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RESEARCH PAPER

An internally-actuated mechanism for endoscopic capsules to reduce capsule retention: proof of concept

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Abstract

Endoscopic capsules are the only medical diagnosis devices that can examine the small intestine entirely. However, capsule retention is a critical side-effect of endoscopic capsules, which has remained unsolved. We aimed to reduce capsule retention probability by controlling the capsule's orientation. In this research, a novel endoscopic capsule equipped with two internal electric motors is designed. This design concept is based on the capsule's actuation using its motors' reaction torques. The theoretical procedure and simulation show that the capsule could not reach every orientation using only one internal motor. It is shown that an orientation-controllable capsule needs two motors, which are necessary and sufficient for controlling the orientation of the active capsule in the intestine. Computer simulations and experiments have proven the desired performance and realization of the actuation mechanism. The developed actuation tool can align the capsule with the intestine; thus, the retained capsule can escape from where it is blocked.

Keywords: endoscopic capsule; internally active capsule; capsule retention; reaction torque; small intestine

1. Introduction

Flexible endoscopy, colonoscopy, and capsule endoscopy are the most frequently used medical tools to observe the gastrointestinal tract closely. Observation of the small intestine is the mission of the endoscopic capsule, as flexible endoscopy and colonoscopy cannot reach all parts of the small intestine. Capsule endoscopy is a new technology that was commercialized and quickly adopted after its invention in 2000 due to its necessity in diagnosing digestive diseases [1]. Despite the key role of capsule endoscopy in examining the small intestine and diagnosing its diseases, this technology still faces limitations. Due to the small cross-section of the small intestine, forced movement, and random orientation of the capsule, the risk of capsule retention in the intestine is probable. The word "Capsule retention" is used when the endoscopic capsule has remained in the Gastrointestinal Intestine (GI) tract for more than two weeks. Some kinds of diseases increase the probability of capsule retention, such as Crohn's disease and diaphragm disease (Fig 1), which limit the use of endoscopic capsules. The capsule retention

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rate varies from 1.5% in the healthy small bowel to 21% in patients with Crohn's disease [2]. Another research reported capsule retention in all cases of diaphragm disease [3].

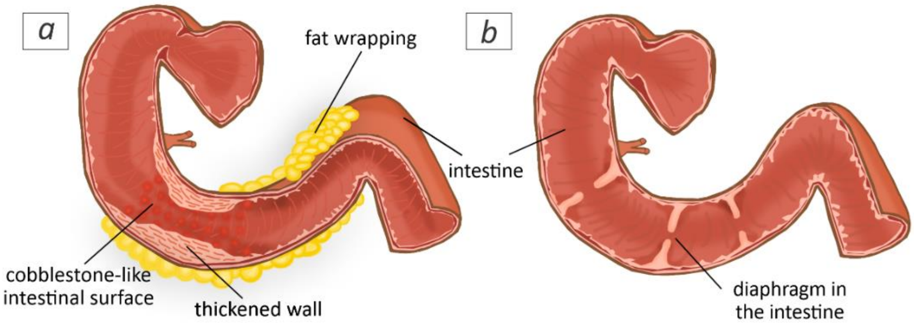

Fig 1: (a) Crohn's disease (b) Diaphragm disease

Although some studies reported non-surgical methods as an effective procedure to treat capsule retention, others reported perforation occurrence for asymptomatic patients within a week or a few years [2]. It is a significant complication since 65% of patients with this problem might need surgery within the next five years [4]. Through field research and interviews, we found that clinicians -who operate on patients with endoscopic capsules- emphasize capsule retention as a significant problem with endoscopic capsules. Studies discussing the risks encountered during capsule endoscopy have identified capsule retention as a primary concern [5].

Many research groups seek practical non-surgical solutions to overcome capsule endoscopy limitations. For example, the addition of active locomotion and axillary equipment (which could also perform the biopsy function [6-8] or the drug delivery [9, 10]) are some of the endeavours made to control the capsule performance in the intestine.

One of the solutions for overcoming the problems of passive endoscopic capsules -such as capsule retention- is changing them into partially controllable devices. Based on their activation types, the active endoscopic capsules (though they remain a research area and have not yet turned into commercial products) could be classified as externally and internally actuated capsules [9, 11].

1.1. Externally actuated capsules

The primary external actuation source of the endoscopic capsule is an external magnetic field applying either a force or a torque to an internal permanent magnet implemented in the device [6]. Scientists use permanent magnets to produce the constant field, and MRI units can provide the rotational magnetic field [9, 12].

Creating magnetically active capsules is quick and simple, offering various benefits like power generation, battery charging, and localization [6, 13-18]. The onboard magnet does not take up much space and enables hermetic isolation [9]. However, achieving precise control is challenging due to nonlinear fields [9]. Jerky movements and loss of magnetic link have been reported [19]. Effective attraction requires specific capsule localization, which adds complexity and interferes with control. Excessive magnetic force could also harm tissues [19, 20]. Additionally, the maximum static magnetic field for human safety is restricted [21], and the compatibility of the magnetic field with onboard equipment, such as batteries, data transfer modules, cameras, etc., is still under consideration. Besides these disadvantages, the torque generated by the magnetic field cannot overcome the friction within the intestine [22].

