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Friction-Assisted Magnetic Holding of an Ingestible Capsule for Esophageal pH and Impedance Monitoring

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Abstract—**24-hour catheter-based ambulatory pH and impedance monitoring is an essential tool for diagnosing esophageal disorders. However, catheter-based monitoring systems are uncomfortable and interfere with normal activities of the patient. To overcome these disadvantages, different wireless monitoring systems have been proposed. However, efficient ways to position and hold wireless capsules are lacking. Currently there is a need to develop safe and reliable methods to hold an esophageal wireless monitoring system in position for 24 hours. Friction-assisted magnetic holding is proposed as an alternative to conventional holding techniques. Permanent magnet and electromagnet designs with the required characteristics to achieve this task were computer-designed and simulated. The size and power requirements of the magnets were considered. Simulation results were verified using laboratory experiments. Permanent neodymium magnets offered the best performance for the intended application. The obtained results show the feasibility of friction-assisted magnetic holding for esophageal monitoring. Improvements to the thread design, friction enhancing pins, magnetic shielding and encapsulation methods are necessary for *in vivo* testing.**

I. Introduction

Esophageal pH monitoring is the gold standard for diagnosing gastroesophageal reflux disease (GERD) [1]. GERD is a chronic disorder that affects 44% of all Americans once a month, 14% once a week, and 7% daily [2]. Traditionally, catheter-based monitoring systems have been used for 24-hour esophageal pH monitoring (Fig. 1). However, this invasive test has shown to be uncomfortable for the patient. Regardless of specific instructions to preserve a normal daily routine during test periods, most patients alter their routine and change their eating habits due to the discomfort caused by the catheter [3]. This causes alterations in reflux-provoking activities, modifying test results [4].

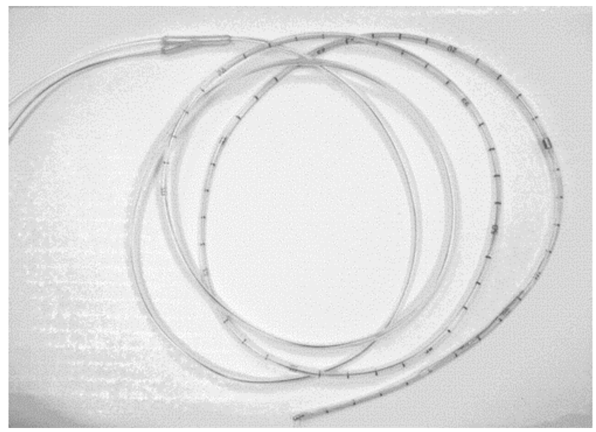

Fig. 1. Esophageal pH catheter

In recent years diverse technologies for wireless ambulatory esophageal monitoring have been proposed to overcome the disadvantages of catheter-based monitoring systems. The Bravo pH monitoring system (Medtronic Inc., Shoreview, MN) is an affixable capsule that monitors pH changes 5 cm above the lower esophageal sphincter (LES) [5]. The “Bravo Capsule” is attached to the esophageal mucosa using a delivery system comparable to traditional esophageal catheters (Fig. 2). The delivery system is endoscopically positioned above the LES. This is an involved clinical procedure and in some cases esophageal perforation after placement of the wireless Bravo pH monitoring system has been reported [6]. This and other affixing problems limit the utilization of the device. Other monitoring capsules have been proposed [7], [3]. However, they are not affixable to the mucosal wall of the esophagus 5 cm above the LES. Thus, these capsules are not useful for 24-hour esophageal studies. A method for magnetically holding an esophageal capsule 5 cm above the LES was previously proposed [8]. However, due to the fact that the distance between the magnets and the monitoring capsule was around 13.5 cm, the required magnets were large in size and weight, jeopardizing the practical applicability of this design approach.

The aim of the present research is to explore different

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magnetic designs for affixing an esophageal monitoring capsule in the esophageal tract causing minimum discomfort to the patient.

