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DYNAMIC MANUSCRIPT

An internal magnet traction device reduces procedure time for endoscopic submucosal dissection by expert and non-expert endoscopists: ex vivo study in a porcine colorectal model (with video)

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Abstract

Background Efficacy of an internal magnet traction device (MTD) for gastric endoscopic submucosal dissection (ESD) by an expert endoscopist has been reported. We hypothesized that use of the MTD would enhance the performance of colorectal ESD in a non-expert endoscopist in ESD compared to the conventional technique. Primary aim of this study was to compare procedure times between conventional ESD (C-ESD) and MTD-assisted ESD (MTD-ESD) by expert and non-expert endoscopists in ESD. Secondary aims included rate of *en bloc* resection, iatrogenic injury, visualization score of the submucosal layer, and endoscopist satisfaction score.

Methods A total of 56 lesions were created in an ex vivo porcine colorectum. Two endoscopists completed C-ESD ($n=28$) and MTD-ESD ($n=28$). Lesions measured 3 cm in diameter and were located on either the anterior or posterior colorectal wall. The MTD consisted of a small neodymium magnet and nylon monofilament attached to a through-the-scope clip. The first MTD was deployed on the opposing colorectal wall of the target lesion and a second MTD was then deployed directly onto the distal margin of the lesion.

Results Total procedure time for MTD-ESD was significantly shorter than C-ESD for both expert (median: 15.8 vs. 19.3 min, $p<0.05$) and non-expert (median: 21.3 vs. 33.9 min, $p<0.001$) endoscopists. All lesions were resected *en bloc.* There was no iatrogenic muscularis propria injury in the MTD-ESD group. For both the expert and non-expert, scores for MTD-ESD were significantly higher for submucosal layer visualization ($p<0.05$) and endoscopist satisfaction ($p<0.001$) compared to C-ESD.

Conclusions Use of the MTD significantly reduced procedure time for both expert and non-expert endoscopists performing ESD. Improving the efficiency, safety, and satisfaction of ESD with such a device particularly for non-expert endoscopists is appealing and could potentially minimize the complexity and duration of the procedure allowing for more widespread use of the technique.

Keywords Endoscopic submucosal dissection · Traction · Magnet · Colon · Porcine

Abbreviations

EMR	Endoscopic mucosal dissection
ESD	Endoscopic submucosal resection
MTD	Magnet traction device
C-ESD	Conventional ESD
MTD-ESD	Magnet traction device-assisted endoscopic submucosal dissection
TTS	Through-the-scope
MAG	Magnetic anchor-guided

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Conventional endoscopic resection, such as snare polypectomy, remains the mainstay therapeutic approach for the vast majority of colon polyps [1]. However, endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are increasingly utilized in the management of large colorectal neoplastic lesions. ESD is preferred for lesions > 2 cm, presence of submucosal fibrosis, or features concerning for advanced neoplasia when *en bloc* rather than piecemeal resection is desirable [2]. However, ESD is labor-intensive and time consuming, in part due to inadequate traction of the mucosal flap interfering with submucosal visualization and dissection.

ESD originally developed in Japan over a decade ago focused on gastric lesions due to the large working space allowing device maneuverability and a thicker muscular layer minimizing the risk of perforation [3]. This technique was subsequently applied to the esophagus and colorectum which are anatomically more challenging [4, 5]. Given the geographic and epidemiological differences, most ESD in the Western hemisphere are performed for colorectal lesions. Higher complication rates, prolonged procedural times, and longer training periods compared to EMR are limiting factors to the widespread use of ESD.

Optimal lesion traction enables submucosal dissection to occur in a more efficient and safe manner [6, 7]. Recently many traction devices have been reported making ESD simpler and more time efficient. Most are designed for use in the stomach with less than optimal traction obtained. We reported on a magnet traction device (MTD) as effective and safe for gastric ESD and submucosal dissection times were significantly reduced when performed by a single Japanese ESD expert [8]. However, the efficacy and safety of the MTD for colorectal ESD is unknown. Furthermore, the benefits of MTD when used by a non-expert endoscopist in ESD are unclear.

