. Collaborative efforts amongst the medical community, regulatory bodies, and industry specialists are vital to ensure the delivery of evidence-based medicine in the discipline of robotics.

### ARTICLE HISTORY

Received 9 July 2024

Accepted 30 December 2024

### KEYWORDS



Robotic-assisted endoluminal systems; IDEAL framework; minimally invasive surgery; evaluation; robotics

## Introduction

Endoluminal surgery, characterised by interventions performed through the body's natural orifices, is used as a tool for diagnosis and treatment across various specialties. It is associated with reduced hospital stay and enhanced post-operative recovery. However, traditional endoluminal surgery is limited due to unstable views of the surgical field and challenges in enabling precise tissue manipulation and traction. At present, instrument insertion is constrained to the axial pathway of the endoscope, hindering off-axis manoeuvres and potentially complicating endoluminal submucosal dissection (ESD) [1].

Simultaneously, robotic surgery continues to spread across an increasingly broad range of surgical procedures [2]. Robotic surgery has obvious advantages,

including enhanced dexterity, three-dimensional visualization, and greater precision, enabling more intricate and delicate manoeuvres. Furthermore, musculoskeletal pain is highly prevalent among endoscopic surgeons [3]. However, robotic surgery minimises the physical strain on surgeons by allowing them to operate from a seated position at the surgical console. As a result, robotic-assisted endoluminal systems focus on improving ergonomic support, which works alongside the goal of improving patient outcomes. System developments centred around surgeons' ergonomics have been suggested to create improved collaborative robots and better outcomes [4]. By leveraging robotic assistance, complex endoluminal surgery can be more effective, with improved field of view, tissue handling, ergonomics, and tool articulation range [2]. However,

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there are concerns about the rapid growth of robotic surgery in areas with limited evidence to support its use [2].

In the last 15 years, an effort has been made to standardise the implementation of novel innovative surgical technology, as robotic surgery has been introduced without the stepwise testing process routinely used in medical therapeutics [2]. Consequently, the Idea, Development, Explore, Assessment and Long-term study (IDEAL) framework was developed [5]. Evaluating each company's adherence to the IDEAL framework promotes patient safety and helps consumers quickly and easily understand the technology's developmental stage. The rapid innovation of these technologies highlights the need for a comprehensive evaluation of this field. This review aimed to evaluate current and emerging innovations in the field of endoluminal robotics, across various specialities, using the IDEAL framework.

## Material and methods

A scoping review was conducted to appraise robotic-assisted endoluminal systems that are currently available or in development according to the IDEAL framework. Our data was sourced using electronic databases including PubMed, Web of Science, and Scopus, as well as company websites and news articles. Systems discontinued on the market were excluded from the review. We collected several data points including company name, founding year, pre-clinical and clinical trials conducted, price, system and instrument description, training and support available, indications for use, countries and hospitals using the system (if applicable), and any additional information differentiating the system from other competitors. Each company was also contacted and, if they consented, they answered a standardised set of questions *via* interview or form. Companies were given the opportunity to provide any additional information.

The platforms were assessed using the IDEAL framework [5] (Table 1). Specific to the IDEAL + Devices (IDEAL-D) framework for device innovation, we

included Stage 0 which involves the preclinical stage of development [6].

## Results

### Systems demography

Sixteen companies were identified and contacted regarding the development of 17 different robotic-assisted endoluminal systems, including two separate systems from Monarch (Auris Health, Redwood City, CA, USA) (Figure 1A–S). Six systems originated from the United States (35.3%) and two systems originated from South Korea (11.8%). Turkey, Italy, Japan, Germany, the United Kingdom (UK), and China, each accounted for a single system development.

These systems support a variety of specialities with colorectal surgery being the most common surgical system, supported by nine systems. This is followed by the upper gastrointestinal tract and respiratory systems with four each (23.5%). Urology, gynaecology, and otolaryngology are each supported by three systems (Figure 2).

### Systems approval

Food and Drug Administration (FDA) clearance has been achieved by seven out of the 17 systems (41%), and a further two (11.8%) have received clearance from regulatory bodies in Korea, The Ministry of Food and Drug Safety (MFDA), and China, the Chinese State Food and Drug Administration (CFDA).

