PROTOCOL TITLE:
Visualization of the colon through use of the Magnetic Flexible Endoscope (MFE) in healthy participants

NCT05833789

Protocol Version Date: December 16, 2022

3. PROTOCOL

3.1 Study Protocol

3.1.1 Protocol Overview

Investigational Device: Magnetic Flexible Endoscope

Study Title: Visualization of the colon through use of the Magnetic Flexible Endoscope in healthy participants

Study Design: Early Feasibility Study

Number of Participants: 5

Study Population: Adult healthy patients who are already scheduled for their standard of care colonoscopy screening examination.

Study Duration: Standard colonoscopy examinations for healthy individuals are relatively short duration outpatient procedures lasting on average 20 to 40 minutes in total procedure time and 90 to 180 minutes in total in-facility time. Navigation and inspection of the colon, from rectum to cecum, using the MFE will be a relatively short duration outpatient procedure lasting no more than 40 minutes in total procedure duration. As is standard of care at VUMC, a post-procedure follow-up phone call is then conducted 3-5 days post-procedure.

Schedule: (1) Screening of patients for meeting inclusion criteria; (2) Administration of pre-study survey; (3) Routine colonoscopy examination with a standard colonoscope; (4) Passage of the Magnetic Flexible Endoscope from rectum to cecum; (5) Post-study structured interview and single question survey; (6) Follow-up phone call 3-5 days post examination as per VUMC standard practice for patients who have undergone colonoscopy.

3.0.0 Study Objective

The objective of this early feasibility study is to determine if travel to the cecum from the rectum and visualization of the colon is possible using the Magnetic Flexible Endoscope

(MFE) system.

3.0.1 Study Design

3.0.1.0 Overview

This early feasibility study will be a prospective clinical trial in which 5 patients will be enrolled. All patients will undergo their routine colonoscopy examination using the standard colonoscope, followed by passage of the Magnetic Flexible Endoscope.

3.0.1.1 Study Endpoints

PRIMARY

1. Cecal intubation rate (success/fail)
    a. Successful cecal intubation will be confirmed per standard endoscopic practice of visualizing and photo documenting at least 2 of the 3 common cecal landmarks (ileocecal valve, triradiate fold, appendiceal orifice).

SECONDARY

1. Mucosal visibility
    a. An operator assessed score, the Colon Visualization Index (Appendix A), will be used.
2. Patient tolerance
    a. Pain perception will be assessed with a validated pain score (Wong-Baker FACES Pain Rating Scale; Appendix B). Qualitative assessment of participant sentiment will be assessed with a post-study structured interview (Appendix C).
3. Endoscopist experience
    a. The usability of the platform in terms of task load for the endoscopist will be assessed using the standardized validated NASA Task Load Index (TLX) instrument (Appendix D).

3.0.2 Study Devices

The Magnetic Flexible Endoscope (MFE) is an investigational device that consists of a flexible catheter with a magnet-embedded tip, a permanent magnet external to the patient manipulated by a collaborative medical robot, and a software control system (Figure 7). The MFE maintains functionality of a traditional endoscope (i.e., illumination, viewing, irrigation, suction, lens cleansing, insufflation) and contains proprioceptive sensors that facilitate magnetic interaction. Knowledge of magnetic field properties allows for precise device movement while maintaining visualization as the MFE moves through the colon.

