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Magnetic flexible endoscope for colonoscopy: an initial learning curve analysis

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Authors

Alexander P. Mamunes[1], Federico Campisano[2], James Martin[3], Bruno Scaglioni[3], Evangelos Mazomenos[3], Pietro Valdastri[3], Keith L. Obstein[4,2]

Institutions

1 Division of Internal Medicine, Vanderbilt University Medical Center, Nashville, Tennessee, United States
2 Mechanical Engineering Department, Vanderbilt University, Nashville, Tennessee, United States
3 STORM Lab UK, School of Electronic and Electrical Engineering, University of Leeds, Leeds, UK
4 Division of Gastroenterology, Vanderbilt University Medical Center, Nashville, Tennessee, United States

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70469 Stuttgart, Germany

Corresponding author

Keith L. Obstein, MD, MPH, FASGE, FACG, AGAF, Vanderbilt University Medical Center, Division of Gastroenterology, 1301 Medical Center Drive, TVC 1660, Nashville, TN 37232, USA
Fax: +1-615-343-8174
keith.obstein@vumc.org

ABSTRACT

Background and study aims Colonoscopy is a technically challenging procedure that requires extensive training to minimize discomfort and avoid trauma due to its drive mechanism. Our academic team developed a magnetic flexible endoscope (MFE) actuated by magnetic coupling under supervisory robotic control to enable a front-pull maneuvering mechanism, with a motion controller user interface, to minimize colon wall stress and potentially reduce the learning curve. We aimed to evaluate this learning curve and understand the user experience.

Methods Five novices (no endoscopy experience), five experienced endoscopists, and five experienced MFE users each performed 40 trials on a model colon using 1:1 block randomization between a pediatric colonoscope (PCF) and the MFE. Cecal intubation (CI) success, time to cecum, and user experience (NASA task load index) were measured. Learning curves were determined by the number of trials needed to reach minimum and average proficiency—defined as the slowest average CI time by an experienced user and the average CI time by all experienced users, respectively.

Results MFE minimum proficiency was achieved by all five novices (median 3.92 trials) and five experienced endoscopists (median 2.65 trials). MFE average proficiency was achieved by four novices (median 14.21 trials) and four experienced endoscopists (median 7.00 trials). PCF minimum and average proficiency levels were achieved by only one novice. Novices' perceived workload with the MFE significantly improved after obtaining minimum proficiency.

Conclusions The MFE has a short learning curve for users with no prior experience—requiring relatively few attempts to reach proficiency and at a reduced perceived workload.

Introduction

Colonoscopy is widely performed for direct visualization and therapeutic intervention in the colon. It comprises the primary or follow-up modality of all screening/surveillance programs for colorectal cancer (CRC) – the third most common cancer diagnosis and second leading cause of cancer death in the United States [1]. Both detection of early-stage CRC and removal of adenomatous polyps during colonoscopy have been shown to reduce CRC mortality [2]. Additional indications for colonoscopy include post-cancer resection surveillance; diagnosis, staging, and surveillance of inflammatory bowel disease (IBD); and evaluation of suspected lower gastrointestinal tract bleeding [3].

While colonoscopy is relatively safe, there are several limitations due to the unintuitive drive mechanism and mechanical design of the endoscope. Conventional colonoscopes are actuated by manipulation of large wheels attached to Bowden cables that traverse a long, semi-rigid insertion tube. As such, a minimum of 275 procedures is recommended to even assess competency – with many studies suggesting that over 500 colonoscopies may be needed to achieve a cecal intubation (CI) rate of at least 90% [4,5]. Even among experienced endoscopists there is well-recognized variability. This includes a risk for adverse events, which in large population studies occur at a rate of approximately 0.1%, sedation-related events, patient discomfort due to looping, and an extended learning curve to perform high-quality exams [6–10].

To overcome these limitations, endoscopy as currently practiced would require a dramatic transformation in both design of the endoscope and technique used for colon exploration/endoscopic actuation. Our team has developed a novel, highly compliant, magnetic flexible endoscope (MFE) with the functionality of a conventional colonoscope (i.e. camera, therapeutic channel, irrigation, insufflation, illumination, lens cleaning) [11]. The MFE is driven by magnetic coupling of the endoscope head that contains an internal permanent magnet and a robotic arm that holds an external permanent magnet. This enables a "front-pull" actuation mechanism to eliminate the need for pushing a semi-rigid insertion tube for advancement. The forward drive mechanism thus prevents buckling of the insertion tube and avoids looping/colon wall stress. This potentially reduces the risk of perforation and pain during the procedure to allow for less (if any) procedural sedation. Manipulation of the external actuating permanent magnet (APM) attached to the robot's end effector is performed in closed-loop control by the endoscopist using a simple handheld controller. Previous studies have demonstrated successful closed-loop magnetic control with autonomous completion of endoscopic maneuvers including retroflexion [11]. With a more intuitive control mechanism, the MFE could substantially shorten the learning curve associated with conventional colonoscopy and potentially facilitate quicker achievement of technical competency. We aimed to evaluate the learning curve associated with the MFE and understand the user experience as it relates to the drive mechanism for advancement in the colon.