### IDEAL-D framework assessment

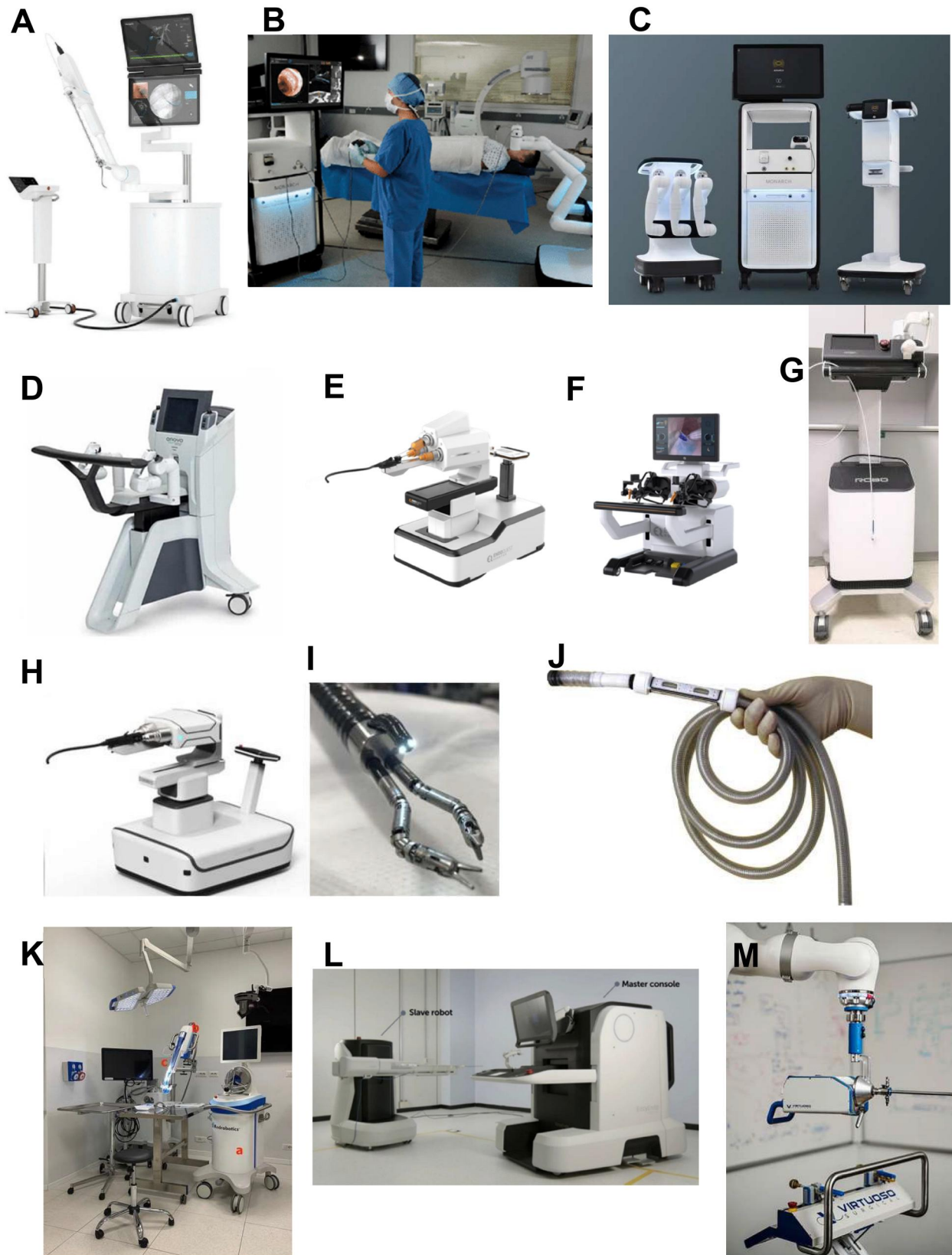
Two systems (11.8%) were assigned Stage 0, seven (41.1%) to Stage 1, and six systems (35.3%) to Stage 2b. Two systems (11.8%) were evaluated at Stage 3 of the IDEAL framework and no endoluminal robotic-assisted platform reached Stage 4 (Figure 3).

Cost data was available for three of the systems: Anovo Surgical System (New York, NY, USA), EndoQuest Robotics (Houston, TX, USA), and Invendoscope (Invendo Medical, Regensburg, Germany). Anovo Surgical System was priced around

**Table 1.** Stages of the IDEAL-D framework.

Stage	Summary
Stage 0: Preclinical *	Evaluation of medical devices prior to first human studies.
Stage 1: Idea	Proof of concept and first use in humans.
Stage 2a: Development	Technical details refined using experience of small case series.
Stage 2b: Exploration	Exploration; defining intervention, indications, and standards by multicentre prospective cohort study.
Stage 3: Assessment	Evaluating intervention against current practice, ideally in randomised control trial.
Stage 4: Long-term study	Assessing rare and late outcomes and widening the list of 'accepted' indications.

