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Intraoperative bowel cleansing tool in active locomotion capsule endoscopy

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***Abstract*— Capsule endoscopy (CE) can be considered an example of "disruptive technology" since it represents a bright alternative to traditional diagnostic methodologies. If compared with traditional endoscopy, bowel cleansing procedure in CE becomes of greater importance, due to the impossibility to intraoperatively operate on unclean gastrointestinal tract areas. Considering the promising results and benefits obtained in the field of CE for gastrointestinal diagnosis and intervention, the authors approached the bowel cleansing issue with the final aim to propose an innovative and easy-to-use intraoperative cleansing system to be applied to an active locomotion softly-tethered capsule device, already developed by the authors. The system, that has to be intended as an additional tool for intraoperatively cleansing procedure of the colonic tract, is composed by a flexible tube with a metallic deflector attached to the distal end; it can be headed to the target area through the capsule operating channel. Performances of the colonoscopic capsule and intraoperative cleansing capabilities were successfully confirmed both in an in-vitro and ex-vivo experimental session. The innovative intraoperative cleansing system demonstrated promising results in terms of water injection, colonic wall cleansing procedure and subsequent water suction, thus guaranteeing to reduce the risk of inadequate visualization of the mucosa in endoscopic procedures.**

I. INTRODUCTION

Colonoscopy is currently considered the gold standard for the investigation of large bowel pathologies, which represent one of the leading causes of death in western countries. However, the rigidity of the endoscope results in limited accessibility and make colonoscopic, and endoscopic procedures in general, significantly traumatic and poorly tolerated by patients [1]. Pain, discomfort and problems due to sedation represent the most significant limitations of endoscopic inspection and these limitations, together with the drawback of flexible endoscopy to reach certain areas of the small bowel, have led to the introduction of capsule endoscopy (CE) into the modern clinical panorama [2]. CE enables inspection of the digestive system without discomfort or need for sedation with the potential benefit of encouraging patients to undergo entire gastrointestinal tract examinations [3]. However, the problem of bowel preparation (essential for an effective diagnosis) and the impossibility to intraoperatively perform cleansing and treatment procedures remain two of the most relevant clinical challenges for making CE an effective diagnostic and potentially therapeutic tool, especially for the colonic inspection.

Bowel preparation is mandatory for providing a clean colon [4]: poor bowel preparation compromises the quality and efficacy of inspection procedures, affecting patient outcomes and increasing overall costs. An example of poor and effective colon preparation is reported in Figure 1.

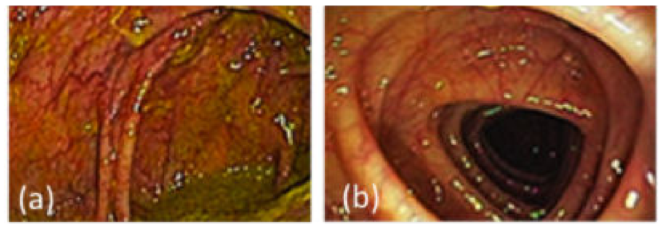

Figure 1 (a) Poor and (b) effective bowel preparation.

Furthermore, inadequate visualization of colonic mucosa or incomplete procedures can result in missed lesions, increased procedural time and potentially increased complication rates [5]. If compared with traditional colonoscopy, bowel cleansing procedure in CE (especially for the new generation of micro-robotic solutions with active locomotion) becomes of greater importance due to the impossibility to intraoperatively treat and thus diagnose unclear areas. Inadequate bowel preparation negatively influences both the reliability of examinations by video capsule endoscopy and the active locomotion strategy [6]. Therefore, preoperative and intraoperative solutions to enhance bowel preparations are vital to improving clinical practice [7]. The ideal bowel preparation and intraoperative cleansing procedure should be safe, well tolerated and effective.

