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Robotic versus manual control in magnetic steering of an endoscopic capsule

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Background and study aims: Capsular endoscopy holds promise for the improved inspection of the gastrointestinal tract. However, this technique is limited by a lack of controlled capsule locomotion. Magnetic steering has been proposed by the main worldwide suppliers of commercial capsular endoscopes and by several research groups. The present study evaluates and discusses how robotics may improve diagnostic outcomes compared with manual magnetic steering of an endoscopic capsule.

Materials and methods: An endoscopic capsule prototype incorporating permanent magnets was deployed in an ex vivo colon segment. An operator controlled the external driving magnet manually or with robotic assistance. The capsule was maneuvered through the colon, visualizing and contacting targets installed on the colon wall. Procedure completion time and number of targets reached were collected for each trial to quantitatively compare manual versus robotic magnetic steering (*t*-test analysis with $P = 0.01$). Then, through a set of in vivo animal trials, the efficacy of both approaches was qualitatively assessed.

Results: In ex vivo conditions, robotic-assisted control was superior to manual control in terms of targets reached (87 % ± 13 % vs 37 % ± 14 %). Manual steering demonstrated faster trial completion time (201 ± 24 seconds vs 423 ± 48 seconds). Under in vivo conditions, the robotic approach confirmed higher precision of movement and better reliability compared with manual control.

Conclusions: Robotic control for magnetic steering of a capsular endoscope was demonstrated to be more precise and reliable than manual operation. Validation of the proposed robotic system paves the way for automation of capsular endoscopy and advanced endoscopic techniques.

Introduction

Wireless capsule endoscopy (WCE) has the potential to dramatically reduce the invasiveness and pain of traditional gastrointestinal diagnostic and surgical procedures, paving the way to mass screening of the gastrointestinal tract [1]. In this context, WCE is an example of "disruptive" technology – one that induces a radical change in the way humans operate. It potentially enables inspection of the gastrointestinal tract without discomfort or the need for sedation, and thus obviates the risks associated with traditional endoscopy [2]. As a first-generation disruptive technology, WCE still presents a number of limitations, for example the inability to control locomotion and camera orientation. As demonstrated by recent comparative studies [3], these open issues make traditional endoscopic techniques still superior to WCE.

Different approaches for controlled locomotion have been proposed by several research groups worldwide [4,5]. Currently the most promising solution seems to be magnetic steering, which is under investigation by two of the main suppliers of endoscopic capsules, Olympus [6] and Given Imaging [7]. In the study by Valdastri et al. [8], a therapeutic endoscopic capsule was steered by a handheld external permanent magnet. Despite the low cost and intuitiveness of this approach, low precision and poor repeatability often make manual magnetic steering frustrating even for an expert and well-trained operator.

As confirmed by the spread of Intuitive Surgical's Da Vinci systems, robotic arms are well accepted in operating rooms [9], thanks to high precision and accuracy. Recently, the Stereotaxis robotic platform [10] was applied to WCE steering in a preliminary in vitro validation [11]. However, it is unsuitable for capsule endoscopy, as the Stereotaxis platform does not generate magnetic field gradients to enable capsule locomotion. We recently proposed a more compact design [12], where an industrial robotic arm is used to sup-

