

Motorized spiral colonoscopy: a first single-center feasibility trial

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ABSTRACT

Background Cecal intubation rate represents a key procedural quality parameter in diagnostic colonoscopy. However, even experienced investigators report 10% of all colonoscopies to be difficult and intubation of the cecum is sometimes impossible. A recently developed novel motorized spiral endoscope might potentially overcome some limitations of standard colonoscopy by actively pleating the bowel onto the endoscope. The study aim was to evaluate the feasibility and safety of motorized spiral colonoscopy (MSC) for diagnostic colonoscopy.

Methods 30 consecutive patients with an indication for diagnostic colonoscopy were enrolled in a proof-of-concept single-center trial.

Results 13 men and 17 women (mean age 68.9 years, range 30–90) were enrolled; 43.3% had diverticula. Mean procedure time was 20.8 min (range 11.4–55.3). Cecal intubation rate was 96.7%. One incomplete colonoscopy occurred because of an unexpected postinflammatory stricture. Adenoma detection rate was 46.6%. No severe adverse events occurred.

Conclusions Results indicate that MSC is safe and effective for diagnostic colonoscopy. It potentially offers advantages in terms of ease and it may facilitate therapeutic interventions.

Clinical.Trials.gov

NCT03000361

TRIAL REGISTRATION: Prospective Study NCT03000361 at clinicaltrials.gov

Introduction

Quality parameters for colonoscopy have recently been reported. Regarding intraprocedural indicators, a cecal intubation rate of $\geq 90\%$ for all colonoscopies is widely accepted [1–4]; even experienced endoscopists classify up to 10% of colonoscopies as difficult [5,6]. In spiral overtube-assisted endoscopy, a manually rotatable long overtube (Endo Ease) is used with a standard thin flexible enteroscope, and it has been widely used for enteroscopy [7]. Spiral overtube-assisted colonoscopy achieved a cecal intubation rate of 92% in 24 patients in whom

conventional colonoscopy had failed [8]. However, the dedicated overtube is cumbersome to use and requires assistance from a second endoscopist for its appropriate use.

The prototype novel motorized spiral endoscope (NMSE; Olympus Medical, Tokyo, Japan) was introduced for clinical evaluation for antegrade enteroscopy in 2015 [9,10]. The aim of the present trial was to evaluate the feasibility and safety of the novel motorized spiral endoscope for diagnostic colonoscopy.

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► **Table 1** Feasibility and safety of motorized spiral colonoscopy (MSC) for diagnostic colonoscopy: patient inclusion and exclusion criteria.

Inclusion criteria
Screening for colorectal neoplasia
Surveillance after previous endotherapy
Positive results of colorectal cancer screening tests
Non-overt gastrointestinal bleeding
Indeterminate iron deficiency anemia
Chronic diarrhea
Indeterminate large bowel symptoms
Exclusion criteria
Age under 18 years
Known pregnancy
Poor health status (ASA classification ≥ 4)
Contraindication for sedation or standard colonoscopy
Known coagulopathy (INR ≥ 2.0 , platelets < 70 /nl) or anticoagulants other than aspirin
Medical history of chronic inflammatory bowel disease or suspected bowel obstruction
Previously identified colorectal polyps/lesions with indication for endoscopic resection
Prior abdominal surgery of the mid or lower gastrointestinal tract except uncomplicated appendectomy
ASA, American Society of Anesthesiologists; INR, international normalized ratio

Methods

A total of 30 consecutive patients with an indication for diagnostic colonoscopy who met the inclusion criteria (► **Table 1**) were enrolled in this prospective proof-of-concept single-center trial (NCT03000361 at clinicaltrials.gov). The primary outcome was whether a cecal intubation rate of 90% or higher was achieved. Secondary outcomes were terminal ileum intubation rate, procedure time, need for external compression, adenoma detection rate (ADR), success rate for removal of polyps, amount of propofol needed for sedation, sedation level and pain score, patient satisfaction score, and adverse events. Patients were recruited from our tertiary referral center.

Study device (novel motorized spiral endoscope [NMSE])

The study device consists of three main component subsystems (► **Fig. 1**):

1. a reusable endoscope with an integrated motor for rotating a short spiral overtube component that is mounted on a rotation coupler located in the middle of the insertion tube;
2. a motor control unit, with foot pedals and a visual force gauge; and

3. a disposable short spiral overtube, that is, a length of tubing of approximately 18 mm in diameter with an atraumatic plastic spiral, 31 mm in diameter, bonded to its exterior.

