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ORIGINAL ARTICLE

Propeller-based wireless device for active capsular endoscopy in the gastric district

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Abstract
An innovative approach to active locomotion for capsular endoscopy in the gastric district is reported in this paper. Taking advantage of the ingestion of 500 ml of transparent liquid by the patient, an effective distension of the stomach is safely achieved for a timeframe of approximately 30 minutes. Given such a scenario, an active swallowable capsule able to navigate inside the stomach thanks to a four propeller system has been developed. The capsule is 15 mm in diameter and 30 mm in length, and it is composed of a supporting shell containing a wireless microcontroller, a battery and four motors. The motors enable the rotation of propellers located in the rear side of the device, thus obtaining a reliable locomotion and steering of the capsule in all directions in a liquid. The power consumption has been properly optimized in order to achieve an operative lifetime consistent with the time of the diagnostic inspection of the gastric district, assumed to be no more than 30 minutes. The capsule can be easily remotely controlled by the endoscopist using a joystick together with a purposely developed graphical user interface. The capsule design, prototyping, *in vitro*, *ex vivo* and preliminary *in vivo* tests are described in this work.

Key words: *Capsular endoscopy, minimally invasive gastroscopy, active locomotion, wireless endoscopy*

Introduction

Traditional endoscopy of the gastrointestinal (GI) tract is performed by means of a flexible endoscope, a tubular device with working channels, an illumination system and an image sensor usually placed on the tip. The endoscope is inserted by the endoscopist through a natural orifice, e.g. the mouth for gastroduodenoscopy, and the anus for colonoscopy.

Johann Miculicz presented the first gastroscope, a rigid device with an illumination system and additional channels, in 1881 (1). However, the first safe endoscopic transoral examination of the stomach became feasible just in 1932, when Wolf and Schindler developed the first semi-flexible endoscope comprising a complex, prism-based optical system (2). The modern flexible endoscope, featuring a fiber-optic illumination system, is based on the concept of the fiberscope presented by Hirschowitz in 1958 (3).

Nowadays, flexible endoscopy is a standard procedure for diagnosis and treatment of a variety of conditions of the upper and lower GI tracts. Moreover, gastroscopy and colonoscopy have become the gold-standard diagnostic procedures for GI cancer screening. A limiting factor for the success of screening endoscopy, however, is the willingness of the patients to undergo the procedure (4,5). Up to 75% of patients are diagnosed in advanced stages of disease, although appropriate measures for early detection of colorectal cancer are available (6).

A significant advancement in the field of GI endoscopy in terms of patient acceptability was provided by wireless capsule endoscopy (WCE) (7,8), enabling a non-invasive examination of the GI tract and bearing

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a high potential for screening. With the introduction of the first wireless endoscopic capsule, developed by Given Imaging (Given Imaging, Yoqneam, Israel), an innovative examination method became available. It provides a straightforward access for inspection to the small bowel, an area of the GI tract that, until 2000, had been difficult to reach with conventional endoscopes. Afterwards, WCE rapidly evolved to become the standard for small bowel screening. Further developments such as the PillCam ESO and the PillCam Colon (Given Imaging), allowing for minimally invasive examination of the esophagus and the colon, are contributing to broaden the medical scope of WCE (9).

Despite the technological progress in this field, current devices still demonstrate deficiencies when they must inspect the stomach and the colon. This is mainly due to the capsule's passive locomotion by peristalsis (the endoscopist cannot control the movement of these devices) and to the lack of active tissue distension. In flexible gastroscopy, the organ is insufflated with air in order to distend the tissue in front of the camera and allow to inspect the mucosal wall, while in WCE the organ is collapsed and just a small area around the capsule can be observed. On the other hand, tissue distension in WCE is a very challenging problem, much more difficult than active locomotion, because forces and torque required for tissue distension are very large. In order to address this issue, gastric distension by means of liquid intake was considered a promising strategy. Initial single trials were performed to evaluate different common protocols for colonoscopy preparation, including the usage of Polyethylene Glycol (Macrogol, PEG) and Sodium Phosphate. These investigations showed favourable results for PEG in both cleaning and providing stomach distension. PEG was initially considered for this purpose also due to a theoretical technical advantage, since it is transparent and therefore does not interfere with the optical system of the capsule endoscope. Moreover, Macrogol is biocompatible, non-toxic and does not induce systemic effects on the patient; it is a laxative commonly used in the preparation of patients for colonoscopy (10). Further trials to assess PEG suitability for stomach distension were performed and the results are reported in the next section.

