




## ORIGINAL ARTICLE

# Endoluminal surgical triangulation 2.0: A new flexible surgical robot. Preliminary pre-clinical results with colonic submucosal dissection

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## Abstract

**Background:** Complex intraluminal surgical interventions of the gastrointestinal tract are challenging due to the limitation of existing instruments. Our group has developed a master–slave robotic flexible endoscopic platform that provides instrument triangulation in an endoluminal environment.

**Materials and Methods:** Colonic endoscopic submucosal dissections (ESD) were carried out in eight pigs. The robot was introduced transanally. A combination of adapted tele-operated instruments was used. Specimens were inspected and measured.

**Results:** Out of 18 ESDs in total, 12 were successfully completed. Among the completed procedures, two perforations and one system failure occurred and were managed intraoperatively. There was no major bleeding. Mean size of the removed specimens was  $18.2 \pm 9.8 \text{ cm}^2$  and mean total procedure time was  $73 \pm 35.5 \text{ min}$ .

**Conclusions:** Experimental colorectal ESDs using the flexible surgical robot were feasible and reflected a short learning curve. After some technical improvements the system might allow for a wider adoption of complex endoluminal surgical procedures.

## 1 | INTRODUCTION

Endoscopic submucosal dissection (ESD) is a valid minimally invasive treatment option for gastrointestinal (GI) lesions with a low metastatic potential. It provides high 'en bloc' resection rates even for large laterally extending tumors. In Eastern countries, ESD has become standard care for early gastric cancer.<sup>1,2</sup> However, ESD is generally a highly challenging technique and requires significant experience and skills to be carried out safely. Colorectal ESDs are even more difficult than gastric ones, with a steep learning curve,<sup>3</sup> due to specific anatomical characteristics (presence of large tissue folds, peristaltic movements, thinner layers), presenting a higher risk for complications.<sup>4,5</sup> These characteristics limit the adoption of colorectal ESDs at a large-scale level.

Current endoscopic technology is another key factor, which has not facilitated the spread of such complex endoluminal surgical techniques. From a surgical standpoint, the most frustrating limitations within the GI lumen include the lack of effective retraction, of clear views, and of instrument triangulation, which are basic elements for

surgery. In recent years, surgeons have focused their efforts of innovation on these issues from a technological as well as a technical point of view.<sup>6–15</sup> However, the majority of proposed solutions were mainly elaborated around standard diagnostic flexible endoscopes with no disrupting concepts. Without moving away from the standard endoscopic mindset, it is difficult to imagine a breakthrough in this specific surgical field.

As demonstrated by the advent of the concept of NOTES (natural orifice transluminal endoscopic surgery), a strong paradigmatic shift is required,<sup>16</sup> inducing fusion between minimally invasive surgery and endoscopy. In this surgical endoscopic perspective, our team, in partnership with Karl Storz, has developed the Anubiscope®, a mechanical flexible surgical platform conceived for NOTES<sup>17,18</sup> as well as the Isis-scope®, a smaller system for Laparo-Endoscopic Single-Site procedures.<sup>19</sup> Those platforms provide the ability for instrument triangulation in flexible endoscopy. Recently, we applied the Anubiscope® to colorectal ESD and demonstrated its safety and efficacy in the experimental setting, with clear benefits over the standard endoscopic

approach.<sup>20</sup> The drawback of this mechanical platform is that it requires fine-tuned cooperative work of two trained surgeons both standing around the endoscope.

Robotic technology has already been used in this field to develop new concepts in order to break current barriers which exist between flexible endoscopy and an efficient, safe and feasible endoluminal surgery.<sup>21,22</sup>

