

Prospective evaluation of the motorized spiral enteroscope for previous incomplete colonoscopy



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ABSTRACT

Background and study aims A significant percentage of colonoscopies remain incomplete because of failure to intubate the cecum. The motorized spiral enteroscope (MSE) technique, originally developed for deep small bowel enteroscopy, may be an effective alternative technique in cases of incomplete examination of abnormally long colons (dolichocolon). We prospectively evaluated the success rate of cecal intubation, safety and the therapeutic consequences of using MSE after incomplete conventional colonoscopy.

Patients and methods A total of 36 consecutive patients with an indication for diagnostic and/or therapeutic colonoscopy were prospectively enrolled in this multicenter trial. All patients had undergone at least one incomplete colonoscopy attributed to abnormally long colons. Patients with incomplete colonoscopy due to stenosis were excluded.

Results Twenty-two men and 14 women (median age 66 years, range 35–82) were enrolled. Median procedure time was 30 minutes (range 16–50). Cecal intubation rate was 100% and median cecal intubation time was 10 minutes (range 4–30). Abnormalities, mostly neoplastic lesions, were detected in 23 of 36 patients, corresponding to a diagnostic yield of 64%. All these findings were in the right side of the colon and had not been described by the antecedent incomplete colonoscopy. No adverse events occurred.

Conclusions In case of a difficult and long colon, MSE is safe and effective for diagnostic and therapeutic colonoscopy. It may provide an attractive solution to accomplish completeness of previous incomplete colonoscopies in these patients.

Introduction

Cecal intubation is the primary quality parameter of colonoscopy examination [1]. Colonoscopy is not always complete: the rate of failed cecal intubation is reported to be between 1.6% and 16.7% [2,3]. Factors associated with failed cecal intubation, other than stenosis or inadequate bowel cleansing, are female sex, older age, prior abdominal or pelvic surgery, low body mass index (BMI), and diverticular disease [1,4]. The anatomic

factors most frequently implicated are a sharply angulated sigmoid and loop formation in a redundant colon (dolichocolon) [5].

Advanced neoplasia was missed in 4.3% of patients [6] in the inaccessible part of the colon, illustrating the necessity for complete evaluation of the colon. Video capsule colonoscopy and modern radiological methods like colonography by computed tomography (CT) are capable of visualizing the entire colon, but histological evaluation or therapeutic interventions are not

possible. Hence, endoscopic methods to complete a colonoscopy are preferable. Repeating conventional colonoscopy can be successful in 50% to 72% of patients [7, 8]. Various other endoscopes have been tested to complete colonoscopy: pediatric colonoscopes [9], gastroscopes [10], variable stiffness colonoscopes [11], and push enteroscopes [12], as well as magnetic imaging-enhanced colonoscopy [13].

Balloon-assisted enteroscopes (BAEs), both double balloon as well as single balloon, have shown to be successful as alternative techniques [7, 13–21]. Manual version of spiral overtube-assisted colonoscopy achieved a cecal intubation rate of 92% in 24 patients in whom conventional colonoscopy had failed [22].

The most recently introduced motorized spiral enteroscope (MSE; Olympus Medical, Tokyo, Japan) has been proven feasible and safe for diagnostic colonoscopy in patients with normal anatomy [23]. Our recent data on MSE for small-bowel enteroscopy showed that retrograde MSE was characterized by short cecal intubation times (median 7 minutes) and it was much easier to intubate the ileocecal valve compared to BAE [24].

Here, we report prospective data from patients in whom we performed colonoscopies using the MSE after previous incomplete conventional colonoscopy in patients with abnormally long colons.

Patients and methods

Patients

Thirty-six consecutive patients who underwent colonoscopy using MSE between May 2021 and April 2022 were prospectively included in this proof-of-concept multicenter trial (NCT04895254 at clinicaltrials.gov).