Methods

Platform

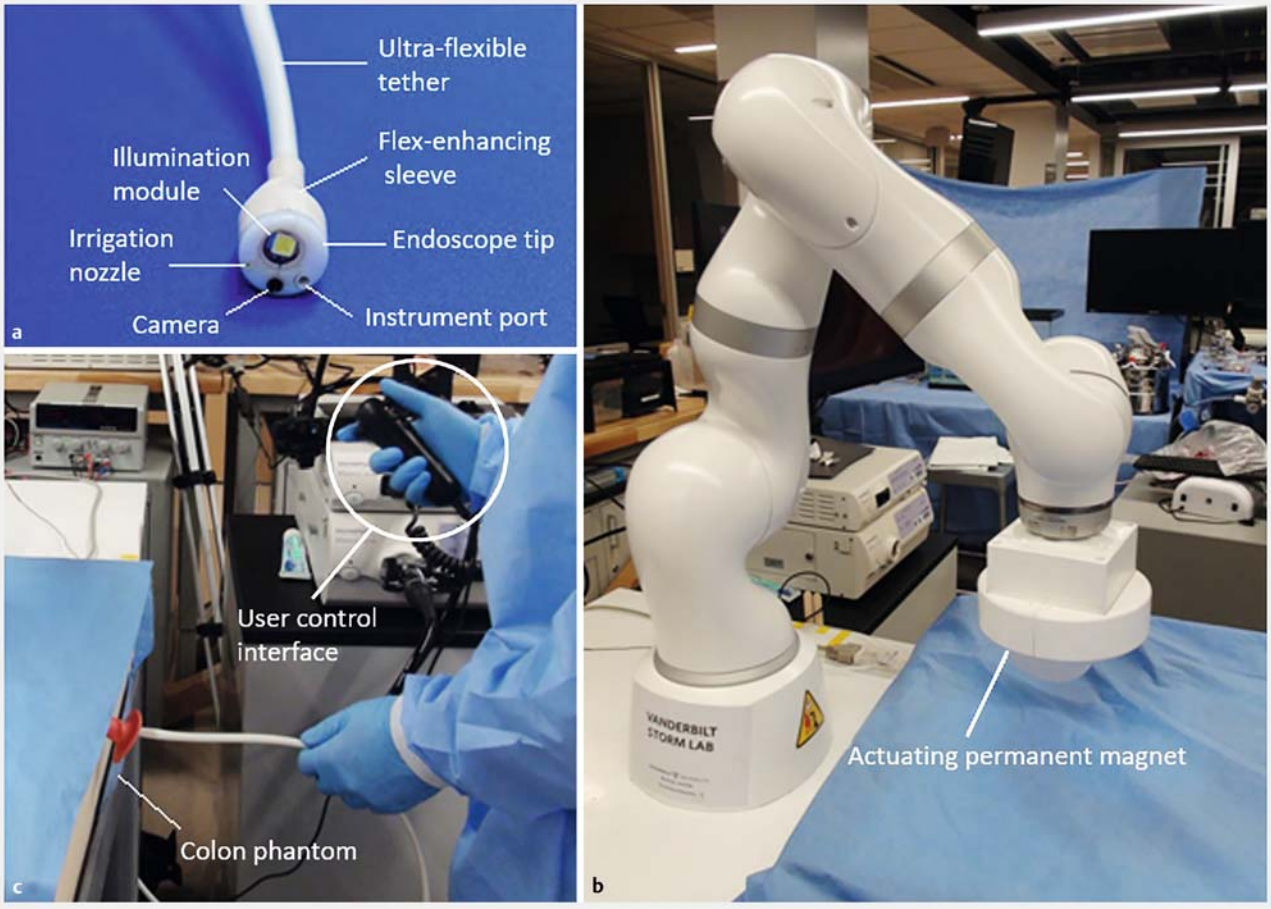
The MFE platform is composed of two main components: (1) a flexible endoscope with a permanent magnet embedded at the tip and (2) a 7 degree-of-freedom (DoF) robotic arm equipped with an APM that stands external to the patient (▶ **Fig. 1**). The endoscope's tip has a 20.6-mm diameter and 18.1-mm length and contains an embedded permanent magnet along with localization sensors (▶ **Fig. 1a**) [12]. The tip also houses a high-definition camera and light source for illumination. A flexible sleeve joins the tip to a 6.5-mm diameter highly compliant tether that contains wiring, a therapeutic channel, and an irrigation channel to allow irrigation, suction, lens cleansing, and insufflation (▶ **Fig. 1c**) [11]. The MFE tip is manipulated by magnetic coupling between the APM (attached to a 7 DoF ISO-certified collaborative robot (Kuka LBR-iiwa-med14-R820, Augsburg, Germany) and the permanent magnet located within the endoscope's tip (▶ **Fig. 1b**). Proprioceptive sensing and software algorithms facilitate various control modes for teleoperation of the endoscope, using both autonomous and transparent control of the robot. This study used a closed-loop mode, allowing users to direct the motion of the endoscope's tip in the reference frame of the visualized endoscopic image stream via a control interface without having to decide where or how to move the robotic arm to generate the desired tip motion (i.e. similar to driving a car, where the steering wheel and accelerator change direction and advance the vehicle, respectively, based on the driver's visual input). A commercially available single-handed PlayStation Move Navigation Controller (Sony Inc., Tokyo, Japan) was adopted as the user control interface (▶ **Fig. 1c**) due to its ease of use and implementation. The left and right and up and down movement of the front joystick communicated turning of the endoscopic tip along the horizontal axis and vertical axis of the visualized frame, respectively; pressing the trigger key communicated forward movement of the tip (both actions facilitated by moving the robot along one or more of its DoF) (▶ **Video 1**). The controller can be held in either hand while the user's other hand passively feeds the tether into the colon (to overcome friction – not to advance the tip) as the tip is actively advanced by magnetic dragging.