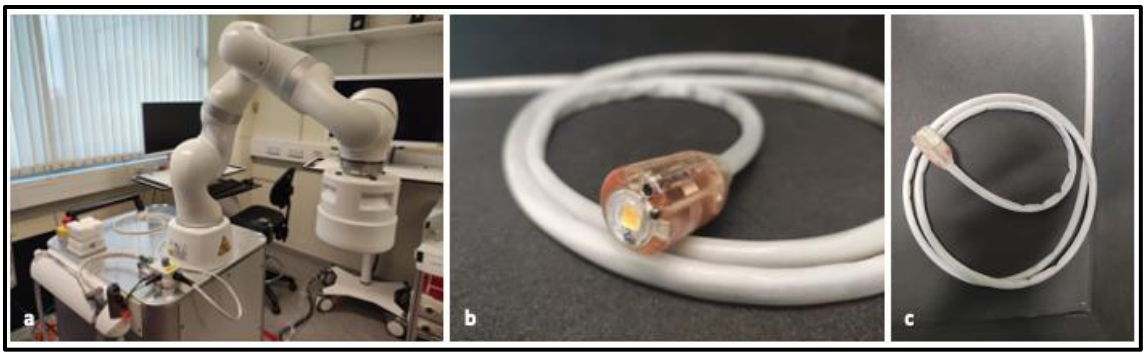

Figure 7. *The MFE platform: (a) human certified collaborative medical robot with permanent magnet attached; (b) magnet-embedded tip with full functionality; (c) ultra-flexible catheter.*

The MFE is a Medical Electrical (ME) system comprising three categories of device: (1) commercially available products (both reusable and single-use/disposable), (2) MFE reusable parts and (3) MFE single-use parts. The following briefly summarizes the plan to manufacture these for clinical use, presented in the three categories mentioned.

(1) Commercially available products

These products include ME devices, non-ME devices and consumables. Each are chosen to integrate with the MFE device in order to perform its intended use. They are sourced and evaluated to ensure they meet the user and functional requirements, including showing conformity to the relevant standards and compatibility with the MFE (assessed via preclinical testing and assessment of the manufacturers' accompanying documentation). Their details are included in the Bill of Materials to maintain traceability. These products are stored securely and used according to the manufacturers' user manuals.

(2) MFE reusable parts

Several parts of the MFE system are designed and manufactured by the STORM Lab UK at the University of Leeds for re-use. Owing to the project scope, the number of these is significantly low (i.e. the robot cart).

These parts are all designed and documented as described in the Design and Development Plan to ensure the quality objectives are met. They are then manufactured within the STORM Lab UK at the University of Leeds using principles of ISO 13485 and the following key elements:

1. The designs are prototyped and tested thoroughly in preclinical testing and this includes evaluation, refinement and approval of the associated manufacturing protocol. The manufacturing protocols are continually developed alongside the prototypes (i.e. device is designed for manufacture and assembly – DFMA).
2. Once the device design and accompanying manufacturing protocol are mature, Process Failure Mode and Effects Analysis (P-FMEA) are used to analyze the manufacturing steps in detail for unacceptable risks and appropriate controls. In this project, the controls take the form of (in increasing strength):
    i. Clear instruction and technical "Tips"

ii. Warnings and Cautions relating to process steps

iii. Mandatory Quality Checks (QCs) in-line with the process steps and summarized in a QC checklist

3. The components specified in the latest approved Bill of Materials are sourced from reputable suppliers and stored securely according to their datasheets.
4. The part is manufactured (largely involving assembly tasks) by a named engineer who is familiar with the technology, according to the approved manufacturing protocol for that part. The QCs are designed to ensure each device is 100% inspected, with focus on high-risk process steps identified in P-FMEA.
5. A QC checklist is filled-in for every device produced, capturing information like the device build, personnel involved and verification that all the QCs were performed.
6. The device is labelled and stored according to the approved Instructions For Use, including in the required packaging and storage conditions. The QC checklist is also securely stored as evidence of compliance to the manufacturing protocol, having a document ID that matches the device UID.

(3) MFE single-use parts

These parts include the main MFE Applied parts: endoscope and endoscope controller. The number of units produced is also limited, but not to the same extent as the re-usable parts. There are approximately 25-50 units of each single-use part planned to be produced during the entire life cycle of MFE version A_01 (MFE-A_01). The parts are all designed and documented as described in the Design and Development Plan.

Owing to their need for greater biological safety consideration and the higher number of units being produced, the manufacture of these is outsourced to MDE s.r.l (a contract manufacturing organization supplier, under contract with the University of Leeds---the legal manufacturer). MDE s.r.l is based in Italy (Via F. Petrarca 165, 25068, Ponte Zanano, Sarezzo (BS), Italy, +39 030-238-2498, VAT: 04023300983) with appropriate experience, facilities, and ISO13485 certification (Appendix E). At a high-level, this ensures reliable, repeatable manufacture.