We hypothesized that use of the MTD would enhance the performance of colorectal ESD in a non-expert endoscopist in ESD compared to the conventional technique. The primary aim of this study was to compare procedure times between conventional ESD (C-ESD) and magnetic traction device-assisted ESD (MTD-ESD) among expert and non-expert endoscopists in ESD using a colorectal porcine model. Secondary aims included rate of *en bloc* resection, iatrogenic injury to the muscularis propria, visualization score of the submucosal layer during dissection, and endoscopist satisfaction score.

Materials and methods

This was a comparative ex vivo study that was exempt from approval by the Institutional Animal Care and Use Committee.

Experimental setting

All procedures were performed in harvested ex vivo porcine colorectum. Each colorectum was inverted and coagulation marks using argon plasma coagulation (Gi4000 generator, Genii Inc., St. Paul, MN) were created around a 30-mm-diameter paper template. Target lesions were placed at 10 to 40 cm from the anal verge on both the anterior and posterior walls. Then, the colorectum was re-inverted to its normal configuration and placed in a commercial ex vivo trainer (Endo-X-Trainer, Medical Innovations Inc., Rochester, MN).

All procedures were performed by an expert and non-expert endoscopist in ESD. The ESD expert (A.D.) had performed more than 500 clinical cases of ESD, while the non-expert (A.C.S.) was a fourth-year advanced endoscopy fellow with 25 supervised clinical cases of gastric ESD. Each endoscopist alternated between performing C-ESD and MTD-ESD on the anterior or posterior walls (e.g., C-ESD for a lesion on the anterior wall followed by MTD-ESD for a second lesion on the anterior wall).

Magnet traction device (MTD)

The prototype MTD consisted of a commercially available small neodymium magnet ring (3/16″ od × 1/16″ id × 1/16″ thick; pulling force of 0.7 lb; K&J Magnetics Inc., Plumsteadville, PA) and a small rubber ring (1/16″ od × 1/64″ id), which were tied together by a 2-lb tested nylon monofilament (diameter: 0.13 mm) (Fig. 1A). The nylon monofilament length between the rubber ring and magnet was fixed at 3 mm. The MTD was attached to a commercially available through-the-scope (TTS) clip (QuickClip and QuickClip Pro, Olympus America Inc., Center Valley,

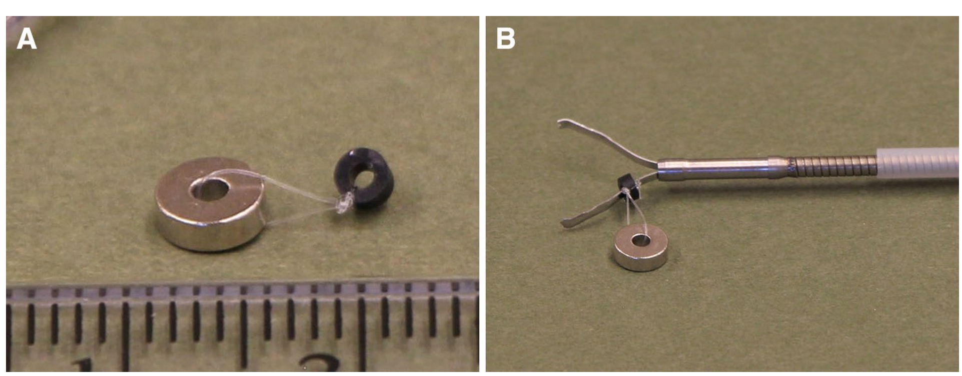

Fig. 1 Magnet traction device (MTD). **A** Neodymium magnet attached to a small rubber ring with a nylon monofilament. **B** MTD attached to a through-the-scope clip

PA; Resolution clip, Boston Scientific Inc., Marlborough, MA, and Instinct Endoscopic Hemoclip, Cook Medical Inc., Bloomington, IN). As the current iteration of MTD cannot be passed through the endoscope, a TTS clip was advanced through the working channel of the endoscope and the rubber ring of the MTD hooked onto one arm of the clip. The closed clip with attached MTD was then pulled and flushed to the endoscope tip prior to intubating the colon (Fig. 1B).