Once a viable solution for stomach distension was identified, we investigated a way to control and steer a wireless endoscopic capsule in a liquid environment. Considering the typical size of the capsule we intend to develop, submarine design rules apply better than a bioinspired approach (11,12). Thus, we tried to scale down traditional propeller-based mechanisms, commonly used in naval engineering. This principle of underwater locomotion is currently used to perform a variety of functions, from mapping the ocean floor to surveying shipwrecks, helping to explore water environments for scientific or military tasks. These systems are mainly equipped with a single propeller to provide thrust and with couples of horizontal and vertical rudders for steering and route adjustment. Several examples are reported in the literature (13–15). The smallest submarines with actuators on board range between 10 cm and 20 cm in size. These devices are conceived mainly as toys (16). Below this size, rudder-based steering systems can hardly be integrated on board due to the fragility of miniaturized mechanisms. Moreover, this mechanism could not be used in endoscopic devices because of the protruding rudders, which would make the capsule difficult to swallow. An alternative solution for 3D propulsion in a liquid environment is obtained by using multiple propellers - instead of rudders or wings - to obtain both steering and trimming control in addition to the thrust along the longitudinal axis. A significant example is represented by the Serafina submarine (17,18), which is a device for marine underwater exploration. Five propellers are placed on two main perpendicular axes. The lateral and the back propellers are mainly used for steering and directional adjustments, while the two propellers in the middle are used for thrust. The total volume of this device is $45.5 \times 14 \times 21$ cm^3. Applying this solution to capsular endoscopy would still result in having protruding features: In this case the two directional propellers would prevent an easy swallowing of the capsule.

A different steering strategy, down-scalable to a swallowable shape, is therefore required for the devised application of capsule endoscopy. Single propeller and water jet capsular devices have been proposed (19), but never effectively demonstrated due to a series of unsolved problems, such as stability and thrust effectiveness. One of the main reasons is that a single actuator rotating around an axis generates a counter rotation of the body holding the actuator. Moreover, because a low amount of liquid is present inside the GI tract in physiological conditions, such areas must be filled by liquid intake to enable an effective propeller-based locomotion. We observed that a good distension is possible only inside the stomach, while other districts are almost not affected by the intake of small amounts of liquid.

In order to achieve effective propulsion and a controllable steering in a swallowable device, a propeller-based locomotion system taking advantage of four independent motors located in the rear part of the capsule is introduced and detailed in this paper. The proposed locomotion solution can be easily integrated in a pill-shaped device due to its small dimension. The resulting capsule can then be swallowed without any discomfort by the patient after ingestion of an amount of transparent liquid. Neutral buoyancy of the capsule, obtained with proper weight trimming, allows the device to hold its position when the motors are off, thus lowering power consumption. Wireless bidirectional communication enables real-time steering of the device by joystick control. The capsule is battery-operated with an operative lifetime of more than 30 minutes, due to specific efforts devoted to optimize power consumption. By these means, a complete inspection of the gastric cavity becomes feasible. The integration of a frontal vision module has been considered in the current design and is completely feasible in terms of available volume.

This paper illustrates the medical rationale, the mechatronic design of the entire system and the control strategy adopted. We first describe the importance of a wireless locomotion system for an endoscopic capsule in the current medical scenario. We then report on the challenges and the motivations of the adopted design, and a detailed description of the device is given. We then present the experimental results in two sets of trials: The first was performed on bench, in a structured environment, to prove the feasibility and the performance of the proposed solution; the second was done on an explanted pig stomach. Animal experiments were performed to assess the system in a real operative scenario. Finally, discussion and conclusions are given.

Principles and methods

Medical prerequisites

The concept we propose for distending the stomach is based on an extended bowel cleaning protocol as it is implemented before any regular colonoscopy. A common scheme for preparation comprises the intake of 2-3 l of PEG solution on the evening before the procedure and 1-2 l in the morning (20, 21). Based on the initial results described in the introduction, a serial trial among healthy volunteers was conducted to evaluate the feasibility of liquid distension with PEG. The study protocol was reviewed by the Institutional Review Board (IRB) and informed consent of the participants was gathered. Eleven subjects underwent a preparation with 2 l of PEG solution on the day before the procedure. Additional 1 l was administered in the morning, two hours before the examination. Capsule endoscopy was performed using a PillCam SB (Given Imaging, Yoqneam, Israel). After swallowing the capsule, 0.5 l of PEG solution was administered. The volunteers underwent different posture changes to provoke position changes of the capsule. After 30 minutes, the intake of 0.5 l of PEG solution was repeated. The participants were asked for discomfort on a subjective scale; when discomfort was reported, the procedure was stopped. The feasibility of the procedure was determined by a predefined set of parameters which included scales for wall visualization, debris and recognition of predefined areas of key interest and bubble formation. Of the ten subjects that completed preparation, visualization of the target areas was achieved in nine cases (90%). It was preliminarily concluded that the oral ingestion of 0.5-1 l of liquid may achieve the desired result without significant discomfort for the subject. Based on these findings, PEG solution was considered adequate for this study (22). Nevertheless, other visible light transparent agents, such as fiber solutions (23), can be investigated in the future in order to improve patient's acceptability.

Technical solution

The use of a liquid to distend the stomach facilitates the development of an active locomotion system for a wireless endoscopic capsule robot. In empty and undistended state, the stomach is collapsed and represents a virtual cavity; thus an endoscopic robot should first distend the tissue and then perform imaging, as described by Quirini et al. (24). Large forces are necessary to achieve effective distension, which requires an amount of power supplied to the device that is impossible to store inside a swallowable volume (25). Liquid distension of the stomach enables the use of smaller and less energy-demanding actuators, used just for locomotion and not for distension.