\*Following the IDEAL-D framework, IDEAL has been expanded to add Stage 0 when focusing on device innovation.



**Figure 1.** Images of fifteen of the robotic endoluminal systems explored in the review. (A) Ion by Intuitive Surgical system; (B) Monarch robot for bronchoscopy; (C) Monarch robot for urology applications; (D) Anovo Surgical System; (E, F) Endomaster system; (G) FASTER system; (H, I) EndoQuest Robotic system; (J) Invendoscope colonoscope; (K) Flex Robotic system; (L) Zaminex R system (Roentix Surgical Inc., Daejeon, Korea); (M) Virtuoso Surgical system; (N) Endotics system; (O) NISImagine system; (P) i2 Snake (Hamlyn Centre for Robotic Surgery, London, UK); (Q) EndoSamurai system (Olympus Medical Systems, Tokyo, Japan); (R) K-FLEX system; (S) W Endoluminal Robotics.

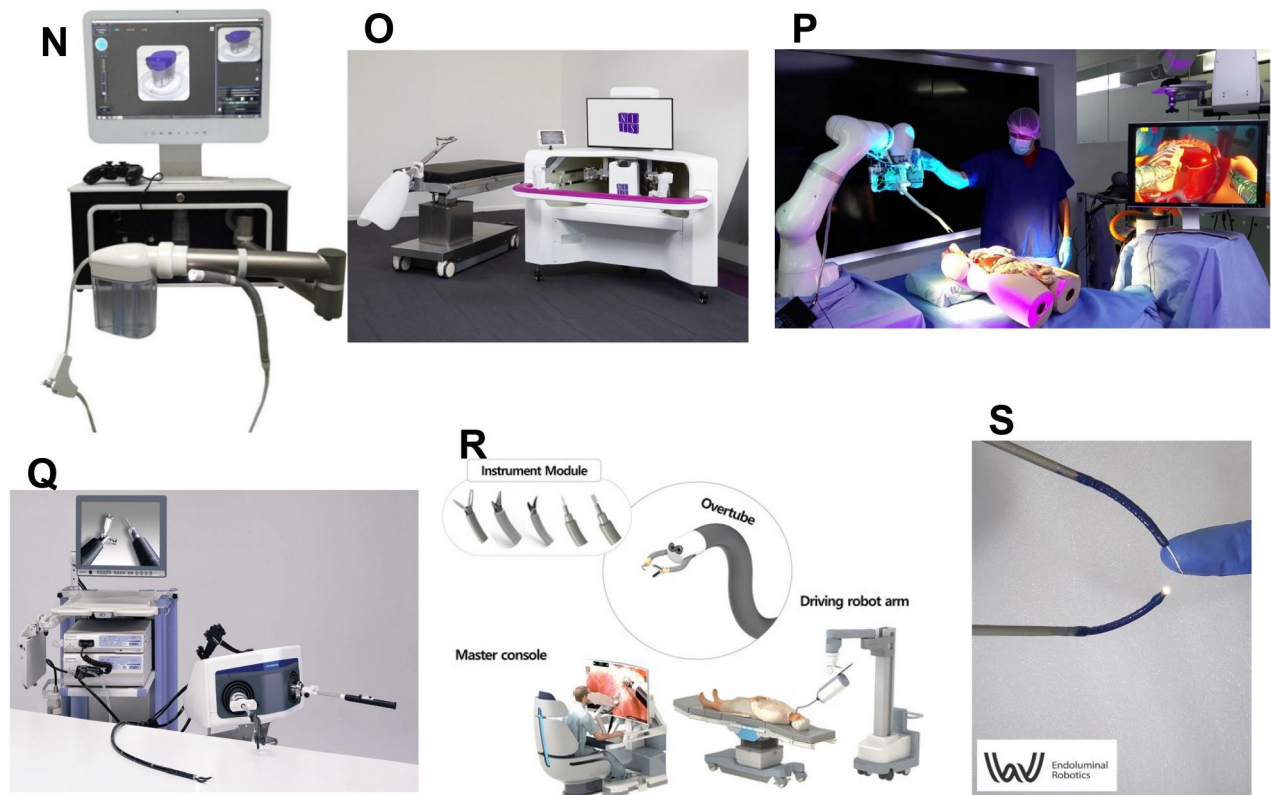


Figure 1. Continued.

