Novel through-the-scope steerable grasper for dynamic traction reduces dissection time and technical demand in endoscopic submucosal dissection in novice endoscopists compared with clip-and-line traction method: an ex vivo randomized study

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Background and Aims: Lack of effective tissue traction devices to facilitate endoscopic submucosal dissection (ESD) leads to prolonged dissection time. We aimed to study the efficacy of a novel through-the-scope steerable grasper arm (SGA) for dynamic traction compared with the clip-and-line (CL) traction method in an ex vivo setting.

Methods: This was a prospective, single-center, randomized ex vivo study. In a porcine stomach model, two 25-mm circular lesions were marked. Novice endoscopists with no prior ESD experience performed ESD with both traction methods (SGA and CL). Each participant was randomized to either SGA first (study group) or CL first (control group). The primary outcome was total dissection time in minutes. Adverse events of muscle injury, perforation, mucosal injury, or fragmentation were noted. The National Aeronautics and Space Administration (NASA) task load index (TLX) was used to grade technical workload.

Results: Ten subjects participated in the study, and 5 were randomized to the SGA method first. The mean dissection time was significantly shorter with SGA compared with CL (5.07 $\pm$ 2.19 minutes vs 20.07 $\pm$ 8.45 minutes, $P <$ .001) irrespective of order of randomization. Four instances of muscle injury and 1 perforation were noted with CL and none with SGA. Mean total NASA-TLX score was significantly lower with SGA (36.1 $\pm$ 11.6) versus CL (81.5 $\pm$ 20.8) ($P <$ .001).

Conclusions: With novice endoscopists performing ESD, SGA traction leads to faster dissection time compared with the CL method with a reduced technical workload in an ex vivo setting. The SGA is a promising tool to improve efficiency and the learning curve of ESD. (iGIE 2022;1:3-10.)

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Endoscopic submucosal dissection (ESD) is a specialized endoscopic resection technique initially developed in Japan to resect premalignant and early malignant lesions in the GI tract.[1] Although initially developed as an alternative less-invasive resection technique for early gastric cancer, it has expanded to include early esophageal and colorectal lesions. ESD is technically challenging and time-consuming, with a higher adverse event rate compared with EMR.[2]

ESD requires adequate visualization of the submucosa for optimal submucosal dissection. Adequate visualization is critical to reduce the risk of perforation and to ensure en-bloc resection. To increase the efficiency and safety of ESD, multiple traction techniques have been described and have shown promise in reducing procedure times.[3] The clip-and-line (CL) method is commonly used where an external string is attached using an endoscopic clip to provide countertraction. Dental floss, nylon suture, and fishing line have been commonly used for this purpose. Most traction methods provide unidirectional traction, and therefore a disadvantage is lack of dynamic traction. Robotic-assisted ESD involves an independent grasper arm to provide dynamic traction. It has been shown to reduce dissection time and endoscopist mental and physical workload.[4] However, such a system is expensive and not readily available at most centers. Tracmotion (Fujifilm Medical Systems USA, Inc, Lexington, Mass, USA) is a novel