In brief, the manufacturing process is as follows:

1. Steps 1. – 3. From the previous section are followed.
2. The components are received by MDE s.r.l before being labelled and stored according to their Quality Management System (QMS), including incoming component inspection.
3. The part is manufactured (largely involving assembly tasks) by trained MDE s.r.l technicians - who are familiar with the technology from preclinical development within University of Leeds - and according to the approved manufacturing protocol for that part which they helped co-create to ensure compliance with their QMS and working-level Standard Operating Procedures (SOPs).

- The assembly (and some decontamination) is carried out within an ISO 7 cleanroom.

4. A Certificate of Conformity is supplied with the packaged devices that states, among other things, the device identity (e.g. Unique Identifier (UID) traceable to the approved technical file), that they have been built according to the approved manufacturing protocol within their qualified facilities and that they meet the technical requirements specified by the STORM Lab UK at the University of Leeds, e.g. "high level disinfected (HLD)" decontamination status.
5. MDE s.r.l is then responsible for securely shipping the packaged devices to STORM Lab USA at Vanderbilt University Medical Center according to the Instructions for Use (IFU) (which includes transport considerations).

The received devices are stored in the STORM Lab USA at Vanderbilt University Medical Center according to the IFU until they are required for use in clinical investigation, or until the expiry date on the package label elapses. The IFU includes instruction and warning relating to the visual inspection and physical testing of the device immediately prior to use in the patient.

Single-use device shelf-life:

The endoscope and endoscope controller are manufactured on-demand. This means that once a clinical investigation date is agreed by all required stakeholders, MDE s.r.l will be commissioned to manufacture the required number of devices. These will have labels that include the manufacture date and expiry date. This means that the effects of aging, including material degradation, are negligible; it also reduces the volume of microorganism growth inside the packaging (if any). This is a practical option for the project considering its use exclusively in clinical investigation and said investigations being small (e.g. the first planned trial includes only 5 participants). The worst-case (longest) shelf-life anticipated – and being included as an expiry date – will be 1 year from date of manufacture.

Single-use device decontamination:

We plan to follow the international guidelines for colonoscopy and pursue a "high level disinfected (HLD)" status for the endoscope and endoscope controller. We plan to achieve HLD status within the manufacturing process – managed by MDE s.r.l - and maintain it during storage until use via appropriate device packaging and clear IFU. We believe this is preferable than only decontaminating the devices prior to use (e.g. manual washing) in terms of risk because, in brief, manual washing presents increased risk of incomplete decontamination from human error and/or process inconsistencies, with the added risk of contamination of the device between washing and use.

MDE s.r.l will manage the cleaning and decontamination process according to their QMS and to an extent that they can include the HLD status in the Certificate of Conformity supplied with the devices shipped to the STORM Lab USA at Vanderbilt University Medical Center.

All materials used in the Magnetic Flexible Endoscope have both been confirmed to be biocompatible and have been shown to withstand high level disinfection (HLD) using the processes described above. For all biocompatibility and HLD testing information please refer to Appendix F.

3.0.3 Participant Selection

3.0.3.0 Inclusion Criteria

1. Male or female, 18 to 70 years of age.
2. Able to provide written informed consent.
3. ASA class < 3
4. No significant medical problems
5. Abdominal circumference < 96 cm