Study model and Set-up

A human-based colon phantom (Kyoto Kaguku, Kyoto, Japan) was placed in standard configuration in a non-magnetic frame in the supine position (▶ **Fig. 2**). The phantom was covered with an opaque sheet to prevent participants from visualizing the location of the endoscope within the phantom. A pediatric colonoscope (Olympus PCF-H180AL, Tokyo, Japan) with an Olympus Evis Exera II light source (CLV-180) and video processor (CV-180) (Tokyo, Japan) was used as the conventional colonoscope. The video feed from the MFE and pediatric colonoscope (PCF) were connected to the same external monitor located above the phantom to display the appropriate single feed when in use (▶ **Fig. 3**).

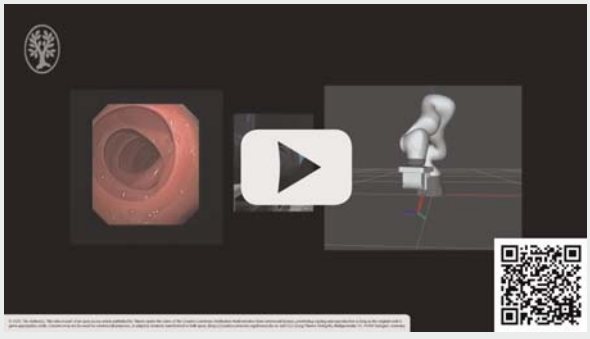
Study design

Fifteen participants were enrolled in the study (5 endoscopists [second- and third-year Gastroenterology fellows with >300 lifetime conventional colonoscopies], 5 endoscopy novices [PGY1–3 Internal Medicine residents who had never held an endoscope], and 5 MFE experienced users [individuals with pre-existing knowledge of the MFE, either through designing the system/platform or testing the device with a minimum of 40 cases using the MFE prior to the study]). Each participant was asked to perform a colonoscopy on the colon phantom 40 times. The device used for each trial (MFE or PCF) was randomly selected using 1:1 block randomization in groups of four with 10 sets being performed per participant. This yielded, per participant, 20 trials with each endoscope. Informed consent was



▶ **Fig. 1** The novel magnetic flexible endoscope (MFE). **a** Close-up view of the tip. **b** Actuating permanent magnet (APM) attached to a 7 degree-of-freedom (DoF) ISO-certified collaborative robot. **c** Flexible endoscope inside the colon phantom and handheld user control interface.

VIDEO

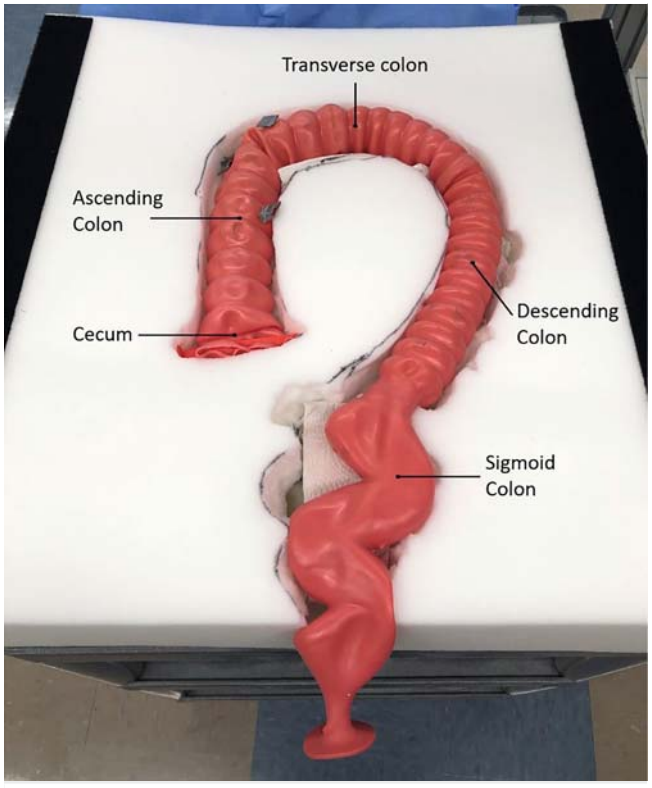


▶ **Video 1** Operation of MFE. Manipulation of the handheld controller (central panel) actuates the robotic arm to move along one or more of its degrees of freedom (right panel) facilitating movement of the endoscopes tip (camera view) within the lumen of the colon phantom (left panel).

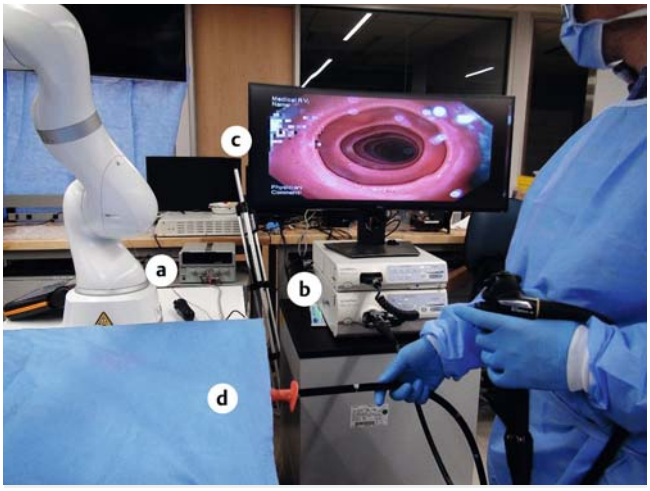
obtained from each participant and the study was approved by the local institutional review board (IRB approval #120102).