Given a target videopill size (typically 26 mm in length and 11 mm in diameter, as the Given Imaging SB) and the hydrodynamic properties of PEG solution, viscosity effects are negligible if compared to inertial forces, thus traditional fluidodynamics is applicable to describe the capsule motion. Thus, we designed a locomotion system (26) inspired by submarines, exploiting the high thrust capability offered by propellers at this scale. Furthermore, propellers can be placed at the back of the capsule and embedded within protective structures, thus avoiding protruding parts.

Usually, a propeller is made up of sections of helicoidal surfaces which act together "screwing" through the liquid environment. The number of blades per propeller usually varies from one to five. Since both thrust efficiency on the one hand and induced vibrations on the other increase with the number of blades, three-blade propellers are commonly used as a compromise.

A major and undesirable effect of propeller actuation is the induced roll torque. The rotation of a propeller on its own axis induces an opposite rotation of the stator. In an endoscopic capsule which holds the motor, this would induce the capsule to roll, according to

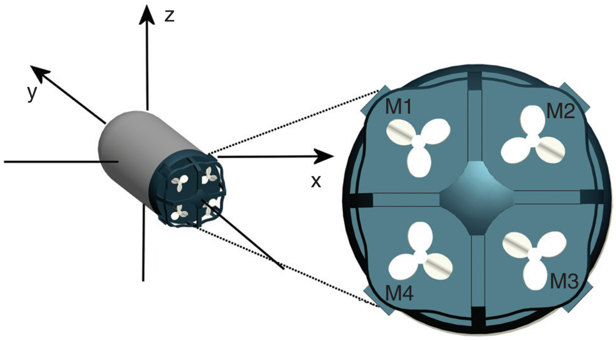

Figure 1. Schematic representation of the capsule and its four propellers.

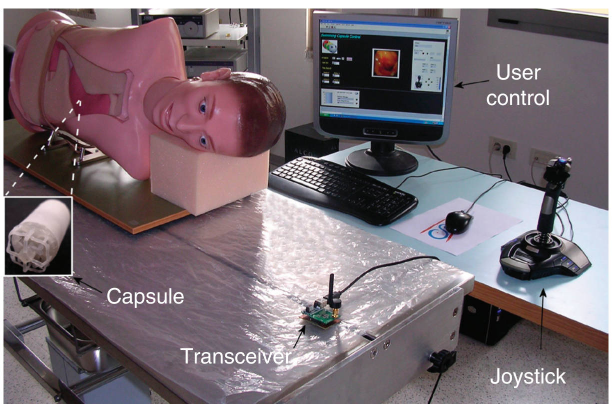

Figure 2. The external unit of the system and the endoscopic capsule located in an upper torso simulator.

the conservation principle of angular momentum. The induced roll torque should be avoided for endoscopic applications, since stable camera images are highly desirable. An effective way to prevent this effect is to activate pairs of counter-rotating propellers. To achieve this goal, particular care must also be devoted to the winding of the single propellers. Having a left winding propeller rotating clockwise and a second one, featuring a right winding, going anticlockwise would balance the roll torque, thus resulting in a net forward propulsion. For this reason the proposed device activates an even number of actuators both during forward motion and steering. Four propellers are active if the capsule has to move forward, while to achieve steering in one direction, the two propellers located on the opposite side must be activated. The schematic in Figure 1 shows that in order to propel the capsule upward, actuators M3 and M4 must be operated, while M1 and M2 are off.

The proposed propeller activation strategy allows for a reliable three-dimensional locomotion if the capsule has a neutral buoyancy. Furthermore, the capsule is able to hold its position when the propellers are idle, thus saving energy for static target observation. In order to achieve a neutral buoyancy, the Archimedes force and the weight force of the capsule in a fluid must be considered:

$$F_A = \rho_{flu}\, g\, V_{flu} \qquad (1)$$

$$F_w = \rho_{cap}\, g V_{cap} \qquad (2)$$

where ρ_{flu} is the fluid density and ρ_{cap} is the capsule density, while g stands for the gravity acceleration, V_{flu} is the volume of fluid displaced and V_{cap} the volume of the capsule. Three different conditions may occur when the capsule is completely submerged ($V_{flu} = V_{cap}$):

1. $\rho_{flu} < \rho_{cap} \rightarrow$ the capsule would sink;
2. $\rho_{flu} > \rho_{cap} \rightarrow$ the capsule floats on the liquid;
3. $\rho_{flu} = \rho_{cap} \rightarrow$ the capsule is in equilibrium, holding its position.

Therefore the density of the capsule must be properly trimmed in order to equal the fluid density, thereby obtaining neutral buoyancy for the device. This can be achieved by selecting the proper compromise between capsule weight and volume.

Hardware overview

Ideally, an endoscopic capsule should be small enough to swallow. However, "swallowable" is somewhat difficult to define, because the maximum swallowable size varies in different persons, especially in those patients affected by specific disorders (i.e. dysphagia) (27). Therefore, since commercial pill cameras are commonly used in clinical practice, any novel capsule device should match their size.

The whole system should be user-friendly and intuitive for the endoscopist, thus minimizing the burden associated with adopting a novel technique. Since the capsule is devised as a disposable system, cost issues must be considered as well.