In order to overcome the intraoperative bowel cleansing problem the authors propose an innovative cleansing system as an additional operating tool for a softly-tethered active magnetic colonoscopic capsule, already developed and tested by the authors [8]. Being the proposed capsule equipped with a working channel, designed for maintaining the therapeutic capabilities provided by a standard colonoscope (i.e., manipulation of standard endoscopic tools such as biopsy forceps, polypectomy snare, retrieval basket, grasper, etc.), an additional cleansing function has been added to the system making it a valid platform for intraoperative cleansing task. In the next sections, analysis of an innovative intraoperative bowel cleansing procedure is described and preliminary in-vitro and ex-vivo results are reported.

II. MATERIALS AND METHODS

A. Robotic platform and capsule endoscope

Robotic magnetic control and steering, developed and already validated in [8], is applied to a colonoscopic device containing a frontal magnetic camera linked to an external remote station by a soft tether. This multilumen connection is used for providing insufflation, passing operative flexible

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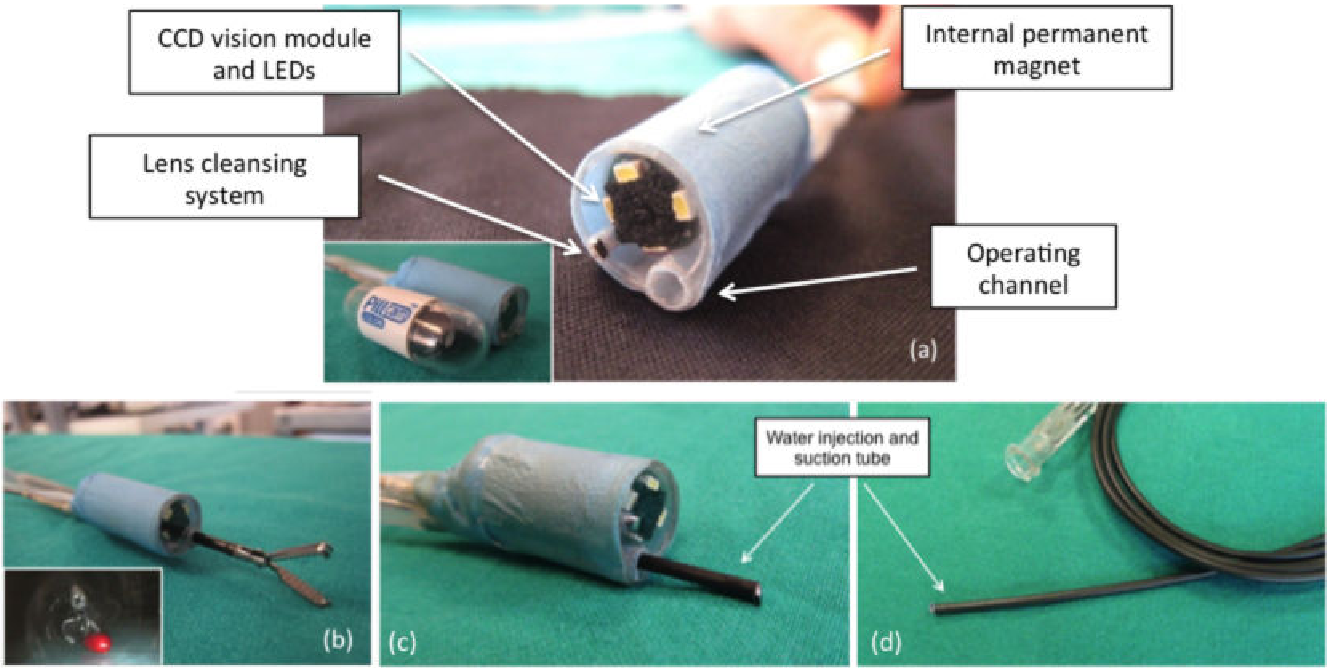

Figure 2 (a) MAC in comparison to a PillCamTM COLON capsule and MAC with a (b) grasper and (c-d) with the water injection and suction tube.