1.2. Internally actuated capsules

For an internally actuated capsule, the onboard mechanisms and actuators apply the required forces for the capsule navigation. Various internal tools perform capsule functions like propulsion, anchoring, or drug delivery [9].

There is various kind of internal actuation methods for endoscopic capsules: Cyclic expansion and compression [23-26], locomotion by the use of wheels [27], blades [28], and moving mass [29, 30]. In addition to method variety, capsules with internal actuators afford better control during their locomotion. Legs or paddles can open the lumen in front of the endoscopic capsules [9]. The performance and control of these capsules are independent of any external driving mechanism [31].

Despite the advantages of internal actuation, research projects in this area face challenges such as design complexity and high energy consumption [9]. Moreover, implementing the propulsion mechanisms, power source, and axillary tools into a small capsule with standard dimensions is also another problem [9, 32]. Capsule components like legs or paddles may harm tissues and injure the intestinal wall. Additionally, water or digestive juices may leak into the capsule through structural gaps where the legs or paddles emerge from the capsule's body. This can cause short circuits and electrical currents in the onboard batteries and electronic equipment.

Although many researchers' efforts (such as activating and controlling the passive capsule or finding non-surgical methods) have prevented and treated capsule retention, to the author's best knowledge, capsule retention is still the most severe risk of current commercial capsules [4]. Previous answers for controlling the movement or orientation of the capsule add many complexities to the capsule, which may increase the capsule retention probability or damage the soft tissue of the GI tract (such as mechanisms used in previous studies and shown in Fig 2)

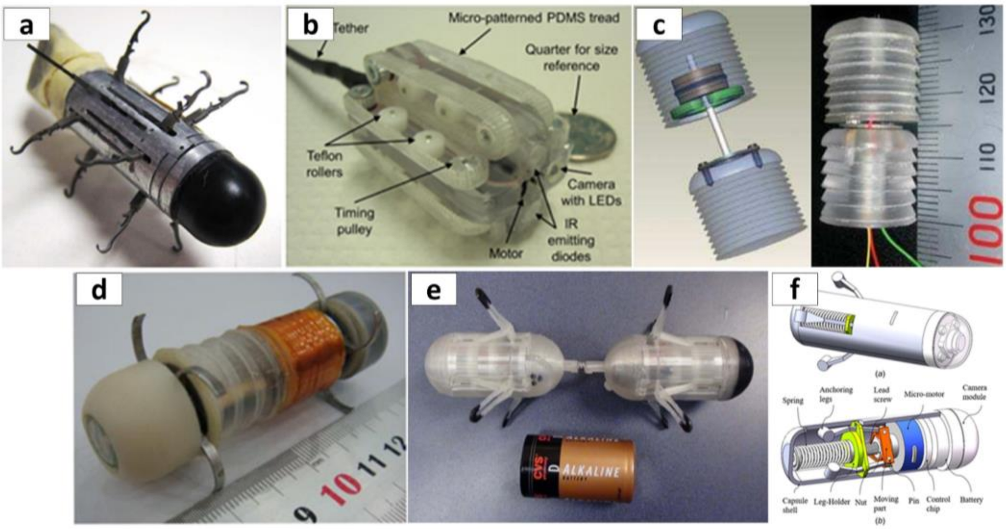

Fig 2: (a) an active capsule with legs [25], (b) an active capsule with treads [27], (c) An Earthworm-Like capsule [33], (d) a capsule with spiral legs [34], (e) a twin capsule with legs [35], (f) an active capsule with legs [35]

The study of endoscopic capsules is a broad field, and no single research group can individually solve all associated problems. For example, the issues related to the biocompatibility and strength of capsule material fall within the realm of polymer engineering and are discussed in related professional articles. Due to the importance of the capsule retention, we have focused on conceptual design and solving the problem. The other aspects of the issue are being addressed in the next phases of the research.

This paper proposes a new method to provide orientation control for the endoscopic capsule, which uses two electric motors embedded inside the capsule. The final configuration of the capsule is straightforward and similar to the passive one. It has no joints, legs, or external components, which could increase the risk of retention or water leakage. Besides, the capsule doesn't need to touch the intestine wall to operate. In addition to solving the problem of capsule retention, the proposed orientation control mechanism allows gastroenterologists to adjust the capsule's direction to navigate stenosis, folds, and villi in the intestine. Fig 3 illustrates an actual common capsule retention [36]. In many cases, the capsule's ability to change its orientation to a situation aligned with the intestine would help it escape from the retention region. The proposed design's main idea, its capability to achieve every desired orientation, and a brief discussion of its advantages are presented in the forthcoming sections of the paper.

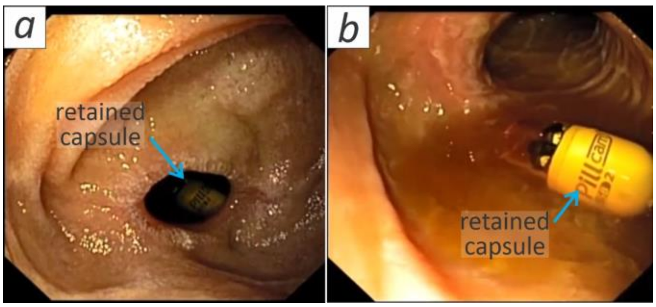

Fig 3: Retained capsule in the small intestine of a patient with Crohn's disease (a) retained capsule and its orientation to the stenosis (b) a closer view of the retained capsule [36]

2. Conceptual design

2.1. Motivation and design expectation

Capsule retention, mainly arising from obstructers in the lumen, has remained the significant side effect of capsule endoscopy. The obstructers narrow the capsule track through the intestine. Thus, proper orientation of the endoscopic capsule could prevent the retention of the capsule in the intestine or escape the capsule after its retention (Fig 4)

Although passive endoscopic capsules have retention hazards, they do their mission entirely in almost 80% of the capsule endoscopy procedure cases. To have a capsule with this ability while preventing the retention issue, we seek a semi-active endoscopic capsule that can change capsule orientation when it faces an obstruction while preforms like passive capsules in other situations.