3.0.3.1 Exclusion Criteria

1. Patients who do not meet inclusion criteria
2. Patients who are unable or unwilling to provide informed consent
3. Magnetic implants and wearable devices (such as insulin pumps)
4. Females who are pregnant. As part of routine pre-operative care, all females of childbearing potential will undergo either urine or blood pregnancy testing.
5. Cancer positive subjects or any patients currently undergoing any treatment or therapy to treat, cure, or mitigate cancer.
6. Symptoms consistent with coronavirus (COVID-19) --- pyrexia, new persistent cough, or anosmia --- or a positive coronavirus (COVID-19) PCR swab result
7. Previous failed colonoscopy
8. Colonic resection
9. Severe diverticulosis
10. Known or suspected colonic stricture
11. Previous radiation therapy to the abdomen or pelvis
12. Any active inflammatory bowel condition (e.g. active IBD or diverticulitis)
13. Known or suspected bowel obstruction
14. Presence of ascites
15. Participants taking anticoagulant medications or antiplatelet therapy (excluding aspirin) within the last 7 days
16. Known coagulation disorder (INR $\geq$ 1.5 or platelets < 150 x 10^9)
17. Known to have phenylketonuria or G6PD deficiency
18. Abdominal surgery within the last 6 months
19. Drug or alcohol abuse

3.0.4 Study Procedures

3.0.4.0 Screening

Potential subjects will be identified from the list of patients in the Vanderbilt University Medical Center Digestive Disease Center who are scheduled to undergo their standard colonoscopy

screening by members of the VUMC clinical research trained personnel team. Those participants who express interest in taking part in the research study will be asked to sign a written informed consent that has been approved by the Vanderbilt University Medical Center IRB. Participants will have the study explained to them and will be given the opportunity to read and review the consent document and have any questions addressed. Once informed consent is obtained, final eligibility for enrollment into the study will be determined based on the inclusion/exclusion criteria.

Participants will undergo pre-operative and post-operative procedures as per routine standard of care for their VUMC colonoscopic exam. We anticipate enrolling 5 patients to complete the study.

3.0.4.1 Day of Endoscopy

The patient will be administered the Pre-Study Survey (Appendix G) consisting of the RAND 36-Item Short Form Survey, PROMIS Scale v1.0 Gastrointestinal Belly Pain, PROMIS Scale v1.1 Gastrointestinal Gas and Bloating 13a, and PROMIS Scale v2.0 Pain Intensity 3a.

Once the patient has been successfully prepared for the colonoscopy procedure and has been administered monitored anesthesia care (MAC) by the VUMC Anesthesia team as per routine care, the following steps will be followed.

Note: only step "B)" below deviates from the current standard clinical practice for colonoscopic examination of healthy patients. Step "B)" is when the investigational Non-Significant Risk (NSR) device is used and the only step that is not usually performed during colonoscopic examinations.

A) *Colonoscopic assessment using a standard colonoscope.* This assessment is the first step in the routine patient colonoscopy examination. During this step, the colonoscopist introduces a colonoscope into the patient to assess the rectum, colon, and cecum for polyps. This will be performed per standard of care without deviation from standard of care procedure.

B) *Colonoscopic visualization of the cecum using the Magnetic Flexible Endoscope (MFE)*. After the colonoscope assessment is complete, anesthesia is stopped, and the standard colonoscope is removed from the patient, the MFE device will be lubricated, introduced into the patient, and navigated to the cecum. Steps in sequential order are:
    1. The MFE device's sterile packaging will be inspected and confirmed intact
    2. The MFE package will be opened
    3. The MFE will be lubricated
    4. The MFE will be inserted into the patient via the anus
    5. The MFE will be navigated to the cecum
    6. The MFE will be removed from the patient

C) *Any adverse events occurring during the surgical procedure will be documented*. Any adverse events that occur during the procedure will be documented and reported in accordance with 21 CFR 812 and Vanderbilt's IRB protocols.

3.0.4.2 Post-operative visit/follow up

In line with standard clinical practice for patients who have received MAC at VUMC, the patient is observed for a minimum of 30 minutes during the immediate post-operative period and then released to a chaperone to leave the endoscopy unit once standard VUMC post-anesthesia discharge parameters are met. The patient then receives a post-operative phone call 3-5 days post procedure to inquire about status of the patient.

Primary Endpoint: Successful navigation of the colon (from rectum to cecum), with successful cecal intubation using the MFE system.

