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Prospective clinical trial of traction device-assisted endoscopic submucosal dissection of large superficial colorectal tumors using the S–O clip

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Abstract
Background Endoscopic submucosal dissection (ESD) allows en bloc resection of superficial colorectal tumors regardless of size. However, ESD is technically difficult, hazardous, and time consuming. New devices may help overcome these drawbacks. We focused on traction methods and designed a new traction device, the "S–O clip." Its main advantage is that it allows direct visualization of the cutting line during submucosal dissection. Moreover, it can be used at any location without withdrawing the endoscope. The purpose of this study was to evaluate the efficacy and safety of traction device-assisted ESD for large colorectal tumors using the S–O clip.
Methods Between August 2010 and December 2011, ESD was performed in 70 patients with a superficial colorectal tumor ≥20 mm in diameter in our department. Patients were randomized into two groups: 27 cases in the S–O clip-assisted ESD group and 23 cases in the conventional ESD group. Included in the analysis were patient's gender and age, tumor form, size, and location, rate of en bloc resection, procedure time, presence or absence of intraoperative perforation or delayed bleeding, and pathological findings. Subgroup analysis stratified by these factors and multivariate analyses were conducted.
Results In the S–O clip-assisted ESD group, all 27 tumors were resected en bloc without any complications. Although a micro perforation occurred in one patient in the conventional ESD group, further surgical treatment was not required. None of the other 22 cases in the conventional ESD group experienced complications. The mean procedure time for the S–O clip-assisted ESD group was significantly shorter than for the conventional ESD group (37.4 ± 32.6 vs. 67.1 ± 44.1 min, $p = 0.03$). No significant between-group differences were found for the other factors.
Conclusion Our results demonstrated that S–O clip-assisted ESD is safe and fast for en bloc resection of large superficial colorectal tumors.

Keywords S–O clip · Traction device · Colorectal ESD · Superficial colorectal tumors

Endoscopic mucosal resection (EMR) is established and widely accepted as a minimally invasive treatment for superficial gastrointestinal tumors [1–3]. However, it is difficult to achieve en bloc resection for lesions ≥20 mm in diameter [4]. En bloc resection is considered the standard criterion for curative EMR because multifragmental resection does not enable sufficient histologic evaluation and the local recurrence rate after multifragmental resection was reported to be significantly higher than that after en bloc resection [5–10].

Endoscopic submucosal dissection (ESD) is a recently developed technique that allows en bloc resection of large gastrointestinal neoplasms [5–8] and is gaining acceptance for colorectal tumors. However, it is not widely used to treat the colorectum because of its degree of technical difficulty and risk of complications, such as perforation [9–11]. To overcome these negative factors, refinements in ESD techniques and perhaps new devices are necessary.

The performance of ESD would be easy if the submucosal layer could be directly visualized after the initial mucosal cut. Countertraction on the lesion could possibly

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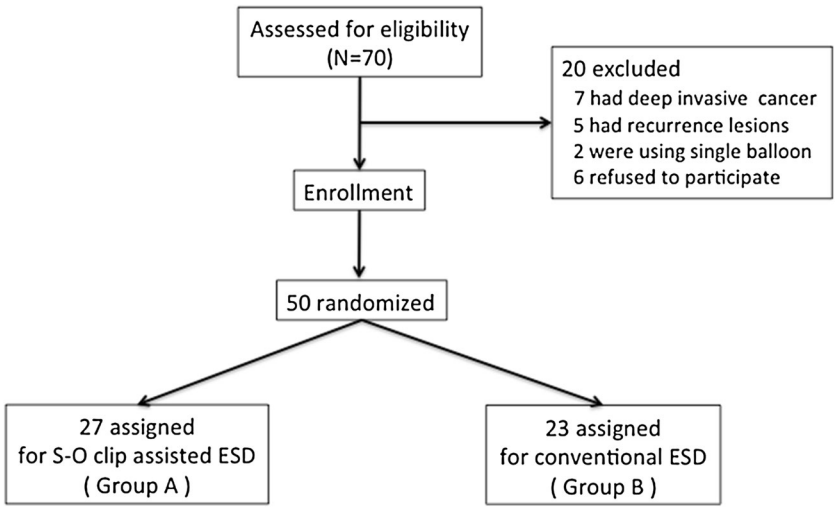

