

Initial multicenter experience using a novel articulating through-the-scope traction device for endoscopic submucosal dissection

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ABSTRACT

Background and study aims A single-operator, articulating, through-the-scope (TTS) traction device was recently developed to facilitate endoscopic submucosal dissection (ESD). Clinical data on the performance of this device are limited. We report an initial multicenter experience with ESD using this articulating TTS traction device.

Patients and methods Retrospective analysis on all consecutive patients who underwent ESD using this traction device (T-ESD) at five centers between August 2021 and December 2022. Endpoints included: rates of en-bloc resection, R0 resection, curative resection, and adverse events.

Results Thirty-six patients (median age 64.8 years; 47.2% women) underwent ESD (median lesion size 40 mm; interquartile range [IRQ]: 27.5–67.5) for lesions in the esophagus (n=2), stomach (n=8), sigmoid colon (n=6), and rectum (n=20). Submucosal fibrosis was encountered in one-third of the lesions (33.3%). Median ESD time was 104.6 minutes (IQR: 65–122). En-bloc, R0 and curative resection were achieved in 94.4%, 91.6%, and 97.2%, respectively. The single patient with non-curative resection of an invasive rectal adenocarcinoma underwent surgery. There were no cases of delayed bleeding or perforation. There was no recurrence on surveillance endoscopy (n=20) at a median of 6 months (IQR: 3.75–6).

Conclusions This initial multicenter experience demonstrates high resection rates and excellent safety profile when performing ESD with this novel articulating TTS device. Dynamic real-time traction may lower the technical difficulty of ESD. Additional studies are needed to assess its cost-effectiveness and compare its usefulness with other traction devices and techniques during ESD.

Introduction

Endoscopic submucosal dissection (ESD) is the standard approach for the treatment of superficial gastrointestinal neoplasia in Asia [1]. However, adoption of ESD in the West has been primarily restricted to specialized centers, given the high technical demand, steep learning curve, longer procedure time, and potential higher risk of adverse events (AEs) [2, 3, 4]. Maintaining adequate visualization of the operating dissection field during ESD is commonly one of the most difficult aspects of the procedure [5]. Providing adequate traction to expose the dissection plane during ESD has been shown to enhance procedural efficiency and safety; yet, current traction techniques are not without inherent limitations, including technical complexity, need for assembly, and a deep understanding of advanced endoscopic resection principles [6, 7, 8, 9, 10].

A novel traction device (Tracmotion, Fujifilm, Lexington, Massachusetts, United States) for ESD was recently introduced and cleared by the U.S. Food and Drug Administration. This traction device is a single-operator, through-the-scope (TTS) retraction device with a 360-degree rotatable grasping forceps that enables tissue manipulation during ESD. A recent pilot study by our group demonstrated that ESD with this traction device by trainees was associated with improved submucosal dissection speed and less physical demand when compared to conventional ESD in an ex vivo animal model [11]. Current clinical experience with this traction device for ESD is limited. The aim of this study was to evaluate the safety and efficacy of ESD using this novel articulation TTS traction device.

Patients and methods

Study population

This was a retrospective multicenter cohort study of consecutive patients ≥ 18 years of age undergoing ESD for non-pedunculated lesions with the single-operator articulating TTS traction device (T-ESD) at five centers in the United States between August 2021 and December 2022. Decision to use the TTS trac-

tion device was determined on a case-by-case basis at the discretion of the endoscopist. All patients provided informed consent for the procedures. The study was approved by the Institutional Review Board for human research at each participating institution, with the Center for Interventional Endoscopy at AdventHealth, Orlando, Florida, United States serving as the central coordinating center.

Overview of the traction device

The Tracmotion is a single-operator, TTS traction device designed for ESD. The device consists of two interconnected parts: a scope-mounted hand controller and an actuating TTS distal end (► Fig. 1). The device must be inserted through the 3.7-mm channel of a double-channel endoscope. Following insertion of the device, the hand controller, composed of a functional distal pivotable shaft and thumb handle, is mounted onto the biopsy port with an adapter. The distal TTS end is equipped with an articulating grasping forceps with a range of motion that includes extension, flexion, 360-degree rotation, advancement, and retraction (► Fig. 1). These functions are performed by rotating and advancing the pivotal shaft and opening/closing the thumb handle, which are controlled by the endoscopist's right hand during the procedure (► Video 1). The articulating grasping forceps can be opened and closed repeatedly, allowing tissue manipulation and real-time adjustment of traction during ESD.