Secondary Endpoints:

i. Mucosal visibility: Operator assessed score, the Colon Visualization Index (Appendix A), will be used.

ii. Patient tolerance: Pain perception will be assessed with a validated pain score (Wong-Baker FACES Pain Rating Scale; Appendix B). Qualitative assessment of participant sentiment will be assessed with a post-study structured interview (Appendix C).

iii. Endoscopist experience: The usability of the platform in terms of task load for the endoscopist will be assessed using the standardized NASA Task Load Index (TLX) instrument (Appendix D).

3.0.4.3 Participant Termination/Withdrawal

Patients may be terminated from the study for the following reasons:

- A change in patient's health status that would preclude continuation in the study(e.g. cardiac event during endoscopic procedure). If this would occur, the patient will continue to be followed as per routine care.
- If the patient changes their mind and requests to be withdrawn from study should this occur, data will continue to be collected unless the patient requests in writing for data collection to cease.

3.0.5 Table of Procedures

Table 2. *Study Procedures*

	Screening	Endoscopic Examination	Follow up
Obtain Informed Consent	X		
Review Inclusion/Exclusion Criteria	X		
Review Medical History	X		
Routine Pregnancy Testing (urine or blood)		X [a]	
Colonoscope assessment of tissue		X	
Colonoscopic Validation of target with the MFE		X[b]	
Review Adverse Events		X	X
Colonoscopic Post-Op NASA/Questionnaire			X[b]

(a) Performed pre-operatively for women of childbearing potential

(b) The Investigational Step in this study procedure. All other steps within the protocol will be performed per the standard of care

3.1 Data Analysis

In this early feasibility study, our primary endpoint is safe, successful, cecal intubation with the MFE. Mucosal visibility, patient tolerance, and endoscopist feedback on the platform will also be captured as secondary endpoints.

We will stop enrolling patients in this study if:

1. We do not believe that additional patients should undergo the procedure becausethe risks of the procedure outweigh the potential benefits to participants

and/or

2. An unanticipated adverse effect would warrant that the study be stopped for assessment of the effect.

3.2 Quality Assurance

The conduction of this early feasibility study will be overseen by the PI. The PI will meet with the sub-investigators and research staff to assure protocol adherence and accuracy of data collection. Prior to study initiation, all study staff will be trained regarding the approved protocol. All data will be entered into a password protected RedCap database by qualified research staff. Any inconsistencies in the data will be reconciled and documented appropriately. As there will be only 5 subjects in this trial, all subject records will be reviewed by the PI.

3.3 Regulatory Considerations

3.3.0 Adverse Events/Effects

3.3.0.0 Definitions

Adverse event is defined as any undesirable experience associated with the use of the device under study that appears or worsens during the clinical study from the period commencing with the surgical procedure through the time the participant completes the study, and that may or may not be related to the investigational device or study related procedures.

A ***related adverse event*** is an event in which there is a reasonable possibility that the investigational device or study related procedures caused or contributed to the event.

An ***unanticipated adverse device effect*** is defined as any serious adverse event on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degreeof incidence in the investigational plan or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

A ***serious adverse event*** is defined as an adverse event whereby the patient outcome meets any of the following criteria:

a. Results in death
b. Is life-threatening (defined as an event in which the participant was at substantial risk of death at the time of the adverse event, or use or continued us of the device might have resulted in the death of the patient)
c. Requires inpatient hospitalization
d. Prolongs an existing hospitalization
e. Results in persistent or significant disability (substantial disruption of a person's ability to conduct normal life functions)
f. Results in a congenital anomaly or birth defect
g. Requires medical or surgical intervention to preclude permanent impairment of a body function or prevent permanent damage to a body structure.
h. The event does not fit above criteria (a) through (g), but may jeopardize the patient and may require medical or surgical intervention to prevent any of (a) through (g) above.

3.3.0.1 Adverse Event Collection and Reporting

The investigator and sub-investigators will assess on a routine basis if any adverse events occur during the colonoscopic procedure through the time the participant completes the study. All adverse events/complications that occur during this time period whether device relatedor not will be reported and recorded.