These guidelines were considered in the design of the whole system, which is composed of two main functional units, namely the wireless robotic pill and the human machine interface (HMI), as represented in Figure 2. The endoscopic capsule is composed of several functional sub-modules integrated inside a biocompatible shell. The capsule is wirelessly connected to the user console, where the endoscopist can look at the real-time video stream coming from the capsule image sensor, while controlling its motion by a joystick interface.

The capsular device, represented in Figure 3, is composed by an actuation unit, with four motors each connected to a single propeller, a vision module, an electronic board, including a wireless microcontroller and motor drivers, and a rechargeable battery.

All the aforementioned units were assembled inside a cylindrical shell. The total volume of the current

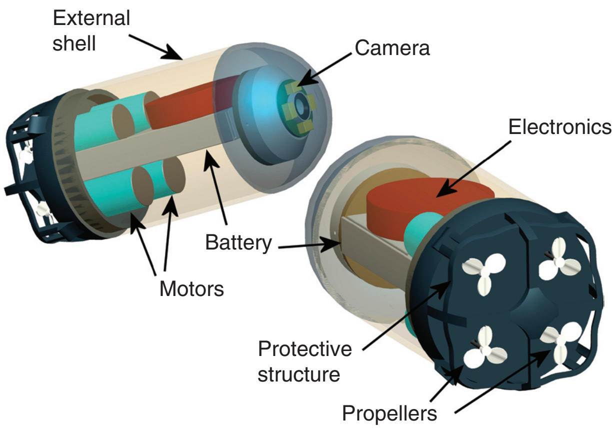

Figure 3. 3D sketch of the capsule and its internal components.

device is 15 mm in diameter and 30 mm in length, with a shell thickness of 0.5 mm. These dimensions can be further reduced down to a fully swallowable size exploiting smaller motors, as detailed below. The shell is composed of three main parts: A middle cylinder, a spherical cup on the front side, to host the vision module, and a rear dome, where the propellers are located. Once those parts were assembled together, all the junctions were sealed with epoxy glue in order to guarantee waterproofing. Rubber rings were used to seal the cavities where the motor shafts are located. The front and the rear domes are functionally and structurally different. The first one is a transparent semi-sphere designed to house a vision system, comprising illumination, optics and camera. The space allocated for the video module is 450 mm^3, currently more than the volume of the PillCam camera (without other components). This space was left empty in the current prototype, since the main purpose here was to design and validate the locomotion unit. A functional video unit will be integrated as a future step. The rear part of the capsule is designed to connect the propellers to the final section of the motor shafts, while preventing potentially harmful collisions between the helixes and the organ walls.

As explained above, pairs of left and right winding three blade propellers were selected for capsule locomotion. The diameter of the single helix is 3.8 mm and each individual blade is 1.50 mm long. This dimensional range is sufficiently large to consider inertial forces dominant over viscous ones (i.e. high Reynolds numbers).

The outer shell and the propellers were manufactured in acrylic material (VisiJet XT 200, Inition, ThingLab, London, UK) by rapid prototyping (Invision Si2 by Inition, ThingLab, London, UK). Specifically, the acrylic material is composed of urethane acrylate polymer (35-45%) and triethylene glycol dimethacrylate ester (45-55%). To improve the biocompatibility of the next prototypes, we will adopt medical grade PEEK (Polyether Ether Ketone), thus also achieving a significant improvement in mechanical properties and structural robustness. The three-blade propellers are illustrated in Figure 4.

Due to the low forces required for navigating in a liquid environment, the required torques can also be generated by relatively small electromagnetic motors. Direct current (DC) motors (MK04S-24, Didel, Belmont/Lausanne, Switzerland) were selected mainly for their small size, low cost and easy operation. Each of the motors is 4 mm in diameter and 8 mm in length with a weight of 0.7 g. Simple on/off control can be implemented with a single digital line per motor.

A wireless microcontroller (μC) (CC2430, Texas Instruments, Dallas, TX, USA), mounted on a specifically developed circular electronic board (9.6 mm in diameter, 2.3 mm thick, 0.28 g of weight) together with motor drivers, was used to enable bidirectional communication and control of the actuators. The miniaturized board, already tested reliably through *in vivo* experiments (28), guarantees a very low power consumption and safe levels of electromagnetic energy emission. A 31 mm long whip antenna departs from the board and is embedded in the lateral part of the capsule shell. Motor control is based on pulse width modulation (PWM) technique, thus allowing to vary the speed of each motor by setting the duty-cycle of a digital signal provided by the μC. Proper connections were already developed in the board for vision and illumination control, in order to be used once those subsystems will be integrated in the device. The code implemented on the μC for wireless motor control allows a real-time operation of the device with a minimum refresh time of 0.15 s.

