DYNAMIC MANUSCRIPT





# A novel flexible auxiliary single-arm transluminal endoscopic robot facilitates endoscopic submucosal dissection of gastric lesions (with video)

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# Abstract

**Background** Using conventional endoscope to perform endoscopic submucosal dissection (ESD) is difficult because of the one-handed operation and blind dissection caused by gravity. Poor visualization of the submucosal plane causes ESD to be associated with a high risk of bleeding and perforation. This study aimed to develop a novel ESD-assistive robot system and to evaluate its efficacy.

**Methods** A novel flexible auxiliary single-arm transluminal endoscopic robot (FASTER) was developed. A total of 36 artificial lesions in ex vivo porcine stomachs were removed using the FASTER-assisted ESD method (n = 18) and the conventional ESD method (n = 18). Lesions were 2 cm or 4 cm in diameter, located on the anterior and posterior walls of the antrum. Primary outcome measurements were dissection time and dissection speed.

**Results** The dissection time in FASTER-assisted ESD was significantly shorter than that in conventional ESD (7 min vs 13 min, p = 0.012), mainly because of the faster dissection speed (148.6 vs 97.0 mm<sup>2</sup>/min, p = 0.002). The total procedure time in FASTER-assisted ESD was shorter than that in conventional ESD, but the difference was not significant (16 min vs 24 min, p = 0.252). Complete en bloc resection was achieved in all lesions. No perforations were detected. The FASTER exhibited the ability of regrasp, multidirectional traction, and proper tension control during ESD.

**Conclusion** FASTER significantly increased the dissection speed by providing proper traction and achieving good submucosal vision. This new device is expected to facilitate ESD in clinical practice.

Keywords Endoscopic submucosal dissection · Endoscopic robot · FASTER

Endoscopic submucosal dissection (ESD) is a widely accepted therapeutic option for early gastrointestinal cancer that achieves en bloc resection regardless of lesion size [1, 2]. Despite being a new technique, ESD is usually performed using a conventional endoscope. The construction of the

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conventional single-channel endoscope limits the deployment of instruments and fails to provide sufficient visibility of the dissection area [3]. As a result, ESD is technically demanding, time-consuming, and associated with a high risk of perforation and bleeding [4–8].

To overcome this limitation, various traction methods have been developed in recent years [9–15]. Position change is a simple method to provide traction by gravity, but it is only suitable for lesions on specific sites [10]. The clip-withline method is useful for gastric, esophageal, and colonic lesions [11]. However, the direction of traction is immutable and the traction power may decrease over time. Endoscopeassisted ESD and magnetic-assisted ESD may provide traction in multiple directions, but they are complicated to use and expensive [12, 14, 15].

Robot-assisted ESD is another attempt to mitigate this difficulty. Different types of endoscopic robot systems are currently under development [16–19]. Using them, bimanual

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manipulation of dual arms is allowed, which is analogous to the surgical Da Vinci robot. Robotic systems had demonstrated their efficacy in endoscopic operation; however, exclusively designed endoscopes and instruments slowed down their large-scale clinical application.

We developed a flexible auxiliary single-arm transluminal endoscopic robot (FASTER) that is designed to be attached to a conventional endoscope and retains endoscopists' original operation habits. In the present study, we evaluated the efficacy, safety, and maneuverability of ex vivo porcine ESD.

## Materials and methods

#### FASTER

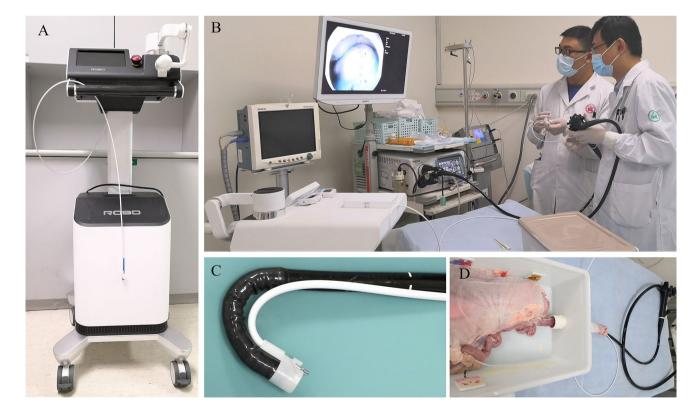
In this study, FASTER, an endoscopic, flexible, detachable, single-arm, master–slave robot was developed (Fig. 1A). FASTER consists of three major components: a robot arm, a driven housing, and a console with a user interface. The robotic arm is designed to be attached to a general-use endo-scope using an elastic white hood. To accommodate the long, narrow digestive tract, the diameter of the robotic arm is 4 mm, and the diameter of end clip is 2.3 mm. The over-all diameter of the endoscope (EG29-i10, Pentax Medical,