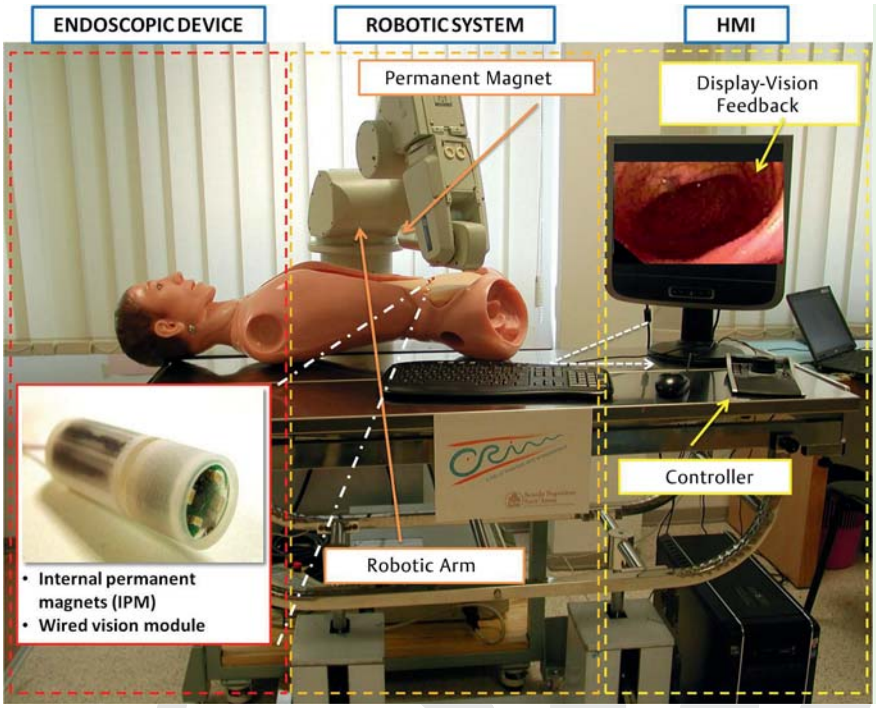

Fig. 1 System architecture of the robotic platform composed of a human-machine interface (HMI), the robotic system and the endoscopic capsular device.

port a permanent magnet for real-time control of an endoscopic capsule.

Considering this background, the main purpose of the present study was to compare, both quantitatively by ex vivo tests and qualitatively through in vivo animal trials, manual versus robotic control in magnetic steering of an endoscopic capsule. A secondary goal was to validate our robotic platform in vivo in terms of portability, effectiveness, and reliability.

Materials and methods

Robotic platform architecture

The robotic platform used in the study (**Fig. 1**) is composed of the following: a 6 degrees of freedom (DoF) anthropomorphic robotic arm (RV-3SB, Mitsubishi Electric, Tokyo, Japan) with an external permanent magnet (EPM) attached to the end-effector, a human-machine interface (HMI) including an intuitive control peripheral, and a capsule with internal permanent magnets (IPMs) and vision module on board (in the current version this is wired).

The robotic arm is used to hold, move, and orient an EPM magnetically linked to the endoscopic capsule, which is provided with IPMs. A proper dimensioning of the EPM-IPM magnetic link was addressed in order to achieve effective magnetic interaction with the capsule at an operative distance of 150 mm [12]. The user imposes robotic arm motion through an intuitive 6 DoF input device (3D SpacePilot, 3Dconnexion Inc., Fremont, California, USA), which interacts with a novel real-time motion control system for use with the robotic arm.

The capsule prototype (**Fig. 1** inset) has a diameter of 14 mm, a length of 38 mm, and a weight of 7.5 g. It incorporates a wired CMOS (complementary metal-oxide-semiconductor) camera (MO-S588-3T-N, Misumi, Taiwan) with illumination system, and a permanent magnetic module (3 sets of neodymium N52 cylindrical magnets with a length of 19.1 mm and a diameter of 3.2 mm; K&J Magnetics Inc., Jamison, Pennsylvania, USA). A wired camera was used for this experiment because there are currently no real-time compact wireless cameras on the market.

Validation studies

The primary goal of the present study was to compare manual with robotic magnetic steering of an endoscopic capsule in a set of ex vivo trials, relying on the real-time image stream coming from the capsule itself. Then, the two steering techniques were qualitatively compared in a set of in vivo animal experiments. A secondary goal of the in vivo experiments was to qualitatively assess feasibility, effectiveness, and reliability of the robotic platform, this being the first in vivo experiment ever reported about robotic magnetic steering under real-time vision control of an endoscopic capsule.

Ex vivo validation study

A standard lower gastrointestinal tract training phantom was used for the ex vivo test session. The phantom consists of an anatomical model of the abdominal, chest, and pelvic cavities with fixtures aligned in the shape of human mesenteries (**Fig. 2a**).

A segment of fresh porcine colon was attached alongside the fixtures. Then, the tissue was arranged to mimic human anatomical angles and alignments of the descending and sigmoid colon tracts, from the rectum to the splenic flexure. A 480-mm colon segment was chosen for the experiment; a longer segment would be difficult to move along because the wire of the camera hampers the motion of the device. Six to eight white spherical targets (4 mm in diameter) were placed along the inside of the colon segment (**Fig. 2b**). A constant 2-mmHg internal pressure was maintained throughout the experiments.

