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ELSEVIER MASSON
Biomedicine & Pharmacotherapy 62 (2008) 546–549
BIOMEDICINE & PHARMACOTHERAPY
www.elsevier.com/locate/biopha

Original article

Magnetic robotic manoeuvring of gastrointestinal video capsules: preliminary phantom tests

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Received 23 June 2008; accepted 1 July 2008
Available online 6 August 2008

Abstract

Ingestible video capsules enable today non-invasive and comfortable gastrointestinal explorations. As such, capsule endoscopy is progressively emerging as an attractively simple wireless technology for optical investigations of the digestive tube and, in particular, as a useful complementary diagnostic tool with respect to traditional probe endoscopy. In spite of this, capsule endoscopes still show at present a major technical lack, capable of seriously limiting their clinical efficacy: their motion cannot be controlled by an external operator. In fact, the lack of a navigation control system makes their movements and orientations totally random, being exclusively driven by visceral peristalsis and gravity. In order to provide motion control properties, a technique based on the application of external magnetic fields, capable of manoeuvring a capsule previously equipped with a magnetic component, was recently proposed. This paper presents preliminary results of the first experimental implementation of this concept with a magnetic robotic system recently introduced in the clinical practice, although for different applications in the field of cardiology. The potentialities offered by this robotic system for magnetic controls of gastrointestinal capsules were preliminarily assessed in this work with manoeuvring tests of a video capsule inside a plastic replica of a human bust. Results showed the possibility of magnetically guiding the navigation of an endoscopic capsule within the considered experimental set-up, by advantageously using the reliable robotic navigation system already employed for clinical applications. Such an outcome encourages further investigations within more challenging experimental conditions.

Keywords: Capsule; Control; Endoscopy; Gastrointestinal; Magnetic; Manoeuvring; Motion; Video; Wireless

1. Introduction

The introduction in the clinical practice of ingestible video capsules for gastrointestinal explorations of the digestive tube begun a few years ago [1-2], followed by an ever improving diffusion, still in progress today. The most common commercial product is the capsule M2A produced by Given Imaging Ltd, Yoqneam, Israel [3], shown in Fig. 1a. As a remarkable outcome of major advances in microelectronics, this pill-shaped device integrates in a small package (26×11 mm, 3.23 g) image capture, wireless data transmission and power supply functions. As it is swallowed by the patient, it travels along the digestive tube until its natural expulsion out of the body. During its operation, that typically lasts 8 h, the video capsule illuminates the wall of the gastrointestinal tube and takes pictures automatically. Acquired data are wirelessly transmitted to a wearable external recorder. At the end of the procedure, data are downloaded from the recorder into a workstation; here, the video frame sequence is reconstructed, to be analysed off-line by the physician.

Since it enables non-invasive and comfortable optical investigations of the digestive tube, video capsule endoscopy is progressively spreading very quickly in gastroenterology.

Nevertheless, this technology today is not alternative to traditional probe endoscopy. In fact, the clinical utility and diagnostic efficacy of the two endoscopic techniques might substantially be regarded as complementary. In particular,

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0753-3322/$ - see front matter
doi:10.1016/j.biopha.2008.07.057

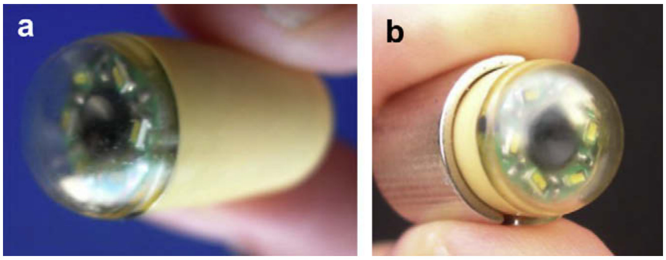

Fig. 1. Endoscopic video capsule (M2A model, Given Imaging Ltd, Israel) (a) and its coupling with the custom-made prototype magnetic shell experimented in this work to provide a magnetic response (b).

capsule endoscopy enables explorations of anatomic regions resulting inaccessible with standard probe endoscopy, owing to their excessive distances from both mouth and anus. As such, the exploration of small bowel is certainly the most important domain of application, in which capsule endoscopes show all their advantageous potential. Their most common clinical indication is the diagnosis of obscure intestinal bleeding [4–6].