In every wireless active device, powering is a crucial issue both in terms of volume occupied on board and in terms of operative lifetime. Wireless power supply of the swimming capsule was investigated and preliminary results are reported in (29). This approach is able to provide an infinite operative lifetime, but it requires a bulky external equipment which can hardly be used in a traditional clinical scenario. Thus, we used Lithium Ion Polymer batteries (LiPo batteries), having the highest energy density (200 Wh/kg) available for off-the-shelf components. In particular we used the LP20 from Plantraco (Saskatoon, Canada), which is a 3.7 V LiPo cell with a nominal capacity of 20 mAh, a weight of 0.75 g, and very small dimension (17 mm × 10 mm × 3 mm). It is able to deliver a peak current of 400 mA, thus allowing to drive all the motors at the same time at full speed. A unipolar magnetic switch (A110x Family, Allegro MicroSystems, Inc, Worcester, MA, USA) was integrated in the capsule and used together with a permanent magnet to keep the wireless

Figure 4. Prototypes of three-blade propellers.

device in an idle state, thus preventing a premature draining of current from the battery. Once the magnet is removed from the capsule, the μC exits from the sleep mode and establishes a wireless communication with the remote console.

The final prototype is reported in Figure 5. As clearly visible from both Figure 3 and Figure 5, a considerable amount of free space (1-1.5 cm^3) is available for reducing capsule size towards that of current swallowable passive devices.

External console

In order to remotely operate the robotic capsule, a specially developed external transceiver must be placed close to the patient, as shown in Figure 2, and connected to a Universal Serial Bus (USB) port of a personal computer (PC). This device is composed by a CC2430EM module from Texas Instruments, allowing bidirectional wireless communication with the capsule, and a USB/serial converter (FT232R from FTDI, Glasgow, UK) to properly interface the telemetric module with the USB port of the PC. Since the external unit has no dimensional constraints, a 2.4 GHz Swivel antenna (Titanis, Antenova, Elgin, IL, USA) was used to guarantee good communication performance. In terms of total polarization, the radiation pattern of this antenna is almost uniform in all the three Cartesian planes.

In order to prevent interferences among different capsules, each of them is programmed with a unique numerical identifier. The graphical HMI, shown in Figure 6, allows to control the desired device by changing the identification number ("Unit ID") inside the panel named "power control". The selected capsule can be placed in idle mode by switching the "power" button. Information coming from the remote device about the battery status ("battery status" panel), the quality of the wireless link ("wireless connection status") and a feedback about propeller activation are also displayed on screen ("speed and direction indicator"panel). Here, virtual LEDs corresponding to a particular direction (up, down, left, right) turn on when the capsule is moving. A vertical indicator reports the actual propeller speed, in addition to a numerical value given for each actuator. The HMI is also able to manage real-time video streaming, thus allowing the direct view of the gastric walls ("visual feedback" panel). The user can control the capsule motion through a commercial triaxial joystick (Cyborg evo, Saitek, San Diego, CA, USA), commonly used for flight simulators. Selective activation of propellers is controlled by the main lever, depending on its inclination (e.g. referring to Figure 1, M1 and M2 are activated by pushing the joystick in the forward direction). Furthermore, the speed of the active propellers is proportional to the lever inclination up to a limit that can be adjusted in the "speed settings" panel of the HMI. The main button of the joystick triggers a battery status request, while other functions can be assigned to remaining buttons as well, depending on the particular application.

Results

In vitro tests

Propeller thrust capability was experimentally evaluated in order to quantify the speed and steerability in a liquid environment consisting of PEG solution. Diagnostic speed (i.e. the normal speed that should be utilized to perform a gastroscopy, thus allowing a good control in a small volume) is between 0 and 5-7 cm/s and can be set from the graphical HMI by setting the PWM control signal to 5-10% of duty cycle.

Traditional gastroscopy performed by the endoscopist using a gastroscope takes several minutes, which are required to advance the endoscopic tube along the oesophagus to the stomach and to inspect the tissue (5 to 15 minutes, depending on the patients' behaviour and medical doctor's ability, and not considering pre-diagnosis time). An effective inspection of a volume comparable with the distended gastric cavity can be achieved with the proposed device in a similar timeframe, but with a dramatically reduced invasiveness. In terms of battery lifetime, the capsule is able to be actively controlled for more than 30 minutes at diagnostic speed (1.5 cm/s) with a mean current consumption below 40 mAh. During this time, a complete scan of a volume comparable to a human