Shanghai, China) with the attached FASTER is 14–17 mm, and the length of the robotic arm is 1.8 m. For safe introduction of the robotic arm during esophageal insertion, the end clip of the arm was designed to be smooth and retractable (Online Video), and no overtube was used. In addition to retractable, another three degrees of freedom (DOFs), including down bending, right/left bending, and open/close, have been designed to ensure multidirectional traction and regrasping.

The movement of the arm was controlled by a master on the console interface. The operation is intuitive for bending down, left, and right based on hand-eye feedback, and the opening and closure of the gripper are controlled by two buttons on the touch bar handle (Online Video). The motion of the end clip is designed within the endoscopic field of view for safe and easy operation. The motion signal is detected, processed, and converted into a force signal by the driven housing to drive the end-effector via a tendon driven. An "emergency stop" button is designed to ensure safety during the operation.

#### In vitro model

Fresh porcine stomachs with the esophagus and duodenum were used for this ex vivo study. After careful washing, the



**Fig. 1** The characteristics of the flexible auxiliary single-arm transluminal endoscopic robot (FASTER). **A** The FASTER appearance. **B** The ESD procedure setup. **C** The flexible arm is flexible enough and

does not influence the movement of the endoscope.  ${\bf D}$  The designed dissection platform for in vitro model

stomach was turned over into an inside-out position and a circular artificial lesion (Fig. 2A) with a diameter of 2 cm or 4 cm was created on the anterior and posterior walls of the antrum (Table 1). The stomach was everted to a normal anatomic position and the duodenal end was sealed. A specially designed dissection platform was used to mount the model (Fig. 1B). For the model simulated in the supine position, the posterior wall was easy to collect water due to gravity, which made it difficult to visualize the dissection plane. To maintain the vitality, all stomachs were flushed with normal saline solution and were not refrigerated until the beginning of the operation. After the operation, the stomach was opened for direct observation of the dissection plane.

## **ESD** procedure

All procedures were performed by an ESD endoscopist who had performed gastric ESD for 3 years, conducted aproximately 200 conventional ESDs and ten FASTER-assisted ESDs. All ESDs were conducted using a conventional single-channel upper gastrointestinal endoscope (EG29-i10, Pentax Medical, Shanghai, China). The FASTER system was operated by an endoscopy nurse after a week of training. The robotic arm was attached to the tip of the endoscope in the FASTER-assisted ESD group, and a transparent attachment cap was used in the conventional ESD group. The ESDs were performed following the same steps. First, the lesion was lifted by submucosal injection of normal saline and indigo carmine mixture. A circumferential mucosal incision was performed using a dual knife (KD-650 L, Olympus Inc.). The robotic gripper was then used to grasp the edge of the mucosa, which was lifted for a good vision in the FASTER-assisted ESD group. Submucosal dissection was performed using a dual knife. Finally, the resected tissue was

Group	Total	Posterior wall <sup>a</sup>		Anterior wall <sup>a</sup>		
		2  cm	4 cm	2 cm	4 cm	
FASTER	18 6		4	5	3	
Conventional	18	6	4	5	3	

*FASTER* flexible auxiliary single-arm transluminal endoscopic robot <sup>a</sup>All the lesions were located on the antrum

extracted with the endoscope using FASTER or by suction for the conventional group.

All experiments were conducted at the Qilu Hospital of Shandong University with approval from the Medical Ethics Committee of Qilu Hospital of Shandong University.