\$600,000–\$700,000. EndoQuest Robotics priced their capital at \$1.75 million and consumables at \$250 per instrument peruse. Invendoscope has been reported to cost \$350 per probe, and its processing unit cost is quote-dependent [7].

### Clinical evaluation









Trial data across the devices included success parameters such as mean operative time, achievement of the primary surgical goal, complication rates, and ease of use. Endomaster EASE Surgical System (Singapore) found lower mean operative times in both animal and human trials for ESD [8]. Endotics (Era Endoscopy Srl, Cascina, Italy) found that their clinical trials indicated significantly reduced patient discomfort during diagnostic colonoscopy, with a 90% lower stress pattern compared to conventional colonoscopy [9]. Although a preliminary study showed a polyp detection rate of 40% [10], subsequent clinical trials showed the detection of all polyps, including smaller polyps not detected by standard colonoscopy [9]. EndoQuest Robotics reported a 100% success rate for polyp resection in transanal local excision of neoplasia, over a period of 5.5 months [11].

Ion (Intuitive Surgical, Sunnyvale, CA, USA) and Monarch have reached Stage 3 in the field of robotic

bronchoscopy, supported by large multicenter trials. Ion's PRECISE study evaluated the system's ability to biopsy pulmonary nodules with 97% biopsy completion [12]. The Monarch system's BENEFIT study assessed lesion localization for peripheral pulmonary lesions and found 96.2% accuracy (13). The diagnostic yield was 82–85% for Ion and 74.1% for Monarch [12,13].

Gynaecological robots were produced by Anovo Surgical System (Stage 2b), Virtuoso Surgical System (Virtuoso Surgical Inc., Nashville, TN, USA) (Stage 0), NISImagine System (Nisi Limited, Hong Kong, China) (Stage 0). Anovo Surgical System conducted a two-center prospective study on vaginal natural orifice transluminal endoscopic surgery (vNOTES) for bilateral salpingo-oophorectomy. The primary outcome was achieved with no patients requiring conversion to open surgery, and surgeons also reported a high usability score [14]. NISImagine was tested in two live models for hysterectomy and salpingo-oophorectomy, showing no intraoperative complications and minimal blood loss [15]. Virtuoso Surgical System has been employed ex-vivo to demonstrate its use in hysteroscopy with a porcine model to remove intrauterine devices (IUD) [16].

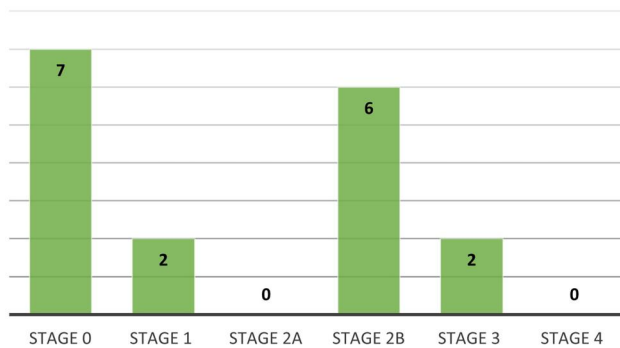
Emerging companies such as W Endoluminal (Or Yehuda, Israel) and K-Flex (KAIST Future Medical

Surgical speciality	Total number of systems	Endoluminal system
<b>Lower Gastrointestinal</b> 	9	<i>EndoMaster EASE Surgical System, EndoQuest Robotics, Invendoscope, Flex Robotic System, Endotics, K-Flex, Flex Robotic System, EndoSamurai</i>
<b>Respiratory</b> 	4	<i>Ion, Monarch (bronchoscopy platform), Virtuoso Endoscopic Robotic System, W Endoluminal Robotics.</i>
<b>Upper Gastrointestinal</b> 	4	<i>EndoMaster EASE Surgical System, FASTER, Flex Robotic System, I2 Snake.</i>
<b>Urology</b> 	3	Monarch (percutaneous nephrolithotomy platform), Zaminex R, Virtuoso Endoscopic Robotic System.
<b>Gynaecology</b> 	3	<i>Anovo Surgical System, Virtuoso Endoscopic Robotic System, NisImagine Surgical Robotic System.</i>
<b>Ear-Nose-Throat</b> 	3	<i>Flex Robotic System, Virtuoso Endoscopic Robotic System, I2 snake</i>
<b>Orthopaedics</b> 	1	<i>Virtuoso Endoscopic Robotic System</i>
<b>Neurosurgery</b> 	1	<i>Virtuoso Endoscopic Robotic System</i>

**Figure 2.** Overview of the number of robotic-assisted endoluminal systems per speciality.

Robotics Research Center, Daejeon, Korea) have limited preclinical data available. W Endoluminal has yet to publish preclinical studies and K-Flex has ex-vivo and benchtop tests. The K-flex ex-vivo study showed

that dissection was almost two times faster than standard endoscopy [17]. A summary of study findings for the robotic endoluminal systems is found in Table 2 [8–51].



