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A New Concept for Magnetic Capsule Colonoscopy based on an Electromagnetic System

Regular Paper

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Abstract

Traditional endoscopy based on flexible endoscopes is reliable and effective, but poorly tolerated by patients; it also requires extended training by physicians. In order to reduce the invasiveness of these procedures, wireless passive capsule endoscopy has been proposed and clinically used during the past decade. A capsule endoscope with an active locomotion mechanism is desirable for carrying out controllable interactive procedures that are normally not possible using passive devices. Due to many difficulties in embedding actuators in swallowable devices, many researchers and companies have adopted an external magnetic field actuation solution. Magnetic resonance modified systems or permanent magnets are used to manoeuvre capsules remotely; however, both these cases present some limitations: magnetic resonance systems are bulky and expensive and permanent magnets are intrinsically unstable to control, and it is impossible to switch them off. Within this framework, the authors present the design and assessment of a magnetic system for endoscopic capsules based on an electromagnetic approach. In particular, the use of a single electromagnet was proposed and investigated: magnetic attraction, locomotion forces and magnetic torques were modelled for guaranteeing the reliable navigation of the capsule and based on these specifications, an electromagnet was designed, developed and experimentally evaluated. The results demonstrated the feasibility of the proposed approach for active locomotion capsule endoscopy.

Keywords robotic magnetic guidance, electromagnetic design, wireless capsule endoscopy

1. Introduction

Colorectal cancer ranks third in terms of incidence rate among all cancers in high-income countries [1]. Its survival rate can reach 90% in cases of early diagnosis and for this reason, regular screening is highly recommended for people above the age of 50 [2]. Endoscopic explorations of the colon are traditionally performed by means of flexible probes (i.e., colonoscopes) introduced into the rectal cavity. This well-established and nonsurgical technique enables a detailed and reliable diagnosis. Nevertheless, this is achieved at the price of considerable invasiveness, with a procedure that is typically ill-tolerated by patients. With the introduction of wireless capsule endoscopy (WCE) in

2001, a new screening method imposing relevant patient comfort became available [3]. A capsule less than 2 cm^3 in size with an embedded camera is ingested and transmits images to a storage device outside the body in real-time. The primary drawback of passive locomotion WCE is that it does not allow the operator to control the navigation. The movement of the capsule is passive, as it proceeds by means of involuntary visceral peristalsis and gravitational forces; this makes the navigation of the capsule purely random and if areas of clinical interest are identified, the physician cannot manoeuvre the capsule locally (e.g., back and forth, right and left) for detailed inspections. Therefore, solving the manoeuvring problem by implementing reliable and accurate control of the movement of the capsule, together with the possibility of tuning the electromagnet current based on the capsule position and orientation feedback, can significantly enhance the accuracy of the endoscopic investigation, thereby effecting a clear impact on diagnostic efficacy and reliability.

In the past few years, steerable endoscopic capsules that can navigate using on-board locomotion or external energy transfer mechanisms have been extensively investigated [4, 5, 26]. Bio-inspired locomotion principles, e.g., insect-like legged capsules or inchworm locomotion probes have been proposed by several research groups, e.g., Sitti et al. [5], Dario et al. [6] and Park et al. [7], with several different technologies having been tested *ex vivo* and *in vivo*. An alternative for avoiding integration problems in a small volume is to actuate the capsule externally using magnetic field sources. Magnetic forces and torques provide an efficient actuation solution whenever traditional motors cannot be easily integrated due to power and size constraints. Magnetic field sources for actuating endoscopic capsules, provided with a magnetic embedded component, can be supplied by electromagnetic coils or by permanent magnets outside the patient's body. Electromagnetic coils have the major advantage of delivering variable fields with no moving parts and can be designed in a variety of ways to create spatially uniform magnetic fields and gradients. Permanent magnets, however, can apply clinically relevant forces and torques to a magnetic device, inexpensively and in a compact form, without the use of large electrical currents and without any heating issues. In this case, the magnetic field can be modulated by translating or rotating one or more external magnets, but motions are constrained by the complex geometry of the dipole field that they produce. Finally, the magnetic field cannot be switched off, but only decreased by moving the external magnets away from the operating workspace, possibly interfering with the surrounding environment and equipment.

Permanent magnets were investigated and exploited by Carpi et al. [8]. A robotic magnetic navigation system (Stereotaxis Inc., St. Louis, USA), developed for cardiovascular clinical procedures, was exploited for obtaining accurate robotic steering of a magnetically modified video capsule (PillCam, Given Imaging Inc., Israel). The system utilizes two permanent magnets mounted on articulated or pivoting robotic arms that are enclosed within a stationary housing, with one magnet on each side of the patient table. Due to the symmetrical placement of the external magnets, the magnetic field can be cancelled in certain locations of the workspace. Furthermore, a small misalignment of the two magnets, obtained by precise robotic steering, can induce a localized magnetic field, thus producing torque on the capsule itself. However, the locomotion of the capsule is not directly obtained by the generation of the magnetic field gradient, but by moving the operating table below the patient. The combination of steering and locomotion for an endoscopic capsule by means of a permanent magnetic approach was developed by Ciuti et al. [9]. The authors developed a magnetic capsule endoscopic platform by using an external permanent magnet, supported and moved by an anthropomorphic robotic arm. In addition, Abbott et al. demonstrated magnetic positioning and orientation control of a capsule endoscope using a rotating single permanent magnet [10].

To improve the control and modulation of the forces on the endoscopic capsule, different systems composed of electromagnets for 3D control of a magnetic capsule were proposed [11, 16, 17, 19, 27]. As introduced in [12] by Siemens, an adapted MRI scanner, consisting of 12 circumferentially located electromagnets, through which a patient is positioned, can be used to enable the combined navigation and localization of a capsule in a liquid-distended stomach.

Although solutions proposed in the literature have shown preliminary promising results, they still have many limitations that need to be carefully considered: i) permanent magnets are hard to control and impossible to switch off; ii) electromagnets require complicated hardware and control strategies; iii) magnetic resonance systems are bulky and expensive.

Within the above framework, the authors combined the advantages of electromagnets with the flexibility of robotic manipulation in order to reduce the number of electromagnetic modules and thus, the size of the related hardware, but at the same time to maintain tuneable and reliable control of the magnetic force in the operating workspace. The primary contribution and innovation of this approach with respect to future state of the art technology is the potential for using only one electromagnet supported and moved within the 3D space by a robotic manipulator for the magnetic control of an endoscopic capsule.

In particular, in this paper, the authors investigated and designed the magnetic coupling for a magnetic capsule by considering an electromagnetic approach compatible with WCE procedures [15]. The target was to design and optimize the magnetic interaction forces and torques induced by a tuneable external electromagnetic controllable source on an endoscopic capsule provided with an internal permanent magnet, which still complied with the limitations imposed by the environment and by the specific application (reduced encumbrance, limited overheating, complete inspection of the lumen, i.e., the colon lumen in the considered application, etc.). Finally, a preliminary experimental evaluation demonstrated the feasibility of the proposed platform within a simulated condition.