#### **Outcome measurements and definitions**

Primary outcome measurements were submucosal dissection time (minutes) and submucosal dissection speed (mm<sup>2</sup>/ min), which was calculated as the area of the resected specimen divided by the submucosal dissection time. Secondary outcome measurements were other factors that were used to evaluate the ESD efficacy, including total procedure time (minutes), incision time (minutes), number of lens cleanings, number of accessory tool replacements, complete resection rate, and en bloc resection rate. The total procedure time was measured from the beginning of the injection to the end of the submucosal dissection. Complete resection was defined as the removal of mucosa inside the markers, and all markers could be identified on the resected specimen. In addition to the efficacy, maneuverability, safety, and operator satisfaction with the robot system were also recorded. The indicators used to evaluate the maneuverability of the robot included the number of attempts for one successful grasp

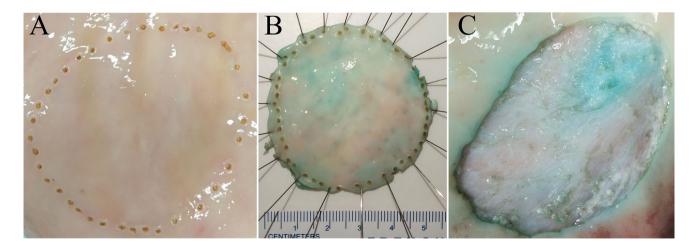


Fig. 2 A Artificial lesion; B resected sample; C dissection plane on the opened stomach

and the number of unexpected falls. "Successful grasp" was defined as when the gripper grasped the tissue with proper counter traction and provided a good submucosal vision. The perforation rate was used to evaluate safety. A graded structured scale of 1 to 3 that was analogous to a unipolar Likert Scale was used to estimate operators' satisfaction, 1 indicated "somewhat satisfied", 2 indicated "satisfied", and 3 indicated "very satisfied".

#### Statistical analysis

Data are presented as the mean  $\pm$  standard deviation (SD) or median (interquartile range) according to normality. Independent t-tests and Wilcoxon rank-sum tests were used to analyze the continuous data. A p < 0.05 was considered significant. All analyses were performed using SPSS version 19 (IBM Corp., Armonk, NY, USA).

## Results

#### Efficacy and safety

A total of 36 lesions were successfully removed using either the FASTER-assisted (n = 18) or conventional ESD method (n = 18). The submucosal dissection time of FASTER-assisted ESD was 7 (4–13) min, which was significantly shorter than that of conventional ESD [13 (8–20) min, p = 0.012]. The submucosal dissection speed of FASTER-assisted ESD was significantly faster than that of conventional ESD (p = 0.002). A lower number of lens cleanings were recorded in the FASTER-assisted ESD group (p = 0.009). No significant differences were

Table 2Outcomes of theFASTER-assisted ESDcompared with conventionalESD

observed in the total procedure time (p = 0.252), incision time (p = 0.055), or the number of tool replacements (p = 0.126) between the two groups. Complete en bloc resection was achieved in all lesions (Fig. 2B and C). No perforations were detected. Table 2 summarizes the outcomes of the study.

For lesions with different sizes, FASTER significantly increased the submucosal dissection speed and decreased the submucosal dissection time for both small (p = 0.023and 0.001) and large lesions (p = 0.039 and 0.026). For lesions with different locations, FASTER significantly increased the submucosal dissection speed (p = 0.001) and reduced the submucosal dissection time (p = 0.011) of lesions on the posterior wall, but did not significantly improve the submucosal dissection speed (p = 0.480) or shorten the submucosal dissection time (p = 0.645) of lesions on the anterior wall. Table 3 summarizes these outcomes.

#### Maneuverability

During FASTER-assisted ESD, 1–3 attempts were needed to achieve a successful grasp; moreover, no incidence of unexpected gripper falls, and tissue damage were observed. FASTER was easy to operate for multidirectional traction, proper tension, and regrasping (Fig. 3). The device operator felt "very satisfied" (grade 3) with the robot's maneuverability in all ESD operations. The endoscopist felt "very satisfied" (grade 3) with the robot's performance in the operations for small lesions and a part of the large lesions, but "satisfied" (grade 2) in the operation for the other part of large lesions.