The study device relies on rotation of the spiral component to “pleat” or “unpleat” the bowel either on or off the insertion tube as the spiral thread rotates in a clockwise or counterclockwise direction, respectively (► **Video 1**). A visual force gauge provides the operator with a visual indication of the direction of rotation and the size of the rotation force throughout the examination.

Endoscopy procedure

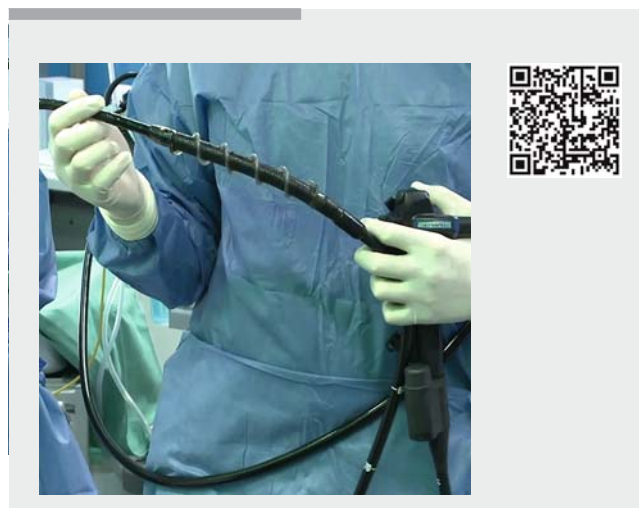
All motorized spiral colonoscopies (MSCs) were performed by two experienced endoscopists (H.N., T.B.). The device was inserted in the colon and advanced with the assistance of motorized clockwise spiral rotation (► **Fig. 2**). Carbon dioxide insufflation was used in all colonoscopies. After reaching and crossing the ileocecal valve, the endoscope was withdrawn using motorized counterclockwise spiral rotation. Tissue sampling and/or treatments were performed during withdrawal as clinically appropriate (► **Fig. 3**, ► **Video 2**).

Statistics

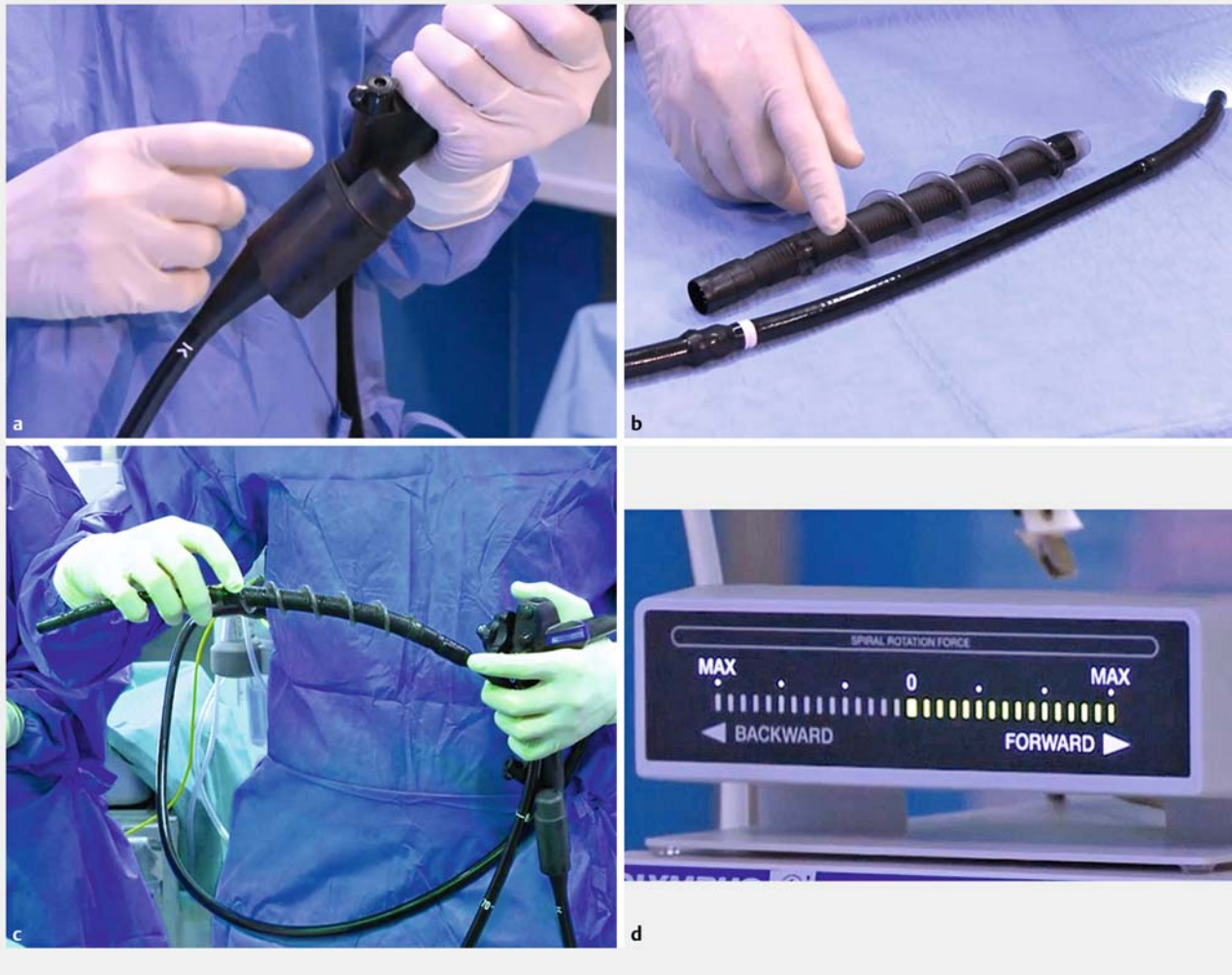
Descriptive statistical methods were used to analyze the data. Data are expressed as mean (range).