The goal of the procedure was to navigate the capsule through the colon tissue from start (rectum) to the end-point (splenic flexure), visualizing and contacting the targets installed on the colon wall. A real-time image stream coming from the capsule was displayed on the HMI. The user, expert in both manual and robotic control, explored the colon segment using only the visual feedback on the HMI. The operator had no prior knowledge of the

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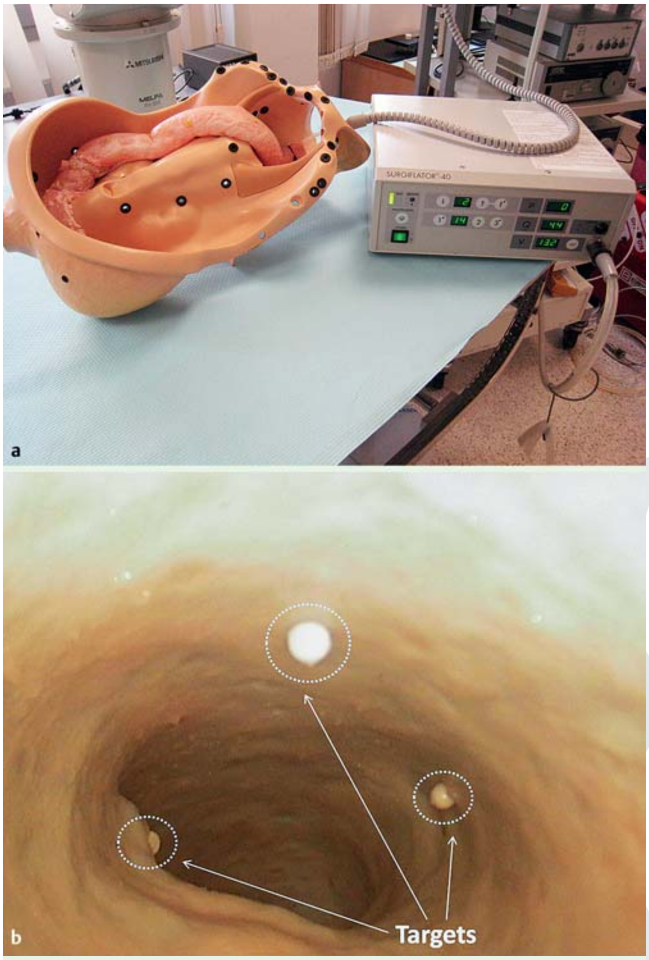

Fig. 2 The lower gastrointestinal phantom model. **a** Colon tissue fixed inside the model. **b** Internal view of colon tissue with white spherical targets installed on the wall.