On the contrary, the diagnostic efficacy of standard probe endoscopy is still superior in those regions resulting accessible with both techniques. In fact, video capsule endoscopy has some intrinsic limitations. First, it cannot insufflate air for bowel distension, aimed at enhancing mucosal visualization. Second, it makes difficult an exact anatomic localization of visualized lesions. Third, it does not offer interventional capabilities (biopsy). Finally, it does not allow the operator to control the exploration, by changing the visualized area during the procedure. In fact, the movement of the video capsule is purely passive, being exclusively determined by visceral peristalsis and gravity. Although such a natural propulsion is attractive from a technical point of view (since it enormously simplifies the device architecture and it does not require an artificial source of energy for motion), it is less effective from a clinical point of view. As a matter of fact, the impossibility of manoeuvring the capsule makes its trajectory and orientation purely random, seriously limiting the diagnostic efficacy of the investigation.

In order to solve this problem, one of the most reasonable approaches allowed by the current state of the art of technology is based on the use of magnetic fields. The idea is to make the capsule magnetically responsive to an external magnetic field, used to manoeuvre the capsule remotely. So far, such a concept has been object of some patents and papers, which have proposed several technical solutions aimed at providing the capsule structure with a specific magnetization. These approaches basically include either magnetic parts or induction coils integrated within the capsule volume or external magnetic shells reversibly applicable to the device [7].

Beyond such designs, one of the most important challenges towards a clinically applicable magnetic control system for endoscopic capsules is completely open today: it is related to the development of an instrumentation capable of reliably and precisely controlling a magnetic field to be delivered inside the patient, close to the capsule.

Aimed at addressing this problem, a robotic magnetic navigation system, recently developed for different types of applications in a different clinical field (cardiology), was previously suggested to represent an attractive platform for the exploration of possible alternative uses in controllable capsule endoscopy [7]. This instrumentation is described in the next section, which presents the overall architecture of the proposed magnetic control technology.

In this work, the application of the selected magnetic robotic system for controlling endoscopic capsules was experimented for the first time, by performing manoeuvring tests of a video capsule inside a plastic replica of a human bust.

2. Materials and methods

The video capsule considered in this work is the Given Imaging M2A model, presented in Fig. 1a.

In order to make this capsule magnetically responsive, a custom-made magnetic shell was applied around it. The shell consisted of two neodymium-based semi-cylindrical parts, as visible in Fig. 1b. The shell had a length of 13 mm and an external and internal diameter of 13 and 11 mm, corresponding to a weight of 3.59 g. Its two parts were manufactured with a uniform magnetization, orthogonal to the main cylindrical axis. Accordingly, the shell-equipped capsule subjected to a uniform magnetic field tends to orient its main axis of symmetry perpendicularly to the applied field. The magnetization of the two parts also allowed them to keep their own arrangement around the capsule (without using any gluing or coating material). Although the simplicity of this solution effectively enabled manoeuvring tests with a real endoscopic capsule, of course the shell could not be used exactly like this for clinical applications, due to obvious safety reasons. In this case, in fact, the capsule and the shell should form a unique body; this would require the application of an external sealing.

As a controllable source of magnetic field, the commercial Niobe® magnetic navigation system produced by Stereotaxis, Inc., St. Louis, MO, USA [8] was used. Recently, this system was specifically identified as a suitable instrumentation for testing the possibility of magnetically manoeuvring video capsules [7], according to its attractively unique features, presented in the following. Fig. 2 shows this instrumentation and the specific set-up adopted for the control tests performed in this work (described at the end of this section).

The Niobe system was recently developed for diagnosis and treatment of cardiovascular diseases and has already received clearance for clinical applications. In particular, it is currently employed to safely and remotely perform computer-controlled cardiovascular interventional procedures. In fact, it enables precise navigation controls of the magnetic working ends of catheters and other disposable interventional devices. They can be magnetically steered through the complex paths of either the heart chambers or the coronary vasculature, as an alternative to manual procedures, in order to treat specific cardiovascular diseases (arrhythmias, heart failure and coronary artery disease) [8–11]. As such, this kind of robotic

Fig. 2. Robotic magnetic navigation system (Niobe® model, Stereotaxis Inc., USA) and experimental set-up for testing the manoeuvrability of the magnetically enabled capsule inside a plastic phantom. The phantom was laid on the patient's table, between the two magnets of the system and below the integrated fluoroscopic scanner.

magnetic navigation system is unique. Several clinical investigations have well assessed its clinical efficacy, by showing its specific ability of overcoming the intrinsic limitations of manual interventional procedures [9–11].