Endoscopic submucosal dissection procedure (video)

A transparent cap (D-201-11804; Olympus America) was attached to the distal end of a standard gastroscope (GIF-H180; Olympus America) and advanced to the target lesion. A submucosal fluid cushion was created using an injection of methylene blue-tinted normal saline. A circumferential mucosal incision was completed along the coagulation marks using an electrosurgical knife (Dual knife 1.5 mm; Olympus America). In the C-ESD group, submucosal dissection was achieved using the Dual knife. In the MTD-ESD group, the first MTD was deployed on the opposing colorectal wall above the proximal margin (oral side) of the target lesion (Fig. 2A). A second MTD was then deployed directly onto the distal margin (anal side) of the lesion. Removing air from the colon with scope suction, as well as manipulation with the clip deployment catheter, allowed for magnet-to-magnet apposition (Fig. 2B). Once the two magnets of the MTDs connected, the observed traction created between the attached devices resulted in lifting of the target lesion towards the opposing wall, improving visibility of the submucosal layer (Fig. 2C). The degree of traction or distance between the lesion and opposing wall was easily and simply controlled by the endoscopist using air insufflation. The total

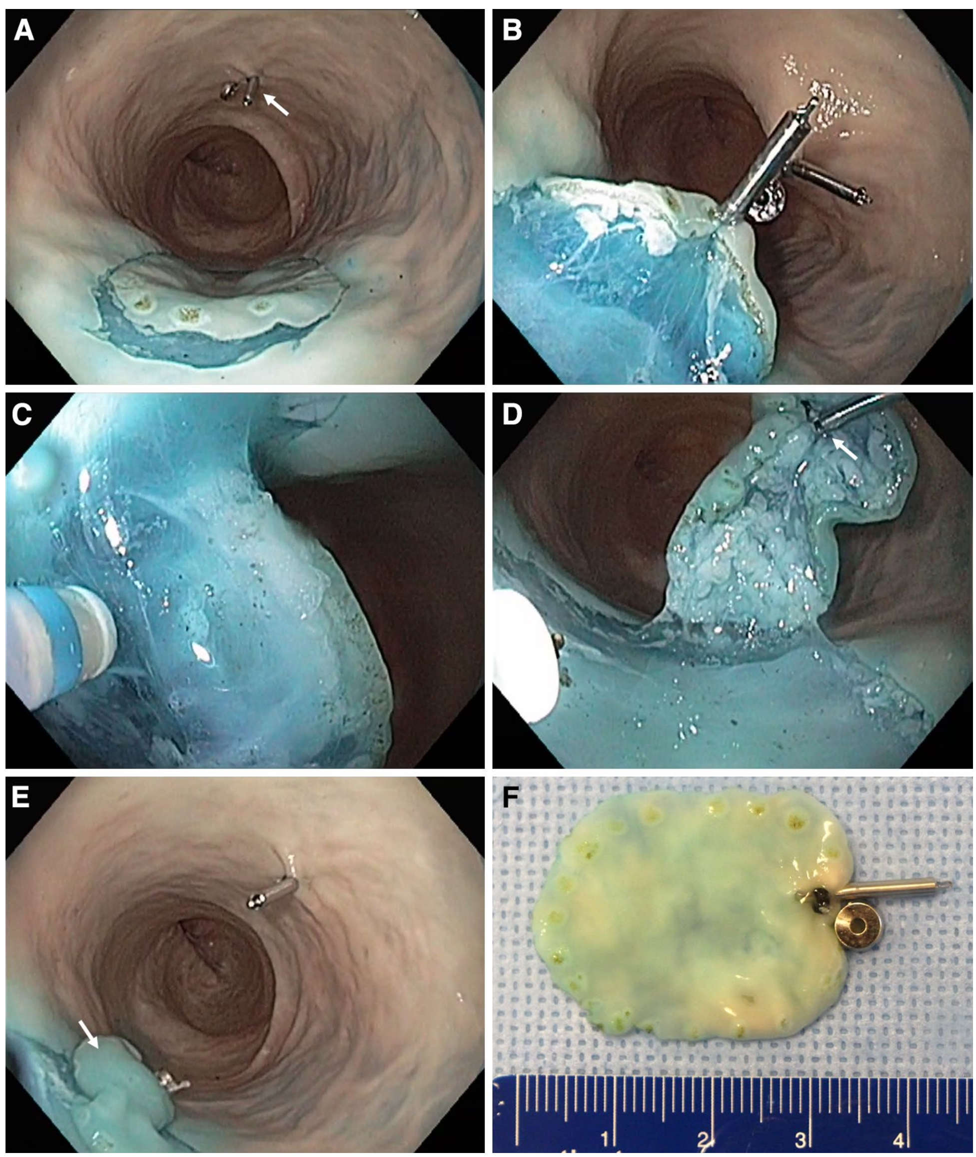

Fig. 2 Endoscopic submucosal dissection using a magnet traction device (MTD) in the colon. **A** A circumferential mucosal incision was completed for a lesion located on the posterior wall of the colon. A MTD (white arrow) was deployed on the opposing colon wall above the proximal margin (oral side) of the lesion. **B** A second MTD was deployed directly onto the distal margin (anal side) of the lesion and both MTDs connected resulting in traction. **C** Optimal traction and clear visualization were obtained during submucosal dissection. **D** Traction was reinforced by deploying a third MTD (white arrow) on the lesion. First and second MTDs are behind the lesion. **E** The lesion was completely resected (white arrow) and the nylon monofilament cut from the clip on the opposing colon wall. **F** Resected specimen with all attached MTDs

suture length when both MTDs were connected was 6 mm (as each MTD has a fixed suture length of 3 mm). Magnetic device-enhanced submucosal dissection was then completed using the Dual knife.

If additional traction was required, a third MTD was deployed directly onto the partially resected lesion. This third MTD then connected to the two previously placed devices (Fig. 2D). Once the target lesion was completely resected, the nylon monofilament connecting the first MTD to the TTS clip on the opposing colorectal wall was cut using the Dual knife (Fig. 2E). The resected specimen with all deployed magnets was retrieved *en bloc* (Fig. 2F). The one TTS clip attached to the opposing colorectal wall was not removed.