The first step in designing a semi-active capsule to address the mentioned goal is to list the design requirements that the novel capsule should meet. We should develop a design concept for the capsule that aligns with our preferences. From a conceptual design point of view, a capsule superficially similar to passive capsules is intended, which is internally activated. This capsule should be able to work similarly to a passive capsule when there are not any bowel obstructions. Besides, its design should be simple and without complexity. Considering the market, since more than 80% of patients do not need the orientation-controllability of the capsule, the new design should burden meagre cost on the overall cost of the capsule. Additionally, the suggested configuration has low power consumption. The proposed actuated capsule is semi-active, only requiring power when the capsule is blocked behind the stenosis, so the required power can be provided by the camera's batteries. The new active endoscopic capsule should satisfy the needs presented in the conceptual design framework.

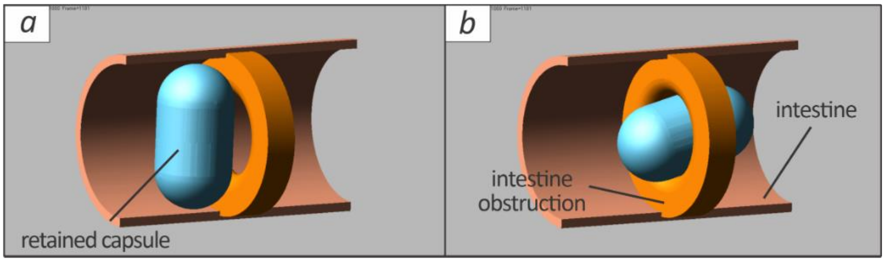

Fig 4: Endoscopic capsule meeting intestine obstruction (a) retained capsule (b) passing the obstruction by changing the capsule orientation

In this case, the mission of the actuation mechanism is to align the capsule with the longitudinal direction of the intestine (Fig 4). The controllable capsule is internally actuated and superficially seems like a passive capsule. However, the capsule should take some rotations to adjust its direction with the intestine.

To produce appropriate rotations, we need proper torques in different directions. We used electrical motors to make the required torques, and we will show that rotations about two perpendicular directions are sufficient to align the capsule with the intestine.

2.2. Actuation mechanism

As an electrical motor begins to rotate, the produced torque is transferred to the motor's housing supporting its stator. The housing reciprocally makes reaction torques to balance the whole system, based on Newton's third law. If ground or a strong wall is not available to burden the motor's reaction torque, the reaction torque will rotate the stator and its housing.

In the case of internally actuated endoscopic capsules, equipping the capsule with an anchoring mechanism, like [37, 38], would result in the whole reaction force or reaction torque being applied to the soft tissue of the GI tract and damaging it. Otherwise (lack of anchoring mechanism), the capsule would accelerate in the direction of the reaction torques (T_r in Fig 5). If we design a well-arrangement of the internal motors, their produced reaction torques will control the capsule's orientation to reach the desired situation.

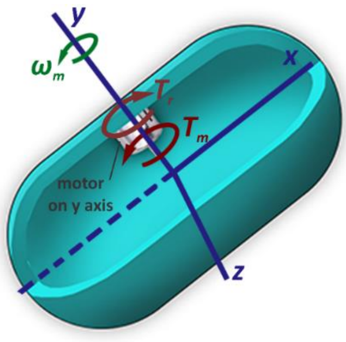

Fig 5: The capsule rotation by the reaction torque (T_r) due to the motor rotation (ω_m)

The capsule has three independent directions in the space (one longitudinal direction - *x*-axis in Fig 5- and two radial directions -*y* and *z*-axes in Fig 5). The torques produced by the actuation mechanism should align the *x*-axis of the capsule with the intestine's longitudinal direction to make the capsule aligned with the intestine. A graphical scheme could help us find the proper direction of the actuation torque. We use $\xi\eta\lambda$ coordinate system to describe the intestine's axes.