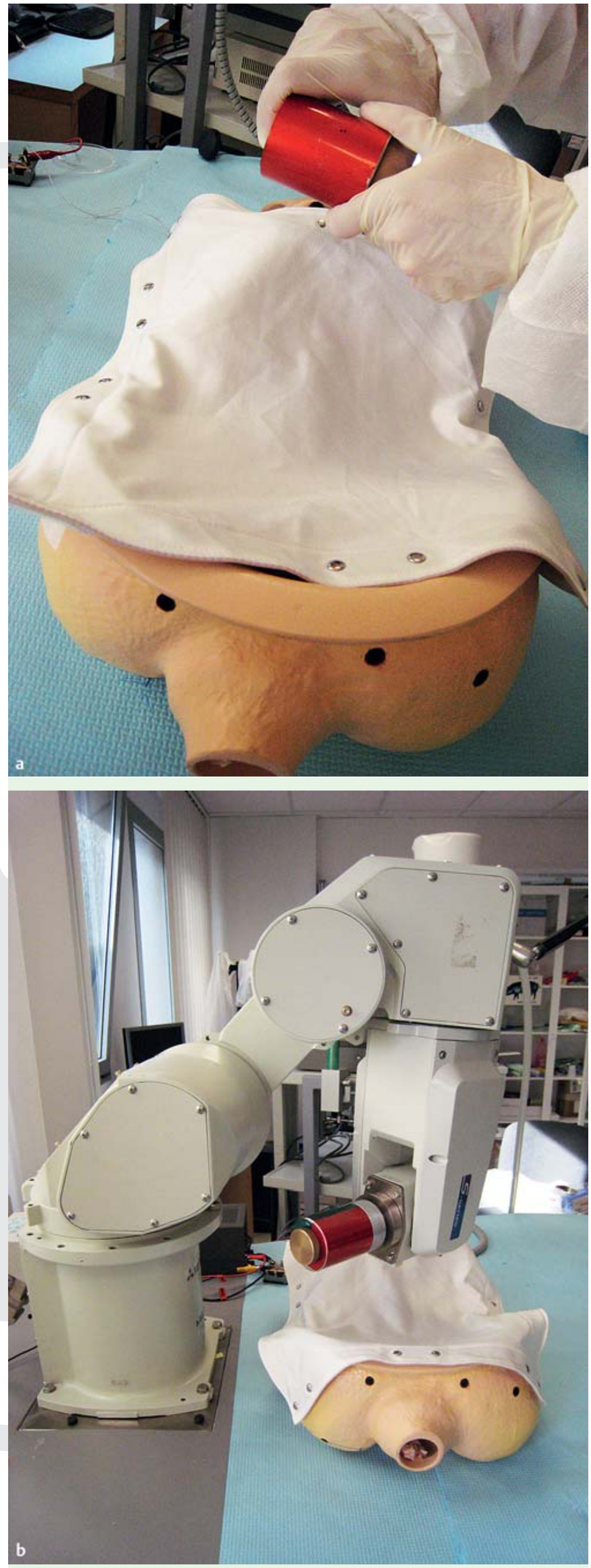

Fig. 3 Movement of the external permanent magnet during the procedure. **a** Manual control; **b** robotic control. The colon simulator was covered by a dedicated layer in order to avoid a bias due to direct vision of the capsule inside the lower gastrointestinal simulator.

target quantity and locations. In order to avoid a bias due to direct vision of the capsule inside the simulator, the phantom model was covered by a dedicated layer. All trials were observed by an assistant to ensure that targets were counted accurately (i. e. targets reached more than once were counted as one target). The quantity and position of targets on the inner wall of the colon were changed between trials by the assistant.

Ten trials were performed with the EPM under manual control (**Fig. 3 a**), and ten under robotic control (**Fig. 3 b**), in random order.

Completion time and percentage of targets reached were recorded by the assistant for each trial. Descriptive statistics are specified as the median values, mean value ±SD, and range of values, for both manual and robotic control. A two-tailed *t*-test was performed to measure statistical significance of the comparison between control methods with the *P*-value set at 0.01.

In vivo validation study

Ten in vivo trials (five for manual and five for robotic steering) were carried out on two domestic female pigs (average weight 30 kg) to qualitatively compare manual steering with robotic steering. The experiments were executed in an authorized laboratory, with the assistance and collaboration of a medical team, in accordance with all ethical considerations and the regulatory issues related to animal experiments. Robotic-aided steering set up under in vivo conditions is shown in **Fig. 4**.

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Fig. 4 Test bench for magnetic capsule steering with the aid of a robotic arm in in vivo conditions.

After intravenous sedation of each animal and preparation of the bowel by water enemas, the experimental procedure was performed maintaining 2 mmHg constant pressure inside the colon. The capsule was inserted transanally up to 300 mm in the bowels. For each trial, movements were performed both with and against peristaltic force within a range of ± 100 mm from the starting position. Steering maneuvers were also completed, while keeping the capsule position stationary. The operator used streaming real-time video from the capsule, displayed on the HMI as control feedback. At the end of each trial, the capsule was magnetically driven down to the anus.

Results

Ex vivo validation study

For all procedures the operator successfully maneuvered the capsule to the end of the colon segment. The mean completion time for manual control was 201 ± 24 seconds, (range 161 – 240 seconds). With robotic control, the mean completion time was 423 ± 48 seconds (range 327 – 475 seconds). The median values were 209 seconds and 433 seconds for manual and robotic control, respectively.

The mean percentage of targets reached by the capsule with manual control was 37 % ± 14 % (range 14 % – 66 %). With robotic control, the mean target percentage was 87 % ± 13 % (range 66 % – 100 %). The median values were 35 % and 87 % for manual and robotic control, respectively. Both the differences in completion times and in the percentage of targets reached between manual and robotic control were statistically significant at the 1 % level.

In vivo validation study

The robotic arm was successfully set up in the operating room, verifying the portability and effectiveness of the overall platform. By using the two approaches for EPM handling, the operator was able to maneuver the capsule both with and against peristaltic forces to perform an inspection of the colon wall using the streaming images from the on-board camera. The comparative results of the ex vivo trials were qualitatively confirmed by the in vivo tests. In particular, manual steering was usually faster, whereas precision and reliability of movement were dramatically improved by the robotic approach.

Discussion

The results obtained in the ex vivo session showed that a higher percentage of targets were reached with robotic assistance than with manual control. In particular, fewer targets were reached with manual control because after obtaining view of a target, the operator was unable to move toward it without the target going outside the visual field. On the other hand, the robotic arm enabled small, precise movements to approach the capsule steadily towards the target. Manual control was more effective for large-scale movements, such as point-to-point translations, which can be achieved in a shorter amount of time. Accuracy is the primary goal of an endoscopic procedure, and the robotic approach improves the ability to perform effective and reliable diagnostic screenings. This finding was confirmed by the in vivo trials, where the robotic approach was demonstrated to be superior to manual operation in terms of accuracy and precision of steering. To the best of the authors' knowledge, this is the first in vivo demonstration of the use of a robotic platform to magnetically steer a capsular endoscope.