Fig. 1 Trial profile

facilitate accurate visualization and easier dissection. Several techniques involving traction on the lesions have been reported to be effective in performing ESDs for large early gastric and colorectal cancers [12–17]. Although these methods are effective in enabling good visualization of the cutting line, traction-assisted methods are not widely employed to date because some limitations still exist. Therefore we designed a new traction device, the "S–O clip," for ESDs. The S–O clip-assisted ESD has several advantages including its ease of use and that it can be used at any location without withdrawing the endoscope. In addition, the S–O clip is independent; thus its movement is not limited by the colonoscope [18, 19]. Also, this technique does not require any additional extracorporeal system or an additional endoscope [16, 17]. We previously reported cases of large superficial colorectal tumors successfully resected by ESD using the S–O clip [18, 19]. The purpose of this study was to evaluate the efficacy and safety of traction device-assisted ESD for large colorectal tumors using the S–O clip.

Patients and methods

Between August 2010 and December 2011, ESD was performed for 70 cases of superficial colorectal tumor, the so-called laterally spreading tumor (LST) $\geq$20 mm in diameter. Sixty-four patients gave written informed consent and were eligible to participate in this research on the use of the device. Exclusion criteria were preoperative evidence of deep submucosal invasion as assessed by colonoscopy, a recurrent lesion after EMR or the for single balloon overtube-guided ESD. This study was approved by the Institutional Review Board of the Juntendo University.

Patients presenting for ESD were randomized into two groups using opaque envelopes; there were 27 cases in the S–O clip-assisted ESD group (Group A) and 23 cases in the conventional ESD group (Group B) (Fig. 1). In Group A patients, the S–O clip could be removed if it was not beneficial to the procedure or interfered with the procedure. In Group B, conversion to the use of the S–O clip for safety when removal of the lesion was technically difficult due to poor visualization or if after a circumferential incision is made an unfavorable situation does not change after 5 min.

Included in the analysis were patient's gender and age, tumor form, size, and location, rate of en bloc resection, procedure time, conversion rate, presence or absence of intraoperative perforation, delayed bleeding and pathological findings. Furthermore, the recurrence rate was assessed by a follow-up colonoscopy. Subgroup analysis stratified by these factors and multivariate analyses were conducted. Procedure time was measured from the submucosal injection of a solution to elevate the lesion till complete removal of the tumor, including retrieval of the S–O clip.

Trial registration

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Design of the S–O clip

We have previously reported two types of S–O clip: a rubber strip type and a spring type [18, 19]. In this study, we used the spring type. This type consists of a metallic clip (Zeoclip: Zeon Medical Co., Ltd., Tokyo, Japan) attached to the end of a spring 5-mm long and 1.8 mm wide, which is then connected on its other end to a single nylon loop (Fig. 2). The S–O clip can be passed through the working channel of a conventional colonoscope (Fig. 3). The length of the spring is not altered by a 1 g force, but it extends approximately tenfold at 20 g. The

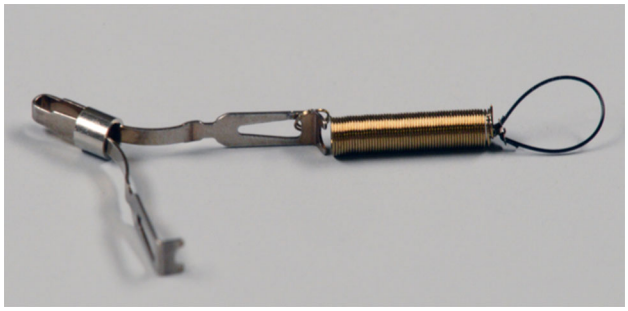

Fig. 2 Spring S–O clip The spring S–O clip consists of a spring 5-mm long and 1.8 mm wide with an attached metal clip at one end and a nylon loop at the other. The length of the spring, which is not altered by a 1 g force, extends approximately tenfold at 20 g