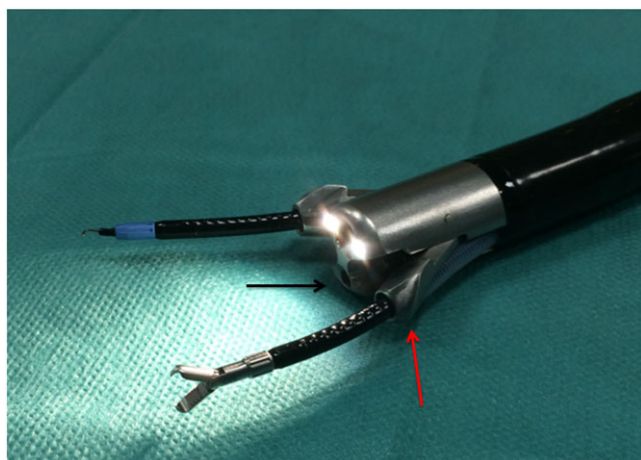
To improve our mechanical platform, we used robotic science resources to maximize performance and ergonomics. In a collaborative work with the ICube laboratory in Strasbourg, the Isis-scope® served as a base to produce the STRAS robot (Single-access Transluminal Robotic Assistant for Surgeons).<sup>23</sup> The STRAS is a master-slave system, which can be handled through a very intuitive control interface in an ergonomic fashion by a single operator. The aim of this study was to evaluate the feasibility of colonic submucosal dissection in an acute porcine model using the STRAS robot.

## 2 | MATERIALS AND METHODS

This was a prospective non-randomized, non-survival animal study involving eight pigs to evaluate the feasibility of our motorized endoluminal platform in colonic endoscopic mucosal dissection.

### 2.1 | The master-slave robotic STRAS system

The STRAS is based on the Isis-scope® therapeutic platform (Karl Storz Endoskope, Tuttlingen, Germany). This is a special 50 cm long flexible endoscope with a maximum shaft diameter of 18 mm. The shaft houses two 4.2 mm working channels for operative instruments and one 2.8 mm working channel for conventional flexible endoscopic instruments. The main motorized operative module has a four-way deflection tip and it can be translated and rotated on a carrier rack. The tip of the endoscope is equipped with two opening arms to provide endoluminal triangulation for the instruments (Figure 1). The



**FIGURE 1** Operating tip of the robotic platform. The instruments are passed through a 4.2 mm channel. Two arms on the side open (red arrow) to provide optimal position for the robotic instruments to be used in a triangulation. The black arrow indicates the exit of a 2.8 mm working channel for a regular endoscopic tool on the middle lower part of the endoscope's tip

robotic operative instruments are either purely mechanical or electric with three or four degrees of freedom (DOF) each. The available tools are graspers with different profiles, an isolated tip knife, and a hook knife (Figure 2). Overall, the system has 10 + 1 DOF. The platform is tele-operated through a very intuitive master interface in an ergonomic fashion by a single operator (Figure 3).

### 2.2 | Set-up and manipulation of the system

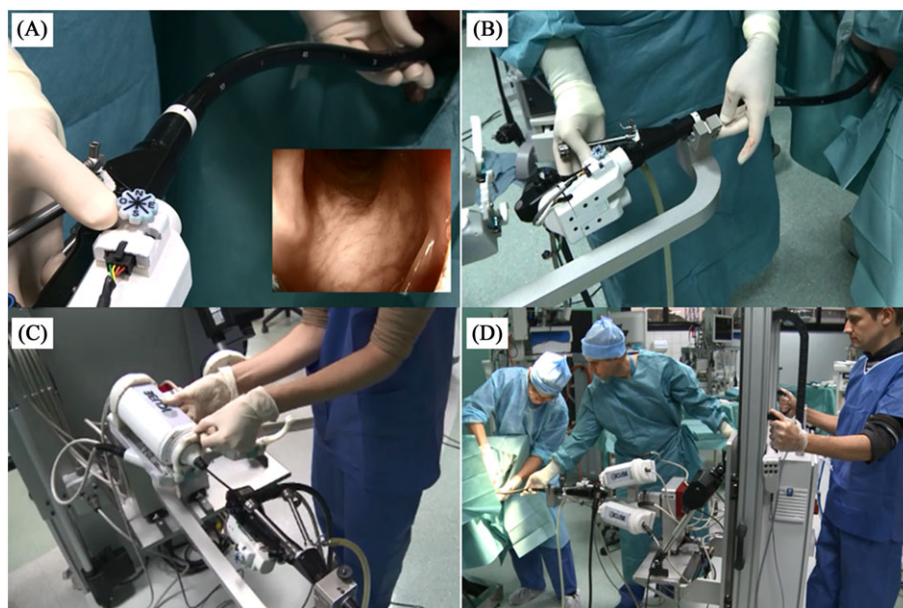
The slave unit is composed of a carrier cart and a detachable flexible endoscope. The slave cart is rollable and houses the electronic system and the endoscope rack. The rack adjusts the height as well as the translation of the surgical platform. The slave unit is set close to the operating table and can be tele-operated remotely from undefined distances. As a first step, the portable motorized endoscope is inserted into the rectum manually, with the tip orientated by a built-in joystick, under endoscopic visual control (Figure 4A). Once the target area has been reached, the portable platform is re-attached to the slave rack and operating tools are inserted (Figure 4B and 4C). A pneumorectum is created by carbon dioxide insufflation to open the surgical space. If required, the clamshell arms can contribute to the stability of the operative field. Once the endoluminal view has been established, the endoscope is positioned for the first steps of the surgery through the master control. From this point onward, manipulation of the system is entirely performed by the surgeon at the master console. The 2.8 mm working channel is used mainly for insufflation, suction, and as an access for additional instruments (e.g. endoscopic injection