This paper is organized as follows: section 2 reports the system overview and the fundamental issues of the WCE application. Section 3 describes the analytical model and the theoretical background for the magnetic navigation of WCE, whereas its requirements and constraints are reported in section 4. Section 5 illustrates the design of the electromagnetic system, whereas the system validation is presented in section 6. Finally, the discussion and conclusions, together with future works, are reported in Section 7.

2. System overview and fundamental issues of the proposed technique

The proposed WCE platform is composed of two main modules: i) a magnetic capsule with dimensions and specifications *ad hoc* for navigation and diagnosis throughout the colon; ii) an external driving system including an electromagnetic source, based on a single electromagnet, as the propulsion means (the driving system can be supported by a manipulator located externally). The physician, as the first action, introduces the endoscopic capsule through the rectum of the patient and he/she insufflates the colon with air. After this, the medical doctor performs a complete exploration of the colon by navigating the endoscopic capsule along the colon, assisted, if needed, by an external electromagnetic manipulator. The steering and locomotion of the capsule is made possible by generating a magnetic link between the capsule and the external electromagnet.

The endoscopic device has the appearance of a small spherical capsule with a diameter of 26 mm (Figure 1).

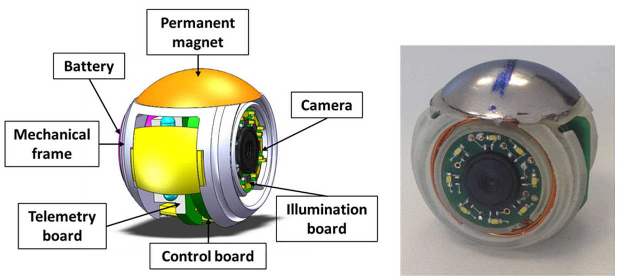

Figure 1. Sketch (left) and photo (right) of the capsule with different embedded components

The inner and outer parts of the capsule are mutually movable and can freely orient at 360° via a system of friction bearings [18]. This double concentric sphere structure allows the capsule to proceed along the colon with reduced friction, while the camera maintains the correct position for optimizing lumen inspection by means of an appropriate combination of weight and magnetic forces. Moreover, the endoscopic capsule integrates a permanent magnet in order to establish the magnetic link with the external electromagnetic source. Considering that the dimensions of the internal magnet have to be compatible with the space constraints due to the integration of other modules (e.g., battery, electronic boards, telemetry, camera) and considering the required degrees of freedom (DoFs) for diagnosis, a cylindrical-shaped axially magnetized permanent magnet with a volume of about 500 mm^3 (this volume corresponds to about 5% of the total; a magnet 8 mm in diameter and 10 mm long was selected. A neodymium magnet (NdFeB, N52, B_r=1.48 T) was chosen, neodymium magnets being the strongest permanent magnets available, thereby minimizing the dimensions and/or currents of the external electromagnet. A rough yet conservative weight prediction for the device, necessary for the design of the electromagnet, was set at two times the PillCam weight (i.e., around 4 g), which is considered the gold standard for capsule endoscopy.

The design of the external electromagnetic source for the endoscopic capsule represents the principal objective of this paper. The system should be able to generate suitable forces and torques for 3D navigation against a high friction and deformable environment, in a range of distances between the external magnetic source and the endoscopic device imposed, and at the very least, by the abdominal thickness (i.e., 70 to 100 mm [23]). Moreover, for fine control of pitch (visualization of upper and lower wall of the lumen) and yaw (visualization of right and left wall of the lumen), specific magnetic torques have to be properly exerted on the capsule. Figure 2 shows the five DoFs that have to be achieved for colon inspection in our operating WCE framework.

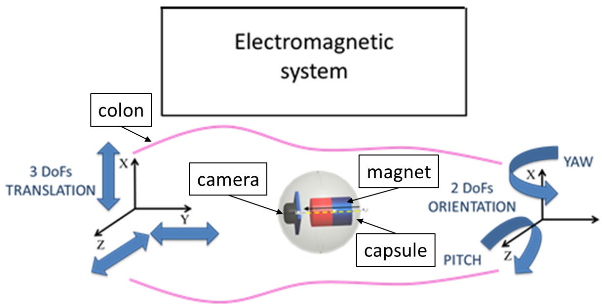

Figure 2. The magnetic WCE has to steer using five DoFs: X, Y, Z translations, pitch (visualization of upper and lower wall) and yaw (visualization of right and left wall) orientations

In this framework, our solution consists of using a cylindrically-shaped electromagnetic system in two different configurations. The configurations correspond to: i) an attraction phase of the capsule (configuration C1 in Figure 3 with the magnetization direction perpendicular to the abdominal wall and along the same axis of the coil); ii) a locomotion and orientation phase (configuration C2 in Figure 3 with magnetization direction parallel to the abdominal wall).

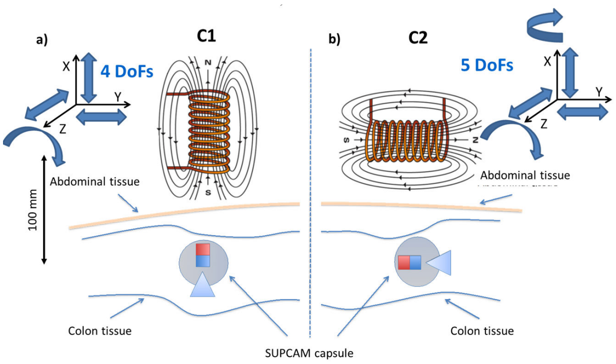

Figure 3. The (a) attraction (C1) and (b) locomotion and orientation (C2) configurations of the electromagnet for capsule control

Due to geometric distribution of magnetic field vectors, configuration C1 allows (with the same amount of current) for a higher magnetic gradient along the attraction axis, pointing toward the capsule and perpendicular to the patient's abdomen, compared to configuration C2. Therefore, configuration C1 will be considered preferable for use at the beginning of the procedure for capturing the capsule (a target distance of 100 mm was considered in the magnetic design [13]).

Once the capsule is attracted in configuration C1, a ±90° pitch rotation of the electromagnet (with the magnetization direction parallel to the abdominal wall, which causes a reduced magnetic link) allows for a shift in configuration C2, thus resulting in a closer capsule-coil distance and preserving the same amount of current needed for capsule attraction and then for locomotion and orientation. In fact, although the magnetic link is reduced in C2, thanks to a decreased capsule-coil distance, the required current remains the same. In configuration C2, due to the already established attraction of the capsule, a reduction of about 30 mm (i.e., half of the average diameter of the colon [13], resulting in a target distance of 70 mm) in the distance between the source field and the capsule itself can be estimated as a specific design hypothesis. Finally, the generation of high magnetic gradients can be facilitated by introducing an iron core in the electromagnetic coil; the iron core also represents an important component in the design of the locomotion source for magnetic capsule endoscopy.