Results

Between December 2016 and January 2017, 30 patients were enrolled (13 men, 17 women; mean age 68.9 years, range 30–90) (► **Table 2**). The distribution of health status according to



► **Video 1** Short flexible spiral overtube connected to the rotation coupler of the novel motorized spiral endoscope (NMSE). Rotation is activated with a foot pedal switch in clockwise (0:04 min) and (not shown) counterclockwise direction. When the device is held in the hand outside the patient, the spiral rotation moves the endoscope forward. Online content viewable at: <https://doi.org/10.1055/s-0043-123577>



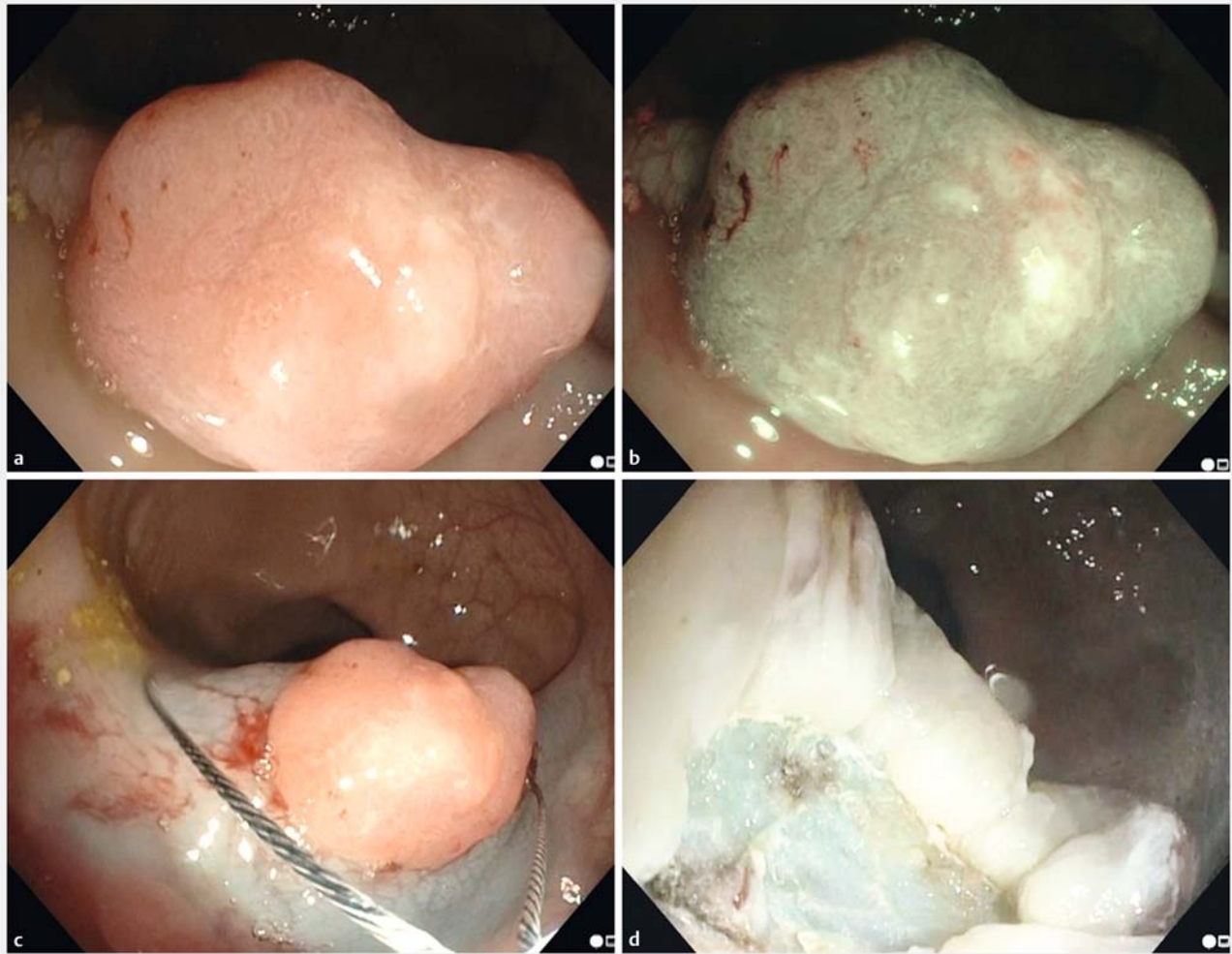
► **Fig. 1** The novel motorized spiral endoscope (Olympus Medical Systems Corporation, Tokyo, Japan). **a** The integrated electric motor. **b** The flexible short spiral overtube with soft fins is attached to the rotation coupler of the endoscope. **c** The novel endoscope (163 cm working length, 11.3 mm diameter at the distal tip, 3.2 mm caliber accessory channel) is ready for colonoscopy. **d** The spiral rotation force is continuously measured by the system and monitored on a display. When resistance exceeds a certain threshold, the system automatically stops the spiral rotation.



► **Fig. 2** View of the flexible spiral overtube in a retroflexed position in the cecum.

American Society of Anesthesiologists (ASA) classification was: ASA 1, 16.7%; ASA 2, 36.7%; and ASA 3, 46.6%. Among the patients 63.3% had undergone prior colonoscopy, at our institution (40%) or elsewhere (23.3%). Diverticula were present in 13/30 patients (43.3%); in 10/13 (76.9%) patients they were restricted to the sigmoid. In 6/30 patients (20%), diverticula were considered, at least