**FIGURE 2** Instrumentation of the system. Currently available robotic tools: Fenestrated and toothed graspers, electric hook, and an insulated tip knife



**FIGURE 3** Master interface with the intuitive controllers. The master unit is set remotely from the patient. The intuitive control interface allows the surgeon to comfortably operate the system, and provides continuous feedback about the actual position of the tools



**FIGURE 4** Device set-up and removal. A, The device is dismantled from the slave rack and inserted hand-controlled into the rectum under direct visual control. B, After insertion, the platform is secured on the slave rack with a single motion. C, The robotic instruments consist of a proximal motor and a flexible shaft with a bendable distal tip, and are loaded one by one. D, After the procedure has been completed, the platform is removed from the rectum by rolling the whole slave unit backwards

needle) if need be. In this prototype, insufflation, suction and lens cleaning functions of the endoscope are controlled by an assistant at the patient site. Robotic instruments can be changed if required during the operation. After the procedure has been completed, the platform can be removed by moving the slave carrier backwards (Figure 4D).

## 2.3 | Animals

Eight pigs (*Sus scrofa domesticus*, ssp large white) weighing 27–40 kg were included in this non-survival study. The study protocol was approved by the Institutional Ethical Committee on Animal Experimentation (ICOMETH No. 38.2011.01.018), and animals were managed in

accordance with French laws for animal use and care as well as European Community Council directive No. 2010/63/EU. Animals were fasted for 24 h before the procedure with free access to water. Ketamine ( $20 \text{ mg kg}^{-1}$ ) and azaperone ( $2 \text{ mg kg}^{-1}$ , Stresnil; Janssen-Cilag, Beerse, Belgium) were administered intramuscularly 10 min before the procedure as premedication. Induction of anesthesia was achieved using intravenous propofol combined with rocuronium ( $0.8 \text{ mg kg}^{-1}$ ). Anesthesia was maintained with 2% isoflurane after endotracheal intubation of the animal in a supine position. Rectal cleansing was performed until the effluent turned clear. All pigs were humanely euthanized immediately after the procedures by an intravenous injection of a lethal dose of potassium chloride.



## 2.4 | Procedures

All procedures were performed by a general surgeon (AL) who acted as a 'test pilot' mainly because of his lack of exposure to flexible endoscopy. He did not do any pilot tests prior to the study.

The surgeon was allowed to practice with the robotic system on bench top for a total of 30 min before the study. The main steps of the procedures were as follows: after bowel preparation and insertion of the platform into the rectum the target areas were marked at different levels up to 25 cm from the anal verge. The objective was to mark and remove 3 to 5 cm diameter specimens. After marking the target areas, the mucosa was lifted by means of submucosal injection of a 10% glycerol solution (Cooperation Pharmaceutique, Melun, France) mixed with a few drops of methylene blue (Figure 5A and 5B). For submucosal injections, a 23 G injection therapy needle (Interject™ Contrast, Boston Scientific, MA, USA) was used. The marked and lifted areas were then completely pre-cut around the marks or only a small mucosal incision was made. As a last step, the target areas were dissected at submucosal level and then removed (Figure 5C-G).

