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Title: The first autonomously controlled magnetic flexible endoscope for colon exploration

Short Title: Autonomous endoscopic robot

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Acronyms: American Society for Gastrointestinal Endoscopy (ASGE), Magnetic Flexible Endoscope (MFE), Embedded Magnet (EM), Actuating Permanent Magnet (APM), Institutional Animal Care and Use Committee (IACUC)

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Kyle B. Musto has nothing to disclose.
Shabnam Sarker has nothing to disclose.

Conflicts of Interest:
Piotr R. Slawinski has no conflicts of interest.
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Author Contributions:
Piotr Slawinski: Study concept and design, application and technology development, acquisition of data, analysis and interpretation of data, drafting the manuscript, critical revision of the manuscript for important intellectual content
Addisu Taddese: Study concept and design, application and technology development, acquisition of data, analysis and interpretation of data, critical revision of the manuscript for important intellectual content
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Traditional flexible endoscopes, which have been in use since the 1950s, rely on rear-push mechanical actuation to advance through the gastrointestinal tract. This necessitates a semi-rigid insertion tube to prevent buckling that may induce patient discomfort or trauma due to tissue stress [1] [2]. To overcome this limitation, magnetic fields have been utilized for endoscope actuation. Unfortunately, manual operation of magnetic actuation is not intuitive and therefore computer assistance has been shown to be beneficial [3]. The use of computers and robotics facilitates autonomy, which may be used to assist the operator during repetitive or complex maneuvers through relief of cognitive burden and potential learning curve reduction.

In our academic laboratory, we have developed a highly compliant magnetic flexible endoscope (MFE) platform (with diagnostic and therapeutic capability) that relies on actuation using an actuating permanent magnet (APM) manipulated by a robot that is external to the patient—thus it does not require push-actuation. Using proprioceptive sensing and software algorithms, we are able to control MFE motion and enact autonomous function.

Within endoscopy, colonoscopy is ripe for autonomous control due to the repetitive nature of some maneuvers and the skill/experience necessary to achieve excellent technique. We focus our demonstration of autonomy on retroflexion as it is a common endoscopic maneuver that is skill-intensive, repetitive, and technically challenging when using magnetic actuation. The ability to safely retroflex the MFE in any area of the colon may potentially increase polyp detection and reduce the incidence of colorectal cancer [4].

Our team has developed an autonomous control algorithm for MFE retroflexion. We conducted 30 autonomous retroflexions in-vivo in a 40 Kg female Yorkshire-Landrace cross swine (Supplemental Material: Retroflexion study design). All of the autonomous retroflexion maneuvers were successful (100%; n=30) with a mean maneuver time of 11.3±2.4 seconds. The visible difference in trajectories and difference in APM position respective to the starting point indicate that the APM did not follow a pre-computed trajectory—but was instead autonomously reacting to external input, in this case the MFE's motion (Video). All of the trials in this study were completed without tissue perforation or trauma (gross or microscopic), or premature animal demise during the trial. The study was approved by the local Institutional Animal Care and Use Committee (IACUC).

In addition, feasibility of the diagnostic capabilities of the MFE was assessed through a series of preliminary experiments on lesion detection and lesion-targeting (Supplemental Material: Lesion detection and targeting study design). The mean lesion detection miss rate for the MFE was 21.7% (completion time 575 s) compared with a miss rate of 5% (completion time 257 s) for the traditional endoscope ($p=0.17$). For the lesion targeting experiments, all lesions were successfully "tagged" with biopsy forceps using the MFE and the traditional endoscope (time: 251 s v. 32 s; $p<0.01$). Despite the differences in time between the MFE and traditional endoscope, likely impacted by endoscopist familiarity with traditional endoscopy, the low polyp miss rate and ability to circumferentially examine the colon lumen suggest promise for continued development and refinement of the MFE.

Description of technology

The MFE system, Figure 1, consists of a flexible endoscope with a magnet-embedded tip, an APM external to the patient that is manipulated by a robot, and a software control system that is described in detail in Ref. [5]. The MFE (Figure 2) maintains functionality of a traditional endoscope (i.e. therapeutic channel, illumination, viewing, irrigation, suction, lens cleansing, and insufflation) and contains proprioceptive sensors that facilitate magnetic interaction estimation harnessed for MFE retroflexion. Knowledge of magnetic field properties allows for precise device movement all while maintaining an applied tissue stress of no more than 0.25 bar, or 12 times less pressure than is necessary to induce tissue damage [5][6].

Video description

The video presents an overall description of the MFE platform and functions followed by demonstration of in-vivo autonomous retroflexion in real time. The robot arm with APM is shown in the upper right of the screen during the demonstration and the corresponding footage of the MFE is shown in the frame below where perspective footage is obtained via an auxiliary endoscope. Furthermore, we demonstrate unique MFE trajectories during retroflexion—a product of the use of autonomy, the use of biopsy forceps during MFE retroflexion, as well as in-vivo use of therapeutic tools as operated from the MFE.