initially, to be lumen-narrowing. The sedation level in all patients was 3 (deep sedation according to European Society of Gastrointestinal Endoscopy guideline levels 1–3 [11]). The mean amount of propofol used was 305 mg (130–880); in 7 patients midazolam (3–5 mg) was additionally used.

The cecal intubation rate was 96.7% (29/30) (► **Table 3**). One incomplete colonoscopy occurred because of an unexpected postinflammatory stricture of the sigmoid that could not be passed with the spiral part of the colonoscope. The terminal ileum was intubated in all successful colonoscopies. The mean total time for insertion to the cecum was 7.1 minutes (2.4–18.8), with mean time to left flexure 2.8 minutes, then to right



► **Fig. 3** The novel spiral endoscope is equipped with high definition white light imaging and narrow band imaging (NBI) and is compatible with the latest generation of standard endoscopy systems. The spiral technology stabilizes the position within the bowel and therefore simplifies therapeutic interventions. **a** High definition white light image of a suspicious sessile polyp of the colon seen during motorized spiral colonoscopy (MSC). **b** NBI image. **c, d** En bloc endoscopic mucosal resection was performed during MSC. Histopathology confirmed R0 resection of a sub-mucosal invasive adenocarcinoma.

flexure 2.5 minutes, then to cecum 1.8 minutes; and the mean total time for insertion to the ileum was 10.1 minutes (2.6–26.8). The mean withdrawal time was 11.9 minutes; the minimum withdrawal time was 6.1 minutes. The mean total procedure duration was 22.3 minutes (10.5–55.4). External compression was needed in only 1 case. Ease of use had a mean rating of 1.3 on a scale of 1 (easy) to 5 (hard).