In the first case, the marking and pre-cut were made by using a conventional flexible gastroscope (Silverscope® 13821 PK, Karl Storz, Tuttlingen, Germany) as well as a triangle tip (TT) electrosurgical knife (KD-640 L, Olympus, Tokyo, Japan) in order to assess the feasibility of a hybrid approach. However, it was felt to be too time consuming for the consultant surgeon and this method was relinquished.

In the case of pneumoperitoneum, a Veress needle was inserted into the abdominal cavity to decrease pressure. The distal colon was harvested and operation sites were inspected for injuries externally

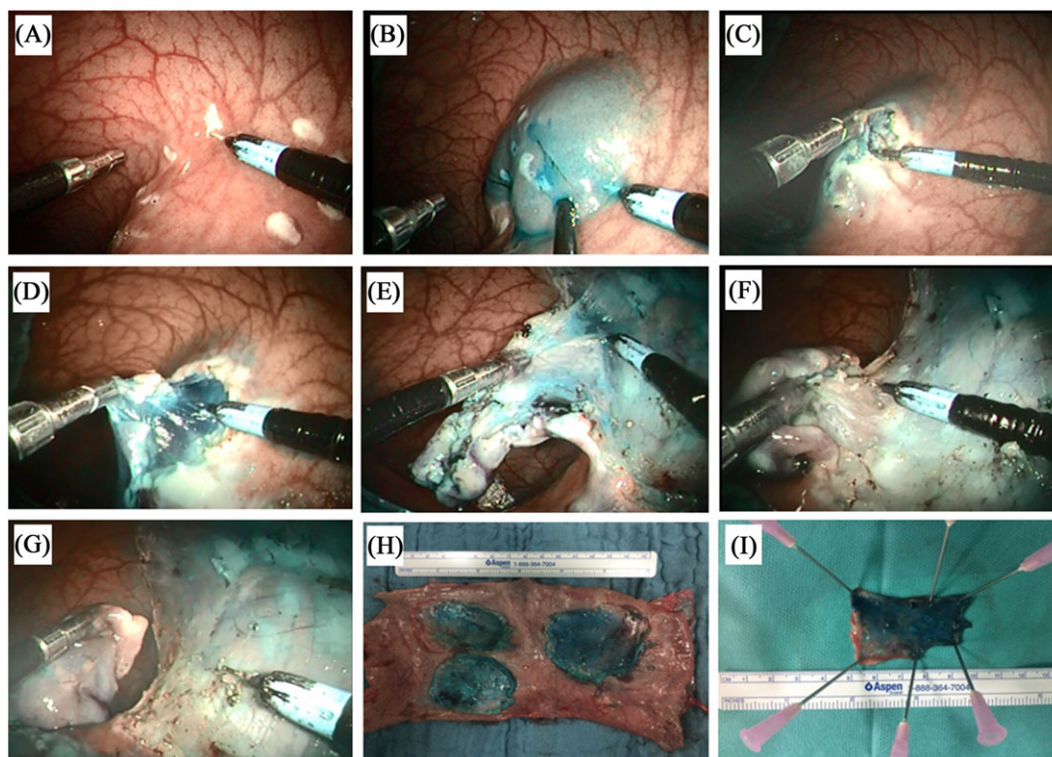
and internally. Specimens were inspected, expanded on a corkboard with pins, measured, and stored in 2% buffered formalin for further pathological evaluation (Figure 5H and 5I).

All procedures were video-recorded through the surgical platform's video camera. Data were either recorded on data collection sheets during the procedures or after reviewing the recorded videos. Total procedure time was defined as time elapsed between insertion of the platform into the anal canal and complete removal of the mucosal specimen. Dissection time was defined as the time required for submucosal dissection after a complete pre-cut or if pre-cut was not made, it was defined as the time elapsed from the first mucosal cut to specimen removal. Procedural speed was calculated from the total procedural time and size of the removed specimen.