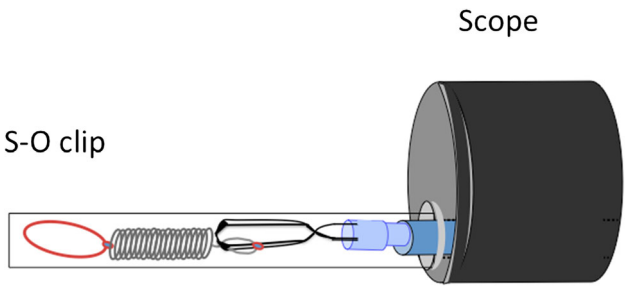

Fig. 3 The S–O clip can be passed through the working channel of the endoscope

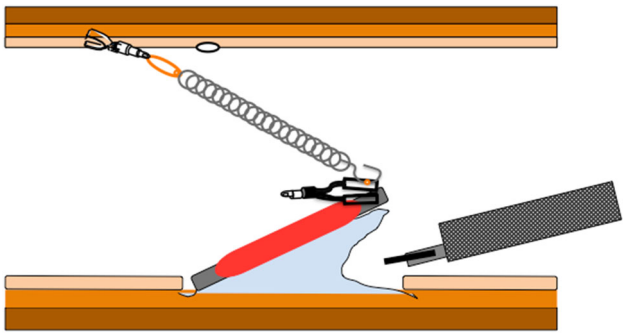

Fig. 4 Illustration depicting S–O clip-assisted ESD

device can pull up a lesion at any location without withdrawing the endoscope (Figs. 4, 5).

Endoscopic procedure

All procedures were performed by a single colonoscopist (N.S.) who has performed more than 1,500 colonoscopies annually. Conscious sedation was induced with intravenous midazolam (2–5 mg) and pethidine (35 mg), and hyoscine butylbromide (5–40 mg) or glucagon 1 USP (1–2 vials) was added to reduce colonic spasm. All lesions were properly cleansed and examined thoroughly using high-magnification colonoscopy (CF-Q240ZI, CF-H260AZI, CF-FH260AZI, or PCF-Q260AZI; Olympus Optical Co., Ltd., Tokyo, Japan) preceding the resection. To predict the depth of invasion and exclude non-resectable lesions, pit pattern analysis based on Kudo's classification [20] and the classification reported by Sano [21] for narrow-band imaging (Olympus Optical Co., Ltd.) were employed. For the resection procedure itself, the endoscope was usually switched to a more maneuverable endoscope with a forward-directed water spray system, that is, the PCF-Q260AZI or PCF-Q260JI (Olympus Optical Co., Ltd.). Firstly, the lesion was elevated creating a submucosal cushion by injecting a solution prepared with normal saline solution, epinephrine (1:10,000), sterile indigo carmine, and Mucoup (Johnson & Johnson, Tokyo, Japan or Seikagaku Corporation, Tokyo, Japan). After making an incision around the lesion with a Flush knife-BT 2.0 (Fujifilm Inc., Tokyo, Japan), submucosal dissection was performed using the same device until complete removal.

With S–O clip-assisted ESD (Group A), the initial steps of the procedure were similar to those of conventional ESD. After separating the tumor from the surrounding normal mucosa, the S–O clip was attached to the proximal edge of the lesion. Then, a regular clip was used to hook the nylon loop of the S–O clip that was attached to the lesion and fasten the nylon loop to the colonic wall opposite of the lesion.

The traction applied by the device on the edge of the lesion allowed good visualization of the cutting line of the submucosal layer, resulting in a safe and easier dissection (Figs. 3, 4). After complete dissection, the S–O clip was detached from the colonic wall and extracted together with the specimen. The endoscope was not withdrawn during the entire procedure.

An electrosurgical unit, VIO300D (Erbe Elektromedizin, Tubingen, Germany) at 40 W Effect 2 Endocut, and carbon dioxide (CO_2) for insufflation were used in all cases.

Statistical analyses

Analysis was made according to intention-to-treat, i.e., patients in whom the S–O clip was removed remained in Group A and patients who had intraoperative conversion to the use of the S–O clip remained in Group B. The relationships between the groups were evaluated by the χ^2 test or Fisher's exact test for categorical data (form, location, gender, and pathological finding) and the Student's t test for numerical data (age, procedure time), as appropriate. In the multivariate analysis, procedure time (median time of all cases) was analyzed with logistic regression analysis.