Pre-existing conditions that are present at the time of enrollment into the clinical study will be

considered concurrent medical conditions and will not be recorded as adverse events unless the subject experiences a worsening or complication of such a concurrent condition,in which case the adverse event will be recorded and evaluated by the investigator.

Patients will be closely monitored in a recovery room setting. All available clinical data, including exam findings, and clinical impressions, will be monitored. The investigator will evaluate any changes in physical status and will determine if the change is clinically important and different from what is anticipated in the course of treatment.

Any events determined by the PI to be unanticipated adverse device effects will be reported to the reviewing IRB and the study team as soon as possible but not more than 10 working days after the investigator first learns of the effect.

Any unanticipated adverse device effect will be immediately evaluated by the investigator. Should it be determined that the unanticipated adverse device effect presents an unreasonable risk to study subjects, the study or the part(s) of the study that present that risk will be terminated as soon as possible but not later than 5 working days after the investigator first receives notice of the effect.

3.3.1 Protocol Deviations

Protocol deviations are defined as any incidents involving non-adherence to the protocol and may result from actions of the participant, investigator, or staff. Protocol deviations will be recorded and will be reported to the reviewing IRB per IRB policy. Protocol deviations intended to protect the life or physical well-being of a participant in an emergency situation and any incidence of failure to obtain informed consent must be reported to the reviewing IRB as soon as possible but no later than 5 working days after the emergency occurred. Except for such an emergent situation, changes that may affect the scientific soundness of the investigational plan or the rights, safety or welfare of study participants, must be approved by the IRB prior to implementation.

3.3.2 Sponsor Responsibilities

The sponsor will select only qualified investigators to participate in the research study and will provide investigators with a study protocol and the information they need to properly conduct the study. The sponsor will also assure monitoring is conducted according to the monitoring plan. IRB approval of the study must be obtained prior to start of the study and this documentation will be kept on file. The sponsor will promptly notify the IRB of any significant new information about this investigation.

3.3.3 Investigator Responsibilities

Investigators are responsible for conducting the study in accordance with the signed Investigator's Letter of Agreement, the investigational plan, any IRB imposed conditions, and applicable FDA regulations for protecting the rights, safety, and welfare of subjects under the investigator's care, and for obtaining informed consent from each research participant prior to any study-related procedures. Investigators are also responsible for maintaining control of the investigational device.

This early feasibility study is being conducted at Vanderbilt University Medical Center, Nashville, TN, USA. Investigators may determine if potential subjects would be interested in taking part in the investigation prior to IRB approval, but written informed consent will not be obtained from study participants and study participation will not be allowed until IRB approval is received.

The investigational device will only be used on research subjects with the investigator's supervision and will not be used on any person who is not authorized under 21CFR812 to receive it.

Investigator will disclose accurate financial information to allow complete and accurate certification or disclosure statements that may be required by Vanderbilt University Medical Center in compliance with the institutions policies, as appropriate, and will update these records promptly if any relevant changes occur during the course of the clinical study and for one year after the completion of this study.

3.3.4 Selection of Investigators

All clinical investigators taking part in this study are accomplished gastrointestinal endoscopists who commonly perform endoscopic procedures as part of their practice. All understand and will comply with their responsibilities regarding adherence to the approved protocol and the signed Investigator's Letter of Agreement. The research protocol will take place at Vanderbilt University Medical Center, Nashville, TN, USA with the principal investigator (PI) being Dr. Keith L. Obstein, MD, MPH, FASGE, FACG, AGAF. His *curriculum vitae* is included in Appendix H.

3.3.5 Informed Consent

Once a potential study subject has been identified, a member of the research team will present the research study to the subject in person, via phone, or via secure electronic transfer (e.g. secure email or My Health at Vanderbilt electronic portal). The potential participant will be provided with a copy of the consent form to read and will be provided with an opportunity to ask questions. Once the study participant's questions have been answered and prior to performing any study-related procedure, an IRB-approved consent form will be signed and dated by the study

participant and by the person obtaining informed consent. A copy of the signed consent form will be provided to the subject and the informed consent process will be documented in the study participant's medical record.