3. Magnetic navigation: Analytical model for magnetic WCE and theoretical background

It is possible to independently apply magnetic forces and torques onto a magnetic endoscopic capsule by using the magnetic field and its spatial gradient, generated by magnetic coils or permanent magnets outside the workspace. The magnetic force F_m and the magnetic torque T_m exerted on a magnetic endoscopic capsule with magnetization M in an external magnetic flux density B, and assuming that no electric current is flowing in the workspace, can be given as:

$$\vec{F}_m = \int (\vec{M} \cdot \nabla)\vec{B} dV \quad (1)$$

$$\vec{T}_m = \int \vec{d} \times (\vec{M} \cdot \nabla)\vec{B} dV + \int \vec{M} \times \vec{B} dV \quad (2)$$

where $\vec{d}$ is the vector from the electromagnetic source to the point about which the torque is computed. When the magnetic field is generated by coils, the field is typically assumed to be proportional to the current through it, an assumption that is valid if there are no nearby materials with nonlinear magnetization hysteresis characteristics. This hypothesis can be confirmed by using no ferromagnetic materials (such as Al6060, AISI316, AISI 303, Delrin) for the parts of the platform close to the electromagnet, where 'close' means a distance less than 1.5 m). The magnetic flux density produced by a cylindrical coil is found by using the vector potential of a circular loop as follows [14]:

$$\vec{A}(\xi) = \frac{\mu_0 I}{4\pi} \oint_C \frac{d\vec{l}}{\left|\vec{\xi} - \vec{\xi}'\right|} \quad (3)$$

where μ_0 is the magnetic permeability of free space, dl is the elementary vector along the direction of the current and ξ is the generic coordinate (the primed variables refer to the source point). By exploiting eq. (3) and the superposition principle, the vector potential of a coil can be derived. Finally, the magnetic flux density can be obtained as $\vec{B} = \nabla \times \vec{A}$. For a cylindrical coil of N turns, inner radius r_{min}, outer radius r_{max} and axial length a, the magnetic flux density in a point $P(r, z)$ in cylindrical coordinates can be expressed as:

$$\begin{pmatrix} B_r \\ B_\theta \\ B_z \end{pmatrix} = \frac{\mu_0 N I r_{\min}^2 \pi}{4(r_{\max} - r_{\min})a} \begin{pmatrix} \int_0^\infty J_1(kr) \cdot (e^{-k|z-a|} - e^{-kz}) \cdot g(k) \cdot d(k) \\ 0 \\ \int_0^\infty J_0(kr) \cdot f(k,z) \cdot g(k) \cdot dk \end{pmatrix} \quad (4)$$

where the functions $f(k, z)$ and $g(k)$ are defined respectively as:

$$f(k,z) = \begin{cases} e^{-k|z-a|} - e^{-kz} & if \quad z \geq a \\ 2 - e^{-k(a-z)} - e^{-kz} \; if & 0 \leq z \leq a \end{cases}$$

$$g(k) = \frac{1}{kr_{\min}} \left[-J_1(kr_{\min})H_0(kr_{\min}) + \frac{r_{\max}}{r_{\min}} J_1(kr_{\max})H_0(kr_{\max}) + \right.$$
$$\left. + J_0(kr_{\min})H_1(kr_{\min}) - \frac{r_{\max}}{r_{\min}} J_0(kr_{\max})H_0(kr_{\max}) \right]$$

in which J_v are the Bessel functions, H_v are the Struve functions and k can be expressed as:

$$k=\sqrt{\frac{4r_{\min}r}{(z-a)^2+(r_{\min}+r)^2}}$$

The coil current I is governed by a differential equation and depends on the voltage v across the electromagnet, the coil resistance R and inductance L as:

$$\frac{dI}{dt}=\frac{-R}{L}I+\frac{v}{L} \tag{5}$$

If the voltage is chosen as the input source, accurate control of the generated magnetic field is not possible, because the current changes depend on the variations of the resistance due to overheating.

For these reasons, in order to generate the magnetic field by means of an electromagnetic system, a current control approach was preferred and exploited in this study.

4. Requirements and constraints for WCE magnetic navigation

4.1 Requirements for WCE navigation

Considering all the features and requirements of the endoscopic approach explained in section 2, the targeting magnetic link has to be sufficient for navigating a capsule (i.e., weight of 8 g) in terms of attraction forces (i.e., at least 78.4 mN in all configurations) and in terms of dragging forces and magnetic torques for orientation. Figure 4 shows a schematic representation of the relevant attraction and locomotion forces and torques in configurations C1 and C2, respectively. For the attraction, the specific magnetic force component (F_{attr}) has to be bigger than the weight force (F_w), as reported in the following equations:

$$\begin{aligned} &F_{attr}>F_w\\ &\vec{F}_w=m\vec{g}\end{aligned} \tag{6}$$

where m and g are the capsule mass and the gravity acceleration, respectively. For locomotion, as well as for the attraction of the endoscopic capsule, the dragging force (F_d) has to be larger than the friction force (F_f) and therefore, the equations for the equilibrium of forces are represented as follows:

$$\begin{aligned} &F_{drag}\geq F_f\\ &F_f=\mu_s(F_{attr}-F_w)\end{aligned} \tag{7}$$

where μ_s is the friction coefficient, assuming that the endoscopic capsule rolls during the locomotion due to its design.

Assuming that $(\vec{M}\cdot\nabla)\vec{B}$ is constant over the volume of the permanent magnet (V), F_{attr} (in cylindrical coordinates) for the C1 configuration is:

$$F_{attraction}=F_{m,z}=V\left(M_r\frac{\partial B_z}{\partial r}+M_z\frac{\partial B_z}{\partial z}\right) \tag{8}$$

Regarding C2, because of the rotation of the electromagnet and as a consequence of the local reference system, F_{attr} is:

$$F_{attraction}=F_{m,r}=V\left(M_r\frac{\partial B_r}{\partial r}+M_z\frac{\partial B_r}{\partial z}\right) \tag{9}$$

During locomotion in C2, in addition to the equilibrium for attraction, suitable values of F_{drag} also have to be generated by the electromagnet. In this configuration, F_{drag} is defined as:

$$F_{drag}=F_{m,z}=V\left(M_r\frac{\partial B_z}{\partial r}+M_z\frac{\partial B_z}{\partial z}\right) \tag{10}$$

where M_r and M_z are the components of the magnetization of the permanent magnet inside the capsule, whereas B_z and B_r are the components of the magnetic flux density generated by the coil.