Such capabilities are enabled by the following basic constitutive parts of the system. Two large permanent magnets are used to generate a uniform magnetic field of 0.08 T inside the patient, when he is laid on a table located in the air gap between them (Fig. 2). The magnets are robotically operated, so as to assume several possible orientations. In particular, by controlling the orientation of both the housings of the magnets (as shown in the examples of Fig. 2) and/or that of the magnets themselves inside their housings (not visible in Fig. 2), the operator can arbitrarily change the direction of the delivered magnetic field. Such a variable orientation of the field can be accomplished within a spherical volume, having a diameter of approximately 20 cm. Therefore, any magnetically responsive tool being introduced within the spherical working volume can be remotely oriented with controllable rotations.

The system provides the physician with remote instrument control capabilities, through a user friendly "point and click" and/or joystick-operated computer interface. Accordingly, the operator can control the overall navigation procedure directly from a remote computer console. The software interface integrates also digital fluoroscopic images that are acquired by means of an X-ray scanner arranged above the working area (Fig. 2). Therefore, the actual position and orientation of the magnetic tool inside the body can be detected at any time.

Such interesting features make this technology an attractive starting tool in order to develop a control system for potential magnetic navigations of endoscopic capsules. Aimed at exploring this possibility, the first preliminary investigation was performed in this work, according to the following experimental procedure.

A hollow plastic replica of a human bust was used as a phantom for simple manoeuvring tests on the video capsule equipped with the magnetic shell. A plastic chamber and a tubular conduit leading to it were inserted inside the bust, as rough geometrical analogues of the gastric chamber and the esophageal tube. Fig. 2 shows the arrangement of the phantom on the table of the magnetic navigation system.

In order to study the controllability of the shell-equipped capsule within the phantom, different types of manoeuvring procedures were tested. For this purpose, the 0.08 T magnetic field was oriented along variable directions, in order to provide the capsule with selectable orientations. Moreover, translations of the patient's table were also applied, either independently or simultaneously with respect to changes of the field direction, so as to achieve either pure rotations, pure translations or combined roto-translations of the capsule. The actual movements being achieved were continuously monitored during the testing phase, by using the fluoroscopic imaging technology integrated with the navigation system, as previously described.

The manoeuvring procedures were entirely automated, owing to the robotic driving of the instrumentation. The control of the system was performed from a remote computer console, as typically permitted by this instrumentation. This allowed the operator to be safely preserved from exposure to X-rays during imaging.