tools, enabling lens cleaning and operating the vision module. The "front-wheel" magnetic propulsion approach was adopted to eliminate the need of pushing the shaft to advance the scope, thus preventing colonic stretching phenomena, looping and pain currently associated with traditional colonoscopy. These advantageous features are enhanced by a drastic reduction in both the bending stiffness of the shaft and the mass of the proposed device (from 1.2 Kg of a standard colonoscope down to 34 g including the soft tether adequately for the current device), while the therapeutic capabilities provided by a standard scope are maintained. The proposed colonoscopic device, also called magnetic air capsule (MAC) and described in details in [8], is composed of a capsule-like frontal unit (11 mm in diameter, 26 mm in length, and 10.5 g in mass) and a compliant multilumen tether (the overall external diameter of the tether is 5.4 mm, while its length is 2 m, increasing the total mass of the MAC up to 34 g), with overall shape, size and volume comparable to a wireless capsule endoscope [1]. The frontal unit contains a vision module, a permanent magnet, and three lumens: one for lens cleaning, one for insufflation/suction/irrigation or insertion of an operative tool (operating channel) and the third lumen allowing electrical connection to the vision module and sensors. The vision module consists of a 500 x 582 CCD camera with 120° field of view (Karl Storz GmbH, Tuttlingen, Germany), four high-efficiency white LEDs (NESW007BT; Nichia Corp., Tokushima, Japan), and a transparent plastic flat cover. A custom-shaped NdFeB permanent magnet is embedded in the MAC to provide for the magnetic link (axial magnetization along the main dimension of the capsule, with residual magnetic flux density of 1.48 T). The external magnet is made of NdFeB in a cylindrical shape (90 mm in diameter and 80 mm in length), resulting in a residual flux density of 1.48 T; it is placed as the end-effector of a 6 degree-of-freedoms (DoFs) anthropomorphic robotic arm (RV-6SL; Mitsubishi Electric, Tokyo, Japan). Magnetic coupling allows for the movement of the permanent magnet in a 3D volume external to the patient's body that drives the position and orientation of the MAC inside the patient. The magnetic link, defined by the features of the two permanent magnets, is designed to properly drag and steer the MAC at a maximum working distance of 150 mm between the external magnet and the endoscopic device. This technique allows the colonoscopic device to be advanced into the colon and oriented toward the lumen wall under direct guidance of the operator by means of the camera images stream. The user controls the position of the external magnet and, thus of the capsule, in real-time by the use of a 6 DoFs control peripheral (3D SpacePilot, 3Dconnexion Inc., USA). As the main channel of the multilumen tether, a polytetrafluoroethylene sheath with inner diameter of 2.8 mm and external diameter of 3.2 mm, allows for gas insufflation, suction, irrigation, or access for standard endoscopic tools such as biopsy forceps, polypectomy snare, retrieval basket, grasper, etc. (matching medical recommendations). Operating tools (inert to magnetic field for obtaining optimal performance due to the presence of an external magnetic source for locomotion) can be inserted and removed intraoperatively once the treatment and therapy is required. Close-up views of the MAC are shown in Figure 2 a and Figure 2 b. In order to guarantee the intraoperative cleansing of the bowel, a dedicated tool has been developed and it is composed by a flexible polyurethane channel with a metallic deflector attached to the distal end. The system, depicted in Figure 2 c and Figure 2 d, can be introduced into the MAC operating channel and headed to a bloodstained or unclean areas inside the colonic tract for a localized cleansing procedure. A proper direction of the pressurized water jet to the target can be achieved through the steering of the capsule by means of the designed magnetic link (3 DoFs – locomotion along the lumen and pitch and yaw orientation of the capsule by the robot) and by the rotation of the water jet tube along its axis (1 DoFs – roll of the cleansing tool). Once the colonic wall has been cleaned,