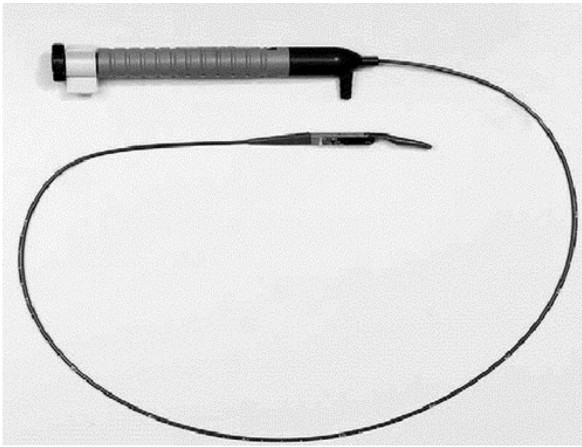

Fig. 2. Bravo pH monitoring system

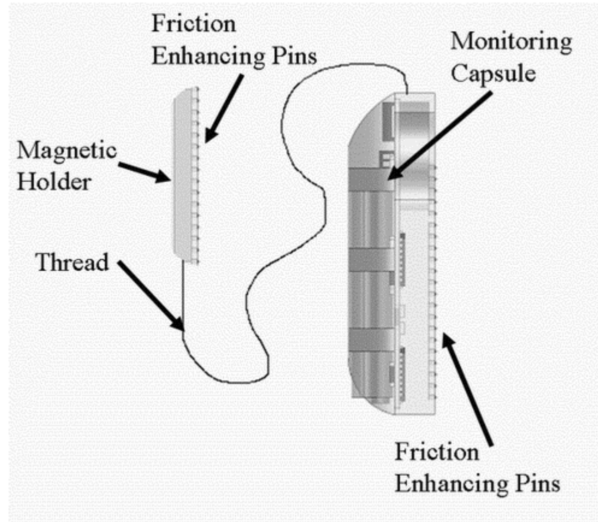

Fig. 3. Proposed capsule design

II. Methods

The human esophagus is a long, hollow organ that transports food from the mouth to the stomach. In order to reduce the size and the weight of the magnet, it is necessary to position the magnet as close as possible to the esophagus. The esophagus is closest to the surface of the skin at the base of the neck. The distance between the esophagus and an external magnet for an average adult male at the base of the neck is around 1/3 of the neck diameter. This is approximately less than 5 cm for an adult male. However, this point is about 15 cm away from the LES. Thus, a capsule design attached to a magnetic holder using a soft flexible thread is proposed (Fig. 3). The proposed design would be held in position using one magnet or electromagnet located at the base of the neck (Fig. 4).

The approximate weight of a miniature monitoring capsule is 6 g. Therefore, a magnet capable of holding a 6 g mass against gravity at 5 cm from its surface is required. Experimentally it was determined that a magnetic field of 200 gauss was enough to hold a 6 g mass against gravity. Maxwell 3D CAD software (Ansoft Corporation, Pittsburgh, PA) was employed to model the magnetic fields of a permanent magnet and an electromagnet capable of generating a 200 gauss field at 5 cm from their surface.

In addition to overcoming gravity, the wireless monitoring system will have to overcome the esophageal propelling peristaltic force (F_{PP}). Due to the propagating nature of peristalsis, F_{PP} can act on either the magnetic holder or on the monitoring capsule only, but never on both at the same time. The magnetic force can be combined with static friction between the shell of the magnetic holder and the inner side of the esophageal wall to overcome F_{PP}. Manometric recordings obtained on healthy volunteers during peristalsis were previously reported and are shown in Table I [9].