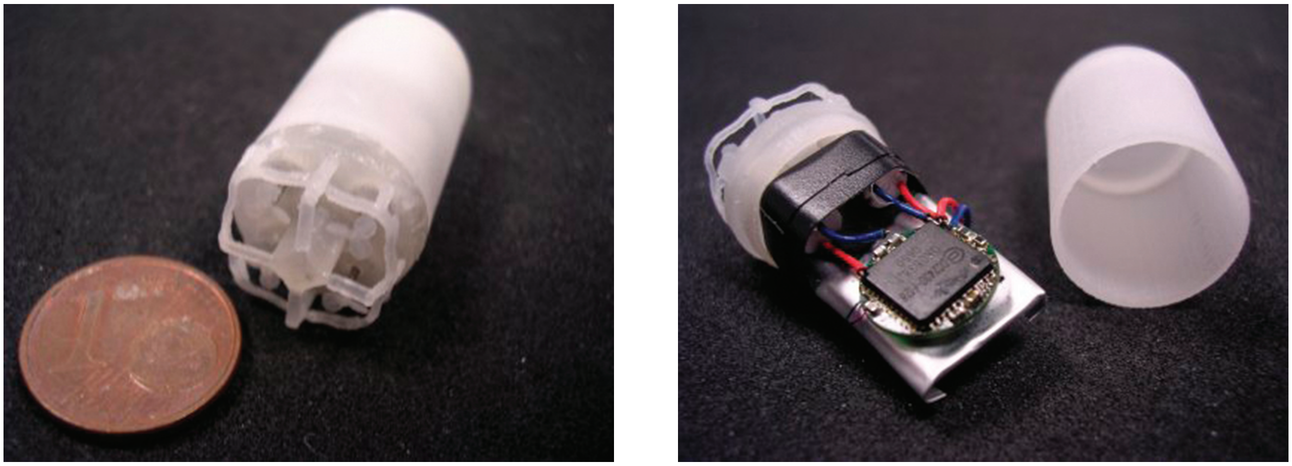

Figure 5. Assembled capsule (left); view of the internal components (right).

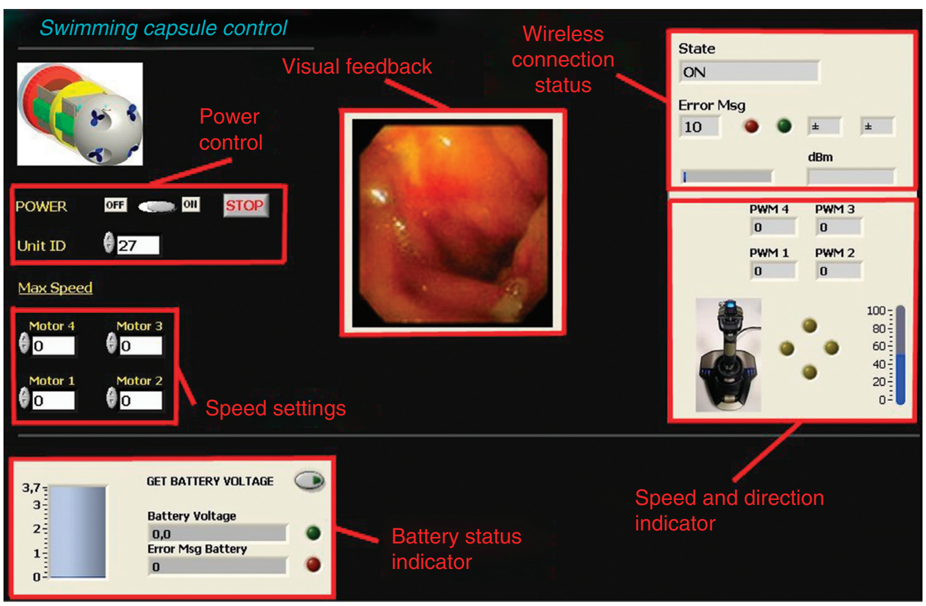

Figure 6. Screenshot of the graphical HMI with descriptions of its different parts.

stomach can be achieved by directing the capsule's frontal part towards all the regions of the inner surface of such a volume. Current consumption decreases to less than 1 μAh in power down mode, when the capsule is maintained in idle mode by the magnetic switch. This allows the capsule to be maintained in idle mode until the moment of medical examination, similarly to Given Imaging capsules. Once the gastric inspection is over, the motor can be switched off and the capsule would naturally proceed toward the anus.

Tridimensional locomotion was qualitatively and quantitatively evaluated. Once capsule neutral buoyancy (as visible in Figure 7) was assessed, free swimming was performed in tanks of different sizes and in flexible low density polyethylene (LDPE) containers, having a volume comparable with a liquid distended stomach (15 cm × 8 cm × 8 cm, that is 0.9 l). The liquid medium was PEG solution, according to the medical requirements described above.

It was possible to control and orient the capsule head towards all the regions of the inner surface of the tank, running it at 1.5 cm/s speed within 30 minutes from the beginning of the procedure. For a quantitative evaluation of the steering, the steering radius was assessed. The steering or turning radius of a steerable device is the radius of the smallest circular turn radius that the device is able to achieve. The capsule has a normal tight turning radius varying from 2 cm to 4 cm, depending on capsule speed, in every direction. Afterwards, several circular targets were placed inside

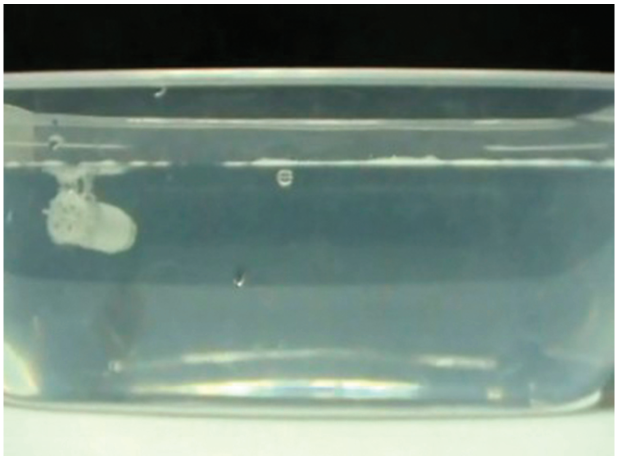

Figure 7. Neutral buoyancy with idle motors.

