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Usefulness of the Bridge Formation Method for Colorectal Endoscopic Submucosal Dissection: A Propensity Score-Matched Study

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ABSTRACT

Aims: Colorectal endoscopic submucosal dissection (ESD) has become a standard treatment for superficial colorectal neoplasms worldwide. However, challenges remain in achieving dissection at the precise layer. In this study, we evaluated the effectiveness of a novel ESD technique involving natural traction, referred to as the bridge formation method (BFM).

Methods and Results: The two main features of the BFM are creating a large mucosal flap and leaving normal mucosa on both sides of the lesion until the bridge is made at the end of the procedure. This retrospective study included consecutive patients with 2647 colorectal lesions resected by ESD from September 2003 to December 2023. We divided them into the BFM group and the non-BFM group and conducted propensity score matching.

After propensity score matching, 1648 cases were enrolled (824 cases in each group). The en bloc resection rate was significantly higher in the BFM than non-BFM group (99.6% vs. 96.7%, $p<0.01$). The R0 resection rate and the average dissection speed (㎟/min) were significantly higher in the BFM than non-BFM group (98.8% vs. 96.4%, $p<0.01$, and 18.9 vs. 18.0, $p=0.03$). The occurrence rates of perforation and delayed bleeding showed no significant difference between the non-BFM and BFM groups (2.8% vs. 3.6%, $p=0.40$, and 1.1% vs. 1.0%, $p=1.00$).

Conclusions: The BFM is a suitable method for colorectal ESD as it enables rapid dissection and improves both en bloc resection and R0 resection rates.

1 | Introduction

Endoscopic submucosal dissection (ESD) is used to resect superficial colorectal neoplasms worldwide [1–7]. However, compared with gastric and esophageal ESD, colorectal ESD is more challenging and has a higher adverse event rate. This is due to the colonoscope's poor maneuverability, which is affected by sharp bends, haustra, peristalsis, and respiratory movement [1, 8–11]. Therefore, the cornerstone of effective and safe colorectal ESD is the appropriate use of traction during dissection.

Several traction methods, such as the clip-flap method, thread-traction method, S-O clip method, and use of a multi-loop traction device, have been reported to overcome the difficulties associated with colorectal ESD, and some positive results have been achieved [12–15]. However, these traction devices require skilled assistance, pose a risk of specimen injury, are less effective in the free colon or at flexures, and are costly [16]. Additionally, they cannot be used in some countries. Therefore, ESD methods that do not use traction devices have been attracting much attention [17–20].

When performing colorectal ESD, en bloc resection is very important because piecemeal resection makes it impossible to confirm a negative margin and increases the local recurrence rate (10.0%–23.5%) [21]. To improve the en bloc resection rate, we devised a novel ESD method called the bridge formation method (BFM). The main features of the BFM are creating a large mucosal flap and leaving normal mucosa on both sides of the lesion until the bridge is made at the end of the procedure. The large mucosal flap stabilizes the endoscope under the lesion, allowing safe dissection of the entire lesion within a fixed layer. Even at the end of the treatment, traction from both sides is continuously applied, facilitated by the traction force from the mucosa on both sides of the remaining lesion. This allows for the safe continuation of the treatment at the appropriate layer until the end of the procedure.

However, the usefulness of the BFM remains unclear. In this study, we compared the treatment results of the BFM with other ESD methods using propensity score matching.

2 | Methods

2.1 | Study Population

This was a retrospective case control study of patients who underwent colorectal ESD for the treatment of colorectal neoplasms at Showa University Northern Yokohama Hospital. From September 2003 to November 2023, ESD was performed at Showa University Northern Yokohama Hospital for epithelial colorectal lesions, excluding advanced cancer, neuroendocrine tumors, and colitis associated neoplasia. Consecutive patients treated during this period were analyzed. We retrospectively reviewed the patients' medical records and enrolled their medical history, endoscopic findings, and pathologic findings in the database. Informed consent was obtained using an opt-out method under the approval of the local ethics committee. Information about the current trial was provided to the patients, and the absence of refusal was regarded as consent to the study. Hospital ethics committee approval was obtained (approval number; 2024-035-A). This study is registered in the University Hospital Medical Network Clinical Trials Registry (UMIN000056387).