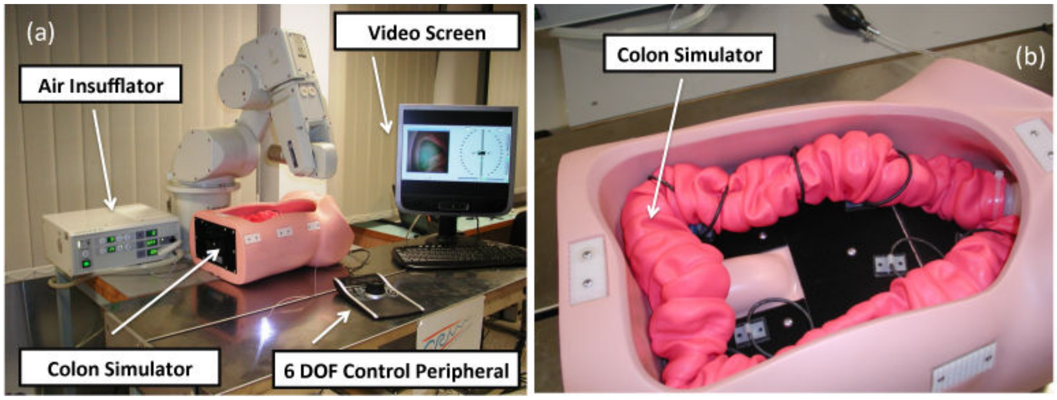

Figure 3 (a) In-vitro experimental test bench and (b) colon simulator.

the tube can be also exploited, when needed, for the suction of the injected water thus allowing a proper view of the entire colonic wall. Injection and suction was performed from the external by means of a traditional syringe; in our case a 10 mL syringe was exploited for injecting water with a volumetric flow rate of approximately 5 mL/s. Moreover, thanks to the compact profile of the MAC and flexibility of the tool, high steerability, up to retroflection of the camera capsule, can be easily achieved.

B. Experimental test

In order to evaluate the effectiveness of the proposed endoscopic tool in an intraoperative bowel cleansing procedure, an experimental test bench has been set up and a dedicated preliminary task has been performed in in-vitro conditions (Figure 3). The test was carried out by an expert operator with the following steps: i) driving the MAC through the latex colon simulator placed in a human body phantom and arranged to mimic the human anatomical structure, ii) finding out a preoperative established artificially stained area and iii) performing the cleansing procedure exploiting the previously described water jet additional tool. The colon simulator has been entirely travelled by the operator from the rectum up to the cecum. A real-time image stream coming from the capsule was displayed on a dedicated screen, representing the only control feedback for the operator driving the procedure. An air insufflator (Surgiflator-40,W.O.M.Word of Medicine AG, Germany) maintained a constant internal pressure of 2 mmHg in order to distend the colon wall during the MAC travel. In addition, in order to validate the cleansing capabilities, the same protocol was applied in an ex-vivo condition. An uncleaned porcine colonic tract was fixed on a human body phantom and the cleansing procedure, by exploiting the MAC and the water injection and suction tube, was carried out for qualitatively assessments.

III. Results and Discussion

Performances of the endoscopic capsule were successfully confirmed in terms of locomotion and steerability in the in-vitro experimental session. The MAC was successfully and reliably manoeuvred by the operator, allowing a complete inspection of the colon simulator under the camera feedback, and towards stained areas to be approached and cleaned. Time for performing the complete colon inspection (less than 16 minutes) resulted consistent with data reported in [8], including insertion and retrieval of the cleansing tool. The cleansing operation, performed 15 times on different spots within the procedure, required a maximum time of about 1 minutes for accomplishment (time is strictly dependent by the significance of the cleansing action). All the identified spots were detected and cleaned successfully using the water jet tool and exploiting the effective steerability properties of the tethered endoscopic capsule system. The magnetic link was always strong enough to hold the MAC in place during the cleansing procedure and during multiple insertions and retractions of the tool through the capsule operating channel. A sequence of pictures during the cleansing procedure and water suction is shown in Figure 4 a-c. In the in-vitro procedure, the capsule was travelled along the colon simulator and arrested once an unclean area has been detected (Figure 4 a). Then, the endoscopic water jet tool was introduced, oriented towards the unclean colonic tract area and the water was injected by the external pumping system (Figure 4 b) until the stain was not completely removed for a reliable and accurate inspection of the simulator wall. Finally, the injected water was removed from the colon exploiting the same endoscopic tool and without occurrences of obstructions (Figure 4 c). The aforementioned results in terms of cleansing capabilities were confirmed by the ex-vivo assessment. In Figure 4 d-f screenshots of the cleansing procedure on porcine tissue are reported, presenting an effective treatment of the unclean area.