**Figure 3.** Bar graph illustrating the number of robotic-assisted endoluminal systems per IDEAL-D stage.

## Discussion

This study provides a comprehensive overview of current and emerging robotic-assisted endoluminal systems using the IDEAL framework, potentially supporting clinicians and healthcare institutions with insights into innovative technologies and their stages of evaluation.

Our findings have highlighted the significant variability in developmental stages, with most systems in early stages and none reaching Stage 4 of the IDEAL-D framework. Despite the diverse range of specialities these systems address, common goals such as high flexibility, manoeuvrability, and visualisation technology are met. FDA clearance or respective regulatory approvals have been achieved by just under half of the systems studied. Regarding the training infrastructure, 47% of systems have a programme explicitly reported. Importantly, FDA or other regulatory body-approved systems more frequently featured training and support infrastructure.

In our study, seven systems (41.2%) were evaluated at Stage 0. The IDEAL framework was developed into an IDEAL-D framework specifically for device innovation, including an extra Stage 0 referring to preclinical studies [6]. This was further developed by the IDEAL Robot Colloquium to create the IDEAL framework for surgical robotics [52]. The IDEAL framework underscores the need for adaptable guidelines, given the complexities of robotics development and the emergence of artificial intelligence (AI). Several barriers hinder the widespread adoption of this technology. Key factors affecting the adoption of technologies include costs (initial and maintenance), lack of standardisation in training, limited clinical evidence to confirm patient safety [53,54], and lack of availability of national guidance on this matter [55]. Although many robotic-assisted endoscopy devices are available, their uptake in many European countries, including the UK, has been limited. To date,

only Ion by Intuitive has been used in the UK [56]. In comparison, the adoption of non-endoscopic surgical robots has been much quicker, with 32.2% of all UK trusts reported to have at least one surgical robot [57]. It is not clear, however, if the lack of uptake is a cause or a result of slow implementation as only seven systems have had FDA approval.

Systems with extensive training and support infrastructures are often more easily adopted in clinical settings because they reduce the learning curve and enhance surgeon confidence. Companies such as EndoQuest and EndoMaster have informed us through interviews or forms of confirmed training programmes prior to FDA approval. This highlights the importance of training availability to ease adoption and support user competency from the outset. A notable trend shown by NisImagine and FASTER pre-clinical robot (Shandong University, Jinan, China; Robo Medical Robotics Institute, Shenzhen, China) across multiple observational studies, indicated a marked reduction in surgical time from initial cohort to final. A standardised endoluminal robotics programme would facilitate consistent and comparable results across different studies, by mitigating the impact of the surgeon's learning curve. Collaborative training modalities across the broader field of robotic surgery are being developed [58] and would be well supplemented by each company's own programme.

Limited cost data was available for emerging endoluminal systems. Robotic endoluminal systems have a significant upfront cost for the capital infrastructure, accompanied by costs of maintenance, disposable parts, and overheads. Often, larger operating rooms are required to accommodate the robot and surgical team [59]. The IDEAL framework for surgical robotics emphasises the importance of early economic evaluation models and the value of research studies to avoid waste if it's unlikely to be implemented into practice. Greater transparency in cost data is required for studies comparing conventional endoscopy and these robotic systems.

A significant portion of our studies are in Stage 2b (35.3%). It is important to consider that progressing from Stage 2b (Exploration) and Stage 3 (Assessment) presents significant challenges. Stage 2b consists of observational studies, preferably multicentre, collecting data about a range of outcomes. Stage 3 typically requires a large multicentre randomised control trial (RCT). In circumstances where this is not feasible, a high-quality observational study, such as a non-randomised control trial or an interrupted time series, is considered acceptable under the IDEAL framework