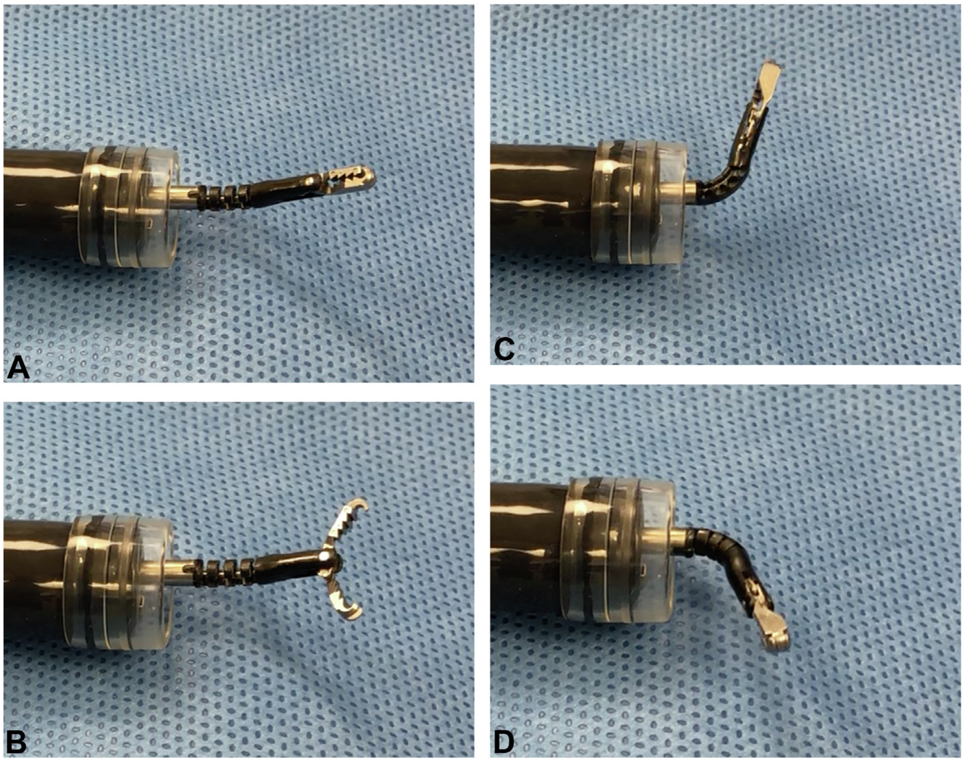

Figure 1. Through-the-scope steerable grasper arm with the grasper (**A**) closed, (**B**) open, and (**C** and **D**) movement with the elbow flexed.

steerable grasper arm (SGA) that allows dynamic traction to facilitate ESD (Fig. 1) At present, the efficacy and safety of this device is unknown. We conducted a randomized study comparing the CL and SGA methods in an ex vivo porcine model to assess dissection time and safety of the 2 methods in endoscopists with no prior experience with ESD.

METHODS

Our aim was to study the efficacy and technical demand of a novel through-the-scope SGA for dynamic traction compared with CL traction in an ex vivo setting.

Study design

This was a randomized, prospective study comparing CL and SGA methods for traction during ESD. Ten trainee endoscopists were enrolled in the study, and all performed ESD with both methods. Each participant was randomized to either SGA first (study group) or CL first (control group). Two resections were performed by each participant.

Participants

The enrolled participants included gastroenterology fellows in their second, third, or fourth years. Participants had 1 to 3 years of experience performing endoscopy. None of the participants had performed ESD in the past. No minimum EMR experience was required. All participants were provided structured learning that included 30 minutes of ESD instructional videos followed by 30 minutes of proctored hands-on ESD practice sessions including practice using CL and SGA methods before randomization.

Ex vivo model

Resected porcine stomach was used as an ex vivo model. Two circles 25 mm in diameter each were marked on the mucosa using a Napolean measuring device (Micro-Tech Endoscopy USA, Inc, Ann Arbor, Mich, USA) and a T-type HybridKnife (Erbe Elektromedizin Ltd, Tuebingen, Germany). Theses circles represented the lesion of interest. All lesions were located at the 6 o'clock position with respect to a straight gastroscope on gastroscope insertion.

Procedure and equipment

A double-channel gastroscope (Fujifilm Medical Systems USA, Inc) with a clear cap (Steris, Mentor, Ohio, USA) was used to perform all procedures. Although double-channel gastroscopes from different manufacturers could accommodate the SGA, this compatibility needs to be individually assessed. Submucosal injection was performed using Orise submucosal lifting agent (Boston Scientific, Marlborough, Mass, USA) (Fig. 2). The T-type HybridKnife was used to