2.2 | Indications for ESD

The indications for colorectal ESD were defined according to the Japan Gastroenterological Endoscopy Society colorectal ESD/endoscopic mucosal resection guidelines [22] as follows:

- colorectal tumors of > 20 mm in diameter for which (i) preoperative diagnosis suggests a possible mucosal tumor or slightly invasive submucosal cancer and (ii) en bloc resection would be difficult
- mucosal tumors or early-stage cancers with fibrosis caused by previous treatment, biopsy, or colonic wall peristalsis
- sporadic and localized tumors in chronic intestinal inflammation, such as ulcerative colitis

2.3 | Definition of Curative Resection

The curability of ESD was evaluated based on the Japanese Society for Cancer of the Colon and Rectum guidelines [7] and was defined as follows:

- It is intramucosal carcinomas that were completely resected with a negative lateral tumor margin.
- T1 (submucosal invasive) carcinoma in which all of the following conditions were satisfied on histopathologic analysis: negative vertical tumor margin (histologic complete resection), papillary adenocarcinoma or tubular adenocarcinoma, submucosal invasion depth of < 1000 μm, no lymphovascular permeation, and tumor budding (limited up to grade 1).

2.4 | Endoscopic System and Devices

ESD was performed by endoscopists specialized in endoscopic colorectal treatment. The ESD procedure and devices have been described in previous reports [23]. The following endoscopes were used: a water-jet system gastroscope (GIF-Q260J; Olympus, Tokyo, Japan, September 2003–September 2008) and two water-jet system colonoscopes (PCF-Q260JI; Olympus, October 2008–February 2018 and PCF-H290TI; Olympus, from March 2018 onward). A triangle-tip knife (KD-630L; Olympus, September 2003–September 2008) and a flush knife (DK2618LN; Fujifilm Medical, Tokyo, Japan, from October 2008 onward) were used as endo-knives. A transparent hood (D-201-11 804; Olympus) was attached to the tip of the endoscope to enhance field visualization and ensure stable dissection. From September 2003 to March 2008, the injected agent was a 1% hyaluronic acid solution (Suvenyl; Chugai Pharmaceutical, Tokyo, Japan) mixed with a 10% glycerin, 5% fructose, and 0.9% saline solution (Glyceol; Chugai Pharmaceutical). From April 2008, a 0.4% hyaluronic acid solution (Mucoup; Johnson & Johnson K.K., Tokyo, Japan) was used [24, 25]. The electrosurgical units used were the ICC 200 (Erbe Elektromedizin, Tübingen, Germany, September 2003–August 2018) and the VIO3 (Erbe Elektromedizin, from September 2018 onward).

2.5 | Bridge Formation Method

The BFM procedure is shown in Figure 1 [26]. First, a mucosal incision is created on the anal side, larger than the width of the lesion. Second, a mucosal flap is created. Third, dissection