The procedures were then retrospectively divided into three equal groups in order to represent the learning curve, procedural and technological refinement.

## 3 | RESULTS

In total, 18 ESDs were attempted and 12 were successfully completed. Five (27.7%) perforations occurred whereof one was closed by using a flexible endoscopic hemostatic clip through the platform, allowing the operator to complete the procedure, and another one which had no effect on the procedure. Four system failures occurred either due to mechanical breakdowns of the platform or insulation problems with the electrical instruments. Three procedures were aborted because of these technical difficulties. In one case, the robot was repaired



**FIGURE 5** The main steps of the procedure. A, As a first step the target area is marked using an electrical instrument. B, The mucosa is lifted with a stained 10% glycerol solution using a regular endoscopic injection needle passed through the 2.8 mm working channel. C, First, a small mucosal cut is made. D–G, The mucosa is dissected in small steps without the need of a mucosal pre-cut. The grasper provides wide mucosal retraction, which allows the surgeon to perform a precise dissection from a distance, having a wide field of view



intraoperatively. All surgical and technological complications occurred during the first 12 procedures. There was no major bleeding. In all animals, a pneumoperitoneum developed irrespectively of the presence or lack of perforation.

The mean size of the removed specimens was  $18.2 \pm 9.8 \text{ cm}^2$  and mean time required per total procedure was  $73 \pm 35.5 \text{ min}$ . Mean pure dissection time was  $49.6 \pm 35.1 \text{ min}$ .

There was a remarkable improvement in the performance during the study. Only two of the first six cases could be completed due to major complications whether surgical or technological; but all the last six procedures were completed, and no complication occurred. Mean procedural speed was almost two times higher in the last group than in the first ( $0.186 \text{ cm}^2/\text{min}$  vs.  $0.344 \text{ cm}^2/\text{min}$ ). Mean procedural time and size of dissected surface in the first and last groups were  $100.5 \pm 7.78$  vs.  $60.8 \pm 27.9 \text{ min}$  and  $18.6 \pm 12.2$  vs.  $21.05 \pm 9.78 \text{ cm}^2$ , respectively. Table 1 shows the study data in details.

## 4 | DISCUSSION

Endoscopic submucosal dissection provides an endoluminal surgical treatment option for premalignant or early malignant lesions of the gastrointestinal tract with a high 'en bloc' resection rate.<sup>24,25</sup> Despite the growing number of patients diagnosed with earlier stage malignant

disease in the Western World, the adoption of colorectal ESD is relatively slow. Besides limited training opportunities, it is related to technical difficulties, consequent higher procedural complication risks, and long operating times. The robotic technology may break this barrier by providing technically facilitated working environments. In the present animal study, we have demonstrated the feasibility of colorectal ESD by using our ergonomic master-slave robotic endoluminal surgical platform. We called this platform 'robotic' similarly to other motorized systems in the field; however a master-slave manipulator would describe more the real nature of the system.

Technical difficulties of ESD originate from the lack of effective retraction to provide wide and clear exposure of the targeted layer. Numerous traction systems have been reported for gastric and colorectal ESDs proposing clips with lines, magnetic anchors, external forceps, clips with rubber rings, sinkers, double endoscopes or even percutaneous instruments.<sup>6-15,26</sup> However, these systems are not optimal as they are either difficult to set up and manipulate, they are invasive or require two endoscopists to operate.