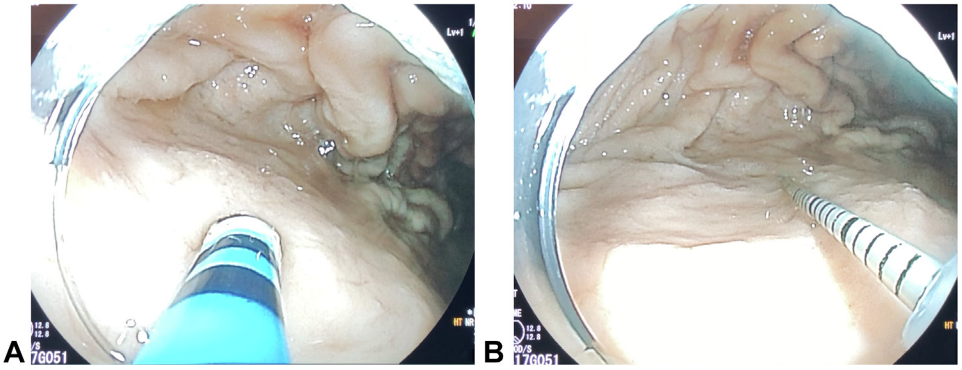

Figure 2. A, Lesion marking using the electrosurgical knife. **B,** Use of the measuring device to aid in marking lesions 25 mm in diameter.

perform the circumferential incision to include the existing circular markings using Endocut-I effect 1, duration 3, interval 2 (VIO 300D; Erbe Elektromedizin Ltd).

Participants were proctored by the ESD expert and the advanced endoscopy fellow. Assistance during the step of circumferential incision was allowed. No assistance or real-time instructions were provided for the step of submucosal dissection and use of either SGA or CL traction. Once complete circumferential incision was performed, submucosal dissection was performed using the swift coagulation effect 2 at 50 W (Video 1, available online at www.igiejournal.org).

Once ESD was complete, the lesion was retrieved, and the lesion and mucosal defect were carefully examined. Perforation was defined as full-thickness injury to the muscle layer visible externally on the stomach. Muscle injury was defined as injury to the muscle layer without overt perforation. Tissue fragmentation was defined as detachment of part of the lesion during dissection and application of an endoscopic clip or during use of traction. Mucosal injury was defined as thermal injury visible on the surface of the resected lesion. En-bloc resection was confirmed when all markings were included in the resected specimen.

SGA method

Tracmotion, a novel SGA, was used for this study. The SGA device was passed through the second working channel of the double-channel gastroscope. The SGA has 3 degrees of motion. It can be moved forward and retracted into the gastroscope channel, the arm can be flexed from 30 degrees to approximately 90 degrees, and the arm can be rotated 360 degrees. The grasper opens on extension of the arm and closes with gentle flexion of the arm. The grasper is controlled by the endoscopist and can be opened and closed multiple times, and different parts of the lesion can be grasped as needed (Fig. 3).

CL method

The gastroscope was withdrawn and an endoscopic clip (QuickClip Pro; Olympus America, Center Valley, Pa, USA) was passed through the gastroscope. A long string (dental floss) was attached to 1 arm of the endoscopic clip. The gastroscope was then introduced into the porcine stomach. The endoscopic clip with string attached was applied over the proximal edge of the lesion and deployed (Fig. 4). Gentle traction was applied as needed by the endoscopist using the attached string.

Data collection

Total dissection time was defined as when circumferential marking was completed to the time when dissection was complete and the lesion was free from submucosa. Incidences of perforation, muscle injury, tissue fragmentation, and mucosal injury were noted. At the end of both ESD methods by each participant, they were asked to rate their preferred method of traction. Subsequently, the National Aeronautical and Space Administration (NASA) task load index (TLX) was administered (Fig. 1). This quantitative scoring system was developed and validated by NASA to evaluate the workload in a procedure[5] and has been used in previous ESD studies.[4,6]

The NASA-TLX comprises the following 6 factors:

1. Mental demand: How mentally demanding was the task?
2. Physical demand: How physically demanding was the task?
3. Temporal demand: How hurried or rushed was the pace of the task?
4. Performance: How successful were you in accomplishing what you were asked to do?
5. Effort: How hard did you have to work to accomplish your level of performance?
6. Frustration: How insecure, discouraged, irritated, stressed, and annoyed were you?

Participants were asked to rate their score on an interval scale ranging from low (1) to high (20), and the mean NASA-TLX score was calculated.