**Table 2.** Summary of current and emerging robotic-assisted endoluminal systems.

Device	Company	Clinical application	Key features	Key study outcomes	Training available?	Approval state	IDEAL stage	References
Ion	Intuitive Surgical Inc.	Respiratory: Peripheral lung biopsy (bronchoscopy)	Robotic catheter, fibre optic shape-sensing technology with real-time feedback. PlanPoint software for 3D mapping to guide procedure.	Multicentre prospective evaluation: 97% biopsy completion, average procedure time 66.5 minutes.	Test drives and observed live cases, onsite assistance during installation	FDA approved	Stage 3	[12,18–20]
Monarch	Johnson & Johnson	Respiratory: Peripheral lung biopsy (bronchoscopy)	Electromagnetic navigation, real-time vision input from the camera at the bronchoscope tip.	Diagnostic yield 82–85%. 96.2% lesion localization in the multicenter prospective study.	Training provided	FDA approved	Stage 3	[13,21]
Monarch	Johnson & Johnson	Urology: ureteroscopic and percutaneous nephrolithotomy (PCNL)	Flexible, robotic-assisted electromagnetic navigation using a handheld controller.	Pneumothorax in 3.7%. 74.1% diagnostic yield. Feasibility study in live porcine models. 80% less radiation, improved accuracy, and fewer needle sticks compared to conventional fluoroscopic guided access techniques.	Training provided	FDA approved	Stage 1	[22–25]
Anovo Surgical System*	Momentis Surgical	Gynaecology: Transvaginal hysterectomy, salpingectomy, oophorectomy, adnexectomy, ovarian cyst removal	Control console, motor unit connected to 2 robotic arms and GYN trocar kit. Humanoid arms with shoulder, elbow, and wrist joint, 360° articulations.	Clinical trial with 15 patients for robotic assisted mini-PCNL. Results not yet published.	Proctored simulation training	FDA approved	Stage 2b	[14,26–28]
EndoMaster EASE Surgical System*	EndoMaster	Upper GI, Lower GI, Colorectal: Gastrointestinal tumour excision	Surgeon and patient carts, 3 working channels. 2 robotic arms with a grasper and monopolar cautery hook. Each instrument has at least 4 DOF. Cautery activated with foot pedals. Arms placed at 9 and 6'clock positions for optimal angles for tissue retraction and dissection.	Animal trials of endoscopic submucosal dissection: mean operative time of 74 minutes, no perforation. Improved safety, precision, and reduced procedure time over regular endoscopy in first human trials.	Mentored training included wet lab and progression to live operation.	Clinical trials – in the process of CE mark.	Stage 1	[8,29]
FASTER: Flexible auxiliary single-arm transluminal endoscopic robot	FASTER	Upper GI: Robotic-assisted endoscopic submucosal dissection (ESD).	Robotic component is an add-on with 4 DOF to the traditional single channel endoscope. Consists of the robot arm, driven housing, and console which has a user interface. Controlled by joystick.	Shorter ESD time, fewer perforations, and fewer lens cleanings in preclinical trials compared to conventional ESD. 96% direct vision dissection compared to 73% in conventional.	Not stated yet	Preclinical trials	Stage 0	[30,31]

(continued)

Table 2. Continued.

Device	Company	Clinical application	Key features	Key study outcomes	Training available?	Approval state	IDEAL stage	References
EndoQuest Robotics*	EndoQuest Robotics	Colorectal: Transanal endoluminal partial thickness resection of benign lesions in the rectum and sigmoid colon	Physicians Console and Patient Cart. Instruments have up to 7 DOF, using Lambda 7 hand controller. Provide a graphic user interface which has an image viewer and side panels showing the instruments range, translation, and rotation. Single use, handheld controlled colonoscope. Length 180cm or 200cm, 10mm inner sheath with an inverted sleeve (allows to 'grow' and 'shrink), attached to a propulsion connector. 180-degree deflection. Connector locked into an endoscope driving unit.	Average operative time of 18 minutes in preclinical studies in ex vivo colon models. Prospective multicentre study showed 100% success rate in polyp and tumour resection over 5.5 months. Mean operative time of 184 minutes. Pilot study with colonoscopy in healthy patients. Caecum intubation rate 82% with no complications. Absence of pain in 92%. Routine endoscopy with polyp removal in 30% of the patients showed 95% intubation rate and no major complications.	Comprehensive training program provided by the company.	FDA approved anticipated in 2025.	Stage 2b	[11,32]
Invendoscope	Ambu	Colorectal: Colonoscopy and endoscopic surgery	Highly articulated, multi-linked "snake" robot. Flex control console – haptic controller, joystick. Flex cart and base. Flex Drive (3D camera on robot arm). 3 flexible instruments can be used.	In vivo porcine models showed mean stone retrieval time to be 1128 seconds with a lower radiation dose than manual RIRS. Clinical study of 47 patients showed a 93.5% stone free rate and 6.5% complication rate.	Workshops, online videos and modular training sessions.	FDA approved	Stage 2b	[33–35]
Flex Robotic System	NovusArge	Upper GI, lower GI, colorectal, ENT: Transoral resection surgery (TORS), Transanal robotic surgery.	Master-slave robot system. Slave robot equipped with flexible ureteroscope. Basket and laser fibre can be inserted through this channel. Hand controller controls the ureteroscope, basket, and laser fibre.	Transoral surgery case series, reports, and multicentre prospective studies show low complications, and reduced morbidity compared to open surgery. Lesion visualisation was 95–100%. Surgical success was 91–100%. In ESD and full thickness mucosal dissection, 115 minutes operative time and 23.1% conversion to standard endoscopic surgery.	Extensive installation support, online clinical team for support.	FDA approved	Stage 2b	[36–38]
Zaminex R	Roen Surgical	Urology: retrograde intrarenal surgery (RIRS)	Master-slave robot system. Slave robot equipped with flexible ureteroscope. Basket and laser fibre can be inserted through this channel. Hand controller controls the ureteroscope, basket, and laser fibre.	In vivo porcine models showed mean stone retrieval time to be 1128 seconds with a lower radiation dose than manual RIRS. Clinical study of 47 patients showed a 93.5% stone free rate and 6.5% complication rate.	Not confirmed – 10 hours of basic robot training was given in the preclinical trial.	Korean MFDS approval	Stage 2b	[39–40]