The resection sites were closely inspected for iatrogenic muscularis propria injury. Microperforation was evaluated using luminal air insufflation along with a liquid detergent placed on the serosal side of the resection site, and the presence of bubbles confirmed a perforation.

Outcome measurements

The primary outcome measured was comparison of total procedure times between C-ESD and MTD-ESD for the expert and non-expert endoscopists in ESD. Total procedure time was defined as the time from submucosal fluid injection to retrieval of the specimen. Secondary outcomes measured were rate of *en bloc* resection, iatrogenic injury to the muscularis propria, visualization score of the submucosal layer during dissection, endoscopist satisfaction score, submucosal dissection time, and resected specimen size. Muscularis propria injury was defined as any defect caused by the Dual knife that was confined to the muscularis propria layer. Visualization of the submucosa during submucosal dissection was evaluated using a visual analog scale ranging from 0 (poor) to 5 (excellent). The endoscopist's satisfaction was evaluated using a modified IBM computer usability satisfaction questionnaire (After-Scenario Questionnaire; ASQ), which consists of three factors [9]: 1. Easiness satisfaction: overall, I am satisfied with the ease of completing ESD (0 = strongly disagree; 5 = strongly agree); 2. Temporal satisfaction: overall, I am satisfied with the amount of time it took to complete ESD (0 = strongly disagree; 5 = strongly agree), and 3. Effect satisfaction: overall, I am satisfied with observed lesion traction during submucosal dissection (0 = strongly disagree; 5 = strongly agree).

Sample size calculation

As this was a superiority study, the sample size was estimated based on the primary endpoint (comparison of total procedural time in a non-expert). In a previous study, the mean and standard deviation of total procedure time in a non-expert for ESD in an ex vivo colorectum model was 23.6 ± 8.2 min [10]. We hypothesized that MTD-ESD would provide a 33% reduction in total procedure time. The sample size was calculated as 13 lesions needed for each group (C-ESD vs. MTD-ESD) to ensure 80% power for a one-sided significance level of 0.05. Taking lesion location into consideration (i.e., anterior or posterior walls), it was determined that 14 lesions were required for each group.

Statistical analysis

Quantitative parameters were compared using Student's t test or the Mann–Whitney U test and qualitative parameters with Pearson's χ^2 test. $p < 0.05$ was considered statistically significant. Statistical analysis was performed using Stata 12.0 software (Stata Corp., College Station, TX).