Outcomes

The primary outcome measure was comparison of the mean dissection time in minutes for both the CL and

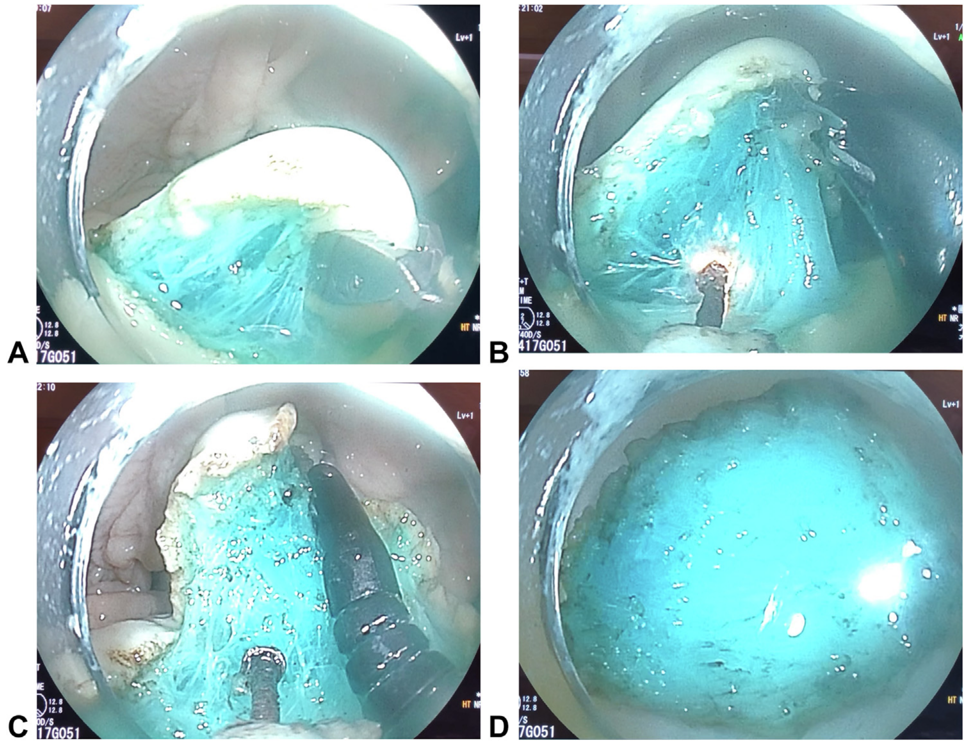

Figure 3. A-C, Steerable grasper arm providing dynamic traction during submucosal dissection. **D,** Resected specimen being examined for adverse events.

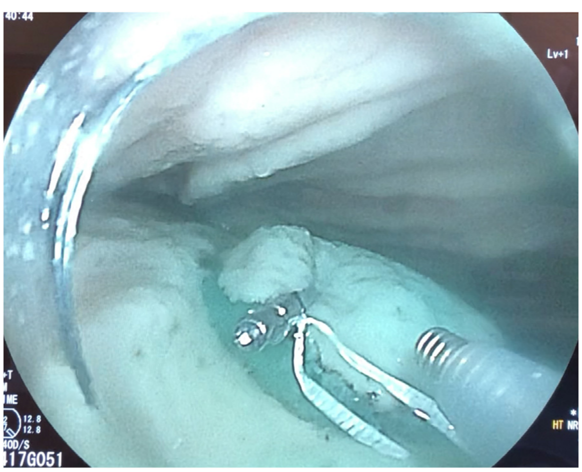

Figure 4. Clip-and-line traction method using an endoscopic clip and dental floss to aid in submucosal dissection.

SGA methods. Secondary outcomes were incidence of muscle injury, perforation, mucosal injury, and specimen fragmentation and domain-specific and mean total NASA-TLX scores for both methods.

Statistical analysis

Continuous variables in both groups are reported as mean ± standard deviation. Outcomes between the 2 groups were compared using a Student *t* test for continuous variables and a Fisher exact test for categorical variables. Subgroup analysis was performed to compare mean dissection time for both methods for the group randomized to CL first and separately for the group randomized to SGA first. Statistical analysis was performed using STATA 16 (StataCorp LLC, College Station, Tex, USA).