Patients were referred for MSE if a previous colonoscopy was incomplete and if there was a clear indication to perform a complete colonoscopy, such as follow-up after previous neoplasia. Conventional colonoscopy was considered to have failed if the cecum could not be intubated or no sufficient positioning of the endoscope for right sided polypectomy could be

achieved. Cecal intubation was documented by a picture of the appendiceal orifice and/or of the terminal ileum.

The index colonoscopies were performed by gastroenterologists, trainee gastroenterologists in various stages of their training, and certified nurse endoscopists. Failed colonoscopies by trainees or nurse endoscopists were only labelled incomplete if the supervising gastroenterologist was also unable to complete the procedure.

Inclusion and exclusion criteria are shown in ► **Table 1**.

Motorized spiral enteroscope

The study device is the MSE (Olympus Medical, Tokyo, Japan). This system utilizes an integrated user-controlled motor. The MSE is composed of three subsystems. The first is a reusable endoscope with a working channel length of 168 cm, a large-caliber, 3.2-mm working channel, and an integrated motor. The electric motor is operated by a footswitch for rotating a short spiral segment/overtube (second subsystem) to pleat and unpleat the bowel. This increases acceleration of the procedure and facilitates insertion. The third subsystem is a control unit with a foot pedal and visual force gauge, which allows monitoring of the direction and resistance encountered by the spiral overtube. Additional features are: high-definition imaging, narrow band imaging, and a separate dedicated waterjet irrigation channel. This irrigation aims to provide a clear vision and to facilitate advancing the endoscope beyond sharp angles.

Endoscopy procedure

All MSE procedures were performed by two experienced endoscopists (AA and JJK). The enteroscope was inserted in the colon with the patient in the left decubitus position and advanced using clockwise spiral rotation. Abdominal compression and change of position were done as required. After reaching the cecum and/or crossing the ileocecal valve, the endoscope was withdrawn using counterclockwise spiral rotation. Tissue sampling and/or interventions were performed during withdrawal as clinically indicated. Carbon dioxide insufflation was used in all procedures.

► **Table 1** Inclusion and exclusion criteria.

Inclusion criteria	<p>Failed previous conventional colonoscopy for one of the following indications:</p> <ul style="list-style-type: none"> ▪ Screening for familial colorectal neoplasia ▪ Surveillance after previous colorectal neoplasia ▪ Positive result of colorectal cancer screening tests ▪ Previously identified colorectal polyps with an indication for endoscopic therapy ▪ Suspected lower gastrointestinal bleeding ▪ Analysis of iron deficiency anemia ▪ Chronic diarrhea ▪ Abdominal pain with/without change in bowel habit
Exclusion criteria	<ul style="list-style-type: none"> ▪ Known pregnancy ▪ Poor health status (ASA classification ≥ 4) ▪ Contraindication for propofol sedation ▪ Known uncorrectable coagulopathy ▪ Clinical suspicion of severe inflammatory bowel disease or suspected bowel obstruction ▪ Known colonic stenosis

ASA, American Society of Anesthesiologists.

► **Table 2** Patient characteristics.

Patients	n = 36
	▪ Men 22
	▪ Women 14
Age, median (range), years	66 (35–82)
ASA* classification	ASA 1 [3 (8.3%)]
	ASA 2 [30 (83.3%)]
	ASA 3 [3 (8.3%)]
Indications for colonoscopy	Surveillance after previous adenoma (n = 19)
	Iron-deficiency anemia (n = 3)
	Surveillance after previous colorectal cancer (n = 3)
	Surveillance familial risk colorectal cancer (n = 2)
	Screening positive iFOBT (n = 2)
	Unexpected findings on radiology (n = 2)
	Chronic Diarrhea (n = 2)
	Abdominal pain with or without change in bowel habit (n = 3)

ASA, American Society of Anesthesiologists; iFOBT, immunochemical fecal occult blood test

Patients were informed about the procedure and gave informed consent. The same bowel cleansing regimen as used for conventional colonoscopy according to local institutional guidelines was followed. However, depending on information gained from the previous colonoscopy, extra cleansing was provided if needed. All procedures were performed under propofol sedation without endotracheal intubation.