Take home message

Our team has demonstrated the first use of in-vivo autonomous control for completion of an endoscopic maneuver in a reliable, efficient, and safe manner. This is also the first study to demonstrate closed-loop magnetic control of a device in-vivo and autonomous maneuvering of an endoscope that has the clinical capability of a traditional flexible endoscope.

We expect the cost of the MFE to be approximately $1000 USD with a one-time cost of $40,000 USD for the actuating robot. Although we have developed the technology for use in the colon, we anticipate that the platform, once further miniaturized, can be used in the upper GI tract and, in general, other areas of the body where there is physical space for maneuvering. In summary, our findings suggest promise in the use of autonomy to assist in endoscopic tasks and in magnetic actuation of endoscopic devices/instruments.

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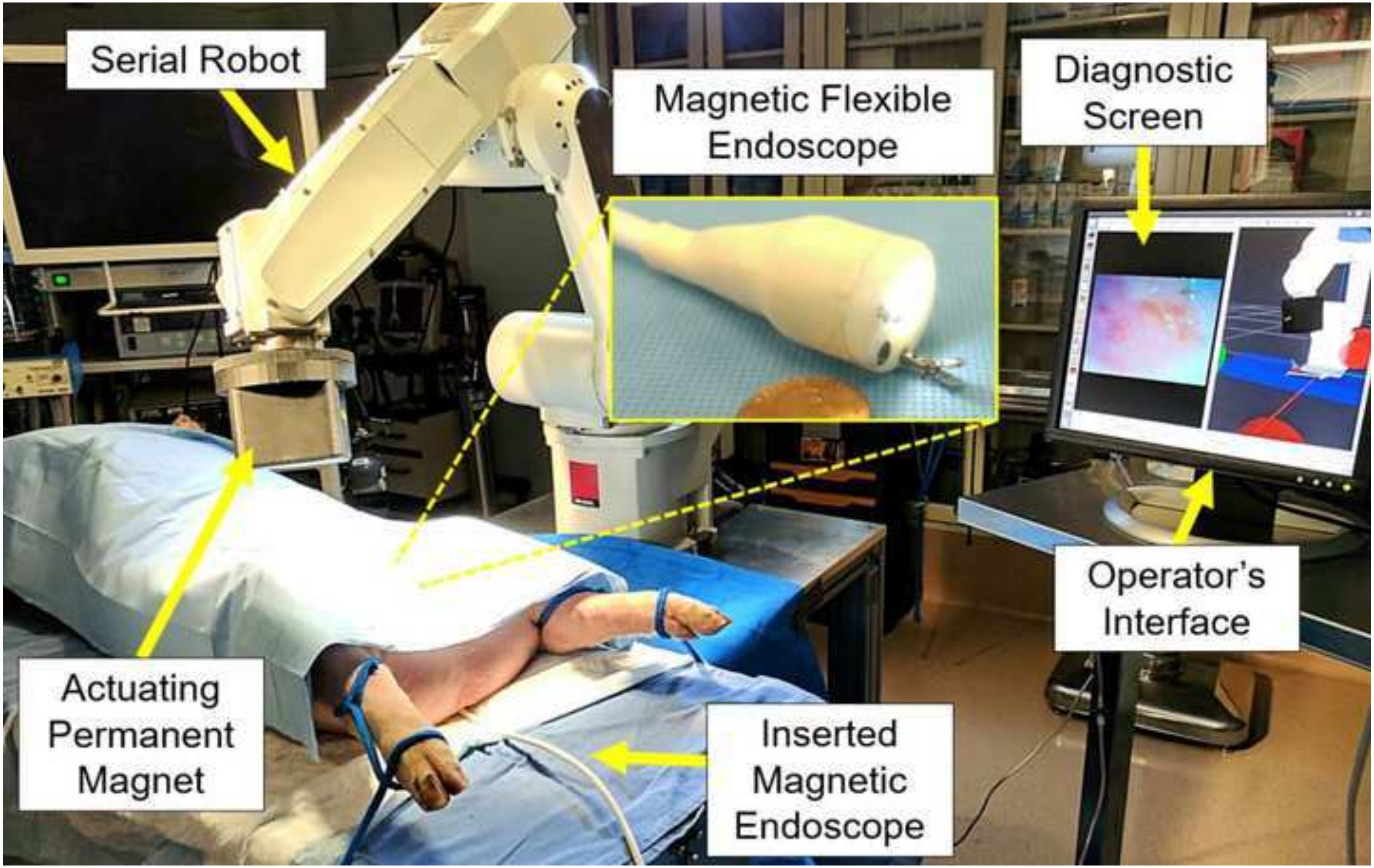
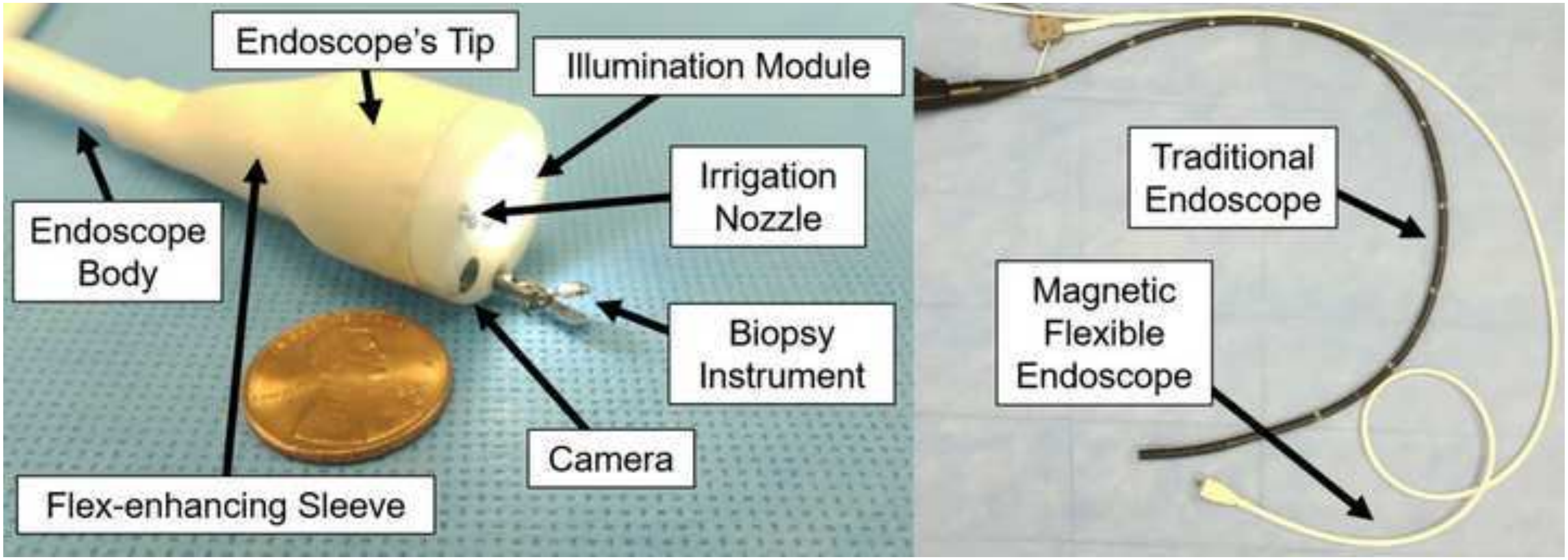
Figure Legends