Sample size

No published data exist on dissection times with the SGA method. Based on the authors' experience, we hypothesized that the dissection time would halve with SGA compared with CL and that the estimated mean dissection time with CL would be 18 minutes. Power was set at .8, and alpha was .05. The sample size was estimated to be 5 for each group. Because each participant would perform both procedures, to allow for subgroup analysis, the estimated sample size was 10 participants.

RESULTS

ESD dissection time

Ten participants completed the study, and each performed ESD successfully using both methods, CL and SGA for traction. Five were randomized to CL first, and 5 were randomized to SGA first. En-bloc resection was achieved in all instances. Pooled data for all 10 participants showed the mean dissection time when using SGA (5.07 ± 2.19 minutes) was significantly shorter compared with CL

TABLE 1. Dissection times between 2 methods across 2 randomized groups

Randomization	No. of participants	Dissection time using the SGA (min)	Dissection time using CL (min)	*P* value
Total	10	5.07 ± 2.19	20.07 ± 8.45	<.001
SGA first	5	5.32 ± 2.21	22.6 ± 11.42	.017
CL first	5	4.82 ± 2.41	17.5 ± 3.70	.002

Values are mean ± standard deviation.
SGA, Steerable grasper arm; *CL*, clip and line.

TABLE 2. NASA-TLX scores across domains for SGA and CL methods

	SGA method	CL method	*P* value
NASA-TLX total score	36.1 ± 11.6	81.5 ± 20.8	<.001
Mental demand	7.9 ± 3.1	15 ± 4	<.001
Physical demand	6.4 ± 2.5	12.9 ± 5.6	.009
Temporal demand	5.6 ± 3.3	13.8 ± 4.3	<.001
Performance	3.9 ± 3.2	9.2 ± 5.0	.02
Effort	8.4 ± 3.5	16.3 ± 2.8	<.001
Frustration	3.9 ± 2.3	14.3 ± 5.1	<.001

Values are mean ± standard deviation.
SGA, Steerable grasper arm; *CL*, clip and line; *NASA*, National Aeronautics and Space Administration; *TLX*, task load index.

(20.07 ± 8.45 minutes, $P < .001$) (Table 1). On subgroup analysis, for the 5 participants randomized to CL first, the mean dissection time when using SGA (4.82 ± 2.41 minutes) was significantly shorter compared with CL (17.5 ± 3.70 minutes, $P = .002$). For the other 5 participants randomized to SGA first, the mean dissection time when using SGA (5.32 ± 2.21 minutes) remained significantly shorter compared with CL (22.6 ± 11.42 minutes, $P = .017$)

Technical workload

The mean total NASA-TLX score was significantly lower for the SGA group (36.1 ± 11.6) compared with the CL group (81.5 ± 20.8, $P < .001$) (Table 2). NASA-TLX scores across the domains of mental demand (7.9 ± 3.1 vs 15 ± 4 , $P < .001$), physical demand (6.4 ± 2.5 vs 12.9 ± 5.6, $P = .009$), temporal demand (5.6 ± 3.3 vs 13.8 ± 4.3, $P < .001$), performance (3.9 ± 3.2 vs 9.2 ± 5.0, $P = .02$), effort (8.4 ± 3.5 vs 16.3 ± 2.8, $P < .001$), and frustration (3.9 ± 2.3 vs 14.3 ± 5.1, $P < .001$) were significantly lower with SGA compared with CL, respectively. All participants answered that they would choose the SGA method for traction over the CL method if given a choice for the given lesion.

Adverse events

Five participants had adverse events when using the CL method compared with 1 participant when using the SGA method ($P = .14$). Muscle injury was noted in 4 cases (40%) with CL and none with SGA ($P = .09$) (Table 3). Perforation was noted in 1 case (10%) with CL and none with SGA. Two instances (20%) of thermal injury to the mucosal aspect of the lesion occurred with CL compared to 1 (10%) such occurrence with SGA ($P = 1$). One case of sample fragmentation with CL was noted and none with SGA.