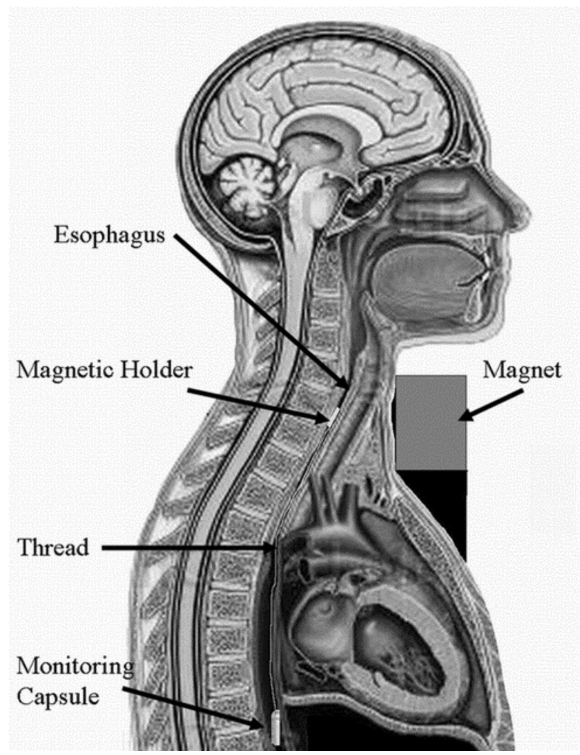

Fig. 4. Sagittal section of the upper human body

TABLE I
NORMAL VALUES IN 24-HOUR AMBULATORY MONITORING OF THE ESOPHAGUS

Median Contraction Amplitude (mmHg)	Supine	Upright	Meals
15 cm above LES	36(20-60)	31(22-49)	43(30-70)
10 cm above LES	45(25-75)	38(27-64)	51(30-78)
5 cm above LES	50(27-79)	40(25-65)	64(32-96)

The highest pressure (P) provoked by peristalsis reported in this study was 96 mmHg during meals [9]. This corresponds to 12,800 N/m^2. The surface area of the magnetic holder is less than half the surface area of the monitoring capsule. Thus, the highest force experienced by the system is the one acting on the monitoring capsule. The force propelling the monitoring capsule depends on the shape of its encapsulation, the angle between its surface and the contracting esophageal wall at the point of contact. Therefore, a capsule housing design at an angle ≥ 45° considerably reduces the propelling force acting on its surface. Peristaltic forces acting at a 90° angle would not propel the capsule, but would only push it against the esophageal wall. Therefore, the surface area ($A = 3.815 \times 10^{-4}$ m^2) of the capsule exposed to F_{PP} is only at the proximal end. If we consider this area to be approximately 1/4 of the capsule total surface area, at a 45° angle, F_{PPY} can be estimated as:

$$F_{PPY} = (P * A/4)\sin(-45°) = -0.863N \tag{1}$$

A force of 0.863 N corresponds to a mass of 88 g against gravity. The negative sign indicates the direction of the force. Therefore, a combination of the external magnetic field and friction-enhancing pins capable of handling a load of about 100 g without penetrating the mucosal wall of the esophagus should be able to overcome F_{PPY}. An array of 18 stainless steel pins (diameter of 0.16 mm and length of 0.7 mm) was built by silver-soldering the pins to a stainless steel plate (Stay-Brite Silver Solder Kit, J. W. Harris Corporation, Manson, OH). The array was attached to the magnetic holder, and a 100 g mass load was utilized in order to test friction-assisted magnetic holding (Fig. 5).