Adenoma detection rate was 46.7%, and the mean number of polyps detected was 2.4 (0–4) with a mean maximum diameter of 10.2 mm (4–25). Endoscopic mucosal resection (EMR) was successfully performed in 9/9 cases, and 5/5 patients had successful forceps polypectomy. All other therapeutic interventions were also conducted successfully (clipping $n=3$; argon plasma coagulation [APC] $n=1$; tissue sampling $n=2$).

Two mild adverse events were recorded (mild superficial mucosal lesions without clinical symptoms). In one patient a first diagnosis of ulcerating Crohn's disease of the colon was es-

tablished and MSC was safely performed. No severe adverse events occurred. The patients' mean overall satisfaction score was 9.6 on a scale of 10 (very satisfied) to 1 (not satisfied at all), and the patients' mean pain score was 1 on a scale of 1 (no pain) to 10 (worst imaginable pain).

Discussion

Quality guideline recommendations by the European Society of Gastrointestinal Endoscopy (ESGE) and the American Society for Gastrointestinal Endoscopy and the American College of Gastroenterology (ASGE/ACG) demand cecal intubation rates of more than 90% and even 95% for screening colonoscopies [1, 2, 12]. In this trial, we found a cecal intubation rate of 96.7%, indicating a high effectiveness of MSC in terms of completeness of examination. However, these results must be interpreted with caution because of the nonrandomized design with a small sample size.

▶ Table 2 Patient data in study of the feasibility and safety of motorized spiral colonoscopy.

Patients (Dec 2016–Jan 2017), n	30
▪ Men	13
▪ Women	17
Age, mean (range), years	68.9 (30–90)
Health status (ASA classification)	
▪ ASA 1	16.7%
▪ ASA 2	36.7%
▪ ASA 3	46.6%
Indication for colonoscopy	
▪ Iron-deficiency anemia	5
▪ Lower gastrointestinal bleeding	6
▪ Surveillance after polypectomy	6
▪ Screening	11
▪ Other	2
ASA, American Society of Anesthesiologists	

All the MSC colonoscopies were performed at a highly specialized endoscopic center.

Among the patients, 43% (13/30) had colonic diverticula and 46.6% were suffering from severe co-morbidities (ASA 3). In our study population 20% (6/30) of the patients had severe diverticulosis (6/13 or 46.2% of all patients with diverticula), with at least initial narrowing of the lumen. In only one of these patients was passage through an unexpected postinflammatory stricture of the sigmoid colon not possible.

The cecal intubation time does not seem to be shorter compared to standard colonoscopy. This is probably because the motorized colonoscope can probably not be rapidly pushed forward as can be done in easy cases of standard colonoscopy. In our feasibility trial, the rotation function was continuously activated during insertion to avoid pushing and to facilitate pleating parts of the large bowel onto the shaft of the endoscope. This technique may prolong the procedural duration but could minimize loop formations.

Adenoma detection rate (ADR) was 46.6% in the present trial. This is not inferior to ADRs that have been published in prospective randomized trials for full-spectrum endoscopy (43.6%) [13] and colonoscopy with additional retroflexion in the right colon (47%) [14]. During withdrawal of the endoscope the soft fins of the spiral overtube were used to straighten the bowel for inspection behind flexures and folds, similarly to other, commercially available attachable dedicated devices or balloon-assisted dedicated endoscopes. Quality guideline recommendations demand an overall ADR of >25%. Although ADR was not the primary outcome of the present trial and patients with increased risk for colorectal polyps (i.e. undergoing surveillance after polypectomy) were included, these findings

▶ Table 3 Procedural data in study of the feasibility and safety of motorized spiral colonoscopy.