IV. Conclusion

Poor bowel preparation compromises the quality and efficacy of inspection procedure, affecting patient outcomes and increasing overall procedural costs. Furthermore, inadequate visualization of colonic mucosa or incomplete procedures can result in missed lesions, increased both procedural time and potentially complication rates. By exploiting the therapeutic capabilities of a miniaturized softly-tethered colonoscopic capsule designed for colon inspection and therapy, additional cleansing function can be added for improving colonic diagnosis and therapy. An innovative intraoperative bowel cleansing system has been designed, tested and validated on a magnetic locomotion endoscopic platform developed by the authors [8]. A dedicated water jet tube was fabricated and can be introduced into the MAC operating channel and headed to a bloodstained or unclean areas inside the colonic tract for a

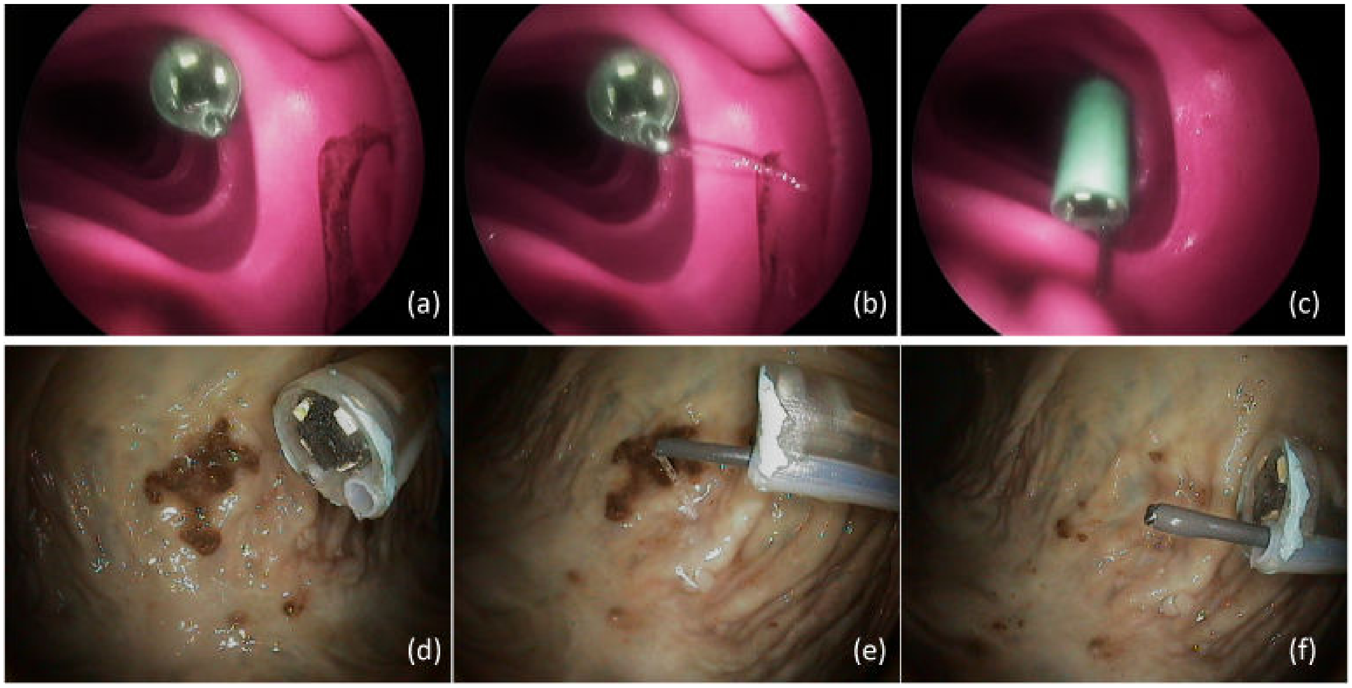

Figure 4 A sequence of pictures recorded by a traditional laparoscopic camera during the cleansing procedure (introduction/orientation of the colonoscopic device and cleansing tool, water injection for treatment of the unclean area and liquid suction for exposing the entire colonic wall) in (a-c) in-vitro and (d-f) ex-vivo conditions.

localized cleansing procedure. In-vitro tests were performed by using a colon simulator and promising results were achieved in terms of water injection, wall cleansing procedure and subsequent water suction. The effectiveness of the proposed cleansing method was confirmed by the ex-vivo experimental test; the cleansing tool allowed for a reliable intraoperative tissue exposure of the colonic wall for a safe diagnosis and reliable treatment.