Prior to starting, each participant was read a standard script that outlined the trial and described operation of both endoscopes (**Appendix A**). A brief (<60-second) demonstration was performed by the study team using each endoscope in the colon phantom. Each participant was then given 1 minute to ask questions about the operation of each device. Participants were not permitted to hold or practice using either endoscope during this time.

The order of the trial within each block of four (two with the MFE and two with the PCF) was determined by selecting a checker randomly. At the beginning of each trial, the selected endoscope was placed at the rectosigmoid junction in the phantom with the camera pointing directly toward the lumen. This ensured the start position was the same for all users and prevented the endoscope from unintentionally falling out of the model. A timer was started at the beginning of the trial and stopped when the cecum was reached. During the trial, participants could ask questions about the operation of the endoscope and were provided general advice by the study team (restricted to the scope of the study script).



▶ **Fig. 2** The human-based colon phantom.



▶ **Fig. 3** Trial set-up. **a** MFE light source/processor. **b** Pediatric colonoscope video processor and light source. **c** Shared external monitor. **d** Colon phantom with endoscope inserted.

Following each trial, participants completed the NASA Task Load Index (TLX) – a validated task assessment tool to quantify the perceived workload (Ames Research Center, Mountain View, CA) [13]. The NASA TLX is composed of six scales: mental demand (how mentally demanding the task was), physical demand (how physically demanding the task was), temporal demand (how hurried the task was), performance (how successful one was in accomplishing the task), effort (how hard one had to work to accomplish one's level of performance), and frustration (how irritated, stressed, or annoyed one was during the task). Participants score each subscale from 0 (very low) to 100 (very high) with the exception of performance that ranges from 0 (perfect) to 100 (failure) [14].

Study outcome and statistical analysis

Outcome measures of this study were successful CI, time to CI, and user experience (NASA TLX). To establish a learning curve, the minimum proficiency level and average proficiency level were determined for each device based on time to CI within the corresponding experienced group. For the MFE, the minimum proficiency level was calculated as the average CI time of all MFE trials of the MFE-experienced user with the slowest time average. The average proficiency level was established as the average CI time of all MFE trials of all MFE-experienced users. The same calculations were performed for the PCF with the minimal proficiency level calculated from the experienced endoscopist with the slowest average CI time using the PCF and the average proficiency level calculated from the average CI time of all experienced endoscopists using the PCF.

The learning curve for each platform was determined by the number of trials needed to reach the calculated minimum and average proficiency levels. For the MFE, this was calculated for both the novice and experienced endoscopist participants (as they had no prior experience with the MFE). For each of these participants, the MFE CI time was plotted against the MFE trial number and fitted with a logarithmic curve. The trial number needed to reach minimum and average proficiency were found by substituting those respective times into the equation for each participant. If more than 20 trials were needed (the total number of actual trials performed by participants during the study), that participant was deemed not to reach that level of proficiency. The same calculations were performed with the PCF for the novice group (the MFE-experienced user group was not included as two participants also were experienced endoscopy users).

NASA TLX scores for MFE trials in the novice and experienced endoscopist groups were averaged for the trials before and after minimum proficiency was reached. For the MFE experienced user group, NASA TLX scores for all MFE trials were averaged. Similarly, NASA TLX scores for PCF trials in the novice group were averaged for the trials before and after minimum proficiency was reached. For the experienced endoscopist group, NASA TLX scores for all PCF trials were averaged. To detect differences in average NASA TLX subscale scores, a paired *t*-test was used. All calculations assumed the probability of a type I error to be 5 %.

Results

Five experienced endoscopists (>300 lifetime colonoscopies), five novices (no endoscopy experience), and five experienced MFE users (two with >300 lifetime colonoscopies; three with no endoscopy experience) completed the study. Six of the participants were female (40 %) and one of the participants was left-hand dominant (7 %) (▶ **Table 1**).

▶ **Table 1** Participants in the study.

Participants	Age (years) (x ± SD)	Women n (%)	Left-hand dominance n (%)	>300 lifetime colonoscopies n (%)
Novices (n = 5)	28 ± 1.2	3 (60)	0 (0)	0 (0)
Experienced endoscopists (n = 5)	31 ± 1.5	3 (60)	1 (20)	5 (100)
Experienced MFE users (n = 5)	32 ± 4.2	0 (0)	0 (0)	2 (40)
All combined (n = 15)	30 ± 3.4	6 (40)	1 (7)	7 (47)

MFE, magnetic flexible endoscope.

▶ **Table 2** Cecal intubation success and time.

Participants	MFE trials (n = 300)		PCF trials (n = 300)	
	CI success n (%)	CI time (s) (x ± SD)	CI success n (%)	CI time (s) (x ± SD)
Novices (n = 5)	88 (88)	121 ± 74	100 (100)	43 ± 17
Experienced endoscopists (n = 5)	85 (85)	101 ± 48	100 (100)	16 ± 7
Experienced MFE users (n = 5)	98 (98)	105 ± 55	100 (100)	26 ± 15
All combined (n = 15)	271 (90)	109 ± 60	300 (100)	28 ± 18

MFE, magnetic flexible endoscope; PCF, pediatric colonoscope; CI, cecal intubation.