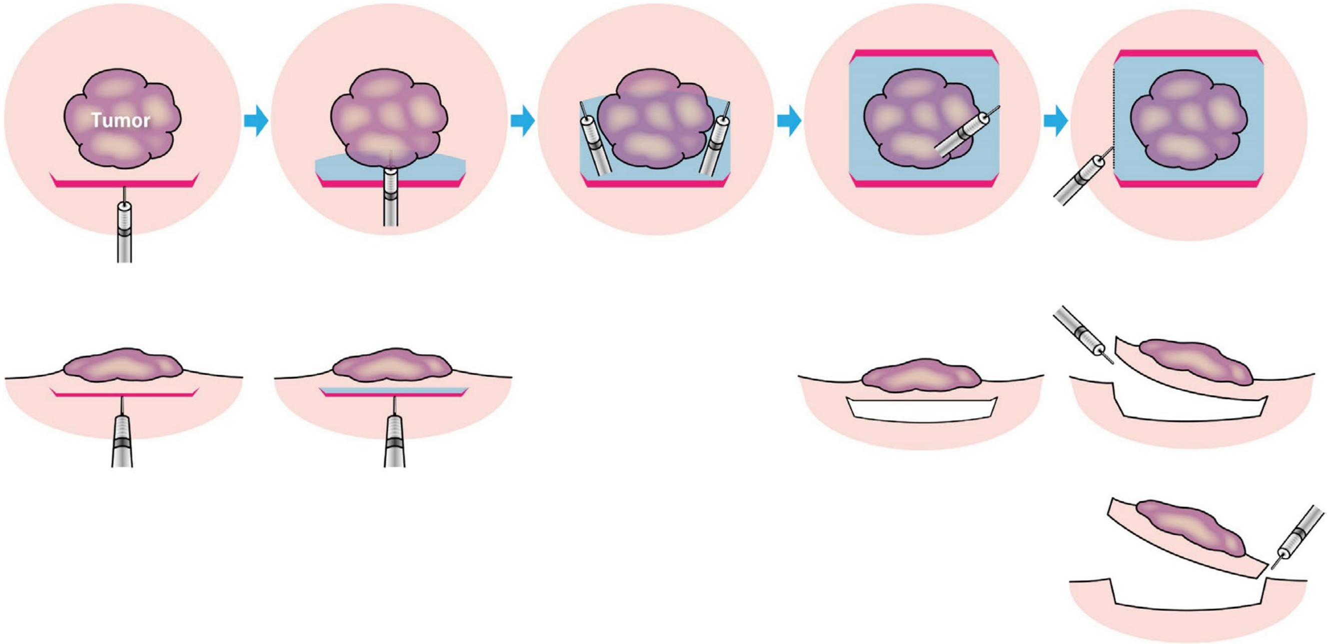

FIGURE 1 | Schematic image of bridge formation method.

is continued in parallel toward the oral side. The large mucosal incision allows the submucosal dissection to be larger than the lesion. When the injection solution enters the oral side of the lesion and a color change is noted, the oral side of the lesion is dissected. Finally, a mucosal incision is created on the oral side, and the submucosal tunnel is opened, leaving normal mucosa on both sides of the lesion. Leaving normal mucosa in this manner provides sufficient traction for the lesion from both lateral sides. In this way, a mucosal bridge is formed. Finally, a mucosal incision of the lateral sides is made from the submucosal side to the luminal side.

2.6 | Non-BFM

We used traction devices for some lesions at the bottom of the cecum or lesions involving the appendiceal orifice. We used the thread-traction method for 1 patient, the S-O clip method for 58 patients, and a multi-loop traction device for 2 patients. For other lesions treated by a non-BFM method, we used the conventional method. The conventional method for ESD was carried out as previously reported [17, 27]. First, sodium hyaluronate solution was injected into the submucosal layer under and around the lesion. An initial mucosal incision was made, extending at least one-fourth of the circumference and approximately 5 mm from the distal side of the tumor. Submucosal dissection was then performed from the distal to proximal edge of the tumor to both ends of the incision line. After dissecting all initially incised areas of the mucosa, additional mucosal incisions and submucosal dissection were repeated toward the proximal side.

2.7 | The Treatment Method

The method was selected at the endoscopist's discretion. In general, if the endoscopist anticipated difficulty in dissecting the lateral side of the submucosal tissue under the lesion or difficulty in creating the mucosal bridge such as with small lesions and lesions located at the bottom of the cecum or at sharp bends, the conventional method or ESD with traction devices was selected instead of the BFM. We reviewed the endoscopic treatment reports and treatment videos to confirm the technique for resections and divided patients into the BFM group and the non-BFM group. All patients who underwent resection with traction devices were classified into the non-BFM group.

2.8 | Comparison of Baseline Characteristic

We compared the differences in mean age, sex, location, morphology, treatment by an expert or non-expert, average tumor size (long diameter), and rate of submucosal invasion of $\geq 1000\,\mu$m between the lesions resected by the BFM and lesions resected by a non-BFM technique. An expert was defined as a surgeon who had performed more than 100 colorectal ESD procedures.

2.9 | Propensity Score Matching

Patient age, patient sex, surgeon expertise, degree of circumference, anticoagulant therapy, antiplatelet therapy, long diameter of the lesion, location of the lesion, and morphology of the lesion were used for matching at a ratio of 1:1. The caliper value for matching was set at 0.2.