Cecal intubation rate, % (n/n)	96.7% (29/30) ¹
Time to cecum, mean (range), minutes	7.1 (2.4–18.8)
Ileum intubation rate % (n/n)	96.7% (29/30)
Time to ileum, mean (range), minutes	10.1 (2.6–26.8)
Withdrawal time, mean (range), minutes	11.9 (6.1–23.5)
Total procedure time, mean (range), minutes	20.8 (11.4–55.3)
Patients with diverticula, % (n/n)	43.3% (13/30)
▪ Patients with diverticula outside the sigmoid colon	23.1% (3/13)
▪ Patients with severe diverticulosis/narrowing of lumen	20% (6/30)
External compression during insertion, % (n/n)	3.3% (1/30)
Adenoma detection rate, % (n/n)	46.7% (14/30)
Total polyps per patient, mean (range), n	2.4 (0–4)
Interventions, n	
▪ Endoscopic mucosal resection (EMR)	9
▪ Forceps polypectomy	5
▪ Others	6
Adverse events ² (asymptomatic mild superficial mucosal lesion), % (n/n)	6.7% (2/30)
Severe adverse events	0

¹ Technical success rate: incomplete in 1 patient with diverticula and unexpected postinflammatory stenosis of sigmoid colon.

² Only in two patients; superficial mucosal lesions occurred without clinical symptoms and were classified as mild, anticipated adverse events. No severe adverse events occurred.

indicate a high potential performance of MSC in terms of detection of neoplastic lesions.

In the present trial, all the attempted therapeutic procedures including endoscopic mucosal resections of polyps up to 25 mm in diameter were successfully performed. The spiral overtube seems to stabilize the position of the endoscope during therapeutic interventions in difficult positions.

All the procedures were performed with patients in deep sedation (ESGE level 3), as requested by all the patients prior to the procedure. Interpretation of the data in terms of patient comfort is therefore limited. However patients rated overall satisfaction at a high mean level of 9.6 (scale 1 to 10, 10 representing “very satisfied”).

The main concern regarding the use of standard long overtubes for colonoscopy is an anticipated higher perforation rate [15] due to the stiffness of the rigid overtube. The novel MSC system utilizes a short overtube, with the main purpose of facilitating advancement of the scope without pushing and thus eliminating the abovementioned anticipated risk. In contrast it has to be emphasized that extended pushing of the scope has to be avoided during MSC. In this trial, no severe adverse events



Video 2 Insertion of the novel motorized spiral endoscope with active rotation of the spiral in the forward direction (0:00 min). Easy passage through sigmoid colon and splenic/hepatic flexure (0:17 min) to the cecum (0:50 min). Retroflexion in the cecum shows the rotating spiral overtube (1:00 min). Easy deep intubation of ileocecal valve to the ileum (1:06 min). During withdrawal folds of the bowel can be straightened by gently pulling the endoscope without spiral rotation and inspection behind the folds is often easier (1:26 min). Detection, characterization, and removal of a suspicious sessile polyp of the colon with en bloc endoscopic mucosal resection is shown (1:38 min). The novel spiral endoscope is equipped with high definition white light imaging and narrow band imaging. Spiral technology stabilizes the position within the bowel and therefore simplifies therapeutic interventions. Histopathology confirmed R0 resection of a submucosal invasive adenocarcinoma.
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<https://doi.org/10.1055/s-0043-123577>

were recorded. In two patients, superficial mucosal lesions were seen during endoscopy without any clinical symptoms. These lesions were anticipated and were most probably attributable to spiral rotation. However, comparable lesions are also seen in standard colonoscopy procedures. Thus, there is no indication that MSC has a higher risk of mucosal injury or bleeding than the standard technique. Because of the larger caliber of the spiral overtube compared to standard colonoscopes, anticipated strictures might be a contraindication for MSC if passage of the stricture with the spiral portion is necessary.

This study represents the first clinical evaluation of a motorized spiral-assisted endoscope for examination of the colon. Our data indicate that MSC is safe and effective for diagnostic colonoscopy. It potentially offers 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 and the nonrandomized uncontrolled design. Therefore, larger randomized trials are now needed to

evaluate the performance of MSC compared to the standard colonoscopy technique.

Competing interests

Authors H. Neuhaus and T. Beyna received consultancy honoraria from Olympus Medical Systems Corporation. Authors M. Schneider, J. Kandler, D. Pullman, and C. Gerges have no competing interests.

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