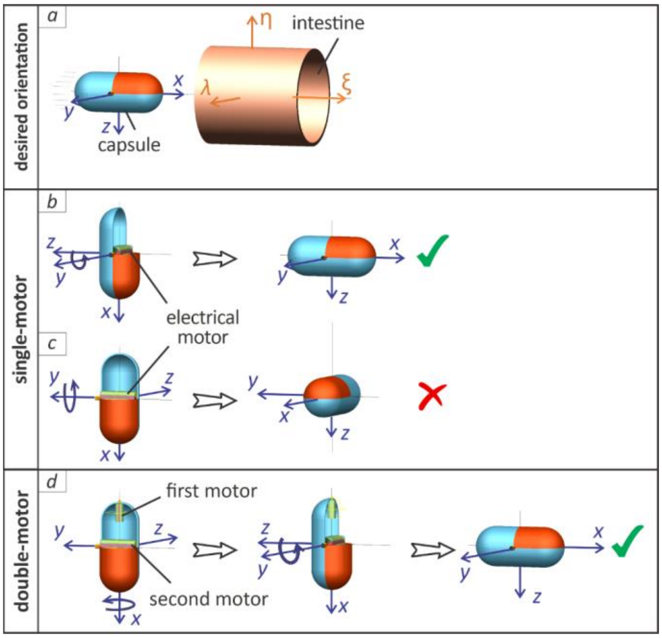

Fig 6: The procedure of aligning the capsule with intestine

Fig 6 illustrates the different orientations of the capsule in the intestine. The *xyz* coordinate system is attached to the capsule and describes the capsule's orientation. The desired orientation of the capsule happens when the capsule and intestine are longitudinally aligned. Assume a single electrical motor is assembled in the capsule to produce its torque in the *y*-axis direction. Besides the desired orientation (Fig 6-*a*), the capsule can take infinite orientations. For the graphical scheme, we consider two independent cases. If the *y*-axis is perpendicular to the ξ-axis (Fig 6-*b*), a single capsule rotation is sufficient to bring it to the desired orientation. However, if the *y*-axis is parallel to the ξ-axis (Fig 6-*c*), a single capsule rotation is insufficient to align the capsule with the direction of the intestine. Thus, we need at least two rotations on two perpendicular axes.

"Two different rotations" means we need two different torques; thus, we need to implement a second motor along a different axis, like the *x*-axis (see Fig 6-*d*). The mission of the first motor is to make the *y*-axis of the capsule perpendicular to the ξ-axis, where the rotation of the second motor could align the capsule with the intestine. Since the capsule is symmetric, the direction of the *y* & *z*-axes is unimportant for the aligned capsule, and a third rotation doesn't make an effective change.

The graphical scheme showed that we need two motors to align the capsule with the intestine from two special initial orientations of the capsule. In other words, two motors are necessary to control the capsule orientation. The kinematic relations of the capsule's rotation help us to find a sufficient number of motors.

2.3. Theoretical modelling

We assume two main assumptions in modelling the mechanism: first, neglecting any external torques on the capsule, and second, starting the motor from a stationary condition. When a motor starts from rest, a considerable start torque transfers to the capsule's body. Thus, the capsule's body would be exposed to rotational acceleration, keeping the angular momentum of the system (i.e., the capsule and the motor) equal to zero. If we consider the external torques applied to the capsule due to the fluid flow or mucosa in the GI tract, the angular acceleration of the capsule would have a value that depends on the external torque. Briefly, the angular motion of the internal motor causes the rotation of the capsule's body reversely.

The reaction torque affects the capsule's angular momentum and angular velocity. The applied torque changes the angular momentum of the capsule by the following equation, which is the angular impulse-momentum principle [39]:

$$(\overline{H}_C)_2 = (\overline{H}_C)_1 + \int_{t_1}^{t_2} \sum \overline{M}_C dt \tag{1}$$

where $\overline{H}_c$ and $\overline{M}_c$ denote the angular momentum of the whole capsule (with motors) and the external torque applied to the outer surface of the capsule body, respectively.

Neglecting the external torque applied on the capsule body, the total angular momentum of the system, consisting of the capsule body and the electro-motors, would be constant:

$$\overline{M}_C = 0 \;\; \rightarrow \;\; (\overline{H}_C)_2 = (\overline{H}_C)_1 \tag{2a}$$

which means:

$$(\overline{H}_b)_2 + (\overline{H}_m)_2 = (\overline{H}_b)_1 + (\overline{H}_m)_1 \tag{2b}$$

$$\Delta\overline{H}_b = -\Delta\overline{H}_m \tag{2c}$$

where $\overline{H}_b$ and $\overline{H}_m$ in Eq. (2b) stand for the angular momentum of the capsule's body and the motor, respectively. Eq. (2c) implies that the angular momentums of the capsule's body and electro-motor are opposite.

The angular momentum of an object about an arbitrary point A is defined as [39]:

$$\overline{H}_A = [I]\overline{\omega} \tag{3}$$

$$[I] = \begin{bmatrix} I_{xx} & -I_{xy} & -I_{xz} \\ -I_{xy} & I_{yy} & -I_{yz} \\ -I_{xz} & -I_{yz} & I_{zz} \end{bmatrix} \tag{4}$$

The matrix *[I]* is the inertia matrix about point A and is defined as Eq. (4), where the terms I_{pp} (repeated subscripts) are moments of inertia about the three coordinate axes attached to point A. The matrix's terms I_{pq} (non-repeated subscripts) are products of inertia [39]. It could be easily deduced that the capsule's rotation depends on the spinning of the internal motor. The body begins to rotate as the motor spins and stops by the time it stops.

Many studies have shown that the rotation of the capsule in its longitudinal direction is sufficient to provide forward and backward propulsion for the endoscopic capsule [40-42]. The propulsion could be achieved by only one internal motor when the capsule is aligned with the intestine. Therefore, capsule alignment is the first step for locomoting the capsule by this method. Thus, the proposed orientation-controllable capsule could be used as a controllable locomotion capsule. In addition, the rotation of the internal motors could reduce friction and prevent adhesion between the capsule and the intestinal tissue by applying the reaction torque to the intestine [11].