2.10 | Outcome Measures

The outcome measures of this study included comparisons of the en bloc resection rate, the R0 resection rate (%), treatment time (min), average dissection speed (mm^2/min), perforation rate (%), post-procedure bleeding rate (%), SM invasion depth $\geq 1000\,\mu$m, and fibrosis between the BFM group and non-BFM group.

2.11 | Statistical Analysis

Normally distributed continuous variables are presented as mean ± standard deviation, and non-normally distributed variables are presented as median (interquartile range). Normally distributed continuous variables were compared using Student's *t*-test, and non-normally distributed variables were analyzed using the Wilcoxon rank-sum test. Dichotomous variables were compared using the chi-squared test or Fisher's exact test, as appropriate. All statistical analyses were performed using JMP Pro version 17.0.0 (SAS Institute Inc., Cary, NC, USA). All p values were two-sided, and $p < 0.05$ was considered statistically significant.

3 | Results

3.1 | Baseline Characteristics of Patients and Lesions

In total, 2647 lesions were analyzed in this study. Among them, 1664 were in the BFM group and 983 were in the non-BFM group (Figure 2). The baseline characteristics are shown in Table 1. There were no significant differences in sex, long diameter, degree of circumference, or anticoagulant drug. The median age of patients in the BFM group was higher than that of patients in the non-BFM group ($p = 0.002$). Variations in lesion distribution were observed ($p < 0.001$). The BFM group exhibited a higher proportion of lesions in the sigmoid, descending, and transverse colon, whereas the non-BFM group had a higher proportion in the cecum and ascending colon. No significant difference was observed in the proportion of lesions in the rectum between the two groups. Treatment by an expert was higher in the BFM group than in the non-BFM group (64.8% vs. 41.2%, $p < 0.001$). The BFM group had a higher number of depressed and laterally spreading tumors (LSTs) (non-granular type) than the non-BFM group ($p < 0.001$). The prevalence of antiplatelet drug use was higher in the non-BFM group than in the BFM group (6.9% vs. 5.0%, $p = 0.004$).

3.2 | Treatment Outcomes

The treatment outcomes of the two groups are summarized in Table 2. The en bloc resection rate was higher in the BFM group than in the non-BFM group (99.5% vs. 97.2%, $p < 0.01$). The average dissection speed was significantly faster in the BFM group than in the non-BFM group (20.8 vs. 18.7 mm^2/min, $p < 0.001$).

The R0 resection rate was higher in the non-BFM group than in the BFM group (98.8% vs. 96.7%, $p < 0.001$).

The adverse events in the two groups are summarized in Table 2. The rate of perforation was higher in the non-BFM group than in the BFM group (3.9% vs. 2.22%, $p = 0.01$). The rate of delayed bleeding was higher in the BFM group than in the non-BFM group, although this difference was not statistically significant (1.3% vs. 1.1%, $p = 0.65$). Neither the BFM group nor the non-BFM group required surgical treatment after adverse events.

3.3 | Outcomes After Propensity Score Matching

Propensity score matching was performed to reduce the heterogeneity of the baseline characteristics. After propensity score matching, 824 cases were selected for both groups (Figure 2). The baseline characteristics after matching are shown in Table 1. The en bloc resection rate was still significantly higher in the BFM group (99.6%) than in the non-BFM group (96.9%) ($p < 0.001$). The R0 resection rate was still significantly higher in the BFM group (98.8%) than in the non-BFM group (96.4%) ($p < 0.001$). The treatment time was similar in both groups. The average dissection speed was significantly faster in the BFM group than in the non-BFM group (18.9 vs. 18.0 mm^2/min, $p = 0.03$).

The rate of perforation was similar in the BFM group and the non-BFM group (2.8% vs. 3.6%, $p = 0.08$). The rate of delayed bleeding was also the same in the BFM group as in the non-BFM group (1.1% vs. 1.0%, $p = 1.00$).