(continued)

**Table 2.** Continued.

Device	Company	Clinical application	Key features	Key study outcomes	Training available?	Approval state	IDEAL stage	References
Virtuoso Endoscopic Robotic System	Virtuoso Surgical	Respiratory, urology, gynaecology, neurosurgery, orthopaedics, thoracic, ENT.	Two robotic controlled needle-sized manipulators at the tip of a rigid endoscope. 1mm diameter manipulators e.g., grasper, spatula, snare, electrosurgical tools. Endoscope equipped with a camera.	Central airway obstruction removed reduced average obstruction from 75% to 14% in ex vivo animal model. Live animal, cadaver and tissue model studies have also been done for the other clinical applications. Clinical trials showed low discomfort of patients- 90% lower stress pattern compared to standard. 27% caecum intubation (82% by conventional). 2 smaller polyps were detected only by Endotics. Single centre prospective preliminary study: system achieve complete colonoscopy in 93% in one group, 100% in another. 40% polyp detection rate.	Not confirmed	Preclinical trials	Stage 0	[16,41–43]
Endotics	Era Endoscopy S.r.l	Colorectal surgery: diagnostic colonoscopy, polyp excision.	7.5mm tip with light source and camera. Inch-worm locomotion mechanism – front part anchors to the colon whilst central segment contracts to bring forward the rear segment. 180° endoscopic steering in every direction. 3mm operative channel.	Studied in 2 live porcine model for hysterectomy and salpingo- oophorectomy. No intraoperative complications, limited blood loss (<20ml per animal). Procedure time was reduced on the second animal.	Not confirmed	FDA approved	Stage 2b	[9,10, 44,45]
Nisimgine Surgical Robotic System	NISI (HK) Limited	Gynaecology: Vaginal hysterectomy, salpingo- oophorectomy, cholecystectomy	Master-slave robot. Monitor has 3D depth perception. Surgeon's console has positional sensors to translate into hand movements of the miniaturized motorized robotic arms (7 DOF with shoulder, elbow and wrist joint). Instruments include bipolar grasper, scissor, needle holder, and cautery hook.	Studied in 2 live porcine model for hysterectomy and salpingo- oophorectomy. No intraoperative complications, limited blood loss (<20ml per animal). Procedure time was reduced on the second animal.	Not confirmed	China FDA approval	Stage 0	[15]
I2 Snake	Imperial College London	ENT, upper GI: tumour resection, sleep apnea surgery, endoscopic submucosal dissection, and peroral endoscopic myotomy.	Camera, light source, and 2 robotic instruments. I2 is fully tendon driven control = more flexibility and force. 13 stainless steel vertebrae (snake-like) made using 3D printing. 12 rolling joints. 7 DOF. 3mm camera 640 × 480-pixel resolution. Space for four 4mm channels.	No preclinical studies published yet.	Not confirmed	Preclinical	Stage 0	[46,47]

(continued)