We showed graphically that two internal motors are essential to align the capsule with the intestine. However, we will consider the kinematic of the capsule rotation to answer the question of how many internal motors are sufficient for transferring the capsule from its initial orientation to a second arbitrary orientation leading to its alignment with the intestine's longitudinal direction.

Consider two coordinate systems, $\xi\eta\lambda$, and xyz, attached to the intestine and the capsule, respectively (see Fig 6). Suppose that the ξ-axis of the $\xi\eta\lambda$ coordinate coincides with the intestine's longitudinal direction. Similarly, the x-axis of the xyz coordinate frame denotes the longitudinal direction of the capsule.

The rotational transformation *[R]* is defined as a transformation of the coordinate system $\xi\eta\lambda$ to the coordinate system *xyz*. Suppose the l_{pQ} ($p = x.y.z$ and $Q = \xi.\eta.\lambda$) is the cosines of the angle between axis *p* and axis *Q*, which are called direction cosines; then, we have:

$$\begin{Bmatrix} x \\ y \\ z \end{Bmatrix} = [R] \begin{Bmatrix} \xi \\ \eta \\ \lambda \end{Bmatrix} \tag{5}$$

$$[R] = \begin{bmatrix} l_{x\xi} & l_{x\eta} & l_{x\lambda} \\ l_{y\xi} & l_{y\eta} & l_{y\lambda} \\ l_{z\xi} & l_{z\eta} & l_{z\lambda} \end{bmatrix} \tag{6}$$

Due to the coordinates' notation (Fig 6), the capsule and intestine are longitudinally aligned when the *x*-axis and *ξ*-axis are aligned.

We choose two perpendicular axes of the capsule where the internal motors can be mounted. The first motor shaft is aligned with the *x*-axis of the capsule to rotate the capsule about its longitudinal axis. For the second motor, rotation about the *y*-axis or *z*-axis is similar to turning the capsule about its radial axis. Herein, we choose the *y*-axis as the second motor axis. To drive the relations of the capsule orientation, we assume that the capsule first undergoes a rotation about the *x*-axis (first rotation) by an angle *α*. After that, it would rotate about the *y*-axis by an angle *β* (second rotation).

For simplicity, the capsule's attached frame (i.e., *xyz*), after its rotations about the *x* and *y* axes, are named *x´y´z´* and *x˝y˝z˝*, respectively, thus:

$$\begin{Bmatrix} x' \\ y' \\ z' \end{Bmatrix} = \begin{bmatrix} 1 & 0 & 0 \\ 0 & c\alpha & s\alpha \\ 0 & -s\alpha & c\alpha \end{bmatrix} \begin{Bmatrix} x \\ y \\ z \end{Bmatrix} \tag{7}$$

$$\begin{Bmatrix} x'' \\ y'' \\ z'' \end{Bmatrix} = \begin{bmatrix} c\beta & 0 & -s\beta \\ 0 & 1 & 0 \\ s\beta & 0 & c\beta \end{bmatrix} \begin{Bmatrix} x' \\ y' \\ z' \end{Bmatrix} \tag{8}$$

Eq. (5) expresses the transformation between the initial orientation of the xyz frame and the ξηλ coordinate frame fixed to the intestine. Employing Eq. (5) results in the following:

$$\begin{Bmatrix} x'' \\ y'' \\ z'' \end{Bmatrix} = \begin{bmatrix} c\beta & 0 & -s\beta \\ 0 & 1 & 0 \\ s\beta & 0 & c\beta \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 \\ 0 & c\alpha & s\alpha \\ 0 & -s\alpha & c\alpha \end{bmatrix} [R] \begin{Bmatrix} \xi \\ \eta \\ \lambda \end{Bmatrix} \tag{9}$$

It is desired that the final orientation of the capsule coordinate frame (i.e., *x˝y˝z˝*) be in such a way that the *x˝*-axis coincides with the *ξ*-axis; it means:

$$\begin{Bmatrix} x'' \\ y'' \\ z'' \end{Bmatrix} = \begin{bmatrix} 1 & 0 & 0 \\ 0 & * & * \\ 0 & * & * \end{bmatrix} \begin{Bmatrix} \xi \\ \eta \\ \lambda \end{Bmatrix} \tag{10}$$

Substituting Eq. (9) into Eq. (10), the following relation arises:

$$\begin{bmatrix} c\beta & 0 & -s\beta \\ 0 & 1 & 0 \\ s\beta & 0 & c\beta \end{bmatrix} \begin{bmatrix} 1 & 0 & 0 \\ 0 & c\alpha & s\alpha \\ 0 & -s\alpha & c\alpha \end{bmatrix} [R] = \begin{bmatrix} 1 & 0 & 0 \\ 0 & * & * \\ 0 & * & * \end{bmatrix} \tag{11}$$