DISCUSSION

ESD has gained popularity as the preferred endoscopic method to resect mucosal neoplasms where the goal is en-bloc resection.[7,8] Ideal pathologies for ESD include neoplasms in the GI tract with moderate to high suspicion of superficial cancers. ESD is superior to EMR for en-bloc resection and compares favorably with surgery because of a reduced adverse event rate and early patient recovery.[9,10] Despite the popularity of ESD in east Asia, acceptance has been slow in the West. Multiple procedure-related challenges remain that have to be overcome before wide adoption of ESD becomes a reality. The critical steps of the procedure include gaining adequate visualization of the submucosa and careful dissection of submucosal fibers under direct vision.[11] Blind dissection increases the risk of bleeding and perforation, which are major adverse events with ESD. Although a clear cap is commonly used to improve visualization of the submucosa, maintaining a good visual field along with a stable endoscope position remain as challenges. Unsurprisingly, ESD procedure time is significantly longer than EMR.[12] Given these challenges, a lack of dedicated tools, and a lack of standardized training opportunities, there is a steep learning curve for ESD in the West.[13]

One way to improve the efficiency and safety of ESD is by using tools to improve visualization of the submucosa. This can be achieved with the use of traction devices.[3] The primary goal of traction devices is to move the mucosal

TABLE 3. Adverse events with the 2 methods

Adverse event	Steerable grasper arm (n = 10)	Clip and line (n = 10)	*P* value
Muscle injury	0	4 (40)	.09
Perforation	0	1 (10)	1
Mucosal injury	1 (10)	2 (20)	1
Tissue fragmentation	0	1 (10)	1

Values are n or n (%).

aspect of the lesion away from the muscularis propria, in turn exposing a larger area of submucosa for safe and efficient dissection. Multiple such devices have been described in literature. A commonly used method is the CL method with or without a pulley countertraction.[14,15] Other methods include use of external grasping forceps,[16] percutaneous traction,[17] a second slim endoscope,[18] a clip with rubber band,[19] and an S-O clip.[20] Although each of these methods is advantageous in certain situations, the major limitation in most circumstances is the lack of dynamic real-time endoscopist-controlled traction with the ability to change the point of traction with relative ease.

To overcome this limitation, novel robotic endoscopy platforms have been described that have a dedicated grasper arm and an endosurgical knife for dissection, such as the Flex Robotic System (Medrobotics, Raynham, Mass, USA) and the Master and Slave Transluminal Endoscopic Robot (EndoMaster Pte Ltd, Singapore).[4,21,22] Turiani Hourneaux de Moura, et al.[4] showed in an ex vivo model that a robotic ESD system leads to a faster dissection time and reduced technical workload. However, robotic systems are expensive, require a dedicated endoscope and equipment, and are available in only a select few institutions. Although most robotic platforms described are limited in the length of their reach, ongoing developments include novel platforms that overcome this limitation. The novel SGA overcomes some of the limitations of the prior traction methods because of its versatile 3 degrees of motion with the ability for a single endoscopist to change traction points and direction in real time. It requires a double-channel endoscope and does not need separate dedicated hardware. A double-channel gastroscope with the SGA device may make accessing angulated locations such as the gastric fundus challenging because retroflexion is somewhat limited compared with a single-channel endoscope.

In our study, we chose novice endoscopists as participants to avoid bias from any prior experience performing ESDs. Although each participant performed ESD using both CL and SGA, they were randomly assigned to either use CL first or SGA first. This was done to avoid the effect of learning from the first method translating to improved dissection times with the second method. The dissection times were significantly shorter with SGA compared with CL regardless of which was performed first. This shows that SGA provides superior traction compared with CL. It is important to note that this was observed in participants without prior experience with ESD.