3.3.6 Confidentiality

Participants will receive a 3 digits identification number from 001 to 005 in the order of their enrollment. Patient identification numbers will be linked to their name on a password secured Vanderbilt University Medical Center RedCap Database only accessible by approved research study staff. Data from the hard copies of the completed surveys and questionnaires will be entered into a RedCap form and securely stored on a Vanderbilt University Medical Center password protected cloud platform accessible only by approved research study staff. The hard copies will then be destroyed after the data has been entered into electronic format. At the conclusion of the research study, the PI will maintain the information on the RedCap secure, encrypted, Vanderbilt University Medical Center system.

3.4 References

Other Publications

1. Corley DA, Jensen CD, Marks AR. Can we improve adenoma detection rates? A systematic review of intervention studies. Gastrointestinal Endoscopy 2001; 74(3): 656–665.
2. Zauber AG, Winawer SJ, O'brien MJ et al. Colonoscopic polypectomy and long-term prevention of colorectal cancer deaths. Obstetrical & Gynecological Survey 2012; 67(6): 355–356.
3. Rex DK, Schoenfeld PS, Cohen J et al. Quality indicators for colonoscopy. Gastrointestinal Endoscopy 2015; 81(1): 31–53.
4. Faulx AL, Lightdale JR, Acosta RD et al. Guidelines for privileging, credentialing, and proctoring to perform GI endoscopy. Gastrointestinal Endoscopy 2017; 85(2): 273–281.
5. Hawkins AT, Sharp KW, Ford MM et al. Management of colonoscopic perforations: a systemic review. The American Journal of Surgery 2018; 215: 712–718.
6. Lohsiriwat V. Colonoscopic perforation: incidence, risk factors, management and outcome. World Journal of Gastroenterology 2010; 16(4): 425–430.
7. Day LW, Kwon A, Inadomi JM et al. Adverse events in older patients undergoing colonoscopy: a systematic review and meta-analysis. Gastrointestinal Endoscopy 2011; 74(4): 885–896.
8. Zhang K, Yuan Q, Zhu S et al. Is unsedated colonoscopy gaining ground over sedated colonoscopy? Journal of the National Medical Association 2018; 110(2): 143–148.
9. Shah SG, Brooker JC, Thapar C et al. Patient pain during colonoscopy: an analysis using real-time magnetic endoscope imaging. Endoscopy 2002; 34(6): 435–440.
10. Vasen, H. F., ... & Wijnen, J. (2008). Guidelines for the clinical management of familial adenomatous polyposis (FAP). Gut, 57(5), 704-713.
11. Groves, C. J., … & Phillips, R. K. S. (2002). Duodenal cancer in patients with familial

adenomatous polyposis (FAP): results of a 10 year prospective study. Gut, 50(5), 636-641.

12. Yang, J., ... & Samadder, N. J. (2020). American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in familial adenomatous polyposis syndromes. Gastrointestinal endoscopy, 91(5), 963-982.
13. Syngal, S., … & Burt, R. W. (2015). ACG clinical guideline: genetic testing and management of hereditary gastrointestinal cancer syndromes. The American journal of gastroenterology, 110(2), 223.
14. Monahan, K. J., ... & Hill, J. (2020). Guidelines for the management of hereditary colorectal cancer from the British Society of Gastroenterology (BSG)/Association of Coloproctology of Great Britain and Ireland (ACPGBI)/United Kingdom Cancer genetics group (UKCGG). Gut, 69(3), 411-444.
15. van Leerdam, M. E., ... & Ricciardiello, L. (2019). Endoscopic management of polyposis syndromes: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy, 51(09), 877-89