Ethical considerations

All patients provided written consent. The study was approved by the institutional review boards of participating centers. The study protocol was registered at clinicaltrials.gov (NCT04895254).

Statistics

Fisher's exact test was used to assess the statistical significance between variables. $P \leq 0.05$ was considered statistically significant.

Results

Forty-three patients were referred for MSE colonoscopy. Six patients were excluded because of presence of a stenotic diverticular sigmoid colon and another patient because of a contraindication for propofol sedation. The remaining 36 patients were included. The characteristics of these patients are shown in ► **Table 2**. Of these patients, 22 were men and 14 were women, with a median age of 66 years (range 35–82 years).

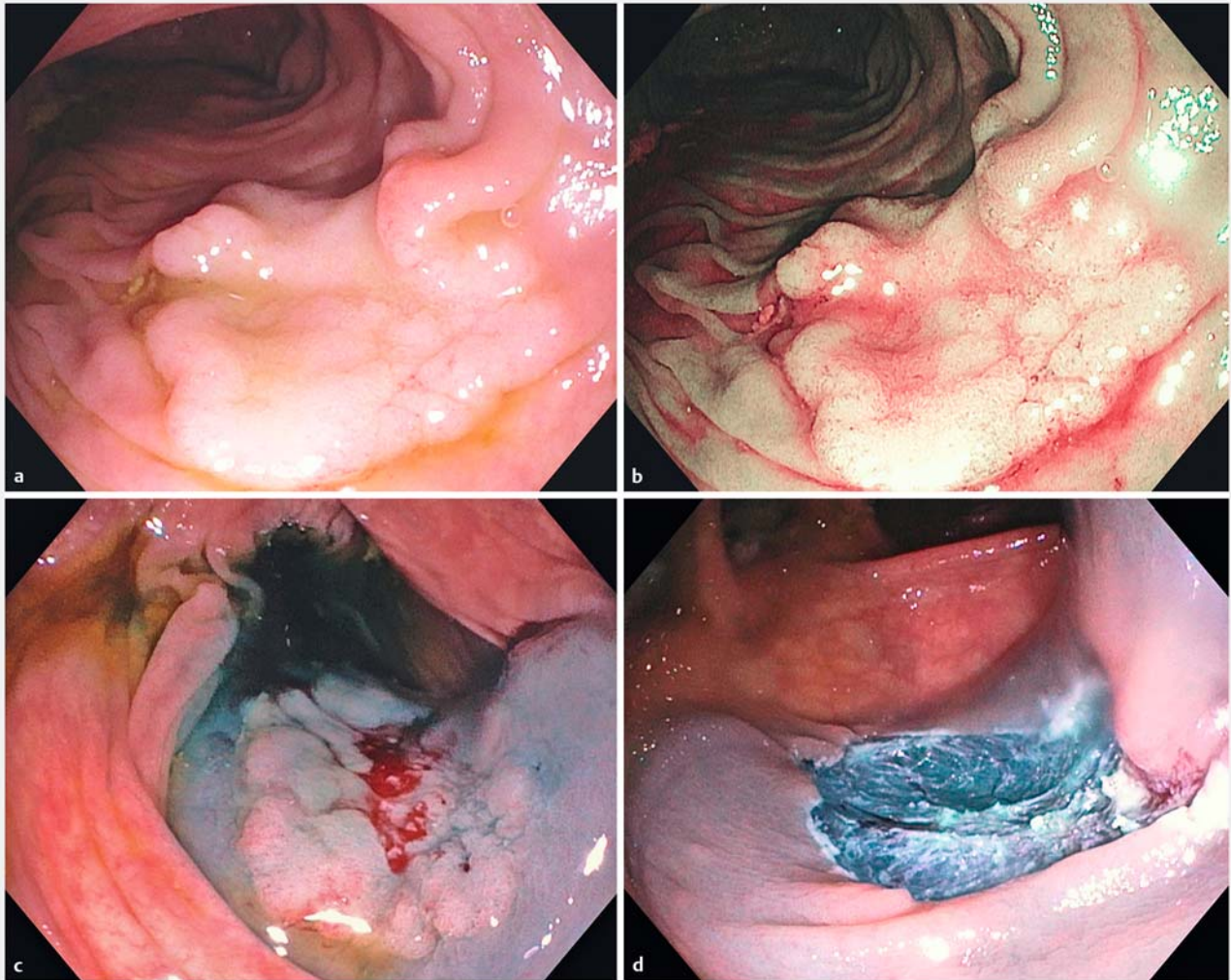
The most common indications for total colonoscopy were surveillance in patients with previous neoplastic lesions. The most common cause for previous failed cecal intubation using