Traction-assisted ESD (T-ESD)

Cases were performed with intravenous conscious sedation, deep sedation, or general anesthesia with endotracheal intubation, at the discretion of the endoscopist and anesthesiologist (if involved). Carbon dioxide was used for insufflation in all cases. Lesions were examined under high-definition white light, near focus, and digital chromoendoscopy. At the discretion of the endoscopist, the ESD knife tip was used to demarcate the outer margin for the resection area; approximately 5 mm from the lesion. The submucosal space was then expanded by injecting a lifting solution containing methylene blue or indigo car-



► Fig. 1 ESD articulating traction device. **a** Traction device consists of a hand controller and a distal articulating arm and jaw. **b** The device is inserted through the 3.7-mm instrument channel of a dual channel endoscope. **c** Arrows depict the movements of the distal articulating arm and rotatable grasper, which include gripping and rotation of the grasper, flexion, rotation, and advancement of the articulating arm.

VIDEO



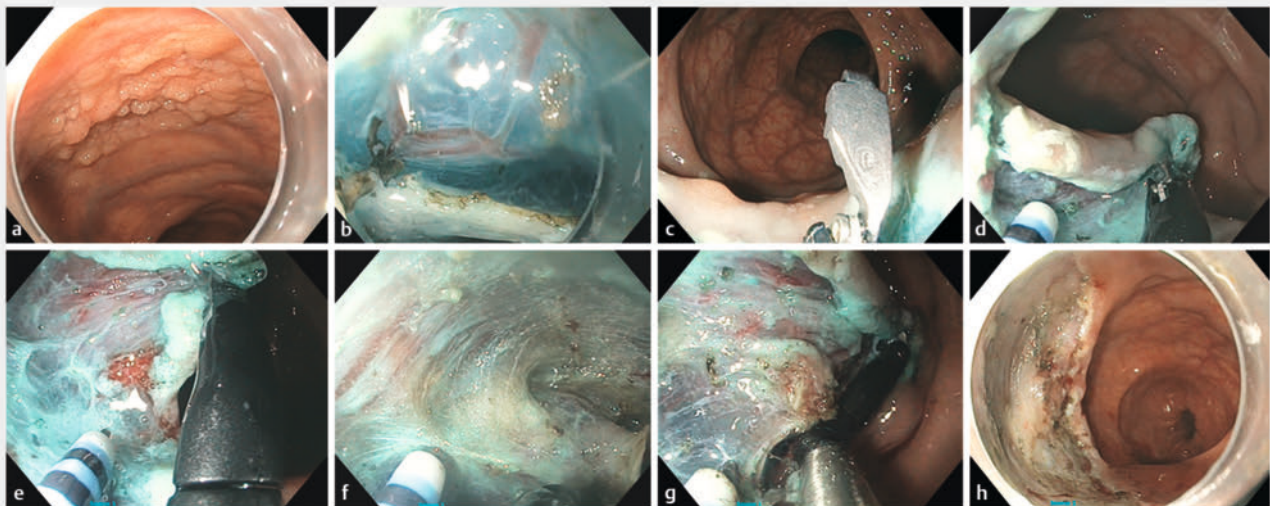
► **Video 1** Demonstration of the set-up of the single-operator traction device onto the dual channel endoscope and operation of the distal arm using the hand controller.

mine admixed with normal saline or with a viscous agent. Initial circumferential mucosal incision was performed with a single-channel endoscope (GIF HQ190; Olympus America, Center Valley, Pennsylvania, United States or EG-760R; Fujifilm, Lexington, Massachusetts, United States). Submucosal dissection was then performed on the proximal side of the lesion until a mucosal flap was created (► **Fig. 2**). Following this, the single-channel endoscope was exchanged for a double-channel endoscope (GIF-2TH180; Olympus America, Center Valley, Pennsylvania, United States or EI-740D, Fujifilm, Lexington, Massachusetts, United States) with the mounted traction device. The mucosal flap was then grasped with the articulating forceps. The articulating arm was lifted upward and rotated either clockwise or counterclockwise to apply traction and maintain visualization of the dissection plane (► **Fig. 2**). Real-time adjust-

ment of traction was performed by opening and closing the forceps with repeated manipulation of the mucosal flap. Dissection was then performed from proximal to distal fashion using the ESD knife.