The matrix *[R]*, as expressed by Eq. (6), describes the initial orientation of the capsule in the intestine. By performing the matrix product of the left side of Eq. (11), we will have the following:

$$\begin{bmatrix} l_{x\xi}c\beta + \left(l_{y\xi}s\alpha - l_{z\xi}c\alpha\right)s\beta & l_{x\eta}c\beta + \left(l_{y\eta}s\alpha - l_{z\eta}c\alpha\right)s\beta & l_{x\lambda}c\beta + \left(l_{y\lambda}s\alpha - l_{z\lambda}c\alpha\right)s\beta \\ l_{y\xi}c\alpha + l_{z\xi}s\alpha & l_{y\eta}c\alpha + l_{z\eta}s\alpha & l_{y\lambda}c\alpha + l_{z\lambda}s\alpha \\ l_{x\xi}s\beta + \left(l_{z\xi}c\alpha - l_{y\xi}s\alpha\right)c\beta & l_{x\eta}s\beta + \left(l_{z\eta}c\alpha - l_{y\eta}s\alpha\right)c\beta & l_{x\lambda}s\beta + \left(l_{z\lambda}c\alpha - l_{y\lambda}s\alpha\right)c\beta \end{bmatrix} = \begin{bmatrix} 1 & 0 & 0 \\ 0 & * & * \\ 0 & * & * \end{bmatrix} \tag{12}$$

The components of the obtained matrices should be equal one by one as follows, and we have five equations:

$$\begin{cases} (1) & l_{x\xi}c\beta + l_{y\xi}s\alpha s\beta - l_{z\xi}c\alpha s\beta = 1 \\ (2) & l_{x\eta}c\beta + l_{y\eta}s\alpha s\beta - l_{z\eta}c\alpha s\beta = 0 \\ (3) & l_{x\lambda}c\beta + l_{y\lambda}s\alpha s\beta - l_{z\lambda}c\alpha s\beta = 0 \\ (4) & l_{y\xi}c\alpha + l_{z\xi}s\alpha = 0 \\ (5) & l_{x\xi}s\beta - l_{y\xi}s\alpha c\beta + l_{z\xi}c\alpha c\beta = 0 \end{cases} \quad (13)$$

Although there are five equations, they are not necessarily independent. Solving the equations for the rotational angles, α, and β, yields:

$$\begin{cases} c\beta = l_{x\xi} \\ s\beta^2 = 1 - l_{x\xi}^2 \\ c\alpha = \dfrac{-l_{z\xi}}{s\beta} \\ s\alpha = \dfrac{l_{y\xi}}{s\beta} \end{cases} \quad (14)$$

The solution for *cos(α)* and *sin(α)* depends on *sin(β)* which has two answers:

$$\begin{cases} \text{answer 1: } \alpha = \text{atan2}\left(\dfrac{l_{y\xi}}{\sqrt{1-l_{x\xi}^2}}, \dfrac{-l_{z\xi}}{\sqrt{1-l_{x\xi}^2}}\right), \quad \beta = \text{atan2}\left(\sqrt{1-l_{x\xi}^2}, l_{x\xi}\right) \\ \text{answer 2: } \alpha = \text{atan2}\left(\dfrac{-l_{y\xi}}{\sqrt{1-l_{x\xi}^2}}, \dfrac{l_{z\xi}}{\sqrt{1-l_{x\xi}^2}}\right), \quad \beta = \text{atan2}\left(-\sqrt{1-l_{x\xi}^2}, l_{x\xi}\right) \end{cases} \quad (15)$$

Apart from the answers mentioned above in Eq. (15), there is another set of acceptable solutions. The other solution arises when the intestine's ξ-axis and the capsule's x-axis are aligned in opposite directions. The opposite alignment would reveal itself in a minus factor on the right side of Eq. (13)-1, where a negative value would be replaced instead of a positive one. Thus, there would be four correct answers which could align the endoscopic capsule from an arbitrary orientation to the longitudinal direction of the intestine. Therefore, two internal motors, one mounted in the longitudinal direction of the capsule and the other perpendicular to the first one, could adjust the capsule's orientation from any desired orientation. Also, after aligning the capsule with the intestine, the first motor actuation can provide the capsule ability for forwarding and backward propulsion.

2.4. Testing the proposed actuation mechanism

Two essential aspects of the capsule's performance should be considered to verify if the proposed mechanism in the capsule could satisfy the conceptual design requirements. They are the ability of the capsule to align itself with the intestine direction; and the sufficiency of the torque produced by the internal motors to rotate the capsule. We examined the first aspect by computer simulation, and a simple prototype was used to explore the second aspect.

2.4.1. Examination of the design by software simulation

We examined the simulated model of the active endoscopic capsule with two internal electric DC motors by Adams View 2018 software. Two motors have orthogonally embedded in the capsule, one on the *x*-axis and the other on the capsule's *y*-axis (Fig 7). The Adams View software enables us to control the capsule's rotation by adjusting the electrical currents of the simulated motors. We have embedded a region with a different diameter in the intestine model (Fig 4) to simulate a stenosis that the capsule must navigate. In this simulation, the interactions between the capsule and the intestinal wall are considered, including impact, contact, and friction. We used a friction coefficient of 0.2 between the capsule and the intestine, as reported in the literature [43].