Results

Fifty-six target lesions were created in nineteen porcine colorectums (two to four lesions per colorectum) at the anterior and posterior walls. The ESD expert and non-expert resected twenty-eight lesions each (7 MTD-ESD anterior, 7 MTD-ESD posterior, 7 C-ESD anterior, and 7 C-ESD posterior walls). Total procedure times were significantly reduced in the MTD-ESD group compared to C-ESD for both the ESD expert (median 15.8 vs. 19.3 min, $p < 0.05$) and non-expert (median 21.3 vs. 33.9 min, $p < 0.001$) (Tables 1 and 2). Total procedure time was reduced by 37% for the non-expert and 18% for the expert. All lesions were resected *en bloc* with no iatrogenic muscularis propria injury for MTD-ESD for both the expert and non-expert, while muscle injury per lesion was observed in C-ESD (expert median = 0 [range 0–2]; non-expert median = 0 [range 0–2]). The submucosal layer visualization score was significantly higher in MTD-ESD (expert 5 vs. 2.5, $p < 0.005$; non-expert 5 vs. 3, $p < 0.001$). The endoscopist satisfaction score was also higher in MTD-ESD for both expert and non-expert (expert easiness 5 vs. 3, $p < 0.001$, temporal satisfaction 5 vs. 3.5, $p < 0.001$, effect satisfaction 5 vs. 2.5, $p < 0.005$; non-expert easiness 5 versus 2.5, $p < 0.001$, temporal satisfaction 5 vs. 2, $p < 0.001$, effect satisfaction 5 vs. 3, $p < 0.001$). The submucosal dissection time for MTD-ESD was significantly shorter than in C-ESD (expert 5.1 vs. 12.2 min, $p < 0.001$; non-expert 7.9 vs. 22.7 min, $p < 0.001$). There was no difference in specimen size (expert MTD-ESD vs. C-ESD = 32.5 vs. 33.1 mm, $p = 0.46$; non-expert MTD-ESD vs. C-ESD = 33.5 vs. 33.3 mm, $p = 0.9$). The median times for maneuver of all MTDs were 2.7 min for deployment and 15 s for removal in the expert and 2.8 min for deployment and 24 s for removal in the non-expert. A third MTD was

Table 1 Procedure details of non-expert endoscopist in ESD

	MTD-ESD Median (IQR) ($n=14$)	C-ESD Median (IQR) ($n=14$)	p value
Total procedure time (min)	21.3 (17.7–28.5)	33.9 (30.1–39.6)	< 0.001
Circumferential incision time (min)	10.4 (8.9–13.3)	11.5 (9.6–13.3)	0.52
MTDs deployment time (min)	2.8 (2.3–3.1)	–	–
Submucosal dissection time (min)	7.9 (5.7–10.3)	22.7 (18.0–26.6)	< 0.001
MTD collection time (s)	24 (14–76)	–	–
Specimen size (mm)	33.5 (31.9–35.1)	33.3 (32.8–34.3)	0.92
Visualization score of the submucosal layer during dissection[a]	5 (5–5)	3 (2–4)	< 0.001
Endoscopist's satisfaction score[b]			
Ease	5 (4–5)	2.5 (2–4)	< 0.001
Temporal satisfaction	5 (4–5)	2 (2–3)	< 0.001
Effect satisfaction	5 (5–5)	3 (1–3)	< 0.001

MTD-ESD magnet traction device-assisted endoscopic submucosal dissection, *C-ESD* conventional endoscopic submucosal dissection, *IQR* interquartile range, *MTD* magnet traction device

[a]Score based on a visual analog scale (0 = poor, 5 = excellent)

[b](0 = strongly disagree, 5 = strongly agree)

Table 2 Procedure details of expert endoscopist in ESD

	MTD-ESD Median (IQR) ($n=14$)	C-ESD Median (IQR) ($n=14$)	p value
Total procedure time (min)	15.8 (12.5–17.2)	19.3 (15.9–21.6)	0.011
Circumferential incision time (min)	6.9 (5.6–7.7)	7.1 (5.9–7.7)	0.83
MTDs deployment time (min)	2.7 (2.1–3.1)	–	–
Submucosal dissection time (min)	5.1 (3.9–6.2)	12.2 (9.4–15.6)	< 0.001
MTD collection time (s)	15 (8–43)	–	–
Specimen size (mm)	32.5 (31.0–33.5)	33.1 (31.3–34.3)	0.46
Visualization score of the submucosal layer during dissection[a]	5 (5–5)	2.5 (1–5)	0.0012
Endoscopist's satisfaction[b]			
Ease	5 (5–5)	3 (2–5)	< 0.001
Temporal satisfaction	5 (5–5)	3.5 (2–4)	< 0.001
Effect satisfaction	5 (5–5)	2.5 (1–5)	0.0012