Data collection and outcome measures

Data were collected from prospectively maintained endoscopic reporting databases and by retrospective chart review of electronic medical records. The data obtained from all participating centers were compiled into a central database. Data of interest included: patient demographics, lesion characteristics (baseline histopathology, lesion location, size, morphology), procedure characteristics (e.g. presence of submucosal fibrosis, procedural time), and post-procedure findings (ESD histopathology, AEs, recurrence). Total procedure time was defined from the time of scope insertion to withdrawal whereas ESD time comprised the period from submucosal injection to completion of resection and any additional endoscopic interventions thereafter (e.g. elective closure). Rectal lesions were defined as any lesion with an upper margin located within 18 cm of the anal verge and/or when more than 50% of the lesion was situated within 15 cm from the anal verge. The degree of submucosal fibrosis was determined based on the findings identified at the time of ESD and classified as F0 (no fibrosis), F1 (mild fibrosis), and F2 (severe fibrosis) [12]. The primary outcomes of this study were the proportion of ESD cases with en-bloc and R0 resection. En-bloc resection was defined as excision of the targeted lesion in a single specimen. Complete (R0) resection was defined as en-bloc resection with lateral and deep margins free of neoplasia. Resection was classified as curative in all benign lesions (low-grade dysplasia [LGD] and high-grade dysplasia [HGD]). If histopathologic assessment showed cancer with low-risk criteria (depth of submucosal invasion: esophageal



► **Fig. 2** a ESD using the traction device on a 25-mm lateral spreading granular tumor (LST-G) in the rectum. b, c A mucosal incision and submucosal dissection were performed on the anal side of the lesion to create a mucosal flap, followed by introduction of the traction device. d The mucosal flap is grasped by the jaws and dissection is performed with the needle type knife. e, f, g Dynamic real-time modification of traction with the traction device permits excellent exposure of submucosal vessels and identification of the dissection plane. h Final resection bed.

squamous cell carcinoma ≤ 200 mm, absence of lymphatic and vascular invasion, well-differentiated; esophageal or gastric adenocarcinoma ≤ 500 mm, colorectal adenocarcinoma ≤ 1000 mm; absence of lymphatic and vascular invasion; well or moderately differentiated), the resection was also considered curative [13, 14]. Recurrence was defined as histological confirmation of the initial lesion on surveillance endoscopy following index R0 resection. AEs were defined and categorized based on the standardized criteria for AEs in gastrointestinal endoscopy (AGREE) classification [15].

Statistical analysis

Descriptive statistics for each baseline variable were obtained and expressed as mean, standard deviation (SD), median, and interquartile ranges (IQRs). Chi-square or Fisher exact test for categorical variables and the *t* test for continuous variables were performed when indicated. All statistical analysis was performed with the open-source statistical software package R (version 3.5.0).

Results

Study population and baseline characteristics

A total of 36 patients (median age 64.8 ± 11.6 years; 47.2% women) underwent T-ESD during the study period. The median lesion size was 40 mm (interquartile range [IQR]: 27.5–67.5 mm). The most common ESD site was in the rectum (20/36; 55.5%), followed by the stomach (8/36; 22.2%), sigmoid colon (6/36; 16.7%) and esophagus (2/36; 5.6%). Most of the lesions (28/36; 77.8%) had been manipulated prior to ESD: 21 (58.3%) were biopsied with biopsy forceps, 7 (19.4%) had prior endoscopic resection attempt, and 4 (11.1%) had been tattooed underneath. Baseline histopathology is summarized in ► **Table 1**.

Procedure characteristics

Procedure characteristics are summarized in ► **Table 1**. A viscous solution was used for submucosal lifting in nearly all cases (33/36; 91.7%). The two most used ESD knives were the Dual-J knife (Olympus America, Center Valley, Pennsylvania, United States) (17/36; 47.2%) followed by the Hybrid knife (ERBE USA, Marietta, Georgia, United States) (13/36; 36.1%). Submucosal fibrosis was encountered in one-third of the cases (12/36; 33.3%), of which seven were classified as severe (30.6%) The median total procedure and ESD times were 119 minutes (IQR: 64–151 min) and 104.6 minutes (IQR: 65–122 minutes), respectively. The resected specimen size was 43 mm (IQR: 30–58). Elective closure of the ESD defect was performed in 23 of 36 cases (63.9%).