Traction devices have been shown to improve the learning curve of ESD.[23] Although the learning curve could not be measured in this study, there is reason to believe that SGA may improve the learning curve for ESD among early learners. We anticipate that with the efficacy of SGA to expose the submucosa, we would notice reduced adverse events compared with CL. Although the current study was not statistically powered to measure differences in adverse events, we found a trend toward increased incidence of muscle injury with CL (40%) versus SGA (0%). This was likely because in many scenarios, static CL traction did not adequately expose the submucosa, thus increasing muscle injury by participants. On the other hand, the effective traction seen in the SGA method may at times lift the mucosal aspect of the lesion perpendicular to the muscle layer. Hence, caution is needed when advancing the electrosurgical knife too far from the scope because this may cause thermal injury and fragmentation of the mucosal aspect of the lesion. We found an instance of such a thermal injury with SGA. Although lesion mucosal fragmentation is a possibility with SGA and multiple grasping maneuvers at different locations, we did not observe this in our study.

Improved visualization of the submucosa, faster dissection time, and a trend toward increased safety of dissection all point toward a much lower technical workload for the endoscopist. We found mean NASA-TLX scores in all domains as well as mean total scores were significantly lower with SGA. Not surprisingly, reduced technical workload has been shown to improve the learning curve in endoscopy.[24] The SGA has the potential to dramatically improve the learning curve of ESD and reduce a major barrier for wider adoption of ESD in the West.

This study has limitations that preclude generalizability of results. The major limitation is that this was an ex vivo study. One of the major challenges of ESD includes management of intraprocedural bleeding and loss of visualization in the setting of bleeding. This was not seen in an ex vivo model. A live porcine model would have been better suited for the study, but with the available resources this was not feasible. However, improved submucosal visualization should reduce the risk of intraprocedural bleeding, because with adequate visualization blood vessels can be preemptively coagulated. The dissection time is likely to be longer in a live setting. This was a controlled setting with a relatively small lesion, 25 mm in size, positioned favorably in a 6 o'clock position with respect to the endoscope. In live scenarios, the location may be less favorable along with movements of the field, which add to the complexity. Despite that, because the conditions for dissection were identical for both CL and SGA, the current findings should remain valid for comparison. A double-channel endoscope is required for SGA, and the same endoscope was used for the CL method for consistency. This is a larger-caliber endoscope compared with the standard gastroscope, which is typically used in gastric ESDs. Although it is usually easier with a slimmer endoscope to gain entry into the submucosa, the overall effect on dissection times was expected to be small, and we wanted to keep all other variables apart from the traction device similar across both arms. However, the magnitude of difference in dissection times comparing a double-channel and single-channel endoscope will be unknown. ESDs are performed by expert endoscopist. In our study we used trainee endoscopists with no ESD experience to minimize procedural bias. Hence, these results may not be generalizable to experienced endoscopists. These results show the utility of SGA during the learning phase in those new to ESD. Although the SGA improved dissection time, the threshold of its cost-effectiveness compared with other traction methods remains unknown and is a direction for future investigation. It is also likely that the SGA may not be appropriate for select lesions, and human studies are needed to identify which lesions are appropriate for SGA use. Larger prospective human trials are needed to further study the SGA for traction in ESDs.

In summary, the SGA is a novel traction device that significantly reduced ESD dissection time compared with the CL method for traction in an ex vivo setting, when used by endoscopists with no previous experience with ESD. Use of the SGA showed a trend toward reduced procedural adverse events. Use of the SGA for ESD in an ex vivo setting leads to significantly lower technical demand on the endoscopist compared with the CL method. This should be further studied in live animal model and human trials.

DISCLOSURE

The following authors disclosed financial relationships: D. E. Loren: Consultant for Boston Scientific, Pinnacle Biologics, Ambu USA, and Olympus. T. Kowalski: Consultant for Boston Scientific, Ambu USA, and Olympus. A. R. Kumar: Consultant for Olympus. A. L. Chiang: Chief Medical Officer (GI) at Medtronic. A. Schlachterman: Consultant for Boston Scientific, Fuji-Film, Medtronic, Olympus, and Lumendi. All other authors disclosed no financial relationships.

Abbreviations: CL, clip and line; ESD, endoscopic submucosal dissection; NASA, National Aeronautics and Space Administration; SGA, steerable grasper arm; TLX, task load index.

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