► **Table 3** Procedural data from the 36 patients.

Technical data	n (%)
▪ Technical success rate (cecal intubation rate)	36 (100%)
▪ Cecal intubation time, median (range), minutes	10 (4–30)
▪ Withdrawal time, median (range), minutes	12 (6–40) ¹
▪ Total procedure time, median (range), minutes	30 (16–50) ¹
Diagnostic yield	n (%)
▪ Adenoma(s)	17 (47.2%)
▪ Colon cancer	2 (5.5%)
▪ Angiodysplasia(s)	3 (8.3%)
▪ Inflammatory changes (ulcers and erosions)	1 (2.7%)
Interventions	n (%)
▪ Polypectomy/endoscopic mucosal resection	17 (47.2%)
▪ Argon plasma coagulation	3 (8.3%)
▪ Others (ink tattoo)	2 (5.5%)
Adverse events	n (%)
▪ Asymptomatic mild superficial mucosal lesions	3 (8.3%)
▪ Severe adverse events	0

¹ Including time needed for intervention.

a conventional colonoscope was looping in a redundant colon (n = 35; 97.2%). One patient with situs inversus was referred from another clinic because of difficult colonoscopy.



► **Fig. 1** Motorized spiral enteroscopy may facilitate polypectomy of adenomas or serrated lesions in previously inaccessible regions of the colon. That includes **a** optimal evaluation of lesions using white light and **b** narrow band Imaging (NBI); **c** performing submucosal injections and then **d** resection.

Cecal intubation was achieved in all patients. This was achieved after a median time of 10 minutes (range 4–30).

► **Table 3** shows relevant abnormalities that were found in the part of the colon not inspected previously, and the therapeutic consequences. In 23 patients (63.8%), a new diagnosis was made, with subsequent treatment. In two patients (5.5%), a carcinoma was found. One or more adenomas were found in 17 patients (47.2%), which were endoscopically removed in all cases. ► **Fig. 1** illustrates some of the important findings and interventions.

No significant adverse events (AEs) were encountered. Superficial mucosal lesions were seen three patients in the sigmoid region during withdrawal, consistent with irritation from the large-diameter overtube. These lesions were considered not clinically relevant and were not associated with post-procedure bleeding or unscheduled hospital admissions.

Discussion

These preliminary proof-of-concept data demonstrate that MSE is a highly effective technique for achieving cecal intubation in cases of previous unsuccessful conventional colonoscopy. A cecal intubation rate of 100% was achieved. The European Society of Gastrointestinal Endoscopy (ESGE) and the American Society for Gastrointestinal Endoscopy and the American College of Gastroenterology (ASGE/ACG) require cecal intubation rates of more than 90% and 95%, respectively, for screening colonoscopies [1, 25, 26].