Most cases (22/36; 61.1%) were performed in the outpatient setting and discharged on the same day from the endoscopy unit. None of the patients who were admitted for routine post-procedure observation stayed beyond postoperative Day 1.

ESD resection outcomes and adverse events

Overall, en-bloc and R0 resection were achieved in 94.4% (34/36) and 91.6% (33/36) of the cases, respectively (► **Table 2**). Incomplete (R1) resection was reported in three cases. The first

case involved positive lateral margins after rectal T-ESD of a 90-mm tubular adenoma with HGD. Surveillance colonoscopy at 6 months showed no endoscopic evidence of residual adenoma and biopsies of the scar were normal. The second case was a R1 resection with deep positive margins after T-ESD of an 80-mm well-differentiated invasive rectal adenocarcinoma (negative for lymphovascular invasion or tumor budding). The patient underwent surgical resection. The third case of R1 resection involved a 20-mm rectal adenoma which had previously undergone an attempt at endoscopic mucosal resection (EMR). The procedure was characterized by severe submucosal fibrosis and T-ESD with en-bloc resection was not feasible, resulting in salvage piecemeal EMR with positive margins. Surveillance at 4 months with biopsies of the scar showed no residual adenoma.

Four patients (11.1%) reported abdominal pain after the procedure. Among these, three (8.3%) required analgesics and hospital admission (< 24 hours) (grade I AE). There were no cases of delayed bleeding or perforation.

Final histopathology and follow-up

Final ESD histopathology is summarized in ► **Table 2**. T-ESD resulted in a change of histologic diagnosis in eight of 36 patients (22.2%). One patient with a preoperative biopsy diagnosis of adenocarcinoma was found to have adenoma with HGD on T-ESD histology. Of the remaining seven cases, a total of five cases of HGD on preoperative biopsy had a final diagnosis of adenocarcinoma in the esophagus ($n=1$), stomach ($n=1$), and rectum ($n=3$) following T-ESD.

Twenty patients had follow-up endoscopy at a median of 6 months (IQR: 3.9–6). There was no endoscopic evidence of residual/recurrent lesion in any of these patients. Of these, biopsies of the ESD scar were performed in 18 patients, none of which showed recurrent disease.

Discussion

This study reports our initial multicenter experience using a novel single-operator TTS articulating traction device for ESD (T-ESD). Our results demonstrate that T-ESD was associated with excellent resection outcomes and safety profile.

ESD is an established technique with a defined role within the spectrum of available therapies for dysplastic and early cancer lesions in the gastrointestinal tract. Yet, ESD is a fundamentally difficult procedure, largely due to the challenge of maintaining adequate visualization of the submucosal dissection plane during the procedure [5]. Several traction devices and strategies have been introduced and developed over the years to facilitate ESD [6]. However, these methods are not without limitations. For instance, techniques using a combination of clip and line or clip with elastic bands are easy to operate but are limited by the uncontrollable traction direction and degree of effective tension [6, 16]. The pocket creation method has been shown to be associated with increased safety and shorter procedure time when compared to conventional ESD [16, 17, 18]. Nonetheless, completion of the mucosal incision after initial pocket creation can be technically demanding and hemo-

► **Table 1** Baseline and procedure characteristics.

Baseline characteristics	
Age, mean (SD) years	64.8 (11.6)
Female, n (%)	17 (47.2)
ASA class, n (%)	
▪ I	3 (8.3)
▪ II	15 (41.8)
▪ III	17 (47.2)
▪ IV	1 (2.7)
Periprocedural anticoagulation, n (%)	
▪ Yes	9 (25)
Periprocedural antiplatelet, n (%)	
▪ Yes	10 (27.8)
Lesion location, n (%)	
▪ Esophagus	2 (5.6)
▪ Stomach	8 (22.2)
▪ Sigmoid colon	6 (16.7)
▪ Rectum	20 (55.5)
Lesion size, median (interquartile range), mm	40 (27.5–67.5)
Interventions prior to ESD, n (%)	
▪ None	8 (22.2)
▪ Tattoo at the base	4 (11.1)
▪ Biopsy	21 (58.3)
▪ Attempted endoscopic resection	7 (19.4)
Baseline histopathology, n (%)	
▪ Esophagus	
▪ Barrett's esophagus with HGD	1 (2.7)
▪ Squamous cell carcinoma	1 (2.7)
▪ Stomach	
▪ Non-dysplastic	3 (8.3)
▪ Adenoma with LGD	1 (2.7)
▪ Adenoma with HGD	2 (5.6)
▪ Adenocarcinoma	2 (5.6)
▪ Colon	
▪ Serrated adenoma	1 (2.7)
▪ Adenoma with LGD	2 (5.6)
▪ Adenoma with HGD	2 (5.6)
▪ Adenocarcinoma	1 (2.7)
▪ Rectum	
▪ Serrated adenoma	1 (2.7)
▪ Adenoma with LGD	8 (22.2)