Additionally, the equilibrium of the torques for allowing pitch and yaw rotations was taken in consideration (Figure 4). It is important to highlight that only the inertial torques (i.e., ωI) were considered, because the frictional torques were negligible due to the shape and the double-sphere configuration of the capsule:

$$\begin{aligned} \tau_{pitch}&\geq\omega I\\ \tau_{yaw}&\geq\omega I\\ I&=\frac{2}{5}mr^2\\ \tau_{pitch}&=VM_xB_x\sin(\alpha)\\ \tau_{yaw}&=VM_zB_z\sin(\alpha)\end{aligned} \tag{11}$$

where r is the radius of the capsule and α is the desired angle of the rotation. Considering the features of the permanent magnet, a minimum angular speed of 5 deg/s [8] and a capsule weight equal to 8 g, the target values of the magnetic flux density and magnetic field gradient modulus are 9.5 10^{-7} T and 0.16 T/m (derived by eq. (8)-(10)), respectively. It is worth noting that the production of forces serves as the real bottleneck with respect to the generation of torques. When the magnetic capsule is actuated at low speeds (e.g., with small accelerations), there is only little resistance to change in the capsule's orientation, which enables the magnetic torque to quickly align the capsule's dipole moment with the applied field. In these conditions, we can assume that the capsule dipole moment is approximately aligned with the applied field in a constant manner and that capsule orientation can be controlled by adjusting the direction of the magnetic field without controlling the magnetic torque.

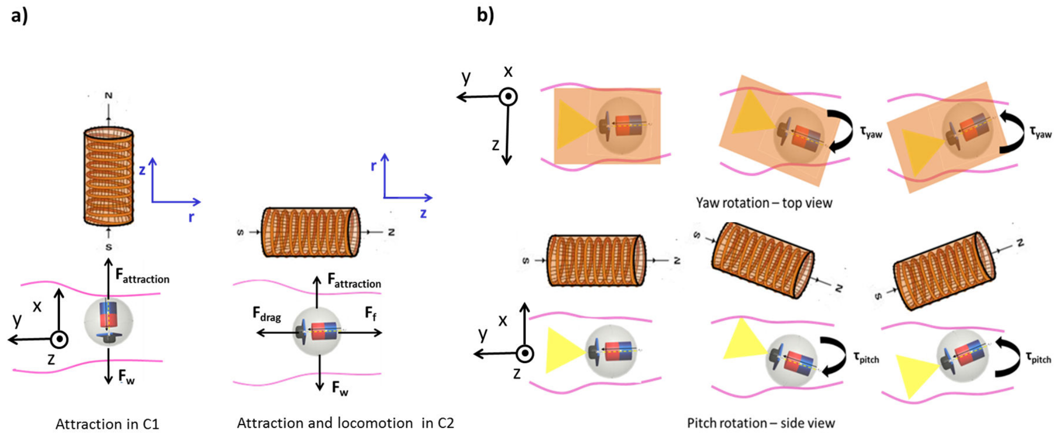

Figure 4. Schematic representation of the forces and torques on the magnetic capsule; a) the attraction (F_{attr}) and locomotion (F_{drag}) forces in configuration C1 and C2, respectively. F_f and F_w are the friction and weight forces. Cartesian (black) and cylindrical (blue) reference systems are reported; b) the torques of the yaw rotations (for angles of ± 60°) and pitch rotations (for angles of± 50°). In the top view the brown rectangle is the electromagnet.

4.2 Constraints for WCE navigation

The endoscopic platform has to i) allow medical examination through an external magnetic control system with a compact and simple manipulation structure; ii) be inexpensive; iii) be usable in normal outpatient settings; iv) be able to ensure an accurate diagnosis. Therefore, in the design phase of the external electromagnet, representing the locomotion external source, compactness has to be considered; moreover, the coil has to be adapted to be transported and easily controlled by the physician for generating a proper link with the endoscopic device. In particular, the dimensions of the handle of the electromagnetic system were defined through continuous collaboration with medical staff in terms of control, manoeuvrability and encumbrance issues; a range of dimensions from 100 to 150 mm was defined for both the height and diameter of the electromagnetic system. In addition to encumbrance constraints, an important parameter in the coil design is represented by the maximum current density, defined as a vector whose magnitude is the electric current per cross-sectional area. In electrical wiring, the maximum current density can vary from 4 $A \cdot mm^{-2}$ for a wire with no air circulation around it to 6 $A \cdot mm^{-2}$ for a wire in free air [24]. For compact designs, such as the windings of transformers or electromagnets, a current density value in the range of 2 to 3 $A \cdot mm^{-2}$ is recommended; higher current density can be allowed for a short time or with the combination of a properly designed cooling system.

5. Design of the electromagentic system

5.1 Magnetic modelling and validation

For designing the system and guaranteeing the generation of the required torques and forces, two different approaches have been used and compared to calculate and simulate the magnetic field produced by the coil: a finite element method (FEM) through the application of COMSOL Multiphysics 4.3a (COMSOL Inc., Sweden) and a (semi)-analytical model represented by eq. (4). In COMSOL, the AC/DC module was chosen to estimate the magnetic field map produced in a workspace around the coil. Thanks to the axial symmetry of the problem, 2D simulation was selected, thus reducing the computational costs and improving the reliability and accuracy of the simulations. For the analytical model, eq. (4) was computed by considering the different parameters of the coil. Both approaches provided results concerning the magnetic field map, which was exploited at a later stage to calculate the magnetic field gradient components by means of an incremental ratio in the region of interest.

The approaches were validated by means of an experimental test bench in the C1 and C2 configurations. In particular, the magnetic flux density was experimentally measured along three different lines (relevant for the attraction and locomotion phases) that represent the directions for the attraction in C1, for attraction in C2 and for locomotion in C2 (Figure 5).

For the analytical model, which considers the implementation of an air-core coil, the iron core was modelled as a proportional coefficient for the magnetic field (this value was found experimentally using a reference electromagnet with and without the internal core and yielded a result equal to 1.8). However, this approximation can be assumed only if the soft-magnetic material of the core operates in its linear non-hysteretic BH curve.

The experimental test consisted of powering a reference coil (already available) with a current of 10 A and measuring the magnetic flux density by means of a Hall-effect probe (Magnetometer KOSHAVA 5, Wuntronic, GmbH) supported and moved by a robotic arm (RV-3SB, Mitsubishi Electric, Japan). The coil had an external diameter of 97.5 mm, a height of 110 mm, an iron core 45 mm in diameter and 550 windings, and was used as our reference system for model evaluation. The probe was positioned and moved with incremental motion steps of 2 mm in the proper directions to reproduce the same conditions used in the simulations.