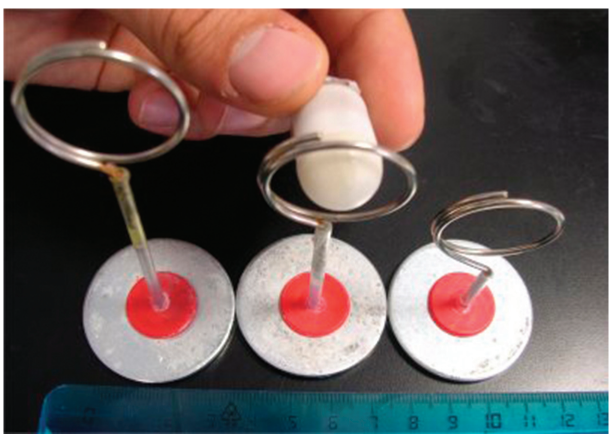

Figure 8. Detail of the ring-shaped targets and comparison with the capsule.

a liquid-filled tank (25 cm × 18 cm × 11 cm) at different coordinates to quantify tridimensional locomotion accuracy and steerability. The targets (Figure 8) are 25 mm in diameter rings located at three different height stands (43 mm, 65 mm, 80 mm from the basement to the centre of the ring). Little training time is required to have precise control of the capsule. Ten beginning users were able to move the capsule to any desired area inside the tank after an average of five minutes of use. The mean speed of the capsule during those trials was 1.5 cm/s. Each of the users was able to control the capsule through at least one target, as shown in Figure 9, within 30 minutes of practice. This kind of test aimed to assess the robustness of control and the steering ability of the device.

Ex vivo tests

Once it had been demonstrated that the capsule can be controlled through a complex path, further validation was done *ex vivo*. An explanted porcine stomach was

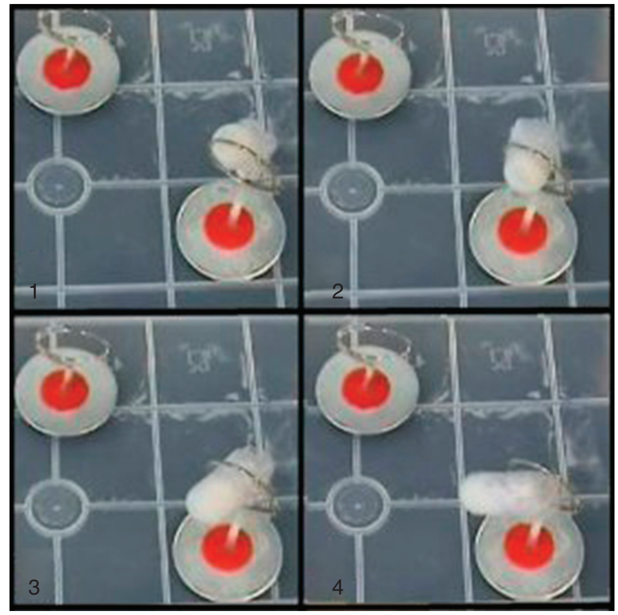

Figure 9. Consecutive frames displaying a complete passage through the medium-height target.

first used during a medical assisted procedure. The pylorus was closed with a ligature, then the stomach was distended by introducing a suitable amount of PEG solution from the esophagus. Then the capsule was inserted and a conventional gastroscope (Pentax, Montvale, NJ, USA) was introduced to allow for visual surveying of the procedures. An image acquired by the gastroscope is visible in Figure 10 while two propellers are rotating for steering the capsule towards the left. 3D locomotion was qualitatively evaluated and free floating has been performed inside the distended gastric cavity. It was possible to reach different target points such as the cardia, the lesser curvature and the pylorus. One of the main limitations of the *ex vivo* model was the reduced image quality due to the great amount of biological debris coming from decomposition of gastric mucosa. It is to be expected that living tissue enables a better image quality both from the endoscope and the camera on board the capsule.

Animal experiments

After successful *ex-vivo* evaluation, further tests were performed on two 40 kg female pigs. The experiments were carried out in a specialized experimental animal facility, with the assistance and collaboration of a specially trained medical team in compliance with the regulatory issues related to animal experiments.

The capsule was introduced into the stomach through a traditional endoscopic procedure, using a commercially available capsule delivery device (AdvanCE™, US Endoscopy, Mentor, OH, USA) with a specially

Figure 10. The capsule seen from the gastroscope inside the pig stomach *ex vivo*.

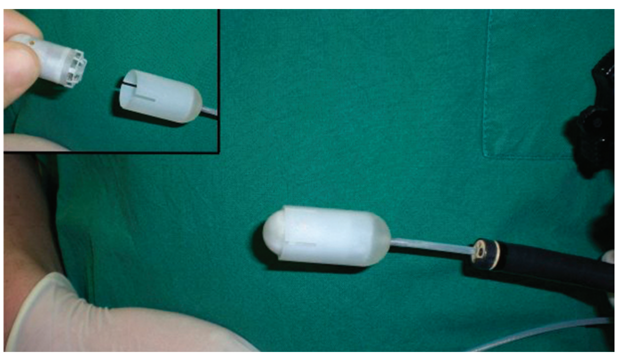

Figure 11. Capsule insertion into the releasing device.

developed distal container, as represented in Figure 11. After capsule release, the stomach was distended with liquid PEG, according to the medical protocol.