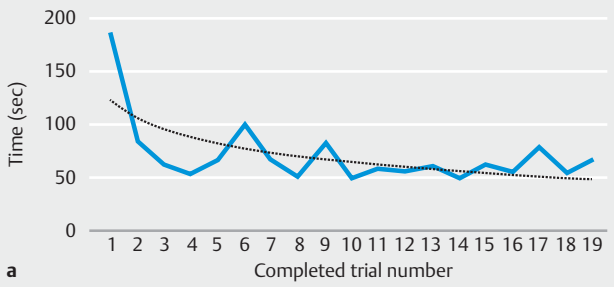
A total of 600 colonoscopies were performed – 300 with the MFE and 300 with the PCF. Novices and experienced endoscopists completed 88 % and 85 % of all trials with the MFE respectively. Experienced MFE users completed 98 % of trials with the MFE. Uncompleted MFE trials were due to loss of magnetic coupling and joint limitations/configuration. All users completed 100 % of trials with the PCF. The mean CI time for all completed MFE trials was 121 ± 74 seconds in the novice group, 101 ± 48 s in the experienced endoscopist group, and 105 ± 55 seconds in the MFE experienced group. The mean CI time for all completed PCF trials was 43 ± 17 seconds in the novice group, 16 ± 7 s in the experienced endoscopist group, and 26 ± 15 seconds in the MFE experienced group (▶ **Table 2**).

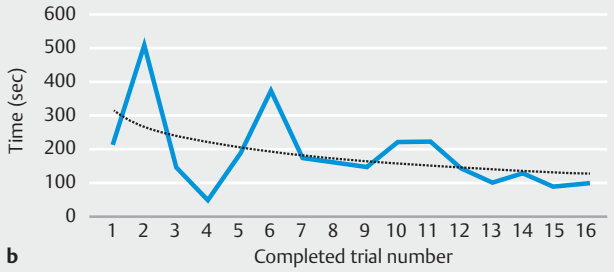
For the MFE, the minimum and average proficiency levels were 151 seconds and 105 seconds, respectively. MFE minimum proficiency was achieved by all five novice users (100 %). The median number of trials needed to reach this level was 3.92. Average proficiency was reached by four novice users (80 %) and the median number of trials needed to reach this level was 14.21 (▶ **Fig. 4**). MFE minimum proficiency was reached by all five experienced endoscopists and the median number of trials needed to reach this level was 2.65. Average proficiency was also reached by all five experienced endoscopists; the median number of trials needed to reach this level was seven (▶ **Fig. 5**).

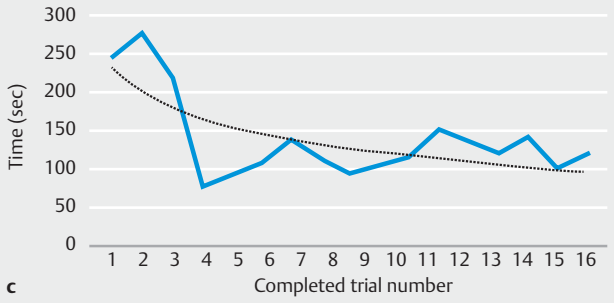
For the PCF, the minimum and average proficiency levels were 21 and 16 seconds, respectively. Both minimum and average proficiency were reached by one of five novice users (20 %) at trial number 12 and trial number 15. With the MFE, in the novice group, perceived workload significantly improved after reaching minimum proficiency (after four completed trials); this included improvement in mental demand (48.3 to 19.6, $P<0.01$), physical demand (17.3 to 6.6, $P<0.01$), temporal demand (34.8 to 14.9, $P<0.01$), perceived effort (40.9 to 17.7, $P<0.01$), frustration (51.8 to 25.8, $P<0.01$), and perceived performance (55.3 to 22.3, $P<0.01$). After reaching minimum proficiency, perceived mental and temporal demand in the novice group were similar to that of experienced MFE users (19.6 vs 17.2; $P=0.32$ and 14.9 vs 16.4; $P=0.45$ respectively) (▶ **Table 3**).

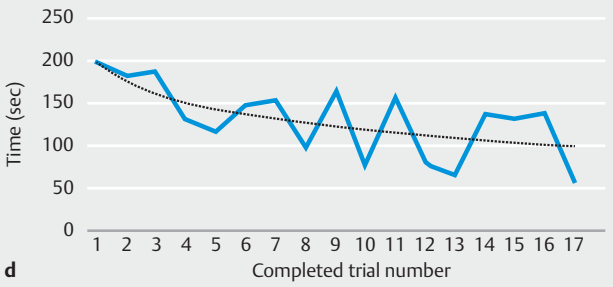
With the MFE, for the experienced endoscopist group, frustration reduced significantly after reaching minimum proficiency (55.7 to 37.2, $P=0.02$), perceived temporal demand became similar to that of experienced MFE users (19.5 vs 16.4, $P=0.23$), and perceived physical demand became lower with the MFE (9.4 vs 13.6, $P=0.02$) (▶ **Table 3**).