Thus far the data available on MSE are mainly dealing with effectiveness and safety of small bowel enteroscopy [24, 27, 28]. Beyna et al reported a feasibility trial on use of MSE as a colonoscope but not specifically for patients with long and difficult colons [23].

BAE was proved to be useful in cases of failed colonoscopies, for which redundant colon with loop formation and an adhesive

angulated sigmoid are the most important anatomical causes [5, 20].

The rates of cecal intubation achieved with different enteroscopies were 88% to 95% for DBE [13–16, 18, 20, 21], 100% using a short double-balloon endoscope [17], 93 to 100% for single-balloon endoscopes [7, 18, 19], and 92% for manually driven spiral overtube-assisted colonoscopy [22]. A meta-analysis that included studies on 667 patients reported that the pooled cecum intubation rate was 97% (95% CI, 95%–99%), with limited heterogeneity between studies [29].

In our study, the median cecal intubation time of 10 minutes and median total procedure time of 30 minutes compare positively with reported cecal intubation times using BAE ranging from 12 to 28 minutes [13, 14, 17, 19, 29] and total procedure times ranging from 45 to 60 minutes [16, 18, 19]. It must be realized that these data are difficult to compare because of a wide range of procedure times reported, different indications and different levels of experience of endoscopists. Until now, there have been no studies in which motorized spiral enteroscopy was compared head-to-head with BAE.

In our study, cecal intubation was clinically relevant, finding significant pathology with therapeutic consequences in the previously inaccessible segments of the colon. Adenomas were removed in 17 of 36 patients (47.2%) and APC was performed in three (8.3%), while two patients had colon carcinoma. All the attempted therapeutic procedures, including removal of polyps up to 25 mm in diameter, were successful.

The spiral overtube appears to stabilize the position of the endoscope during therapeutic interventions in difficult positions. Furthermore, during withdrawal of the endoscope, the soft fins of the spiral overtube seem to straighten the bowel folds, which may facilitate inspection behind flexures and folds.

Although there are no comparative data available between MSE and BAE, MSE may have some advantages over BAE devices by providing a much more stable position for effective therapeutic interventions in the right side of the colon. The working channel (3.2 mm) of the MSE is larger than that of BAE and about 32 cm shorter than with standard BAE, except the short version of the DBE. These features further facilitate performing interventions.

Completion of the colonic investigation endoscopically has the advantage of providing histological diagnosis and endoscopic therapeutic possibilities, as compared with video capsule colonoscopy and radiological methods such as CT or MR colonography.

No severe AEs were reported. Superficial mucosal abrasions were seen during withdrawal of the endoscope without any clinical significance, in accordance with an earlier report [23]. The MSE system, which does not need forceful advancement, may decrease risk of complications, especially perforations, compared to BAE. However, we have to emphasize that vigilance is required when advancing the MSE in severely affected diverticular areas and all effort should be made to avoid the risk of introducing the endoscope into a large diverticulum. Because of the larger caliber of the spiral overtube and the relative rigidity of the attachment segment, fixed sigmoid segment

with strictures might be a contraindication for MSE if passage of the stricture with the spiral portion is necessary.

Conclusions

Our data indicate that MSC is safe and effective for diagnostic and potentially therapeutic colonoscopy in long and difficult colons. It offers potential advantages for patients and endoscopists in terms of ease and success of intubation of the cecum and terminal ileum and it may facilitate therapeutic interventions.

Limitations of the present study include the low number of patients (because of the proof-of-concept intention) and the nonrandomized, uncontrolled design.

Therefore, larger randomized trials are needed to evaluate the performance of MSE compared to the standard colonoscopy technique or BAE.

In conclusion, MSE appears to be a safe and effective technique to complete a previously incomplete conventional colonoscopy procedure.

Competing interests

The authors declare that they have no conflict of interest.

Clinical trial

ClinicalTrials.gov
NCT04895254

TRIAL REGISTRATION: NCT04895254. Prospective multicenter study at <http://www.clinicaltrials.gov/>

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