Outcome <sup>a</sup>	Conventional ESD $(n=18)$	FASTER-ESD $(n=18)$	p value	
Resected specimen area, mm <sup>2</sup>	1010 (723–2196)	699 (546–2270)	0.293	
Total procedure time, min	24 (17–34)	16 (12–32)	0.252	
Incision time, min	$4.9 \pm 2.2$	$3.7 \pm 1.4$	0.055	
Dissection time, min	13 (8–20)	7 (4–13)	0.012	
Dissection speed, mm <sup>2</sup> /min	$97.0 \pm 37$	$148.6 \pm 53$	0.002	
Number of tool replacements	1 (1–7)	1 (1–3)	0.126	
Number of len cleanings	1 (0–6)	0 (0–1)	0.009	
Perforation	0	0	NA	
En bloc resection, %	100	100	NA	
Complete resection, %	100	100	NA	
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FASTER flexible auxiliary single-arm transluminal endoscopic robot, ESD endoscopic submucosal dissection

<sup>a</sup>Data of incision time and dissection speed were present as the mean $\pm$ standard deviation; data of resected specimen area, total procedure time, and dissection time were present as the median (interquartile range); data of the number of tool replacements and the number of lens cleanings were present as the median (minimum, maximum)

Table 3	Subgroup outcomes o	the FASTER-assisted ESD compared with conventional ESD	
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Outcomes <sup>a</sup>	Dissection time, min			Dissection speed, mm <sup>2</sup> /min		
	FASTER-ESD	Conventional ESD	p value	FASTER-ESD	Conventional ESD	p value
Lesions with different sizes						
2 cm in diameter $(n=22)$	5 (3–7)	10 (7–13)	0.001	$137.9 \pm 47.7$	$91.8 \pm 40.1$	0.023
4 cm in diameter $(n = 14)$	16 (10–19)	21 (20-30)	0.026	$165.4 \pm 69.7$	$105.1 \pm 34.2$	0.039
Lesions with different locations						
Fluid side $(n=20)$	5 (3–12)	13 (9–23)	0.011	$173.0 \pm 52.0$	$92.5 \pm 28.9$	0.001
Opposite side of the fluid $(n = 16)$	8 (6–18)	13 (6–19)	0.645	$118.1 \pm 37.2$	$102.6 \pm 47.6$	0.480

FASTER flexible auxiliary single-arm transluminal endoscopic robot, ESD endoscopic submucosal dissection

<sup>a</sup>The data were present as the mean ± standard deviation or the median (interquartile range)

# Discussion

A novel robot system named FASTER was developed. Compared with the existing ESD-assistive devices, FASTER has several advantages: (1) it can be simply installed on a general-use single-channel endoscope, convenient for widespread clinical application; (2) it has four DOFs to ensure multidirectional traction and regrasping. In addition, it is not restricted by the joint construction and moves flexibly because of the structure of a pair of soft steel wires with steel coils, (3) although the arm of the robot is attached to the outside of the endoscope, the spring structure balances its flexibility and rigidity so that it does not affect the control of the endoscope during the ESD operation. Hwang et al. had recently reported a novel portable endoscopic tool handler (PETH) [20]. Although PETH is similar to FASTER, they have two main differences: (1) FASTER has the capability of translational movement. The robotic arm can be retracted during endoscope insertion to present mucosal injury. In addition, the forward and backward movements allow FASTER to optimize the viewing distance during operation. (2) in FASTER, the motion of the clip is designed within the endoscopic view, which is beneficial for safe hand-eye feedback control, especially in human applications.