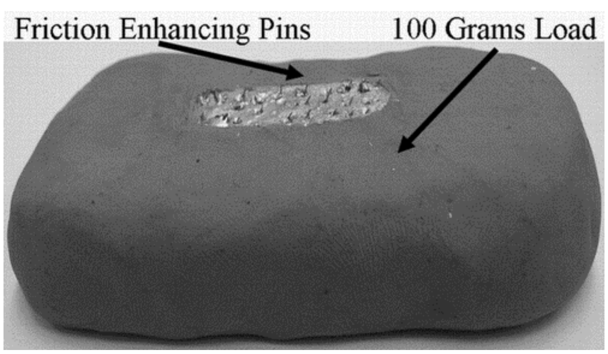

Fig. 5. Friction enhancing pins

III. RESULTS

A 5 cm x 4 cm x 2.5 cm permanent neodymium magnet generated the desired magnetic field at 5 cm from its surface (Fig. 6). An electromagnet capable of generating a similar field was also designed. Assuming a 3A current, 1000 turns would be required to generate the desired field. A square iron core was used to enhance the shape of the magnetic field on the x axis. The final dimensions of the electromagnet were 10 cm in diameter by 5 cm in height (Fig. 7).

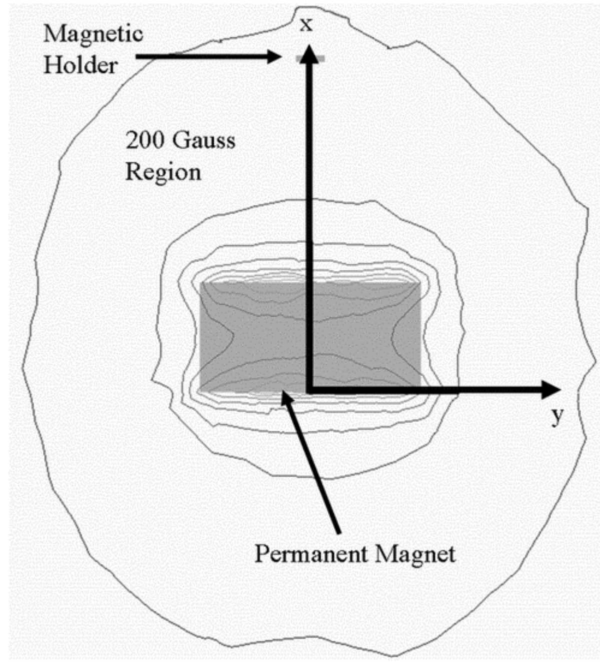

Fig. 6. Modeled permanent neodymium magnet

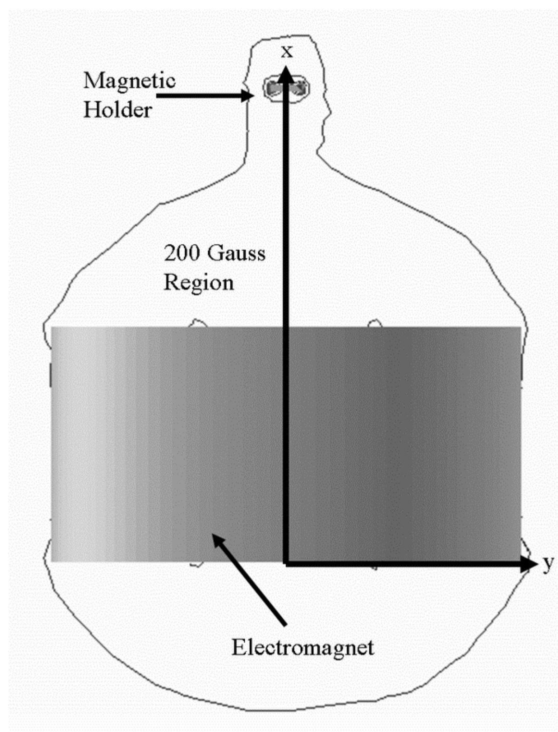

Fig. 7. Modeled electromagnet

A permanent magnet with the characteristics of the designed magnet was capable of affixing the magnetic holder at 5 cm distance from its surface (Fig. 8). A load of 100 g was successfully held against gravity utilizing the same permanent magnet and the friction enhancing pins (Fig. 9).