Complex manual multitasking platforms can overcome the difficulty of intraluminal retraction. They were developed originally in the era of NOTES for intra-abdominal use, and some of them were successfully applied to perform operations within the GI lumen. The advantages of these multi-channel systems are that they provide retraction by allowing the use of multiple instruments; they are stable

**TABLE 1** Detailed operative data of the overall study

Procedure no.	Procedure completed	Perforation	System failure	Size of dissected area ( $\text{cm}^2$ )	Level of dissection ( $\text{cm}$ ) <sup>a</sup>	Procedure time (min)
1	Yes	No	No	$5.1 \times 5.3$ (27.3)	25	106
2	No	No	Yes	NA	18	NA
3	No	Yes	No	NA	25	NA
4	No	Yes	No	NA	20	NA
5	Yes	Yes	No	$4.0 \times 2.5^{10}$	18	95
6	No	No	Yes	NA	14	NA
Average/Total	2	3	2	(18.6)		100
7	Yes	Yes <sup>b</sup>	Yes <sup>c</sup>	$5.2 \times 4.1$ (21.3)	25	128
8	Yes	No	No	$4.5 \times 5.0$ (22.5)	20	55
9	Yes	No	No	$3.5 \times 2.4$ (8.4)	25	107
10	No	Yes	No	NA	20	NA
11	Yes	No	No	$1.5 \times 1.5$ (2.2)	10	18
12	No	No	Yes	NA	25	NA
Average/Total	4	2	2	(13.6)		77
13	Yes	No	No	$3.4 \times 3.1$ (10.5)	17	30
14	Yes	No	No	$3.3 \times 2.8$ (9.2)	5	39
15	Yes	No	No	$5.5 \times 4.7$ (25.8)	20	92
16	Yes	No	No	$6.3 \times 5.5$ (34.6)	22	84
17	Yes	No	No	$6.1 \times 4.2$ (25.6)	14	82
18	Yes	No	No	$5.4 \times 3.8$ (20.5)	22	38
Average/Total	6	0	0	(21.0)		61
Overall average/Total	12	5	4	(18.2)		73

<sup>a</sup>As measured from the anal verge.

<sup>b</sup>This perforation was closed by using a flexible endoscopic hemostatic clip.

<sup>c</sup>The system was repaired on site.

NA- not applicable



and usually control bendable tools. Many of them showed benefits when used within the upper GI tract. The R-scope (Olympus, Tokyo, Japan) was originally designed to improve endoluminal surgical performance at difficult gastric locations. The drawback of the device is that it requires two or three persons to operate the endoscope with the end effectors in harmony.<sup>27,28</sup> The EndoSamurai™ (Olympus, Tokyo, Japan) is a 15 mm modified double-channel endoscope with handles similarly to laparoscopic instruments. The working channels become two short independent arms, which can be moved only over a small angle. The platform is stabilized by a locking overtube, which is manipulated by a second operator to always keep the endoscope stable in a desired position.<sup>29</sup> The Incisionless Operating Platform™ (USGI, USA) incorporates four large-size working channels; one for a 4–6 mm flexible endoscope and three (4–7 mm) channels for special articulated instruments.<sup>30</sup> Manipulation of the platform requires the perfectly synchronized work of two skilled operators.

Our group in collaboration with Karl Storz has previously developed two flexible endoscopic manual platforms for NOTES (Anubiscope®) and for single-port intra-abdominal surgery (Isis-scope®) and recently successfully applied it for rectal ESD.<sup>17–20</sup> Such platforms combine the capabilities of a flexible endoscope with the advantages of laparoscopy resulting in a highly efficient system. A pair of intuitive, strong and bendable instruments is used in triangulation, allowing the operator to work precisely and distantly from the target area in a well-exposed operating field. However, the fact that their operation requires strong cooperative work by two surgeons makes the device control more challenging.

To overcome this limitation, a robotic version of the Isis-scope® has been recently developed. This master–slave system – called STRAS® – provides all the advantages of the mechanical platform and can be used remotely through a very intuitive master interface by a single operator. There has been only one robotic flexible endoscopic multitasking platform developed, which demonstrated the feasibility to perform complex intraluminal tasks in the gastrointestinal tract. The MASTER is one of the first robotic surgical endoscopic systems. It was conceived to be used in tandem with a commercially available double-channel flexible endoscope. The operating arms are placed on top of a dedicated flexible endoscope (Olympus 2 T160), and they are controlled by a surgeon through the master interface from a distance. The flexible endoscope itself is held and manipulated by the endoscopist standing at the patient's bedside. Five human gastric submucosal dissections were successfully carried out to show feasibility and safety.<sup>31</sup> The advantage of the STRAS® over the MASTER system is that its manipulation requires only one surgeon after set-up. A new concept for single operator endoluminal surgery has been recently published.<sup>32</sup>