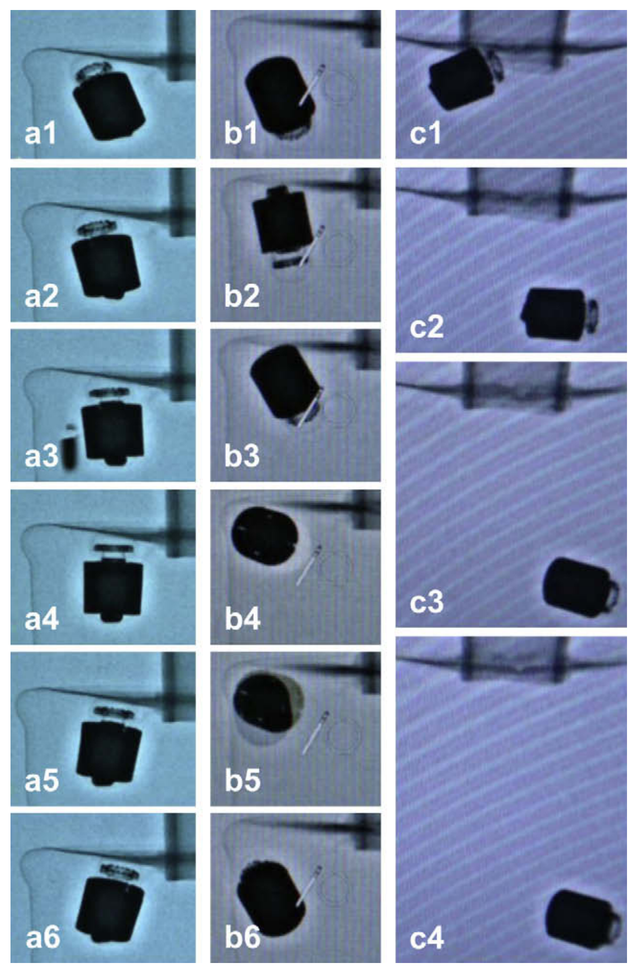

Fig. 3. Fluoroscopic images of the phantom's internal chamber acquired during the following controlled movements of the capsule: a small rotation (a1–a6); a rotation of 180° (b1–b6); a roto-translation (c1–c4). As an observation, we stress that the stick-like drawing superimposed to frames b1–b6 represents a virtual catheter that can be visualized by the standard control software for cardiovascular applications (magnetic steering of endocardial catheters), which was borrowed in this work to perform the different types of tests here reported.

3. Results

Results of the performed manoeuvring tests permitted to preliminarily assess the capabilities and the potentialities of the Niobe magnetic navigation system to control the magnetically enabled capsule within the considered experimental set-up.

As examples of the experimented manoeuvres, Fig. 3 presents some motions, recorded as sequences of fluoroscopic images.

In particular, pure rotations with different amplitude are reported in Fig. 3a and b, while Fig. 3c shows a roto-translation, obtained from the combination of a rotation of the applied field with a translation of the phantom's table.

Such preliminary results suggest the possibility of magnetically guiding the navigation of an endoscopic capsule by using a reliable robotic navigation system, which is already employed for clinical applications, although in a different medical discipline.

Nevertheless, despite these first encouraging results, further detailed investigations are needed, in order to overcome, as a next necessary step, the simplicity of the experimental conditions considered in this initial work. Such investigations are currently in progress and will be object of future communications.

4. Conclusions

In order to provide endoscopic video capsules with motion control properties, this paper presented the first prototype implementation of a new technique being currently studied. The proposed solution relies on the use of external magnetic fields capable of manoeuvring a capsule equipped with a magnetic component. The paper presented preliminary results of an experimental testing of this concept with a magnetic robotic system recently introduced in the cardiovascular clinical practice. Positive outcomes of phantom tests encourage further investigations in this direction.

References

[1] Iddan GJ, Swain CP. History and development of capsule endoscopy. Gastrointest Endosc Clin N Am 2004;14:1–9.

[2] Iddan G, Meron G, Glukhovsky A, Swain P. Wireless capsule endoscopy. Nature 2000;405:417.

[3] Given imaging web site. Available from: <http://www.givenimaging.com>.

[4] Remedios ML, Appleyard M. Capsule endoscopy: current indications and future prospects. Intern Med J 2005;35:234–9.

[5] Bresci G, Parisi G, Bertoni M, Emanuele T, Capria A. Video capsule endoscopy for evaluating obscure gastrointestinal bleeding and suspected small-bowel pathology. J Gastroenterol 2004;39:803–4.

[6] Appleyard M, Glukhovsky A, Swain P. Wireless-capsule diagnostic endoscopy for recurrent small-bowel bleeding. N Engl J Med 2001;344:232–3.

[7] Carpi F, Galbiati S, Carpi A. Controlled navigation of endoscopic capsules: concept and preliminary experimental investigations. IEEE Trans Bio-Med Eng 2007;54(11):2028–36.

[8] Stereotaxis web site. Available from: <http://www.stereotaxis.com>.

[9] Pappone C, Vicedomini G, Manguso F, Gugliotta F, Mazzone P, Gulletta S, et al. Robotic magnetic navigation for atrial fibrillation ablation. J Am Coll Cardiol 2006;47(7):1390–400.

[10] Pappone C, Santinelli V. Remote navigation and ablation of atrial fibrillation. J Cardiovasc Electr 2007;18:S18–20.

[11] Stereotaxis web site – list of clinical publications. Available from: <http://www.stereotaxis.com/Medical-Professionals/Clinical-Publications/>.