► **Table 1** (Continuation)

Baseline characteristics	
▪ Adenoma with HGD	8 (22.2)
▪ Adenocarcinoma	3 (8.3)
Type of submucosal injectate, n (%)	
▪ Normal saline solution	3 (8.3)
▪ Viscous solution	33 (91.7)
Type of ESD knife, n (%)	
▪ Olympus Dual-J Knife	17 (47.2)
▪ ERBE Hybrid knife	13 (36.1)
▪ Combination of knives	6 (16.7)
Submucosal fibrosis, n (%)	
▪ None	24 (66.7)
▪ Mild	5 (13.9)
▪ Severe	7 (19.4)
ESD procedural time, median (IQR), minutes	104.6 (65–122)
Total procedural time, median (IQR), minutes	119 (64–151)
Elective closure, n (%)	23 (63.9)
Resected specimen size, median (interquartile range), mm	43 (30–58)
Outpatient procedure, n (%)	22 (61.1)
SD, standard deviation; ASA, American Society of Anesthesiologists; ESD, endoscopic submucosal dissection; LGD, low-grade dysplasia; HGD, high-grade dysplasia; IQR, interquartile range.	

stasis in the setting of severe bleeding can be troublesome inside the pocket or tunnel [6]. In all, the ideal traction device/method should be easy to operate and permit dynamic adjustment of traction during ESD, independent of endoscope movement. The novel TTS traction device used in this study consists of a rotatable grasping forceps that can be opened and closed repeatedly to allow real-time tissue manipulation and adjustment of traction during the procedure. An advantage of this novel device over a clip with thread, clip and rubber band or even pocket creation method is that the direction/axis of traction can be continuously adjusted. The distal grasping forceps has 360-degree rotatability, which allows unrestricted manipulation of the mucosal flap for optimal exposure of the dissection plane at any given point during the procedure.

In this study, T-ESD was associated with en-bloc, R0, and curative resection rates of 93.5%, 90.3%, and 96.8%, respectively. Our results compare favorably to the recently proposed thresholds for ESD as outlined by the 2019 European Society of Gastrointestinal Endoscopy (ESGE), which set the goal for en-bloc resection at > 90%, R0 resection > 80% and for curative resection > 75% [19]. Importantly, these high resection outcomes

► **Table 2** Resection outcomes, adverse events, and final histopathology.

En-bloc resection, n (%)	34 (94.4)
R0 resection, n (%)	33 (91.7)
Curative resection, n (%)	35 (97.2)
Adverse events, n (%)	
▪ Abdominal pain	3 (8.3)
▪ Post-procedure bleeding	0
▪ Perforation	0
Final ESD histopathology, n (%)	
▪ Esophagus	
▪ Esophageal adenocarcinoma	1 (2.7)
▪ Squamous cell carcinoma	1 (2.7)
▪ Stomach	
▪ Non-dysplastic	3 (8.3)
▪ Adenoma with LGD	1 (2.7)
▪ Adenoma with HGD	1 (2.7)
▪ Adenocarcinoma	3 (8.3)
▪ Colon	
▪ Serrated adenoma	1 (2.7)
▪ Adenoma with LGD	2 (5.6)
▪ Adenoma with HGD	3 (8.3)
▪ Rectum	
▪ Serrated adenoma	1 (2.7)
▪ Adenoma with LGD	6 (16.7)
▪ Adenoma with HGD	8 (22.2)
▪ Adenocarcinoma	5 (13.9)
ESD, endoscopic submucosal dissection; LGD, low-grade dysplasia; HGD, high-grade dysplasia.	

were achieved despite one-third of the lesions being complicated by submucosal fibrosis, further suggesting the potential advantage of traction assistance during these difficult cases.