Another advantage of our robotic platform is that there is a 2.8 mm working channel for conventional flexible endoscopic tools in addition to the two bendable instruments. This prevents the necessity of multiple endoscope intubations when an extra tool is required (e.g. injection needle, hemostatic clips, etc.). We also found this channel very useful for the cleaning of electrical devices by using a small brush. The control cables of the MASTER's slave unit run in the working channel of the flexible carrier endoscope blocking access for other instruments.

During more complex procedures, robotic tool exchange may be necessary. The operative tools of our system can be removed and relatively easily replaced by another one without changing the position of the platform. The spectrum of robotic tools for the STRAS system allows the surgeon to tailor the instrumentation to the operative situation. There is an actuator-driven master–slave system called ViaCath®, which controls two interchangeable articulated robotic instruments with 7 DOFs each.<sup>33</sup>

The variety of the tools may also facilitate the adoption of flexible endoscopic robotic platforms. These systems should be easy to adopt not only for complex clinical situations but also for both endoscopists and surgeons. The procedures of the present study were performed by a surgeon with initially very limited flexible endoscopic experience. Complex flexible endoscopic procedures require both excellent technical skills and a thorough knowledge of intramural anatomy. The robotic technology reduces the technical challenges that interventional endoscopists are faced with and may render the understanding of GI intramural anatomy easier for inexperienced operators. The last six procedures in the current study were carried out in a safer and faster fashion while larger mucosal pieces were removed, compared with the first phase of the experiment. This suggests that the unique feature of the STRAS® system (ability for a single surgeon to bimanually manipulate triangulated instruments at a distance – an environment similar to laparoscopy) allows for easy adoption even of complex endoluminal procedures.

There was a high pneumoperitoneum rate independent from full thickness perforation of the colon. The muscularis propria layer of the porcine intestine is extremely thin, especially in the case of 30–40 kg pigs, allowing the carbon dioxide to permeate through the denuded colon wall into the abdominal cavity. Intra-abdominal air is seen in about 30% of human stomach ESD cases without perforation; however, the muscular layer of the human gastric wall is much thicker.<sup>34</sup> In such cases the pneumoperitoneum can be managed by insertion of a Veres-needle or it can be resolved spontaneously.

Endoluminal motorized operative systems may have to face certain limitations. Our current prototype was designed to be relatively short in order to overcome possible issues regarding friction and to be able to provide strong enough instruments for more precise and effective tissue manipulation. Based on our test results our intention is to develop a longer version of the system.

The future clinical adoption of flexible endoluminal surgical systems – mechanical or robotic – will be determined in addition to safety, efficacy and ergonomics through their ability for suturing. Reliable and easy intraluminal suturing through a flexible endoscopic platform is one of the most awaited tasks that such platforms should accomplish. Robotics may help to overcome this challenge. Single port surgery also bears great promise for flexible platforms, especially for those with a suturing capacity.

## 5 | CONCLUSIONS

Experimental colorectal ESDs using a new STRAS® intuitive flexible surgical robot were feasible and reflected a short learning curve. Although some technical improvements are still required, the system





might allow for wider adoption of complex endoluminal surgical procedures among interventional endoscopists.

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## DISCLOSURES

András Légner, Michele Diana, Péter Halvax, Yu-Yin Liu, Lucile Zorn, Philippe Zanne, Florent Nageotte, Michel de Mathelin, Bernard Dallemagne, and Jacques Marescaux have no conflicts of interest or financial ties to disclose.

## AUTHORS' CONTRIBUTIONS:

Conception and design: BD, MD, AL.

Animal work: AL, PH, YYL, BD, MD, LZ, PZ, FN.

Data analysis and interpretation: AL, MD, BD, YYL.

Drafting of the article: AL, MD, BD, PH, LZ, PZ, FN.

Critical revision of the article for major intellectual content: AL, BD, MD, JM, MM.

All authors approved the final version of the manuscript.

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