The proposed solution rises from a clinical need; it has to be intended as an easy-to-use additional tool for improving inspection procedure by magnetic locomotion colonoscope after a traditional preoperative bowel preparation diet. Moreover, the same system can be directly exploited for a local release of drugs on the colonic wall for the treatment of colonic pathologies, such as ulcers, tumours or Crohn's disease. Obviously, additional studies are mandatory to assess its efficacy in in-vivo conditions, as well as head-to-head comparison with standard colonoscopy.

REFERENCES

[1] G. Ciuti, A. Menciassi, P. Dario, "Capsule Endoscopy: From Current Achievements to Open Challenges", *IEEE RBME*, vol. 4, pp. 59-72, 2011.

[2] M. Waterman and R. Eliakim, "Capsule endoscopy of the small intestine," *Abdom. Imag*., vol. 34, no. 4, pp. 452–458, 2009.

[3] I. Fernandez-Urien , C. Carretero, A. Borda, M Mun˜oz-Navas , "Colon capsule endoscopy", *World J Gastroentero*, vol. 14, pp. 5265–5268, 2008.

[4] P.J. Athreya, G.N. Owen, S.W. Wong, et al., "Achieving quality in colonoscopy: bowel preparation timing and colon cleanliness", *ANZ J Surg*, vol. 81, pp. 261-265, 2011.

[5] S.D. Wexner, D.E. Beck, T.H. Baron, et al., "Aconsensus document on bowel preparation before colonoscopy: prepared by a task force from the American Society of Colon and Rectal Surgeons (ASCRS), the American Society for Gastrointestinal Endoscopy (ASGE), and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)", *Surg Endosc,* vol. 20, pp. 1147–1160, 2006.

[6] S.J.B. Van Weyenberg, H.T. De Leest, C.J. Mulder, "Description of a novel grading system to assess the quality of bowel preparation in video capsule endoscopy", *Endoscopy*, vol. 43, no. 5, pp. 406-411, 2011.

[7] M. Van Dongen, "Enhancing Bowel Preparation for Colonoscopy: An Integrative Review", *Gastroenterol Nurs*, vol. 35, no.1, pp. 36-44, 2012.

[8] P. Valdastri, G. Ciuti, A. Verbeni, A. Menciassi, P. Dario, A. Arezzo, M. Morino, "Magnetic air capsule robotic system: Proof of concept of a novel approach for painless colonoscopy", *Surg Endosc*, vol. 26, no. 5, pp. 1238-1246, 2012.