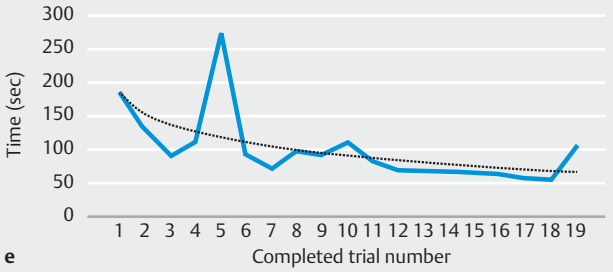
In the novice group, mental demand and frustration were lower with the PCF when compared to the MFE, even after MFE minimum proficiency had been achieved (16.3 vs 25.4; $P<0.01$; 21.0 vs 31.0; $P<0.01$ respectively). Perceived performance was also higher with the PCF (28.9 vs 17.4, $P<0.01$). Perceived physical demand was lower with the MFE when compared to the PCF both before and after MFE minimum proficiency was achieved (8.7 vs 34.0, $P<0.01$). Perceived effort was similar for the two devices prior to achieving minimum proficiency with the MFE, but became lower thereafter with the MFE (17.7 vs 24, $P=0.01$). Temporal demand was similar between the two platforms (18.9 vs 17.5, $P=0.48$).











Participant	Logarithmic line of best fit	Trials needed to reach min proficiency n	Trials needed to reach avg proficiency n
A. Novice 1	y = 25.22 ln(x) + 122.16	0.32	1.97
B. Novice 2	y = 67.41 ln(x) + 311.67	10.84	21.45
C. Novice 3	y = 48.06 ln(x) + 232.55	5.46	14.21
D. Novice 4	y = 35.24 ln(x) + 199.11	3.92	14.45
E. Novice 5	y = 38.99 ln(x) + 178.57	2.03	6.60

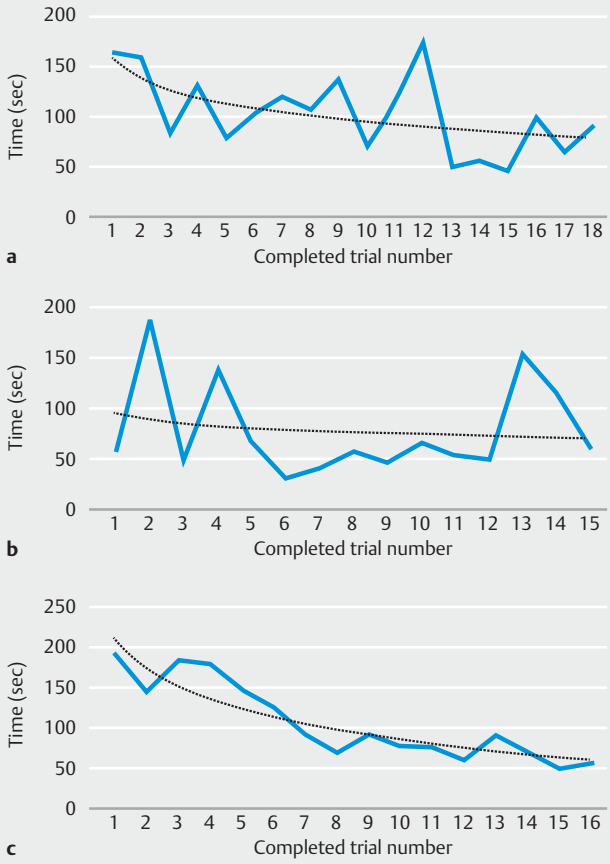
▶ **Fig. 4** MFE time to cecum versus completed trial number for novice participants (logarithmic line of best fit).

Discussion

Users without any prior knowledge or experience with the MFE were able to successfully operate the platform through a human phantom colon to the cecum. The MFE functioned successfully, with 90 % CI success, and demonstrated a short learning curve – with all users new to the MFE reaching a minimum level of proficiency after four completed trials and 80 % achieving average proficiency within the trial set of 20. These results suggest that closed loop operation of the MFE, a system that in the background (un-noticeable to the user) requires complex algorithms and static and time-varying magnetic fields to localize and maneuver in real-time, is intuitive to users.

Achievement of MFE minimum proficiency in the novice group was coupled with significant improvement in mental, physical, and temporal demand, effort, frustration, and performance. Novice MFE users were both faster and found the operation of the platform to be significantly easier after only four trials. While this effect was not seen to the same degree in the experienced endoscopist group, this is likely due to their experience and comfort with the conventional colonoscope – as the MFE has an inherently different drive mechanism (i. e. not advanced by applying force to the insertion tube).

While CI times were significantly faster with the PCF than the MFE for all participants, this was an expected finding given different mechanisms of operation. Conventional colonoscopes, with rear-push mechanical actuation of a semi-rigid insertion tube, allow for immediate maneuvers with simultaneous visual feedback. The relatively uncomplicated tract of the human phantom colon used in this study further facilitates speed via this mechanism. In contrast, the MFE, which uses a highly compliant tether, is directed via a front-pull mechanism and will not advance by pushing. Therefore, the user is required to truly navigate the lumen under direct visualization and subsequent visual feedback based on the action of the external robot. While this inherent feature may lengthen overall procedure time, it more importantly reduces tissue stress delivered by the endoscope – as the tether is passively dragged along the colon. Interestingly, perceived temporal demand with the MFE and PCF were not statistically different in the novice group – suggesting that the procedural time difference may not significantly influence user experience. Furthermore, based on safety analysis and the forthcoming first-in-human trials, we anticipate faster MFE navigation by relaxation of our robotic arm speed constraint.