**Table 2.** Continued.

Device	Company	Clinical application	Key features	Key study outcomes	Training available?	Approval state	IDEAL stage	References
EndoSamurai	Olympus	Lower GI: Natural orifice transluminal endoscopic surgery (NOTES)	Command console and tube. Tip has 2 articulated arms (5 DOF, 2.8mm diameter). Requires 2 physicians – one at the tube, one at the command console. Three different sets of forceps can be used replaceable at the same time.	In coordination tasks and ex vivo porcine models, EndoSamurai prototype was shown to enhance performance time and accuracy compared to dual-channel endoscope.	Not confirmed	Preclinical studies	Stage 0	[48–50]
W Endoluminal Robotics	W Endoluminal Robotics	Respiratory: Peripheral lung biopsy	2-armed bronchoscope with real-time imaging. 3.2mm bronchoscope, 2mm working channel, and 5mm radius of curvature. Soft mode of bronchoscope for threading and stiff mode for acute biopsy taking and therapeutics.	No preclinical studies published yet.	Not confirmed	Preclinical studies	Stage 0	[51]
K-Flex	KAIST Future Medical Robotics Research Group	Colorectal: NOTES, colon ESD	3.7mm robotic arms. 17mm diameter endoscope – ensures transgastric applications. Overtube, driving robotic arm, master control, instruments.	Benchmark tests like peg transfer test which showed dropping in 2/12 instances due to weak grip. Ex vivo tasks confirmed the ability to grasp tissue with the left surgical arm and dissect using the right. Dissection was almost 2 times faster than standard endoscopy.	Not confirmed	Preclinical studies	Stage 0	[17]

\* Indicates companies that were interviewed or completed the form.

[60]. The difficulty in implementing such studies results in there being limited high-quality evidence across the field of robotics. A systematic review showed several issues with research quality in robotic surgery. This includes a high number of duplicate publications, unregistered or prospectively registered clinical trials, changes in primary outcomes from protocol to publication, no power calculations, and no funding declarations [61].

With new devices, both the surgical team's trust and patient perception are ethical barriers to implementation. Many clinical studies of the robotic-assisted endoscopic systems included qualitative reports of surgeon ease of use and comfort, as well as reporting of conversion rate from robotic-assisted endoscopy to a standard endoscope. This metric was investigated by Flex Robotic System (Medrobotics, Raynham, MA, USA), which reported a 23.1% rate of conversion to standard trans-anal endoscopic operation for ESD and full-thickness mucosal dissection [37]. This can serve as an indirect metric of the surgical team's trust in the device. The perception of robotic-assisted endoluminal systems has not yet been investigated; however, existing research on robotic surgery more broadly indicates prevalent misconceptions and fears that pose challenges to its widespread adoption [62].

Our study contributes a breadth of information regarding 17 distinct systems from multiple data sources including direct communication with developers. Our findings display significant advancements in the field, such as enhancing patient outcomes and surgical efficiency, while also highlighting gaps such as the lack of systems at Stage 4 and limited implementation. These insights can inform and guide clinicians, healthcare institutions, and regulatory bodies in making evidence-based decisions regarding the adoption of such technologies.

We acknowledge the study has a number of limitations. Due to the nature of the methodology, the scope of information was not standardised across companies. Information was gathered through screening published studies, articles, company websites, technology news articles, and multiple contacts to the company *via* email and LinkedIn. There was likely greater accuracy of data of the companies who responded to our contact. Nevertheless, we believe that the information presented in this paper is accurate to the best of our knowledge at the time of publication, albeit within a rapidly changing environment.

Furthermore, there may be emerging systems that are missed as they are not yet reported on, despite a

comprehensive search. Our study encountered constraints in gathering comprehensive cost data for the systems, due to a lack of transparency during early developmental stages and the quote-dependant nature of pricing. The dynamic nature of the field means that this review will require updates on new technological advancements and market entries.

In conclusion, this review has shown a range of robotic-assisted endoluminal systems from early stages of development to large multicentre trials. With many systems in the idea, development, and exploration phases, there is a promising future ahead in the field of endoluminal robotics. The IDEAL framework proves to be a beneficial and adaptable structure, evolving in tandem with advancements in robotic technology. Our exploration of current and emerging endoluminal robotic platforms through the framework offers a comprehensive summary of the field. Collaborative efforts amongst the medical community, regulatory bodies, and industry specialists are vital to ensure the delivery of evidence-based medicine in the discipline of robotics.

### Ethical statement

According to local UCL ethical guidelines, this study was exempt from ethical approval.

### Disclosure statement

The authors have no conflicts of interest and no previously copyrighted material in this work.

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