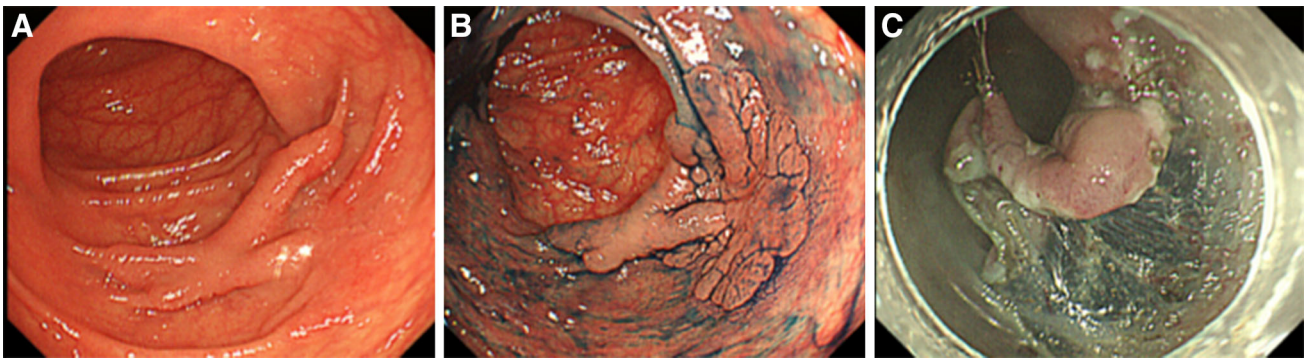

Fig. 5 Submucosal layer is well exfoliated by direct visualization. **A**, **B** A lateral spreading tumor—granular type is located in the transverse colon. **C** After separating the tumor from the surrounding normal mucosa, the S–O clip is attached to the edge of the exfoliated mucosa. A regular clip used to grasp the distal nylon loop attached to the S–O clip is then inserted and applied to the colon wall. The regular clip is generally applied opposite the lesion, enabling traction that opens the resection margin. Traction on the lesion maintains visualization of the tissue cutting line of the submucosal layer, resulting in a safe and successful en bloc dissection. After dissection, the nylon loop is cut with a loop cutter. The endoscope remains in position during the entire procedure, and the specimen is removed with forceps

A p value <0.05 was considered statistically significant. Statistical analysis was performed using the SPSS 19.0 software package for Windows (SPSS Inc., Chicago, IL, USA).

Results

Of the 70 patients who underwent ESD for a superficial colorectal tumor ≥20 mm in diameter during the study period, 64 patients gave written informed consent to participate in the study. Among those patients, 7 were excluded because of deep submucosal invasive cancer, 5 had recurrent lesions, and 2 because they were single balloon overtube-guided cases. The remaining 50 patients (30 males, 20 females; mean age 66.3 years, range 42–88) were enrolled. Twenty-seven (54 %) of the 50 lesions were the LST granular-type (LST-G) and 23 (46 %) were the LST non-granular type (LST-NG). Each was diagnosed preoperatively as an intramucosal neoplastic lesion or slightly submucosal invasive cancer. Mean tumor size was 35.5 ± 13 mm. Thirty of the lesions were adenomas and 20 were adenocarcinomas (16 intramucosal carcinoma; 4 submucosal invasive cancer). Forty of the lesions were located in the colon, and 10 in the rectum. Patients were randomly assigned to Group A ($N = 27$) and Group B ($N = 23$); 8 of the Group B patients were conversion cases (Fig. 1). Characteristics of patients are summarized in Table 1.

There were 27 tumors (mean size 33.5 ± 12.5 mm) in Group A, with 24 located in the colon and 3 in the rectum. The mean procedure time was 37.4 ± 32.6 min (mean ± SD), which included the few additional minutes required for the application of the S–O clip. All tumors were resected en bloc without any complications.

In Group B, there were 23 tumors (mean size 37.8 ± 13.1 mm) with 16 tumors located in the colon and 7 in the rectum. The mean procedure time was 67.1 ± 44.1 min (mean ± SD), and the en bloc resection rate was 95.7 % (22/23). In 1 case, a conventional snare was employed to complete the resection. Eight of the 23 cases initially assigned to Group B were converted and required the use of the S–O clip. Although the mean size of the tumor in these converted cases (36.4 ± 11.1 mm) was similar to that in the non-converted cases (37.7 ± 14.0 mm), a longer procedure time was required for the converted cases (88.3 ± 53.3 vs. 55.9 ± 33.3 min). In the converted cases, some tumors were in flexural portions, such as the sigmoid colon (3 cases), hepatic flexure (1 case), and splenic flexure (1 case) and the tumor in 1 case was in the cecum. Micro perforation occurred in 1 of these cases, a patient in which a 40-mm LST granular-type was located in the sigmoid colon; the perforation was resolved endoscopically using the S–O clip. No complications occurred in the other 22 cases. In Group A 24/27 (88.9 %) patients were followed for 8 months (median, range 1–34), while 21/23 (91.3 %) of Group B patients were followed for 11 months (median, range 1–23). There were no recurrences in either group.