Participant	Logarithmic line of best fit	Trials needed to reach min proficiency n	Trials needed to reach avg proficiency n
A. EE 1	y = 26.91 ln(x)+157.52	1.27	7.04
B. EE 2	y = 9.036 ln(x)+96.407	0.0024	0.39
C. EE 3	y = 54.59 ln(x)+211.22	3.01	7.00
D. EE 4	y = 36.36 ln(x)+186.74	2.56	9.31
E. EE 5	y = 58.22 ln(x)+217.09	3.11	6.83

▶ **Fig. 5** MFE time to cecum versus completed trial number for experienced endoscopist (EE) participants (logarithmic line of best fit).

▶ **Table 3** NASA TLX data for MFE by group before and after minimum proficiency obtained (mean ± standard deviation).

Subscale	Novices			Experienced endoscopists			Experienced MFE users
	Before minimum proficiency obtained	After minimum proficiency obtained	*P* value	Before minimum proficiency obtained	After minimum proficiency obtained	*P* value	All trials
Mental demand	48.3 ± 28.7	19.6 ± 18.2	< 0.05	37.3 ± 21.1	31.5 ± 22.6	0.34	17.2 ± 14.6
Physical demand	17.3 ± 13.1	6.6 ± 4.4	0.34	14.0 ± 14.0	9.4 ± 9.0	0.24	13.4 ± 13.1
Temporal demand	34.8 ± 14.9	14.9 ± 9.2	< 0.05	30.7 ± 20.3	19.5 ± 19.1	0.06	16.4 ± 16.5
Performance	55.3 ± 31.4	22.3 ± 23.2	< 0.05	50.7 ± 31.6	33.4 ± 27.8	0.06	14.6 ± 17.9
Effort	40.9 ± 28.8	17.7 ± 17.3	< 0.05	44.1 ± 24.4	31.7 ± 22.1	0.08	15.0 ± 11.0
Frustration	51.8 ± 21.5	25.8 ± 19.8	< 0.05	55.7 ± 25.7	37.2 ± 25.5	< 0.05	18.0 ± 18.9

NASA TLX, NASA task load index; MFE, magnetic flexible endoscope.

Perceived physical demand for the MFE was significantly lower in the novice group and in the experienced endoscopist group (after minimum proficiency was obtained). Additionally, effort with the MFE in the novice group became significantly lower than that with the PCF after minimum proficiency was obtained. This can be attributed to the fact that all movements are directed by a simple joystick with essentially no physical force required. Conventional colonoscopes require manipula-

tion of two angulation knobs to move Bowden cables, which can be ergonomically challenging based on the user's hand size and grip position, coupled with active forward advancing and torqueing of the colonoscope's insertion tube to change direction.

While trial data for each participant were assumed to follow a logarithmic curve, used to calculate the trials needed to reach the minimum and average levels of proficiency, this may not be true. Based on data obtained, we considered best-fit options and selected the logarithmic curve as most learning curves follow this model and independently our data fit this model well. By using block randomization, we ensured balanced exposure to each device to prevent bias toward one platform or the other that would potentially be gained through experience in using the colon phantom repetitively. While our calculation for minimum proficiency was based on one user from each experienced group, the CI times for all experienced users for each platform fell within one standard deviation of the average, negating any outlier effect.

As MFE trials were inherently longer in duration, more absolute time was spent using the MFE than the PCF by participants. There were also a small number of MFE trial failures due to occasional technical challenges that yielded reduced overall completion rates. Despite these occurrences, failed CI was a small percentage of the overall trial numbers (10 %) and participants still received exposure time during these attempts to drive the MFE (thus not interrupting the balance of trials in establishing a learning curve). In addition, as these occurrences were evenly distributed across the progression of participants' trials and not solely at the beginning of trials when participants were first learning, the impact on the users' overall learning curve, if any, would be minimal. Lastly, reliability of the platform was not assessed as this is a topic that is beyond the scope and design of the current study; however, based on the results from this study, a formal platform reliability assessment is currently underway.

The study script, intended to explain how each device is handled and maneuvered, was longer for the MFE compared to that for the PCF. We felt the MFE required additional explanation to convey the intended information, given the novelty of the system (i. e. commands sent to the robotic arm that are then reflected in the endoscopic tip) and additional variables added to the user's cognition by not having immediate visual or haptic feedback. Participants could still ask questions regarding either devices' operation that were not restricted to the exact wording of the study script.

We used a human-based colon phantom without loops for this study. The Kyoto phantom box and configuration cut-out with anchors and springs can introduce variability between each trial, as it requires re-setting the model within the anchor and spring system to ensure common configuration after each endoscopy. Variability therefore may easily be introduced between each trail run, even if reset properly. To eliminate this possibility, the Kyoto configuration 1 template was used to create the configuration within a mold. This created the same scenario for both devices, allowing measurement of the initial learning curve to be performed in the most basic ideal environment. Users were still required to perform maneuvers including re-orienting to the lumen, turning, and passing over folds. Studies comparing performance in other colon configurations, including loops, redundancy, and tight angulations will be pursued in future studies to better evaluate clinical utility now that preliminary results are available and demonstrate platform success. Similarly, the current study did not evaluate the ability of users to identify pathology or perform therapeutic intervention, subjects beyond the scope of this basic learning curve study that will be the focus of future investigations.