STORM Lab Publications

16. Slawinski PR, Taddese AZ, Musto KB, Sarker S, Valdastri P, Obstein KL. Autonomously controlled magnetic flexible endoscope for colon exploration. Gastroenterology 2018; 154(6).
17. Martin JW, Scaglioni B, Norton JC, Subramanian V, Arezzo A, Obstein KL, Valdastri P. Enabling the future of colonoscopy with intelligent and autonomous magnetic manipulation. Nature Machine Intelligence 2020; 2. 595–606.
18. Taddese AZ, Slawinski PR, Obstein KL, Valdastri P. Closed Loop Control of a Tethered Magnetic Capsule Endoscope. Robot Sci Syst. 2016 Jun; 2016:10.15607/RSS.2016.XII.018.
19. Slawinski PR, Taddese AZ, Musto KB, Obstein KL, Valdastri P. Autonomous Retroflexion of a Magnetic Flexible Endoscope. IEEE Robot Autom Lett. 2017 Jul;2(3):1352-1359.
20. Taddese AZ, Slawinski PR, Obstein KL, Valdastri P. Nonholonomic Closed-loop Velocity Control of a Soft-tethered Magnetic Capsule Endoscope. Rep U S. 2016 Oct;2016:1139-1144.
21. Norton JC, Slawinski PR, Lay HS, Martin JW, Cox BF, Cummins G, Desmulliez MPY, Clutton RE, Obstein KL, Cochran S, Valdastri P. Intelligent magnetic manipulation for gastrointestinal ultrasound. Sci Robot. 2019 Jun 26;4(31):eaav7725.
22. Natali CD, Beccani M, Obstein KL, Valdastri P. A wireless platform for in vivo measurement of resistance properties of the gastrointestinal tract. Physiol Meas. 2014 Jul;35(7):1197-214.
23. Taddese AZ, Slawinski PR, Pirotta M, De Momi E, Obstein KL, Valdastri P. Enhanced Real-Time Pose Estimation for Closed-Loop Robotic Manipulation of Magnetically

Actuated Capsule Endoscopes. Int J Rob Res. 2018 Jul;37(8):890-911.

24. Scaglioni B, Previtera L, Martin J, Norton J, Obstein KL, Valdastri P. Explicit Model Predictive Control of a Magnetic Flexible Endoscope. IEEE Robot Autom Lett. 2019 Apr;4(2):716-723.
25. Pittiglio G, Barducci L, Martin JW, Norton JC, Avizzano CA, Obstein KL, Valdastri P. Magnetic Levitation for Soft-Tethered Capsule Colonoscopy Actuated With a Single Permanent Magnet: A Dynamic Control Approach. IEEE Robot Autom Lett. 2019 Apr;4(2):1224-1231.
26. Slawinski PR, Simaan N, Obstein KL, Valdastri P. Sensorless Estimation of the Planar Distal Shape of a Tip-Actuated Endoscope. IEEE Robot Autom Lett. 2019 Oct;4(4):3371-3377.
27. Barducci L, Pittiglio G, Norton JC, Obstein KL, Valdastri P. Adaptive Dynamic Control for Magnetically Actuated Medical Robots. IEEE Robot Autom Lett. 2019 Oct;4(4):3633-3640.
28. Slawinski PR, Simaan N, Taddese AZ, Obstein KL, Valdastri P. Sensitivity Ellipsoids for Force Control of Magnetic Robots with Localization Uncertainty. IEEE Trans Robot. 2019 Oct;35(5):1123-1135.
29. Mamunes AP, Campisano F, Martin J, Scaglioni B, Mazomenos E, Valdastri P, Obstein KL. Magnetic flexible endoscope for colonoscopy: an initial learning curve analysis. Endosc Int Open. 2021 Feb;9(2):E171-E180.
30. Barducci L, Scaglioni B, Martin J, Obstein KL, Valdastri P. Active Stabilization of Interventional Tasks Utilizing a Magnetically Manipulated Endoscope. Front Robot AI. 2022 Apr 14;9:854081.
31. Martin JW, Barducci L, Scaglioni B, Norton JC, Winters C, Subramanian V, Arezzo A, Obstein KL, Valdastri P. Robotic Autonomy for Magnetic Endoscope Biopsy. IEEE Trans Med Robot Bionics. 2022 Aug;4(3):599-607.