Between-group comparisons showed that the mean procedure time was significantly shorter when using the S–O clip (37.4 ± 32.6 vs. 67.1 ± 44.1 min, $p = 0.03$). (Table 2; Fig. 6). Logistic regression analysis for resection time within 36 min, which is the median time of all cases, showed the following odds ratios: gender (male/female) 0.23 (95 % CI [0.04–1.10], $p = 0.07$); age 0.99 (95 % CI [0.92–1.07], $p = 0.91$); tumor form (LST-G/LST-NG) 0.88 (95 % CI [0.12–6.05], $p = 0.89$), tumor size 1.12 (95 % CI [1.01–1.24], $p = 0.03$), pathology (adenoma/cancer) 0.75 (95 % CI [0.14–3.93], $p = 0.73$), and location (rectum/

Table 1 Characteristics of patients

	Overall	Group A	Group B	*p* value
Patients	50	27	23	
Gender (male/female)	30/20	18/9	12/11	0.30
Age (year, mean ± SD)	66.3 ± 9.3	66.2 ± 9.6	66.4 ± 8.9	0.95
Tumor form (LST-G/LST-NG)	27/23	14/13	13/10	0.74
Tumor size (mean ± SD)	35.5 ± 13.0	33.5 ± 12.5	37.8 ± 13.1	0.25
Pathology (adenoma/cancer)	30/20	19/8	11/12	0.10
Depth of cancer (M/SM)	16/4	5/3	11/1	0.11
Location (rectum/colon)	10/40	3/24	7/16	0.09

Group A S–O clip-assisted ESD, *Group B* conventional ESD. *M* mucosal cancer, *SM* submucosal invasive cancer

Table 2 Results of colorectal endoscopic submucosal dissection

	Overall	Group A	Group B	*p* value
En bloc resection rate	98 % (49/50)	100 % (27/27)	95.7 % (22/23)	0.28
Procedure time (min, mean ± SD)	51.12 ± 41.1	37.4 ± 32.6	67.1 ± 44.1	0.03*
Perforation	1	0	1	0.28
Delayed bleeding	0	0	0	1.00

* A *p* value of <0.05 was considered statistically significant

Group A S–O clip-assisted ESD, *Group B* conventional ESD

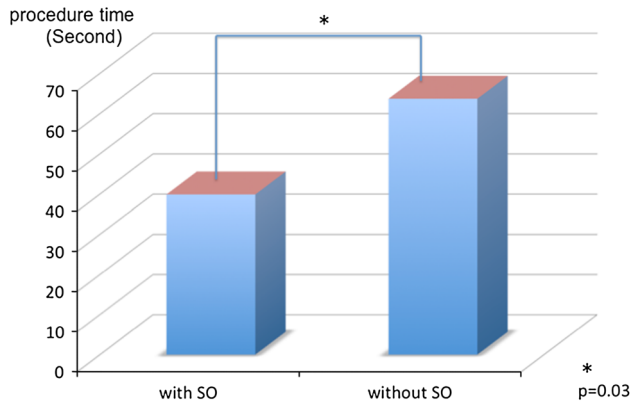

Fig. 6 The mean procedure time for ESD was significantly shorter with the device than without the device

Table 3 Multivariate analyses for successful en block resection rate within the median resection time of all cases (36 min)

	En bloc resection rate within 36 min		
	OR	(95 % CI)	*p* value
Gender	0.23	(0.04–1.1)	0.07
Age	0.99	(0.92–1.07)	0.91
Tumor form	0.88	(0.12–6.05)	0.89
Tumor size	1.12	(1.01–1.24)	0.03*
Pathology	0.75	(0.14–3.93)	0.73
Location	1.60	(0.20–12.2)	0.65
Traction	0.15	(0.02–0.86)	0.03*

* A *p* value of <0.05 was considered statistically significant

By logistic regression, *OR* odds ratio

colon) 1.60 (95 % CI [0.20–12.2], $p = 0.65$), and the use of the S–O clip 0.15 (95 % CI [0.02–0.86], $p = 0.03$). Therefore, tumor size and use of traction were strongly associated with procedure time within 36 min (Table 3).