Conclusion

Our findings show that closed-loop control of the MFE can be used to successfully navigate a human based colon phantom with a very short learning curve. This provides important evidence that the MFE platform has the potential to be integrated into an endoscopist's practice without a lengthy training period to attain technical proficiency. Application of this technology has the potential to significantly impact multiple aspects of colonoscopy including patient safety, patient satisfaction, resource utilization, endoscopist ergonomics/longevity, and endoscopic capability.

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Competing interests

Drs. Valdastri and Obstein have submitted an invention disclosure to Vanderbilt University.

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Appendix A. Study Script

The purpose of this trial is to compare the use of two endoscopic devices to navigate through a model colon and intubate the cecum. You will use both a traditional endoscope and the magnetic flexible endoscope, or MFE. We will describe the operation of both devices prior to beginning the study. You will not be provided with a practice period but will have an optional 1 minute to ask questions for each device.

Trials and set-up

In total you will complete 40 trials of navigating the model colon, 20 with each of the mentioned devices. These will occur in 10 sets of four trials. Within each set you will complete two trials with the traditional endoscope and two trials with the MFE. The order of these four trials will be random. To randomize, you will draw one of four checkers from a concealed container: "black" for the traditional endoscope or "red" for the MFE. Hand the checker to the researcher after choosing.

The scope for each trial will be placed at the entrance of the model colon. With the MFE, a short initiation period is needed to couple the endoscope to the robot and check the system. For each trial, the researcher will say "Go" at which time the trial timer will start and the participant can begin navigating. The goal is to navigate through the colon to reach the cecum. When the participant has visualized cecum (this will be a closed end at the end of the model), the researcher will stop the timer and record. Both devices will be hooked up to the same monitor for each trial for visualization.

Traditional Endoscope: This device is the current tool used to perform gastrointestinal endoscopy. The device is controlled by rotating two dials that articulate motion and the shape of the probing tip. The standard technique involves holding the scope with the left hand and rotating the knobs with the fingers on your left hand. The right-hand drives and steers the cord and probing tip as you navigate the colon (i.e pushing forward, pulling back, twisting cord to advance and change orientation in conjunction with movement of the probing tip via the dials).

MFE: This device functions by coupling the tip of the endoscope magnetically with a robotic arm that moves under the direction of the user and thereby moves the tip with it. It is operated via this controller. It can be held in either hand, but generally is held in the left. It is important to hold it down and away from the robotic arm as it can cause interference. The other hand will hold and advance the tether. You can sit or stand; most users choose to sit. There are two buttons you will use on the controller: the joystick and trigger. There are two operations you perform with the controller. Moving left and right with the joystick will rotate the robot such that it will magnetically shift the camera left and right. You will use this operation to change orientation along the horizontal axis within the colon. The second operation is advancing forward. This is done by holding the trigger and pressing up on the joystick. This causes the robot to move forward, thereby pulling the tip along with it. You will feel it be pulled forward by the magnet during advancing. This may not occur in a smooth motion due to some friction with the colon. The endoscope should not be manually pushed forward like a traditional endoscope. Driving the MFE consists of performing these two operations. When you have lumen visualized in your frame, you can advance forward. You should be orienting in between these advances to maintain visualization of the lumen. After each advance, the robotic arm will have moved forward and then will need to return to the tip to maintain coupling. During this period, you can begin reorienting your tip by using the joystick to rotate the robotic arm. Patience is key during this period as trying to advance while the arm is returning to couple can delay re-coupling even further or cause the arm to extend so much a joint limit is reached. Also note that feedback, unlike with a traditional scope, is not immediate while re-orienting as it needs to occur through the robotic arm. You will primarily be looking at the endoscopy monitor, but can look at the robot during these periods to watch as re-coupling and a change in orientation is occurring. Tapping the joystick in the intended direction, instead of holding it, may be a more effective way to re-orient while the robot is re-coupling with the tip (again, you will be able to see if this is happening by visualizing the robot turning.) It is also crucial that you feed extra cord with your free hand into the colon as the endoscope advances to allow it to continue to move. You should maintain an equal amount of tether throughout, meaning with each movement forward you feed about an equal amount of cord with it. You may also need to jiggle the cord to reduce friction. Getting stuck- when this occurs, this is generally for one of two reasons. It may be the capsule is physically stuck against the model wall due to friction. This prevents reorientation. You will see the robot trying to turn but the camera not moving with it. In this scenario it is recommended to pull the tip back a short distance. You should start reorienting as the arm begins to re-couple. The other reason is that the robot occasionally is in a position where it cannot calculate the correct solution to make the intended reorientation and therefore will not turn despite you holding the joystick. You can see this happening by looking at the robot and seeing it not rotate. The solution again is to pull back a short distance and then attempt re-orientating.

NASA TLX: After each trial you will complete a NASA TLX form which quantifies your perceived mental workload with the given device during each trial. The description of each component is provided on the form (please note that all scales go from "Very Low" on the left to "Very High" on the right except for the "Performance" question, in which "Perfect" is on the left and "Failure" is on the right.) Each scale ranges from 0–100. Please mark a vertical line on each scale to indicate your score. You are not required to make your mark directly on one of the vertical incremental lines.