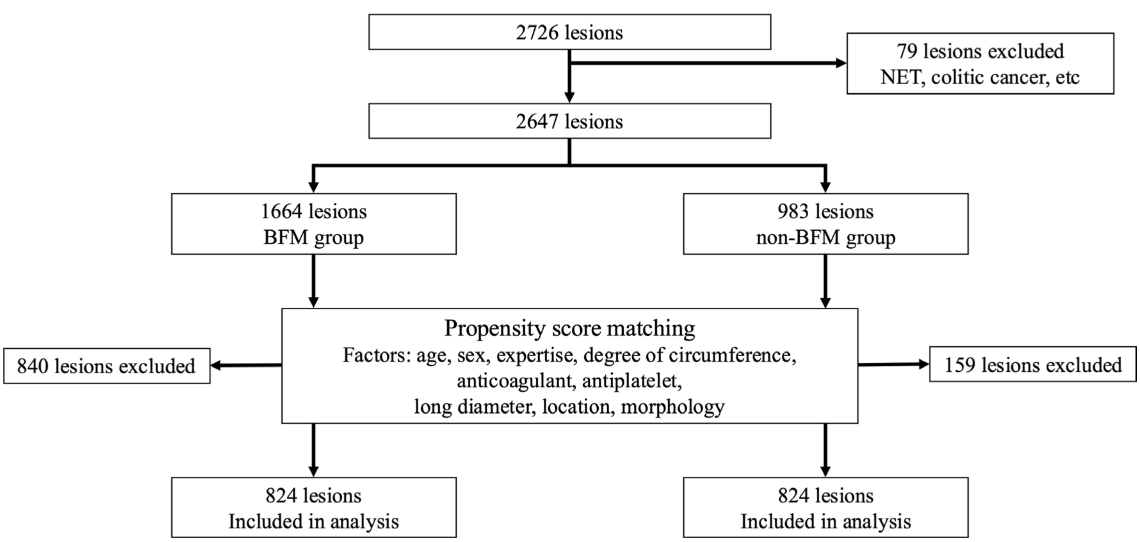

FIGURE 2 | Study flow chart. BFM, bridge formation method; NET, neuroendocrine tumor.

TABLE 1 | Baseline characteristics before and after propensity score matching.

Variables	Overall cohort			Matched cohort		
	BFM group ($n=1664$)	Non-BFM group ($n=983$)	p	BFM group ($n=824$)	Non-BFM group ($n=824$)	p
Median age	69.0 (60.0–76.0)	68.00 (60.0–75.0)	0.02	67.5 (59.0–75.0)	68.0 (60.0–75.0)	0.83
Sex (%)			0.12			0.96
Male	989 (59.4%)	554 (56.4%)		460 (55.8%)	462 (56.1%)	
Female	675 (40.6%)	429 (43.6%)		364 (44.2%)	362 (43.9%)	
Location (%)			< 0.01			0.23
Rectum	270 (16.2%)	159 (16.2%)		125 (15.2%)	128 (15.5%)	
Sigmoid colon	354 (21.3%)	167 (17.0%)		135 (16.4%)	145 (17.6%)	
Descending colon	125 (7.5%)	42 (4.3%)		42 (5.1%)	41 (5.0%)	
Transverse colon	393 (23.6%)	154 (15.7%)		157 (19.1%)	146 (17.7%)	
Ascending colon	393 (23.6%)	245 (24.9%)		240 (29.1%)	207 (25.1%)	
Cecum	129 (7.8%)	216 (22.0%)		125 (15.1%)	157 (19.1%)	
Morphology (%)			< 0.01			0.37
Protruded	90 (5.4%)	41 (4.2%)		27 (3.3%)	39 (4.7%)	
Depressed	37 (2.2%)	5 (0.5%)		3 (0.4%)	5 (0.6%)	
LST-G	506 (30.4%)	469 (47.7%)		325 (39.4%)	338 (41.0%)	
LST-NG	1004 (60.3%)	452 (46.0%)		456 (55.3%)	426 (51.9%)	
Recurrence	27 (1.6%)	16 (1.6%)		13 (1.6%)	16 (1.9%)	
Long diameter (mm)	25.0 (20.0–35.0)	27.0 (20.0–36.0)	0.17	26.0 (20.0–35.0)	26.0 (20.0–35.0)	0.64
Treatment by expert (%)	1079 (64.8%)	405 (41.2%)	< 0.01	320 (38.8%)	369 (44.8%)	0.02
Degree of circum ≥ 0.5 (%)	124 (7.5%)	55 (5.6%)	0.07	46 (5.6%)	47 (5.7%)	1.00
Anticoagulant (%)	200 (12.0%)	125 (12.7%)	0.60	94 (11.4%)	103 (12.5%)	0.54
Antiplatelet drug (%)	83 (5.0%)	68 (6.9%)	0.04	52 (6.3%)	52 (6.3%)	1.00

Note: Results are expressed as median (interquartile range) or number of patients (%), as appropriate.
Abbreviations: BFM, bridge formation method; LST-G, laterally spreading tumor-granular type; LST-NG, laterally spreading tumor-non-granular type; circum, circumferential.