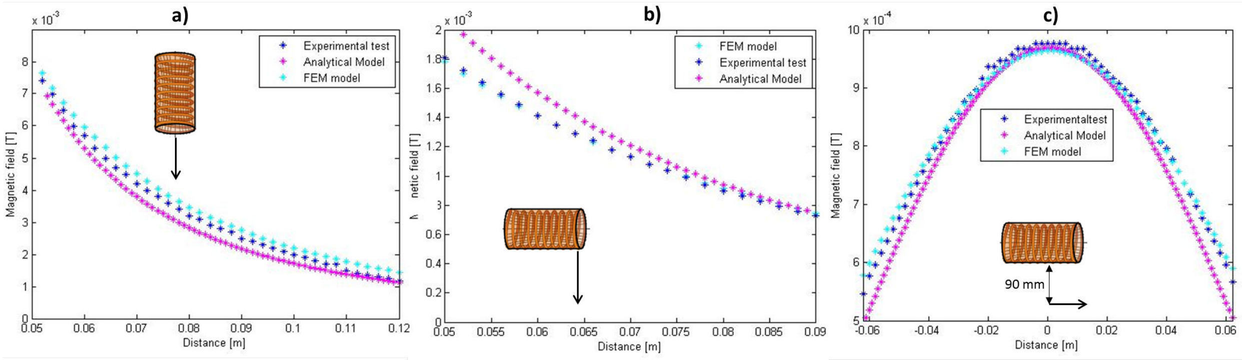

Figure 5. The magnetic flux density used for attraction in (a) C1 and in (b) C2, and for (c) locomotion in C2, calculated by FEM (light blue dots) and analytical approaches (blue dots), compared with the experimental results (purple dots)

The obtained results are shown in Table 1 and Figure 6, and demonstrate that both approaches had small errors (less than 5%) with respect to the magnetic flux density derived experimentally. However, FEM simulations demonstrated a more reliable approximation, especially in the case of C2; therefore, considering the experimental evaluation as our ground truth, the FEM approach was chosen for the optimization of the system design.

	Experimental-FEM error (10^{-4} T)	Experimental-Analytical error (10^{-4} T)
Attraction in C1	1.88±1.65 (2.4%)	1.54±1.50 (1.9%)
Attraction in C2	0.15±0.08 (0.8%)	0.55±0.15 (3%)
Locomotion in C2	0.11±0.06 (1.2%)	0.15±0.13 (1.7%)

Table 1. The mean errors and standard deviations expressed in Tesla and the mean errors expressed in % between experimentally measured magnetic flux density and the FEM or analytical results for the directions of attraction in C1, attraction in C2 and locomotion in C2

5.2 Design of the electromagnetic system and approach

The endoscopic capsule is controlled by an external magnetic source consisting of an electromagnet. In this context, the electromagnetic system design entails advanced analysis and definitions of physical qualities leading to a trade-off in the parameters selection (e.g., power, current, resistance and dimensions of copper wire, and the number of turns). The aforementioned parameters strictly depend on one another and system design constraints have to be preliminarily fixed with regards to the operating conditions in order to derive the electromagnetic source system performance.

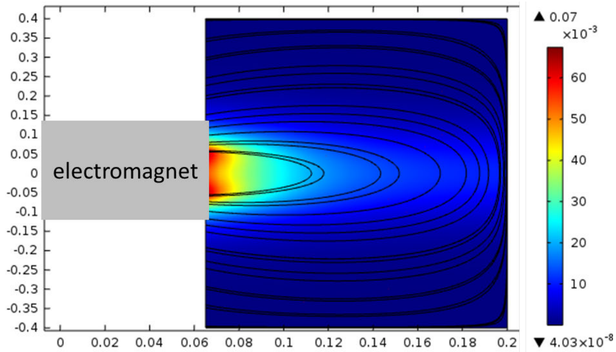

Figure 6. The magnetic field map with streamlines produced by the electromagnet using Comsol Multiphysics Inc. An axial symmetry was used for the simulation. The current density was 3.2 A/mm^2.

The optimization problem considers the maximization of the magnetic field gradient modulus ($|\nabla B|$) and at the same time, the minimization of the power dissipated by Joule effect from the coil (P):

$$\begin{cases} \max(|\nabla B|) \\ \min(P) \end{cases} \tag{12}$$

They can be expressed as:

$$\begin{gathered} P = \rho \frac{L}{S} I^2 \\ |\nabla B| \approx N_{tot} J = N_{tot} \frac{I}{\varphi^2} \end{gathered} \tag{13}$$

where:

$$
\begin{aligned}
L &= 2\pi r_{mean} N_{tot} \\
S &= \frac{\pi \varphi^2}{4} \\
r_{mean} &= \frac{N_{tot}\varphi^2}{2h} + r_{\min}
\end{aligned}
\tag{14}
$$

J (A/m^2) is the current density, I (A) is the current and φ (m) the copper wire diameter, h (m) the height of the electromagnetic system, r_{min} (m) the inner radius, r_{mean} (m) the mean radius and ρ (A/m) the resistivity parameter of copper. The variables of the optimization problem were N_{tot}, φ, I, h and r_{min}. The optimization problem was implemented by using the FEM analysis for the design of the coil, as assessed and motivated in the previous section.

The FEM analysis was used because it allows for fast implementation while maintaining adequate accuracy, as demonstrated in section 5. However, it is worth mentioning that the analytical approach can also be exploited for the specific design purposes (the aim of the paper is also to provide methodologies for electromagnetic design in WCE). The simulation results demonstrated that a coil of 130 mm in external diameter, 70 mm in internal diameter (i.e., the diameter of iron core) and 110 mm in length, composed of a wire with a diameter of 3 mm and a maximum current density of 3.2 A/mm^2, was a suitable solution with respect to the previously illustrated specifications and constraints.

More specifically, the 110 mm length was chosen because it represents a good compromise between high forces and coil manoeuvrability for optimal orientation of the capsule. Preliminary experiments and simulations have demonstrated that the ratio between the length of the electromagnet and the length of the internal magnet has to be less than 11 (the length of the magnet is 10 mm so the length of the electromagnet needs to be less than or equal to 110 mm). The authors supposed that the reason for this ratio was due to the fact that the magnetic torques mainly depended on the values of the magnetic field, while the forces depended only on the spatial gradient of the fields. If the ratio is too big, the permanent magnet will feel only the influence of single magnetic poles and will require more complex manoeuvres in order to obtain fine and accurate control of the position of the capsule. In this scenario, the capsule is alternatively attracted by either one magnetic pole or the other, depending on its distance from the poles. If the ratio is too small, the required forces and torques will not be generated.

An external diameter of 130 mm was selected in order to obtain a suitable force with the minimum size of the coil, as represented in Figure 7a.

The internal diameter, which represents the diameter of the electromagnetic core, was chosen to optimize the magnetic forces and torques (Figure 7b) in C2 with a commercially available ferrous core (i.e., iron magnetic permeability equal to 2000).