Discussion

The present study is the first clinical trial of the use of traction device-assisted ESD for colorectal tumors. The duration of colorectal ESDs with the traction device was significantly shorter than that of conventional ESDs ($p = 0.03$). Furthermore, there were no differences in tumor form, size, and location, and pathological findings between the two groups. Although the rates of en bloc resection and complications did not differ between groups, resection by conventional ESD was difficult in some cases. To prioritize patient safety above the research goals, conversion of conventional ESD to S–O clip-assisted ESD was necessary in 34.8 % (8/23) of patients. In most of those patients, the tumor was located in flexural areas, which could increase the risk of perforation due to perpendicular positioning of the colonoscope with respect to the colonic wall. In the remaining patients (15/23) in the conventional group, a longer procedure time was required (55.9 ± 33.3 min) than in the S–O clip-assisted group (37.4 ± 32.6 min) even though these cases were initially considered to be simple. This suggests that the S–O clip is effective not only for difficult cases but also for cases considered as being ordinary.

ESD of the colorectum is technically difficult compared to gastroesophageal ESD due to the unfavorable

characteristics of the colon such as the thin wall, presence of folds and flexions, existence of peristalsis, and fecal fluid. It is especially dangerous when the cutting line of the submucosal layer is not clear and a lack of full control over the scope can cause unexpected incisions, resulting in a serious complication, such as perforation. The rate of complications in this trial was not significantly different between the groups. Even though our study was of a limited number of cases, the overall rate of complications (2 %) was much lower than previous studies. The perforation rate in two reports analyzing the results of more than 1,000 colorectal ESDs performed in specialized centers for endoscopic treatment in Japan and Korea were 4.1 and 5.3 %, respectively [22, 23]. A possible reason for this difference is that for all cases, including those in the conventional ESD group, we had the S–O clip available as an alternative for use in technically difficult lesions. The only case of perforation that we experienced was in the conventional group. This patient had an LST-G measuring 40 mm located in the sigmoid colon and unfavorable conditions arose for resection during the procedure. As this case required a long procedure time and perforation occurred, we decided to use the S–O clip, which allowed us to obtain better visualization. Finally, the lesion was completely resected and the perforation was closed endoscopically without surgical intervention. The lesion would have been easy to resect if the case had been assigned to the S–O clip-assisted group from the beginning.

A major disadvantage of colorectal ESD compared to EMR is the longer procedure time as reported in a previous study, which varied considerably from 45.5 to 134.5 min [24]. Procedure time is an important factor, since a long procedure time can result in mental and physical exhaustion of the operator, causing at the same time unstable and imprecise movements of the scalpel. A long procedure time was reported as a risk factor for perforation in gastric ESDs [25]. Since colorectal ESD was approved by the Japanese government's medical insurance system only for lesions $\geq$20 mm, it can be considered that ESDs for larger colorectal lesions require a longer operative time than gastric ESDs. Added to the inherent characteristics of the colorectum and its contents, a long procedure time for colorectal ESDs can increase the risk of perforation and resultant peritonitis. Shortening the operative time with the use of devices like the S–O clip would be valuable in overcoming this drawback.

The S–O clip was simple to use, and no difficulties were encountered during or after the procedure, with resections successful without obstacles in all 27 cases. As we reported [18, 19], the S–O clip was indeed applicable and helpful for any lesion throughout the large bowel, including those located in the right colon. Also the recurrence rate using the S–O clip was as low as that previously reported [22]. Since dissection of the submucosal layer is considered to be the most difficult step in ESD and since the S–O clip is effective at this step, it can play an important role in the development of ESD in non-specialized centers.

Although our study showed the efficacy of the traction device, the study had some limitations. Firstly, the sample size was relatively small. In the future, a trial with a larger sample size could address this limitation. Secondly, all ESDs were performed by an extremely experienced colonoscopist in a single high-volume center. To address the question of generalizability of the present results, a multi-institutional trial would be ideal.

In conclusion, this prospective clinical trial proved that the time required for colorectal ESD was reduced by the S–O clip, while maintaining a high en bloc resection rate with no serious complications. The S–O clip-assisted ESD can be expected to become the standard for colorectal ESDs.

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Disclosures Hideaki Ritsuno, Naoto Sakamoto, Taro Osada, Shingo P. Goto, Takashi Murakami, Hiroya Ueyama, Hiroki Mori, Kenshi Matsumoto, Kazuko Beppu, Tomoyoshi Shibuya, Akihito Nagahara, Tatsuo Ogihara, Sumio Watanabe have no conflicts of interest or financial ties to disclose.

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