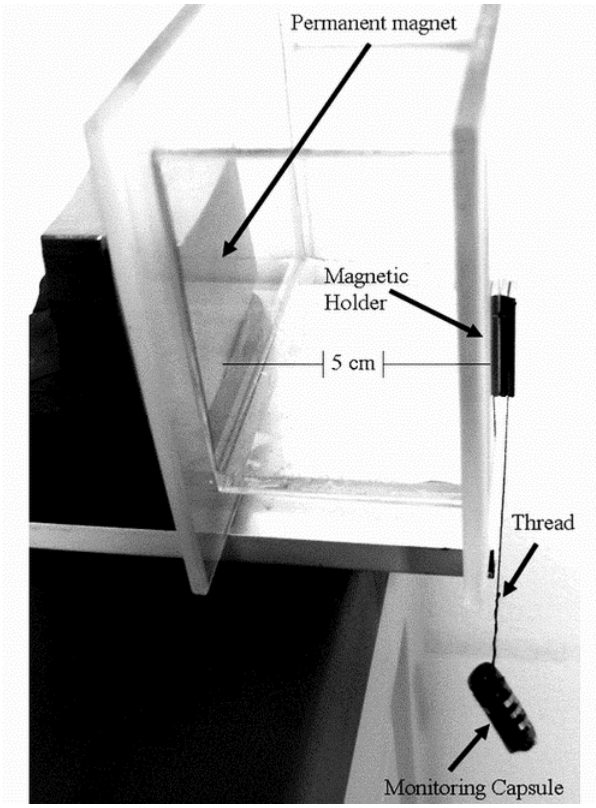

Fig. 8. Permanent magnet holding the monitoring capsule

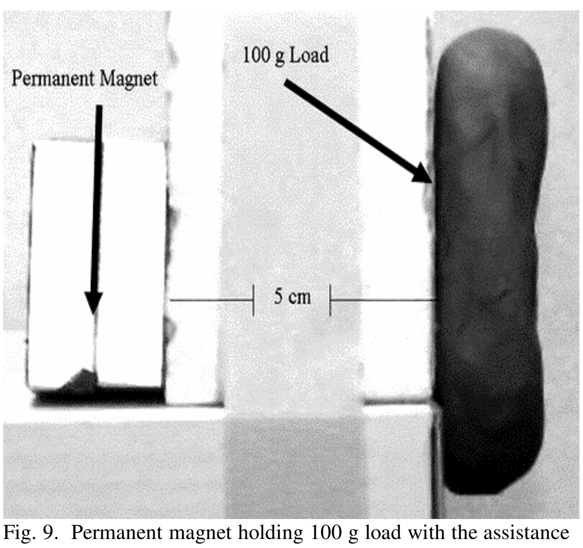

Fig. 9. Permanent magnet holding 100 g load with the assistance of friction enhancing pins

IV. Discussion

The Bravo capsule by Medtronic [5] is presently the only commercially-available wireless technique for ambulatory esophageal pH monitoring. However, the invasive affixing method associated with this technique has been considered problematic [6]. In the present study we offer an alternative for affixing a pH-monitoring capsule using magnetism. Simulation results demonstrated that both design approaches, utilizing electromagnets and permanent magnets, were capable of holding the capsule in position. However, electromagnets are larger in size and require a power supply to continuously deliver 3 A. On the other hand, permanent magnets can be of smaller size and do not require a power supply. The main disadvantage of permanent magnets is the lack of control over the magnetic field. However, precise control of the magnetic field is not necessarily required for the intended application. Friction-enhancing pins were proposed to assist the magnetic force in overcoming esophageal peristalsis. While the results were satisfactory, more powerful permanent magnets could potentially further reduce the size of the pins while diminishing the discomfort to the patient and any risk of irritating the esophageal mucosa. However, these magnets could be larger in size and weight, and the design of an adequate magnetic shielding for ambulatory 24-hour testing could be required.

V. Conclusion

An innovative method for holding an esophageal monitoring capsule has been presented and tested in laboratory conditions. This method offers an alternative to clinically invasive methods for affixing esophageal monitoring capsules.

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