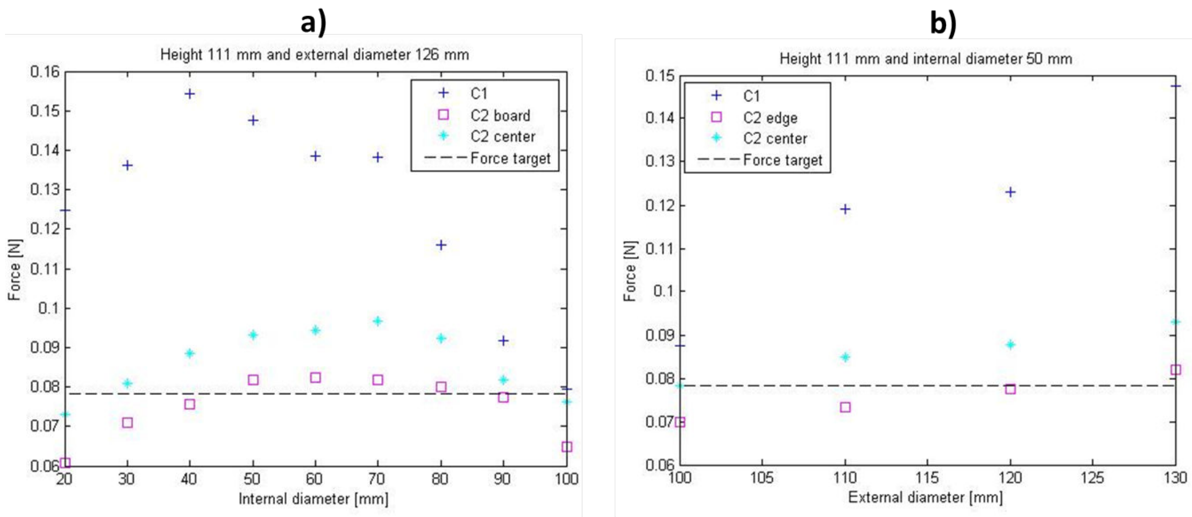

Figure 7. The attraction force versus the (a) external diameter and (b) internal diameter of the electromagnet. The target force is calculated by eq. (8) and (9). The density of the current was set at 3.2 A/mm^2. C1, C2 edge and C2 centre represent, respectively, the force in the C1 configuration, the C2 configuration when the capsule is at the edge of the electromagnet and in the C2 configuration when the capsule is in the centre with regards to the external coil.

Regarding the locomotion issue, the forces for lifting and dragging the endoscopic capsule were defined as a function of different friction coefficients. The results showed that the attraction of the capsule was always possible. Moreover, no locomotion was possible for a friction coefficient equal to 1. If the friction coefficient was around 0.8, dragging the capsule was possible at the edge of the electromagnet in the C2 configuration; displacements between 33 mm and 45 mm (or even more) from the edge of the electromagnet were still adequate for moving the capsule when considering a friction coefficient equal to 0.6 and 0.4, respectively (Figure 8). Considering that the friction coefficient of the colon can range between 0.1 and 0.7, depending on the operation conditions [13] (insufflation, cleaning of colon, etc.) and that the innovative spherical structure of the capsule, as previously illustrated, can further drastically reduce friction, we can assert that this design of the system is suitable for the navigation of the magnetic capsule. Considering that the required torques are small, as previously explained, the designed coil will be able to generate magnetic fields that align the endoscopic device nearly instantaneously with respect to the desired angle (i.e., a mean torque of 1.5 mNm).

Following an optimization phase, the system was fabricated using dimensions derived by the magnetic design and had a resulting weight of 8.5 kg (Figure 9).

Due to manufacturing limitations, some features of the fabricated coil are slightly different from their theoretical counterparts (68 mm versus 70 mm for internal diameter and 128 versus 130 mm for external diameter). However, prior to the fabrication, the real features were demonstrated as still suitable for the navigation of the endoscopic capsule, thereby guaranteeing the magnetic requirements. Table II shows the target forces and the minimum current density alongside the relative generated forces for attraction in C1 and C2, as well as for locomotion in C2.

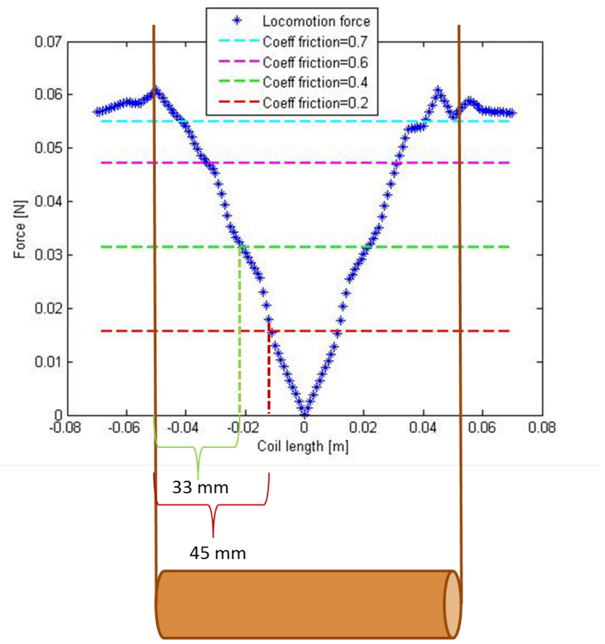

Figure 8. Dragging force (blue line) as a function of the position of the capsule in C2 with respect to the electromagnet, for different friction coefficients (the cyan, pink, green and red lines represent the required dragging forces at different friction coefficients). The electromagnet is considered in configuration C2 and placed between -0.055 and +0.055 m. Asymmetrical behaviour in the curve resulted due to edge effects.

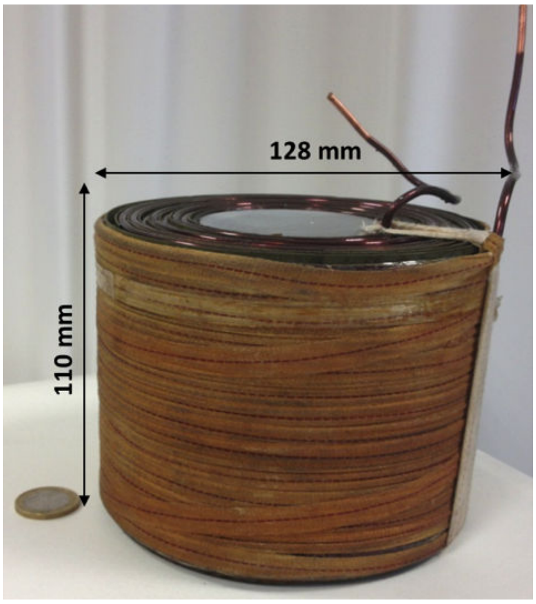

Figure 9. The fabricated coil with its real dimensions. The weight is 8.5 kg.