MTD-ESD magnet traction device-assisted endoscopic submucosal dissection, *C-ESD* conventional endoscopic submucosal dissection, *IQR* interquartile range, *MTD* magnet traction device, *MTD* magnet traction device

[a]Score based on a visual analog scale (0 = poor, 5 = excellent)

[b](0 = strongly disagree, 5 = strongly agree)

used when traction became inadequate in two of 14 cases (14.2%) for the expert and three of 14 (21.4%) cases for the non-expert. All magnets were successfully retrieved.

Subgroup analysis

Table 3 shows the results of subgroup analysis based on lesion location (anterior vs. posterior wall). For the non-expert, there were significant differences between the groups irrespective of lesion location with regard to total procedure time (anterior MTD-ESD vs. C-ESD = 22.3 vs. 32.2 min, $p < 0.05$; posterior MTD-ESD vs. C-ESD = 20.3 vs. 35.9 min, $p < 0.01$), submucosal dissection time (anterior MTD-ESD vs. C-ESD = 10.1 vs. 19.3 min, $p < 0.005$; posterior MTD-ESD vs. C-ESD = 5.9 vs. 26.6 min, $p < 0.005$) and submucosal visualization score (anterior MTD-ESD vs. C-ESD = 5 vs. 3, $p < 0.005$; posterior MTD-ESD vs. C-ESD = 5 vs. 2, $p < 0.005$).

In contrast, for the expert, there were no significant differences in total procedure time ($p = 0.14$) and submucosal

Table 3 Subgroup analysis based on location of lesions

	Non-expert endoscopist		p value	Expert endoscopist		p value
	MTD-ESD	C-ESD		MTD-ESD	C-ESD	
Total procedure time (min), median (IQR)						
Anterior	22.3 (17.7–28.5)	32.2 (29.5–34.3)	0.0181	14.9 (11.3–16.0)	15.9 (13.5–18.6)	0.14
Posterior	20.3 (17.5–25.2)	35.9 (30.1–48.6)	0.004	16.5 (14.1–17.8)	21.6 (19.9–25.3)	0.0088
Submucosal dissection time (min), median (IQR)						
Anterior	10.1 (7.4–13.7)	19.3 (17.1–23.2)	0.0026	3.9 (3–5.6)	9.4 (6.9–11.2)	0.0017
Posterior	5.9 (5.6–8.5)	26.6 (22.2–35.7)	0.0017	6.2 (5–7.1)	15.6 (12.2–18.5)	0.0027
Visualization score of the submucosal layer during dissection, median (IQR)[a]						
Anterior	5 (5–5)	3 (3–4)	0.0026	5 (5–5)	5 (5–5)	0.31
Posterior	5 (5–5)	2 (1–2)	0.0013	5 (5–5)	1 (1–1)	< 0.001

MTD-ESD magnet traction device-assisted endoscopic submucosal dissection, *C-ESD* conventional endoscopic submucosal dissection, *IQR* interquartile range, *MTD* magnet traction device

[a]Score based on a visual analog scale (0 = poor, 5 = excellent)

visualization score ($p = 0.31$) for lesions on the anterior wall. However, for lesions on the posterior wall, there were significant differences in total procedure time (MTD-ESD vs. C-ESD = 16.5 vs. 21.6 min, $p < 0.01$) and submucosal visualization score (MTD-ESD vs. C-ESD = 5 vs. 1, $p < 0.001$).

Discussion

Our group recently reported the efficacy and safety of MTD-ESD in the stomach when performed by an ESD expert [8]. However, the effectiveness of MTD-ESD in the colorectum remained unclear given the confined working space and thinner wall. Furthermore, we sought to determine if the MTD would be beneficial in the hands of a non-expert as well as an expert in ESD.