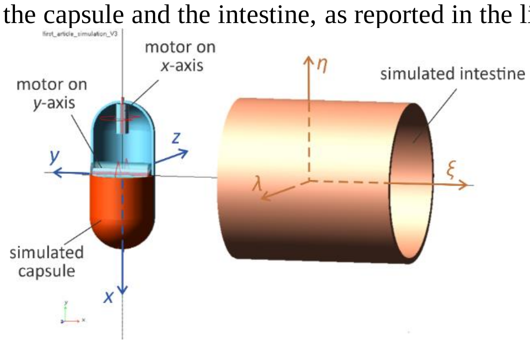

Fig 7: Simulated model in the Adams View software

2.4.2. Capsule prototype and experiment

We fabricated a capsule prototype to examine whether the reaction torque imposed by the internal motors could change the capsule's orientation (Fig 8-a). The prototype consists of two electric DC motors (motors on the *x*-axis and y-axis as defined in Fig 7). The capsule shell is made by 3D printing of ABS filament. The examination was performed inside a synthetic model of the intestine and an in-vitro cow's intestine. We chose a transparent membrane for the artificial intestine to allow observation of the capsule's rotation. The cow's intestine generates more resisting torque against the capsule's rotation due to the microscopic villi and viscous mucus. However, the friction coefficient and mucus viscosity in a living intestine are less than in a dead intestine [43]. The external torque about the radial axis of the capsule is more critical due to the longer torque arm. Therefore, we evaluated the capsule's rotation about the radial axis to show the performance of the internal motors to rotate the capsule.

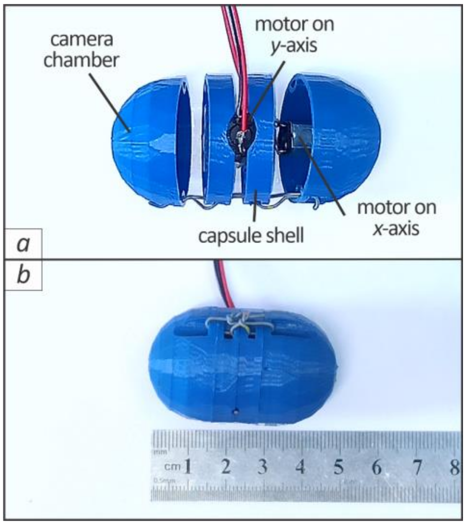

Fig 8: Explosive and assembled scheme of the active capsule prototype

3. Results

Besides the graphical description (Fig 6), the theoretical modelling showed that using only one internal motor could not change the capsule's arbitrary orientation to the desired orientation. Thus, we use two internal motors to provide the necessary actuation to bring the capsule from every random orientation to the direction aligned with the intestine's longitudinal direction. The mathematical modelling described the capsule's orientation after each actuation of the internal motors and showed the ability of the proposed active capsule to find any desired orientation, which has been evaluated by computer simulation (Fig 9).

The obstructions through the intestine -like polyps, thickened walls due to Crohn's disease, and diaphragmic wall- usually narrow the capsule's passage inside the intestine. The ability of the capsule to adjust its moving face with the longitudinal direction of the intestine decreases the probability of capsule retention. It enables the gastroenterologist to adjust the camera head for taking photos of a particular section of the intestine.

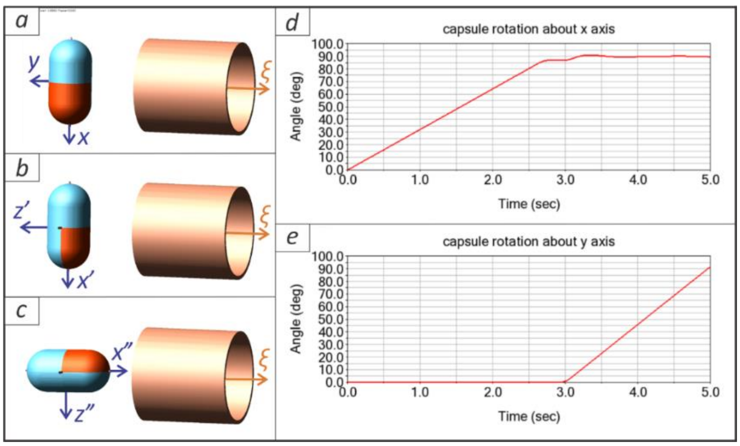

Fig 9: Simulation of t capsule rotation by using two motors; (a) initial orientation, (b) capsule orientation after 90º rotation about the x-axis, (c) final orientation aligned with the intestine, (d) and (e) the angle of the rotations of the capsule

We compared the passive and active capsules when they encountered an obstruction, using another simulation. The active capsule (Fig 10-b) was able to pass the lumen's obstruction by changing its orientation. In contrast, the passive capsule (Fig 10-a) remained stuck behind the obstruction.

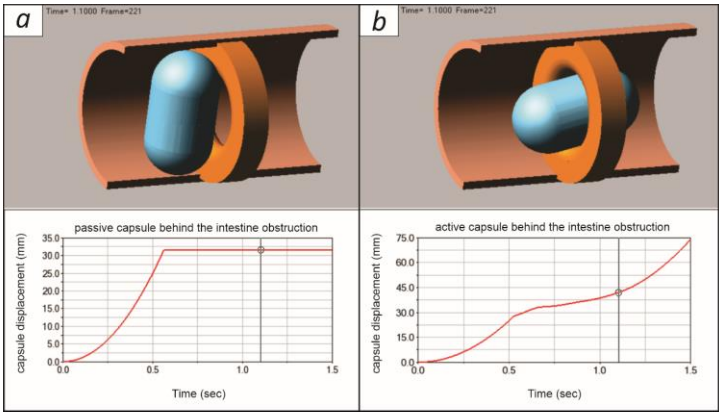

Fig 10: Comparing the passive capsule with the active capsule. (a) The passive capsule is blocked behind the obstruction. (b) The active capsule is passing the obstruction.