	J (A/mm^2)	Targeted force (mN)	Simulated Force (mN)
Attraction C1	1.9	78.4	82.1
Attraction C2	2.9	78.4	78.9
Locomotion C2	2.6	47.1	47.9

Table 2. The target forces and minimum current density with the relative generated forces for attraction in C1 and C2, and for locomotion in C2. The friction coefficient was considered equal to 0.6. The distance between coil and capsule was 100 mm and 70 mm, respectively, in configuration C1 and C2.

6. System validation

A preliminary experimental test session was performed in vitro and ex vivo in order to validate the design of the electromagnetic system. A user-friendly human machine interface (HMI) was implemented for controlling the electromagnetic system and consequently, the capsule/electromagnet link during the WCE procedure. A power supply system (EA-PS 8080-60 2U, Elektro-Automatic, range of power between 0 to 1500 W) that can generate currents between 0 and 60 A (0 to 60 V) was used for powering the electromagnetic system. The power supply communicates with the HMI implemented in LabVIEW (National Instruments Labview 2012, Texas, USA) by a USB protocol and the values of the imposed current (thus, increasing the resultant magnetic forces) can be selected by the user through the control of the joypad. In particular, the analogue signal generated by the joypad is acquired and computed by the software in order to calculate the required current, which has to be sent to the power supply. In particular, the user can control the amplitude of the current by deflecting the user control knob. The maximum deflection of the knob corresponds to the maximum current's value imposed in the software interface under safety conditions for capsule attraction. The safety condition that the authors have considered is that the forces exerted on tissues by the capsule do not cause any damage. Half of the capsule surface being in contact with the colon is guaranteed by considering an exerted pressure of 0.035 bar, that is, hundred times less than the maximum allowed pressure and compatible with the forces generated in other endoscopic platforms [25]. The maximum value, which is always displayed in the HMI, is chosen by the user within a set of values (from 5 A to 60 A). A capsule prototype scaled up by a factor of about 1.5 (compatible with colonic constraints) was fabricated for the experimental evaluation (dimensions were chosen according to the commercial availability of the external shell) (Figure 1). It consisted of a transparent shell (external diameter of 37 mm and internal diameter of 33 mm), a mechanical frame produced by means of a rapid prototyping technique with several Teflon bearing balls for friction tuning, a NdFeB N52 magnet (diameter of 8 mm and height of 10 mm, equal to the internal permanent magnet in terms of volume, which will be embedded in the final capsule), a LED powered by a LiPo battery (20mAh, voltage of 3.3 V) and a switch for simulating the position of the camera during navigation. The total weight of the prototype capsule is 18.5 g (twice as large as the final capsule). Since the prototype was fabricated using off-the shelf components not optimized for the target application, the weight that resulted was larger than what had been supposed in the model (i.e., 8 g). Therefore the electromagnet-capsule distance was reduced in accordance with the model (Figure 3) in order to reproduce the same conditions in terms of magnetic field gradient, which will be set up in real experiments. Based on the above considerations, an in vitro experimental evaluation was performed as a preliminary proof of concept of the system for assessing i) the developed magnetic model and ii) the navigation of the capsule device.

6.1 Magnetic model assessment with the capsule prototype

The comparison between experimental and simulated magnetic attraction forces was investigated. The experimental magnetic forces were measured by a six-axes force sensor (Nano17, ATI Industrial Automation, USA, resolution of 1/320 N) attached to the capsule. The electromagnet was placed in configuration C2 at a distance of 35 mm (selected as an experimental distance) and a current ranging from 28 A (corresponding to the minimum current to overcome the capsule weight) to 60 A was imposed. For each value of the current, five tests were repeated. The force sensor acquired data for 10 s and the mean value was recorded, then the current inside the electromagnet was switched off. An image of the set-up and the results are shown in Figure 10, considering the mean value and the standard deviations for experimental forces. The obtained mean error was 8.6 mN, corresponding to a percentage error of 2.6%. Considering this, the results demonstrated that the simulated magnetic forces were a good approximation of the real magnetic forces.

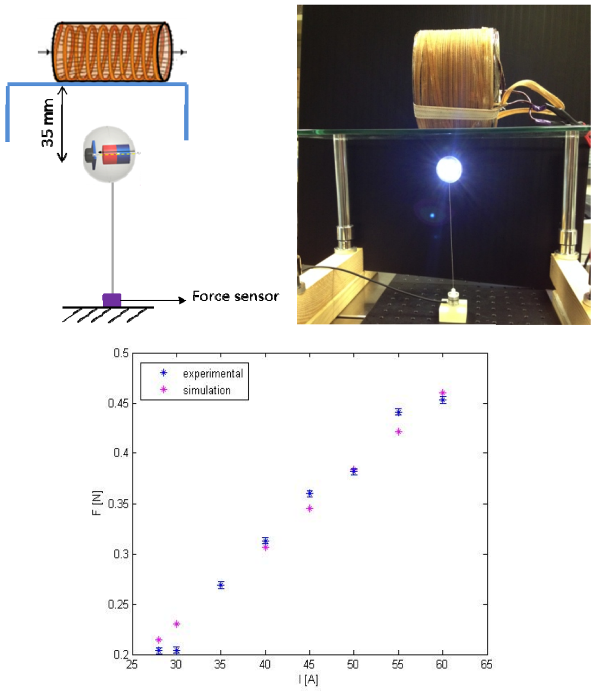

Figure 10. The force measurement set-up (sketch and real photo) and results for the comparison between experimental and simulated magnetic forces by increasing the current. The capsule was constrained to the force sensor by an inextensible wire. Only the force component for the attraction was considered. The magnet was in configuration C2 (attraction).

6.2 In vitro assessment of capsule navigation

A set of tests was performed to evaluate the effective navigation of the capsule. The task consisted of exploring a rigid tube arranged to mimic the anatomical shape of the human colon, from the rectum to the cecum (about 900 mm in total length), as shown in Figure 11, with a distance of 30 mm between the capsule and the electromagnet (i.e., in order to reproduce the same conditions, a smaller distance was needed because of the scaled up weight of the capsule).

The endoscopic capsule was controlled by the user by moving the external electromagnet, which was supported by an opaque structure in a horizontal position. The current was preliminary set to a fixed value that represented a suitable compromise between generated magnetic forces and safety values. A total number of five novice users participated in the study. All trials were observed by an assistant who recorded the completion time and moved a traditional colonoscope in a retrospective condition for providing visual feedback to the user, because the capsule prototype did not yet have an integrated camera. The users involved in the tests had no previous experience with the proposed platform. Each session began with a theoretical briefing about the platform and practical training for 5 min.