This study demonstrated the efficacy, efficiency, and safety of MTD-ESD in the colorectum. Compared to C-ESD, MTD-ESD significantly reduced procedure times for both the expert and non-expert in ESD. Notably, total procedure time was reduced by 37% for the non-expert and 18% for the expert. There was improved visualization of the submucosal layer during dissection, excellent endoscopist satisfaction score, and no iatrogenic muscularis propria injuries. Subgroup analysis showed no significant differences for the expert in total procedure time and submucosa visualization score for lesions located on the anterior wall, which is attributed to the ability of an expert to adequately maneuver using the inherent traction from gravity. The attractive feature of the MTD is the endoscopist's ability to control the degree of tissue traction by air insufflation or placement of an additional MTD. Deployment and removal of the devices were quick and simple, and cutting of the nylon monofilament avoided traumatic removal of the TTS clip attached to the opposing colorectal wall. The non-expert performed MTD-ESD satisfactorily without any prior training.

Clear visualization of the dissection plane is essential for safe and efficient ESD [6]. Several methods have been reported to provide appropriate traction during submucosal dissection [11], such as clip-with-line [7], percutaneous traction [12, 13], external forceps [14], internal-traction (clip-band method) [15], medical ring [16], S-O clip [17], double-channel [18], and robot-assisted [19] approaches. However, traction created by current devices depends on the endoscopic longitudinal direction, with ineffective traction attained in the majority of cases. The S-O clip is a promising system that has been described clinically as a traction device for colorectal ESD [17]. The advantages of the S-O clip, which are also seen with the MTD, are traction independent of the endoscope and traction that pulls a lesion vertically towards the opposing colonic wall. However, the main disadvantages of this system are the inability to reposition the S–O clip and a more cumbersome endoscopic placement. Future comparative studies between the MTD and S–O clip would be beneficial.

Magnetic anchor-guided (MAG) ESD was described with an external magnet set outside the body and an internal magnet within the gastrointestinal lumen [6, 20]. The concept of MAG ESD was to pull a lesion with a small internal magnet towards a larger external magnet. The main disadvantage of using an external magnet was the inconsistent magnetic field and attraction that vary with thickness of the abdominal wall and lesion location. Matsuzaki et al. reported that adjusting the traction force was challenging in some cases with 14% of internal magnets prematurely detaching from the lesion [21]. Our internalized MTD system is not influenced by the thickness of the abdominal wall or the location of the lesion and exerts a relatively weak and consistent magnetic force.

This study has several limitations. First, this was an ex vivo model and the study involved two endoscopists. The ex vivo model also obviates the need for hemostasis often required during ESD. Second, the MTD in its current iteration cannot be advanced through the working channel of the endoscope, necessitating multiple intubations. Modifications are presently underway to allow a TTS approach. Third, appropriate traction necessitates a distensible segment of the colon, which may not be readily achieved in narrowed, angulated colonic lumens in the clinical setting (e.g., diverticular-filled sigmoid colon).

EMR and ESD are increasingly adopted worldwide for management of large colonic lesions over invasive surgery given their favorable outcomes [22]. A key advantage of ESD is the ability to perform an *en bloc* resection, which provides a more accurate oncologic evaluation of the deep and lateral margins for tumor assessment and reduces the risk of lesion recurrence that may result from residual islands of tissue remaining after piecemeal resection [23, 24]. There is ongoing emphasis on research targeted at rendering these endoscopic procedures simpler and time efficient, which includes development of new tools for submucosal dissection.

In conclusion, use of the MTD for colorectal ESD is feasible, efficient, and effective compared to C-ESD, particularly for a non-expert. Improving the efficiency and safety of ESD with such a device is appealing and could potentially minimize the complexity and duration of this technique.

Author contributions The endoscopic procedure and manuscript writing: AD. Endoscopic procedure and manuscript review: ACS. Preparation for ex vivo experiment: JLD, CAM, CJT. Data analysis and manuscript review: ER, LMWKS, CJG.

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Compliance with ethical standards

Disclosures Akira Dobashi and Elizabeth Rajan have intellectual property with Medtronic related to the magnet traction device. Christopher Gostout is Chief Medical Officer for Apollo Endosurgery and a consultant for Olympus Medical Systems. Andrew Storm, Louis M. Wong Kee Song, Jodie Deters, Charles Miller, Crystal Tholen have no conflicts of interest or financial ties to disclose.

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