Fig 11 illustrates the capsule's rotation about its radial axis during the experiment and details the procedure for aligning the capsule with the direction of the intestine. Fig 11-a shows the capsule's rotation in the synthetic intestine, while Fig 11-b illustrates the capsule's rotation on the cut-open cow's intestine. The capsule could overcome the walls' friction and rotate until it was aligned with the intestine's direction. The experiment proved that the conceptual design of the proposed actuation mechanism with two internal motors could be realized as an actuation mechanism for releasing a retained capsule in the intestine.

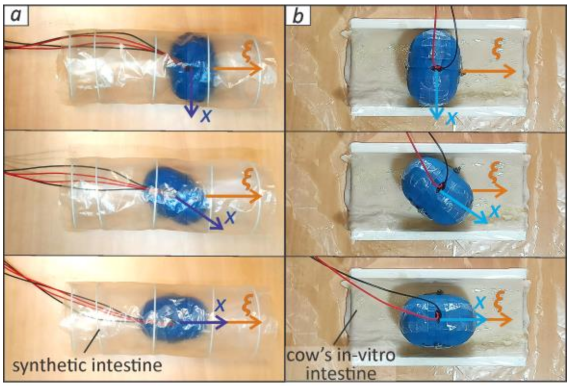

Fig 11: capsule's rotation about its radial axis to align the capsule with the intestine

4. Discussion and conclusion

Endoscopic capsules are the only devices that enable gastroenterologists to capture close-up images of the small intestine, as flexible endoscopy and colonoscopy cannot reach all parts of the small intestine. Most commercial endoscopic capsules can complete their mission and leave the GI tract. However, the risk of capsule retention is probable in patients with healthy intestines or patients suffering from Crohn's disease or diaphragm disease This can lead to severe complications such as intestinal obstruction, bleeding, perforation, and may require surgical intervention. [44].

This research aims to find a simple way to release a retained endoscopic capsule from retention in the intestine. The small intestine is structurally complex and some diseases can cause obstructions and lumen stenosis. Because of the intestine's peristalsis and the fluid's flow into the GI tract, the capsule would find any orientation when it meets a stenosis in the intestine. The endoscopic capsule may become blocked behind stenosis and remain in the intestine, due to improper orientation of the capsule.

First, we considered the effects of controlling the capsule's orientation on its retention-free movement in the intestine (Fig 10) We simulated the movement of the capsule both with and without rotation capability against a stenosis in the intestine using Adams View software. The simulation showed that the capsule with rotational ability could adjust its orientation and successfully navigate the stenosis. Based on these results, we are hopeful that this method will effectively address the problem of capsule retention. We then modelled the orientation procedure to align the capsule with the intestine's direction (Fig 6 and Fig 9). We showed that two independent rotations are necessary and sufficient to rotate the capsule from every arbitrary orientation to every desired one. Thus, the degrees of freedom for the active capsule have been obtained.

The next challenge is determining the actuation method and selecting an actuator that can provide the necessary rotation for the capsule while overcoming the resisting torque from the intestine. Three types of actuators have been proposed for activating endoscopic capsules: 1) magnetic fields, 2) actuators based on Shape Memory Alloys (SMAs), and 3) electrical motors [9, 11]. Magnetic fields provide limited force and torque, which are insufficient to overcome the strong peristalsis and resisting forces in the intestine [22] Actuators based on SMAs suffer from high energy consumption and heat production due to their thermal performance, which is not desirable. Therefore, we chose DC electric motors to achieve the required actuation for the capsule.

We used two internal electric motors to control the capsule's orientation. Our challenge was to provide the necessary torque with the electric motors while keeping the capsule's dimensions small. Despite the small size of the motors, our experiments showed that the motors' torque could rotate the capsule in both radial and longitudinal directions of the capsule (Fig 11).

Apart from the earlier internally actuated capsules, we designed a controllable one, superficially similar to passive capsules. Thus, the proposed capsule benefits from the simple shape of passive capsules, which ensures it is isolated from water and digestive juices, and eliminates the risk of damaging legs or paddles. Besides, power consumption is not a serious challenge since the capsule can operate semi-actively.

The capsule could change its orientation behind a stenosis in the intestine to pass through it. Gastroenterologists can control the head of the capsule and keep it aligned with the longitudinal direction of the intestine to prevent capsule retention and increase the quality of the photos taken. When the capsule is aligned with the intestine, its rotation about its longitudinal axis could propel it, which is considered a wide field of study for future research.

The design of an endoscopic capsule with rotational capability to reduce retention probability is not limited to the scope of this article. This article presents the conceptual design of an internally actuated endoscopic capsule that does not incorporate any external components such as legs or paddles. The dynamics modeling of the capsule's rotation, its verification, and the calculations of resisting torques that support this novel approach will be detailed in a separate report. In the current research, the performance of the capsule is evaluated using a dead cow's intestine. Ethical considerations require that testing of the capsule's functionality in living tissue and clinical trials will only commence after full assurance of the capsule's safety and effectiveness.

Declaration of Conflicting Interests

The Author(s) declare(s) that there is no conflict of interest

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