4 | Discussion

In this study, we clarified the usefulness of the BFM for colorectal ESD compared with non-BFM ESD using propensity score matching. BFM significantly facilitated colorectal ESD by increasing the dissection speed, and its use improved the en bloc resection rate and R0 resection rate.

En bloc resection is very important when performing colorectal ESD because piecemeal resection makes it impossible to confirm a negative margin and increases the local recurrence rate (10.0%–23.5%) [21]. After propensity score matching, the en bloc resection rate was significantly higher in the BFM group. We suspect that this may be due to the large mucosal flap in BFM, which facilitates dissection at an appropriate depth and the treatment of challenging lesions, such as those with fibrosis, highly invasive submucosal cancers, and giant lesions. Furthermore, this advantage may improve both the R0 resection rate and dissection speed.

The pocket-creation method (PCM) is a representative technique that uses natural traction. The PCM was first reported in 2014 by Hayashi et al. [20] It provides good traction by creating a wide pocket under the lesion. The key feature of PCM is the creation of a large submucosal pocket under the lesion after a minimal mucosal incision using a needle-type knife. Subsequently, an endoscope with a small-caliber hood is introduced, and the submucosal dissection is completed within the pocket. PCM uses a small mucosal incision and an ST hood, making it easier to create a mucosal flap and penetrate

TABLE 2 | Treatment outcomes before and after propensity score matching.

Variables	Overall cohort			Matched cohort		
	BFM group (n = 1664)	Non-BFM group (n = 983)	p	BFM group (n = 824)	Non-BFM group (n = 824)	p
En block resection rate	1656 (99.5%)	955 (97.2%)	< 0.01	821 (99.6%)	797 (96.7%)	< 0.01
R0 resection rate	1644 (98.8%)	951 (96.7%)	< 0.01	814 (98.8%)	794 (96.4%)	< 0.01
Treatment time (min)	60 (40–85)	60 (40–95)	< 0.01	60 (40–85)	60 (40–90)	0.67
Average dissection speed (mm^2/min)	20.8 (14.1–30.8)	18.3 (11.7–29.3)	< 0.01	18.9 (13.1–28.3)	18.0 (11.3–28.3)	0.03
Perforation rate	37 (2.2%)	38 (3.9%)	0.01	23 (2.8%)	30 (3.6%)	0.40
Post-bleeding rate	22 (1.3%)	11 (1.1%)	0.65	9 (1.1%)	8 (1.0%)	1.00
SM invasion ≥ 1000 μm	229 (13.8%)	57 (5.8%)	< 0.01	79 (9.6%)	54 (6.6%)	0.03
Fibrosis	85 (5.1%)	35 (3.6%)	0.67	28 (3.4%)	31 (3.8%)	0.79

Note: Results are expressed as average ± standard deviation, median (interquartile range) or number of patients (%), as appropriate.
Abbreviations: BFM, bridge formation method; SM, submucosal.