Figure 1: The MFE platform consists of a magnet-embedded custom endoscope, a serial robot with an APM mounted at its end-effector, and control software. The system is shown during an in-vivo trial.

Figure 2: The compliant MFE contains a camera, illumination module, therapeutic channel, an irrigation and insufflation channel, and a flexible sleeve joint that joins the endoscope's tip to its body (left).


Serial Robot
Magnetic Flexible Endoscope
Diagnostic Screen
Operator's Interface
Actuating Permanent Magnet
Inserted Magnetic Endoscope


Endoscope's Tip
Illumination Module
Irrigation Nozzle
Endoscope Body
Biopsy Instrument
Camera
Flex-enhancing Sleeve
Traditional Endoscope
Magnetic Flexible Endoscope

Supplementary Material

Retroflexion study design:

A standard colonoscope (Olympus, CF-Q160L, Tokyo, Japan) was initially inserted into the anus of the anesthetized swine and advanced proximally until further proximal advancement of the endoscope was not possible due to the swine's spiral colon. The colonoscope was then withdrawn to a distance of 25 cm from the anus and retroflexion was performed in this location. The colonoscope was then kept in this location while the MFE was inserted into the anus of the swine. The MFE was then advanced under magnetic control to 25 cm from the anus, where retroflexion trials were performed. Each experiment was conducted under full autonomy; the only human input was the pushing of a keyboard button on a personal computer to initiate the algorithm (a functionality that can be easily integrated into the operator's handle for the system). A total of 30 independent autonomous retroflexion maneuvers were performed.

Lesion detection and targeting study design:

As in Laborde CL, et al. (GIE 2017; 85:559-565), a series of polyps (size < 10 mm) were placed in a colon phantom in one of five location scenarios. The MFE and traditional endoscope were used for visual inspection of the colon upon withdrawal. The location scenario and endoscope utilized for the scenario were randomized between each trial. Each scenario was performed twice for a total of 10 inspection trials.

For lesion targeting, the colon phantom (Kyoto Kagaku, Kyoto, Japan) was prepared so that eight polyps (< 10 mm in size) were placed along the colon circumferentially, 180-degrees apart per distance pair, that rotated every 2 cm when moving in a retrograde manner with the endoscope (0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, 315˚). The MFE and the traditional endoscope were then used to identify and "tag" the polyp using a cold biopsy forceps that was advanced through the therapeutic channel of the endoscope. A "tag" was considered successful, when the cold biopsy forceps was open and touched the polyp for removal. A total of 10 trials were performed (MFE n=5; traditional endoscope n=5).

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Video (supplemental)

Revised_GIM_video.mp4