During the first session, the wireless link was not continuous, thus causing an unreliable capsule control. This occurred mostly when the capsule was moved to the dorsal wall of the stomach, thus maximizing the distance between the capsule and the external receiver. In order to improve capsule performance, the on-board antenna was positioned in the centre to prevent contact with the shell and the length was doubled, passing from a fourth to half of the wavelength. Then, a reliable wireless link was successfully established. This enabled a real-time propeller activation and control, thus performing different locomotion tasks. The procedure was followed real-time by the endoscope in order to assess the effective controllability of the device towards different areas. The capsule was successfully directed from the pylorus to the cardia at low speed (1.5 cm/s), thus assuring enough stability for image acquisition. The total duration of the procedure was below 30 minutes. Further experiments will be performed exploiting the direct view from the camera that will be integrated as a future step. Figure 12 shows two endoscopic pictures taken during animal experimentation.

Discussion and conclusion

This work presents the development of a propulsion system applicable to a wireless device for active capsular endoscopy in the gastric cavity. The use of PEG to distend the stomach and the relaxation of constraints for powering and torque enables the integration of all the required components in a swallowable volume. Inside an external pill-shaped shell, the system comprises four motors and propellers, a wireless µC for control and telemetry, a rechargeable battery and a magnetic switch. The capsule is able to move in all directions inside the stomach under wireless control by the medical doctor. From a dedicated HMI, the endoscopist is able to watch a real-time image stream, coming from the camera that will be integrated on board, and to control the capsule towards interesting areas, by using a triaxial joystick. The HMI also allows to set the essential operative parameters and to get the battery status, the wireless link quality and a feedback about propeller activation. The proposed system was tested in a stepwise approach comprising *in vitro*, *ex vivo* and *in vivo* experiments. *In vitro* trials consisted of qualitative and quantitative performance evaluation. Freestyle swimming was feasible inside tanks with different sizes and in flexible LDPE containers. High precision of movements can be achieved by the joystick control, enabling a fine locomotion of the capsule through small ring-shaped targets. Preliminary tests on ten subjects were performed to assess HMI intuitiveness. *Ex vivo* trials confirmed the feasibility of the propelled capsule solution, allowing smooth locomotion inside an explanted porcine stomach. Afterwards, animal experiments were performed, and tridimensional locomotion of the capsule inside the stomach was tested. The capsule size was small enough to be safely introduced through the mouth and the esophagus of a 40 kg pig using a readily available endoscopic capsule delivery system. Some problems related to the telemetric link quality were encountered and successfully solved during the development and testing phases. Further *in vivo* tests will be necessary to validate the system once the vision module is integrated on board.

Regarding future work, several steps are still required to have a fully functioning device. Further miniaturization of the overall capsule can be achieved by using DC brushless miniaturized motors (SBL02-06, Namiki, Akita, Japan), 2 mm in diameter and 6.5 mm in length with a weight of 0.12 g, thus reducing the volume of

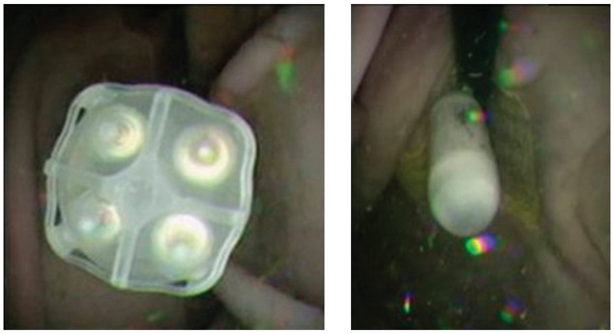

Figure 12. Animal experiments: Four propellers rotating (left); frontal-upper view (right).

the four motors down to 82 mm^3 rather than 402 mm^3. The control of brushless motors can be achieved with the same control board used for the current prototype. Our next main target is to include a real-time video module on the front part of the capsule.

The imaging system must be light and compact, providing a sufficient depth of focus to observe the entire gastric cavity with a good resolution (VGA) and at high frame rate (at least 20 frames per second to control the active motion, according to medical advices). An adjustable-focus system would enable the acquisition of sharp images regardless of distance between the camera and the target, also allowing a better understanding of depth for control (30). The imaging module integration will lead to the development of an autonomous and innovative endoscopic system for the stomach. A full and controlled inspection of this peculiar district, at the best of authors' knowledge, is still not covered by any commercial solution for capsular endoscopy. Once the design, including the camera, will be fully defined, different fabrication techniques, such as shape deposition manufacturing (SDM), as in (31), may be investigated in order to improve waterproofing and decrease fabrication costs.

The development of a wireless device for active capsular endoscopy in the stomach holds great promise for improving patient comfort during gastroscopic exams and might thereby increase the number of people undergoing targeted screening programs. The development of such device would pave the way to new perspectives regarding non-invasive diagnostic procedures inside the stomach.

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