The current version of the capsule is not yet swallowable due to the size of the current camera module. The next generation swallowable capsule, currently under development [13], will be wireless with comparable dimensions to the commercially available devices (e. g. 11 mm in diameter and 26 mm in length). A mock-up of the wireless prototype (without vision module) was successfully maneuvered by robotic control in in vivo conditions (**Video 1**), paving the way for a wireless capsular diagnostic procedure of the entire gastrointestinal tract.

It is worth mentioning that in order to achieve the desired capsule movement without the knowledge of capsule position and orientation, one can hardly predict the motion to be imposed to the EPM relying only on real-time visual feedback. Even though this limitation affects both manual and robotic steering, with the robotic-aided approach it will be possible to integrate real-time localization of the capsule by using either magnetic, ultrasound or inertial sensing. Moreover, a fusion of information from pre-operative images and intra-operative motion detection systems with the aid of the robotic arm has the capability to enable automated procedures, thus finally achieving the disruptive potential of WCE.

An issue still to be addressed regarding magnetic locomotion is related to lumen distension, for example capsule motion can only be achieved once a light insufflation of the lumen has been provided. A promising solution has been reported by Toennies and Webster [14], where a wireless insufflation system for capsular endoscopy is proposed.

Video 1

A mock-up of the final wireless prototype (without vision module) successfully maneuvered by robotic control in in vivo conditions.

online content including video sequences viewable at:
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Robotic-aided magnetic steering demonstrated in this study may also be applied to other procedures, such as minimally invasive surgery or natural orifices transluminal surgery (NOTES), whenever a magnetic tool requiring external control is used in the operating room [15, 16].

Acknowledgments

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Competing interests: None

References

1 *Iddan G, Swain P.* History and development of capsule endoscopy. Gastrointest Endosc 2004; 14: 1 – 9
2 *Moglia A, Menciassi A, Dario P, Cuschieri A.* Capsule endoscopy: progress update and challenges ahead. Nat Rev Gastroenterol 2009; 6: 353 – 362
3 *Van Gossum A, Munoz Navas M, Fernandez-Urien I et al.* Capsule endoscopy versus colonoscopy for the detection of polyps and cancer. N Engl J Med 2009; 361: 264 – 270
4 *Wang X, Meng M.* A magnetic stereo actuation mechanism for active capsule endoscope. IEEE Eng Med Biol Mag 2007; August: 2811 – 2814
5 *Quirini M, Menciassi A, Scapellato S et al.* Feasibility proof of a legged locomotion capsule for the GI tract. Gastrointest Endosc 2008; 67: 1153 – 1158
6 Olympus, Inc., Tokyo, JAPAN. www.olympus.it/Publication date: 8. December 2009
7 *Volke F, Keller J, Schneider A et al.* In-vivo remote manipulation of modified capsule endoscopes using an external magnetic field. Gastrointest Endosc 2008; 67: AB121 – AB122
8 *Valdastri P, Quaglia C, Susilo E et al.* Wireless therapeutic endoscopic capsule: in vivo experiment. Endoscopy 2008; 40: 979 – 982
9 Intuitive Surgical, Inc., Sunnyvale, USA. www.intuitivesurgical.com/patientresources/hospitals_doctors/index.aspxPublication date: 8. December 2009
10 Stereotaxis, Inc., St Louis, USA. www.stereotaxis.comPublication date: 8. December 2009
11 *Carpi F, Pappone C.* Magnetic maneuvering of endoscopic capsules by means of a robotic navigation system. IEEE Trans Biomed Eng 2009; 56: 1482 – 1490
12 *Ciuti G, Valdastri P, Menciassi A, Dario P.* Robotic magnetic steering and locomotion of capsule endoscope for diagnostic and surgical endoluminal procedures. Robotica 2009; 156: 49 – 58
13 VECTOR European Project. www.vector-project.com/Publication date: 8. December 2009
14 *Toennies JL, Webster RJ III.* A wireless insufflation system for capsular endoscopes. ASME Design of Medical Devices Conference, 2009. Poster Presentation. http://research.vuse.vanderbilt.edu/MEDLab/publications.htmPublication date: 8. December 2009
15 *Park S, Bergs RA, Eberhart R et al.* Trocar-less instrumentation for laparoscopy magnetic positioning of intra-abdominal camera and retractor. Ann Surg 2007; 245: 379 – 384
16 *Ryou M, Thompson CC.* Magnetic retraction in natural-orifice transluminal endoscopic surgery (NOTES): addressing the problem of traction and countertraction. Endoscopy 2010; 42: 143 – 148

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