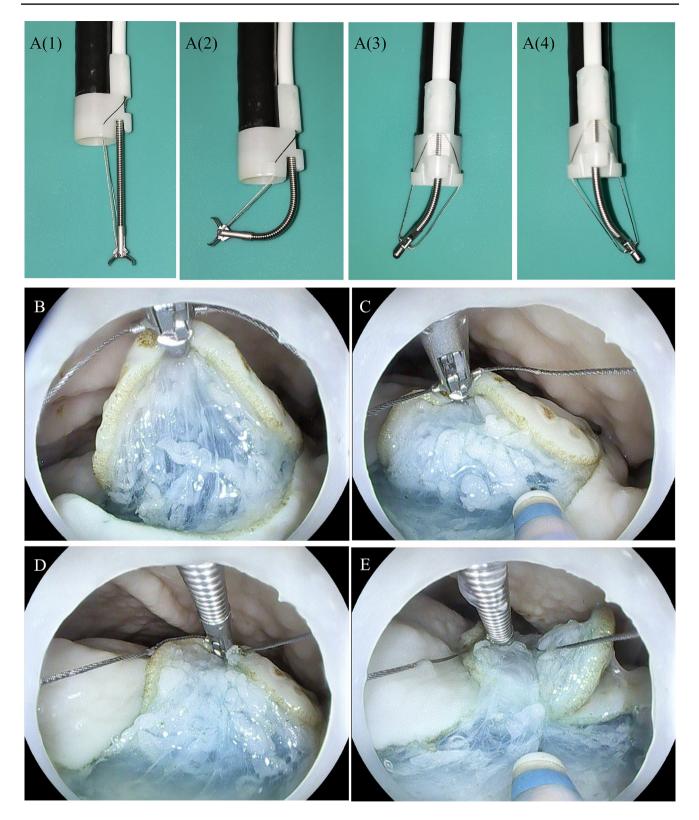
In this comparative ex vivo study, FASTER-assisted ESDs were successfully performed in the antrum. The median dissection time was 7 min in the FASTER-assisted group, which was significantly shorter than that in the conventional group. This result was mainly attributed to the faster dissection speed, which was increased by 53% with the help of FASTER. The endoscopic application of the flexible robotic arm enabled the endoscopist to maintain visualization of the submucosal layer more easily, assisting them in overcoming the technical difficulty of ESD. The median total procedure time was 16 min in the FASTER-assisted group; however, it was not significantly different compared with 24 min in the conventional group. As the total procedure time consisted of individual steps, the FASTER was only used in submucosal dissection, but not in submucosal injection and

circumferential incision, which may be the main reason for the insignificant difference in our results.

The lesion size was associated with incomplete dissection. ESD for larger lesions is challenging. In this study, the dissection speed in FASTER-assisted ESD increased by 1.5 times compared with that of the conventional ESD where the cap was used to stake the flap, and the improvement was similar between small and large lesions. The traction pattern was an important factor affecting the procedure efficiency and endoscopists' satisfaction. For most small lesions, upward traction once or twice was efficient. However, in terms of large lesions, the traction pattern become more complicated. The traction site needed to be replaced from the edge of the mucosal flap to the inner side, and multiple multidirectional traction was necessary.

Another factor that made ESD difficult was the site of the lesion [21]. In this study, the lesions on the posterior wall required more difficult operations because water was easily collected by gravity. The dissection time of posterior wall ESD was significantly reduced using FASTER. For lesions on the anterior wall where the traction force can be achieved through gravity, no significant difference in dissection time was observed. However, FASTER was still very helpful in the early stage of the dissection before the flap was sufficiently prepared, and in case where the flap was contracted inward.

Coaxial motion was the main limitation of FASTER because it was attached to the outside of the endoscope. Although this attachment was beneficial in the clinical application, coaxial motion was inevitable. In addition, endoscopists should be careful to avoid mucosal injury during esophageal insertion. Due to its smooth appearance, mucosal injury never occurred during ex vivo and in vivo animal studies. However, this risk can not be ignored. This study had some limitations. First, all procedures were performed in the antrum, the results were not generalizable for lesions in more challenging locations. Since this was a pilot ex vivo study, further in vivo studies with multiple locations and a larger sample would be scheduled. Second, all ESDs



**Fig. 3** The flexible auxiliary single-arm transluminal endoscopic robot (FASTER) exhibits multidirectional motion and multidirectional traction. A (1), translational movement. A (2), down bending.

A (3), right bending. A (4), left bending. B Upward traction. C Leftward traction. D Rightward traction. E Forward pushing

were performed by a single endoscopist; although this was good for controlling for bias, results were less representative. Finally, novices were not included, and their learning effects may be more obvious. The learning curve in novices should be evaluated in future studies.

In conclusion, we developed a novel ESD assistant robot system named FASTER and evaluated its efficacy, safety, and maneuverability in ex vivo porcine stomach ESD. Our result verified that FASTER facilitated ESD by providing various directional tractions and enhancing the operation visualization. FASTER is expected to promote the clinical application of the ESD procedure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-022-09194-x.

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## Declarations

**Disclosures** Xiao-Xiao Yang, Shi-Chen Fu, Rui Ji, Li-Xiang Li, Xiu-Li Zuo, and Yan-Qing Li have no conflicts of interest or financial ties to disclose.

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