the submucosa compared to BFM. However, PCM also has some limitations. The use of a transparent hood with a small-caliber tip is essential for PCM; therefore, the endoscopic view tends to be narrow. Additionally, the pocket-opening phase of PCM is often cumbersome and time-consuming [15]. To overcome these problems, we devised BFM, with a large mucosal flap and preserving the normal mucosa on both sides of the lesion until the bridge is formed at the end of the procedure. BFM utilizes a large mucosal incision, allowing visualization of the entire submucosa beneath the lesion. This enables dissection at the appropriate layer, which may facilitate the treatment of lesions with fibrosis and highly invasive SM cancer. One meta-analysis compared the outcomes of the PCM with the conventional method [17]. The meta-analysis included five studies (two randomized controlled trials and three retrospective studies) involving 1481 patients. The pooled analysis showed that PCM achieved a higher en bloc resection rate (99.8% vs. 92.8%; OR, 9.9; 95% CI, 2.7–36.2), a shorter procedure time (minutes) (29.5 to 79.6 vs. 41 to 118.8, mean difference, −11.5; 95% CI, −19.9 to −3.1), a faster dissection speed (mm^2/min) (14.3 to 23.8 vs. 11.8 to 20.9, mean difference, 3.6; 95% CI, 2.8–4.5), and a lower overall adverse event rate (4.4% vs. 6.6%; OR, 0.6; 95% CI, 0.3–1.0) compared with the conventional method. In the present study, the en bloc resection rate was 98.8%, the median procedure time was 56 (36–85) min, the average dissection speed was 20.8 mm^2/min, the perforation rate was 2.22%, and the post-bleeding rate was 1.32% in the BFM group. These results suggest that BFM may provide outcomes comparable to PCM. However, BFM and PCM were not directly compared in this study. Moreover, this study was subject to selection bias. Therefore, we believe that a prospective randomized controlled trial is necessary to accurately evaluate and compare the outcomes of BFM and PCM.

Zou et al. reported Endoscopic submucosal tunnel dissection (ESTD) [28]. The concept of ESTD and BFM is similar; however, there are some differences. First, in ESTD, the oral mucosal incision is made first to create the endpoint, and then the anal mucosal incision is made. In BFM, the anal mucosal incision is made, and the oral mucosal incision is made after the dissection has progressed. This may not be an issue in the rectum, but in the colon, making the oral mucosal incision first is thought to pose a risk of the lesion collapsing toward the anal side due to reduced traction from the oral side. Therefore, in BFM, the oral mucosal incision is made after a complete mucosal flap has been created and the dissection has progressed. Second, in ESTD, the width of the anal mucosal incision is not specified, whereas in BFM, it is defined to be larger than the lesion. This is because a large mucosal flap makes it possible to visualize the entire area below the lesion, and dissection can be performed at the appropriate depth.

Several traction methods, such as the clip-flap method, thread-traction method, S-O clip method, and the use of a multi-loop traction device, have been reported to overcome the difficulties associated with colorectal ESD, and some positive results have been achieved [12–15]. Fujinami et al. reported the outcomes of ESD with the S-O clip (SO group) compared to conventional ESD (CO group) [29]. Compared to the CO group, the SO group had a significantly shorter procedure duration (70.7 ± 37.9 min vs. 51.2 ± 18.6 min; $p = 0.017$), a significantly higher dissection speed (15.1 ± 9.0 mm^2/min vs. 26.3 ± 13.8 mm^2/min; $p < 0.001$), a significantly higher en bloc resection rate (80.9% vs. 98.8%; $p \leq 0.001$), and a significantly lower perforation rate (4.3% vs. 1.3%).

The en bloc resection rate was higher in BFM than in ESD with the S-O clip, whereas the dissection speed was lower in BFM than in ESD with the S-O clip. However, these traction devices require additional time to attach, skilled assistance, and increased costs [16]. BFM may be a viable alternative for physicians who do not have access to or prefer not to use traction devices.

However, the BFM has some limitations. It is not useful for lesions with strong fibrosis in the early stages of the procedure because this makes it difficult to create the large mucosal flap. Additionally, the BFM is not suitable for small lesions and lesions located at the bottom of the cecum or at sharp bends because such conditions make it difficult to create the mucosal bridge.

This study had several limitations. First, it was a retrospective single-center study, and some selection bias existed. We therefore compared the BFM and non-BFM using propensity score matching to minimize the effects of selection bias. Prospective multicenter studies are needed to clarify the usefulness of the BFM. Secondly, the treatment method was selected based on the endoscopist's choice. Therefore, selection bias is inevitable. A prospective randomized trial is needed to clarify the usefulness of the BFM.

In conclusion, BFM is a suitable method for colorectal ESD as it enables rapid dissection and improves both en bloc resection and R0 resection rates.

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Conflicts of Interest

The authors declare no conflicts of interest.

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