Colorectal ESD is notoriously challenging due to multiple factors, including the thin colon wall and limited endoscopic maneuverability. As such, it comes as no surprise that resection outcomes have been historically lower in non-Asian countries, generally with en-bloc and R0 resection rates being reported in the 81% to 83% and 71% to 75% ranges, respectively [3, 20]. In our study, en-bloc and R0 resection rates with T-ESD in the colorectum were 95.5% (21/22) and 86.4% (19/22), respectively. Nonetheless, it should be noted that the colorectal lesions in this study were all located in the left colon. The TTS traction device requires a double-channel endoscope, which limits its reach and accessibility of colorectal lesions located more proximally. This is a limitation of the current device, which does not

provide a consistent alternative for traction during ESD for right-sided lesions. Furthermore, despite the range of motion of the grasping forceps, the traction that it provides is not independent of scope movement, as it remains a TTS device.

The risk for serious AEs is one of the main impediments to widespread adoption of ESD in North America. A recent registry from Germany consisting of 1000 ESDs reported an overall AE rate of 8.3%, with perforation occurring in 4.2% of the cases [21]. A separate multicenter study from North America consisting of 692 patients reported bleeding and perforation rates of 2.3% and 2.9%, respectively [22]. Traction-assisted ESD has been shown to be associated with improved safety when compared to conventional ESD. A recent meta-regression of randomized clinical trials demonstrated that traction-assisted ESD had a lower AE rate (OR: 0.47; 95% CI: 0.29–0.76) when compared to conventional ESD [23]. In this initial multicenter experience, there were no cases of bleeding or perforation reported with T-ESD. We speculate that dynamic traction with T-ESD enhances exposure of the dissection plane, which in turn facilitates preemptive hemostasis when indicated and reduces the risk of inadvertent muscle injury.

In this study, T-ESD resulted in a change of histologic diagnosis in 22.2% of the patients. Notably, five cases of adenocarcinoma on ESD histology were not initially identified on preoperative biopsies. Our results are congruent with recent studies demonstrating that ESD serves as a potential diagnostic and staging tool and should be considered for patients with advanced neoplasia on index histopathology (i. e. HGD) or in those with features suspicious for invasive disease [24, 25].

We acknowledge the limitations of this study. First, the study was performed by endoscopists specialized in ESD, and therefore, the results may not be generalizable. Second, the study was retrospective and limited by its uncontrolled design and inherent selection bias. There were no predefined criteria for when to use the T-ESD. Similarly, the decision to perform ESD was not uniformly established and was at the discretion of the endoscopist. Hence, it is likely that endoscopists may have conceivably selected lesions most suitable for T-ESD, thereby enhancing the positive outcomes.

Nonetheless, clinical practice should be directed by what is the preferred treatment of choice for any given setting as opposed to a “one-size-fits-all” strategy. Third, this study aimed to report the initial experience with this novel traction device; hence, the overall sample size was relatively small and does not provide insight into how this traction device compares with other currently available traction techniques for ESD. Notably, without a comparative arm (control group), we cannot definitively ascertain that the favorable resection outcomes achieved in this study were due to the assistance of this traction device. Hence, future prospective comparative trials will be needed to further corroborate our initial findings. Fourth, we recognize that cost-analysis was not performed as part of this retrospective study. Several factors besides the cost of the device, including procedure time, should be factored into cost-effectiveness analysis in the future to determine the clinical utility of the device. Lastly, we recognize that minor AEs may have not been reported or captured during follow-up.

Conclusions

In conclusion, this multicenter study reports the initial clinical experience of ESD using this novel TTS articulating traction device. T-ESD was associated with excellent resection outcomes and safety profile. Additional prospective comparative trials and cost-effective analyses are needed to establish the role of this device in our ESD armamentarium.

Conflict of Interest

D Yang is a consultant for Olympus, Fujifilm, Apollo Endosurgery, Medtronic and Microtech. DYang receives research support from Microtech and 3D-Matrix. MK Hasan is a consultant for Boston Scientific and Olympus. PV Draganov is a consultant for Olympus, Boston Scientific, Fujifilm, Cook Medical, and Medtronic. V Kumbhari is a consultant for Boston Scientific, Medtronic, FujiFilm, and has received research support from FujiFilm. M. Mizrahi is a consultant for Olympus, Boston Scientific, Fujifilm, Cook Medical, and Medtronic. A. Schlachterman is a consultant for Fujifilm, Lumendi, Apollo Endosurgery, Olympus. All other authors have nothing to disclose.

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