After the briefing, each user performed the task three times. The results demonstrated that all users were able to perform the task and the mean ± standard deviation, minimum and maximum times were 44 ± 8 s, 26 s and 67 s, respectively (Figure 11).

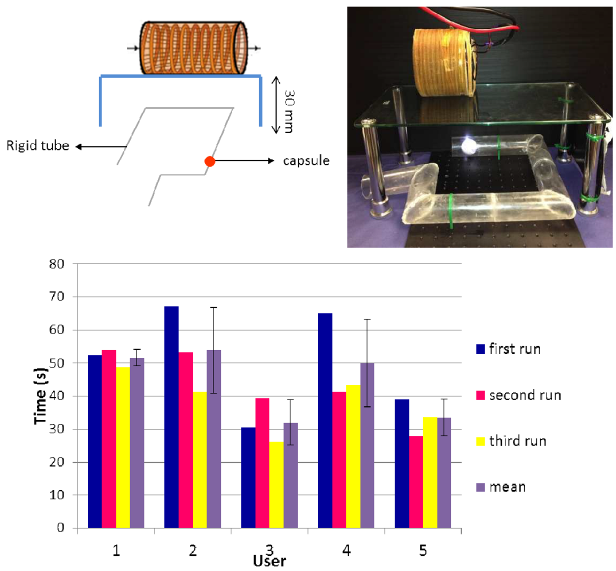

Figure 11. The set-up (sketch and real, top) and results (bottom) for evaluating the navigation effectiveness of the capsule inside a colon-shaped phantom. The supporting structure, here transparent, was covered during the test so that the user had only the visual feedback by colonoscope, which was always in front of the capsule and moves backwards. The total length of the path was 900 mm. It is worth noting that an improvement by learning was detected by the results.

Finally, another test in the navigation assessment framework was performed to demonstrate and assess the pitch and yaw steering of the capsule by using the magnetic control. In this test, a laser (LC-LMD-650-17, Laser Components GmbH, Germany) was embedded inside the capsule in order to evaluate the steerability effectiveness for capsule rotation. The task consisted of focusing the laser towards the different squares of a checkerboard (dimensions 7.6 mm x 4.6 mm, divided in 9 squares) placed at a distance of 15 mm (reasonable distance in a colonic environment) from the capsule (Figure 12).

The endoscopic capsule was controlled by the user by rotating and moving the external electromagnet. The current was initially set to a fixed value, which represented a suitable compromise between generated magnetic forces and safety values. In the test, each time a square was focused on and pointed at by the laser for at least 1 s, the capsule had to return to the initial position (that corresponded to focus square 5, Figure 12) before focusing on a new square. This setup enabled a range of ± 50° for pitch angles and ± 60° for yaw angles. A total of five users participated in the study and all trials were observed by an assistant who recorded completion times. The results showed that the control of pitch and yaw angles was easy and the test was completed by users in a time of 30.1 ± 8.2 s.

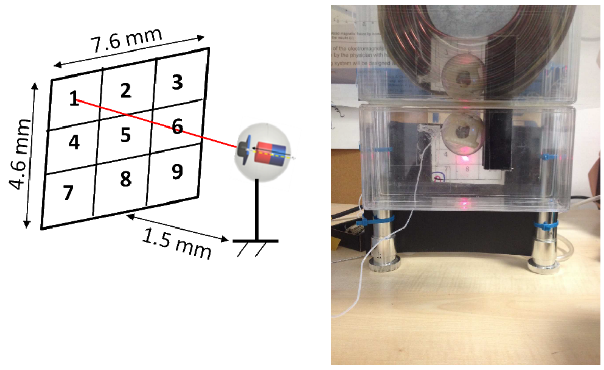

Figure 12. The set-up for evaluating the steerability effectiveness for capsule rotation. The sequence of the laser focus was in numerical order.

7. Discussion and future work

The objective of this paper was to design and develop an active magnetic capsule based on a single electromagnet for performing diagnostic procedures in the colon. The proposed idea is to design a system that combines the tunability typical of electromagnet-based systems (i.e., MRI scanner or OctoMag-like systems [19]), with the feasibility and intuitiveness of controls featuring external permanent magnets.

Within this framework, a magnetic design for an electromagnetic system based on a single electromagnet was performed for locomotion and orientation of a concentric double sphere capsule for diagnostic procedures in the colon. Firstly, a comparison between simulations, an analytical model and experimental results was carried out in order to evaluate the use of both approaches. Although both demonstrated trustworthiness for the design of the electromagnet, the simulations were chosen for this paper because of their greater accuracy. However, the authors do not exclude the possibility that in the future, the analytical model will be used for further investigations when a parametric analysis is needed. Magnetic attraction and locomotion forces and torques were modelled for guaranteeing the reliable navigation of the capsule, by paying attention to the trade-off in the parameters selection based on endoscopic constraints (e.g., friction of colon lumen, distances between electromagnetic system and capsule).

The electromagnetic design resulted in the development of a real electromagnetic source based on a single electromagnet; the data obtained in the modelling process were evaluated by a direct field measurement analysis, by exploiting a magnetic field measurement probe. Then, tests were performed with the developed electromagnetic source and with a capsule prototype in vitro conditions in order to evaluate the magnetic navigation principle and test the electromagnetic system. Tests aimed at demonstrating the possibility of finely tuning and manoeuvring the electromagnetic system for effective navigation. Although an in vitro setup represents the weakness of the experimental evaluation, because it does not completely reproduce the clinical real environment and conditions, it was used in order to demonstrate the effective manoeuvrability of the capsule. In addition, the use of a rigid plastic tube guarantees a higher repeatability and reduction of random effects in the tests, conditions needed at this level for accurate validation of the model. Further investigations in ex vivo and in vivo conditions will be needed to overcome the limitations of an in-vitro setup, in order to have a more realistic scenario and to assist in the clinical transfer of the platform.

In addition, future works will be focused on the evaluation and to compensation of a large number of possible sources of instability, which may render the capsule very difficult for use in an in vivo application. The authors suppose that the most appropriate solution might be a combination of magnetic field modulation based on localization feedback, as well as the motion of the external electromagnet assisted by a robotic manipulator.

Moreover, during tests, we observed substantial heating of the coil. The need for a cooling system will be evaluated considering a commercial system (i.e., volumetric pump, oil and radiator) with regards to the real operating conditions and required forces for navigation. Due to the high weight of the complete electromagnetic system (12.8 Kg), a five-DoFs robotic manipulator will be designed for the holding and moving of the electromagnetic source and the cooling system by the physician in the future. The use of a controllable manipulator and the possibility of tuning the electromagnet current based on the capsule's position and orientation feedback [20, 21] will contribute to the implementation of a navigation strategy for the fine control of the endoscopic capsule.

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9. . References

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