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Electropermanent magnetic anchoring for surgery and endoscopy

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***Abstract*—The use of magnets for anchoring of instrumentation in minimally invasive surgery and endoscopy has become of increased interest in recent years. Permanent magnets have significant advantages over electromagnets for these applications; larger anchoring and retraction force for comparable size and volume without the need for any external power supply. However, permanent magnets represent a potential hazard in the operating field where inadvertent attraction to surgical instrumentation is often undesirable. The current work proposes an interesting hybrid approach which marries the high forces of permanent magnets with the control of electromagnetic technology including the ability to turn the magnet off when necessary. This is achieved through the use of an electropermanent magnet, which is designed for surgical retraction across the abdominal and gastric walls. Our electropermanent magnet, which is hand-held and does not require continuous power, is designed with a centre lumen which may be used for trocar or needle insertion. The device in this application has been demonstrated successfully in the porcine model where coupling between an intraluminal ring magnet and our electropermanent magnet facilitated guided insertion of an 18Fr Tuohy needle for guidewire placement. Subsequent investigations have demonstrated the ability to control the coupling distance of the system alleviating shortcomings with current methods of magnetic coupling due to variation in trans-abdominal wall thicknesses. With further refinement, the magnet may find application in the anchoring of endoscopic and surgical instrumentation for minimally invasive interventions in the gastrointestinal tract.**

***Index Terms*— Electropermanent magnets, minimally invasive surgery, magnetic coupling, magnets, electromagnets, endoscopy.**

I. Introduction

MAGNETIC coupling in surgery and endoscopy facilitates coupling and anchoring across the abdominal wall and, in the case of permanent magnets, eliminates any electrical power requirements.

A. Clinical Background

The use of magnetic coupling has been reported in a variety of clinical settings. Magnet-assisted resection and dissection has been demonstrated by a number of groups and magnetic assistance has been proposed in single site laparoscopic surgery access and manipulation of internal targets. One of the first and most developed magnetic assistance systems is the University of Texas Southwestern Medical Centre system called MAGS (Magnetic Anchoring and Guidance System) [1]–[9]. The original MAGS was mainly for camera manipulation in abdominal surgery. However, the system has since been demonstrated in assisting with porcine nephrectomy [6] and urological procedures [9]. The system is also purely passive (i.e., relies solely on permanent magnetic Neodymium Iron Boron (NdFeB) coupling) and has no electromagnetic component. In 2011, MAGS was evaluated for coupling distance [5] and a best-case drop-off threshold distance of 4.78cm was established (defined using a nominal load of 39g). To date the system has only been tested in porcine and human cadaveric models [8]. However, it remains the most advanced and best tested magnetic system developed specifically for magnetic anchoring in surgery procedures. In a 2013 study, Salerno et al. have demonstrated a method for increasing possible coupling distance using a novel shape memory alloy actuator which deploys as a cylinder via either a transabdominal trocar or a natural orifice transluminal endoscopic surgery (NOTES) port. The shape memory alloy (SMA) actuator is activated in vivo, changing to a triangular shaped configuration, provides a larger area for magnetic coupling and a stable base for robot modules. This work has been demonstrated in vitro via a plastic phantom and in vivo in the porcine model [10]. Other work includes that of the Development Endoscopy Laboratory at Harvard who have demonstrated removal of pancreatic and biliary stents in pigs by means of magnetic coupling [11], [12]. Kume et al. demonstrated porcine laparoscopic cholecystectomy [13] and colonic resection [14] with the aid of magnetic retraction. The Hospital de Clínicas in Buenos Aires has reported the clinical use of magnetized instruments (NdFeB) for single site laparoscopy [15], [16]. Clinical investigation of single-port laparoscopic colectomy was demonstrated to be safe and effective with the aid of magnetic retraction by Uematsa et al. [17] while single site laparoscopy investigations by Cho et al. have been limited to canine ileocecectomy (resection of the lower small intestine) [18]. In one of the only clinical examples of an electromagnet used for coupling, Kobayashi et al [19] demonstrated the use of the Pentax-developed magnetic anchoring system. The MAG-ESD (magnetic-anchor guided endoscopic submucosal dissection) procedure was performed with 25 patients under conscious sedation and all

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tumors were resected en bloc, without any perforations or severe uncontrollable bleeding.

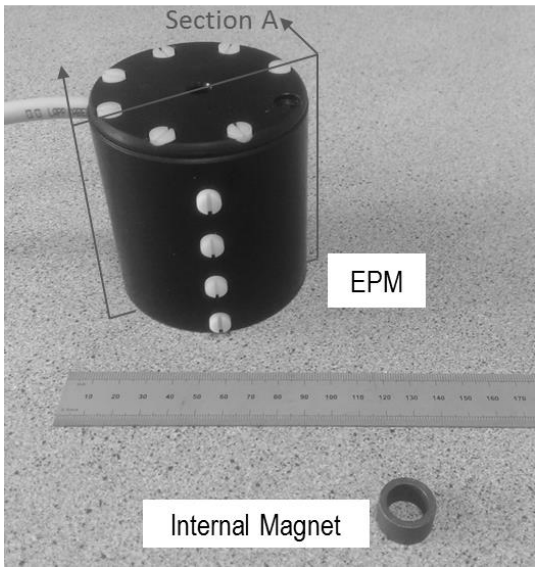


Fig. 1. Photograph of external Electropermanent magnet with Delrin casing and internal magnet actuator (internal magnet) with ruler for scale. Section A refers to schematic section as shown in Fig. 2 (b) and 2 (c).

B. *Electropermanent Magnets*

Electropermanent magnets (EPMs) are solid state, permanent magnet devices which can be turned on and off using short, momentary, pulses of energy. EPMs have been demonstrated as actuators for millimeter scale modular robotic systems [20], controllers for valves in fluid robotic systems [21] and as actuators in optical MEMS switches [22]. The primary advantage of electropermanent magnetic technology in clinical applications is stronger magnetic attraction of permanent magnets compared to electromagnets of a similar form factor, while eliminating the undesired magnetic 'pollution' by enabling on/off operation. The ability to instantaneously change the strength of the magnet, dependent on the required coupling distance would help to alleviate current issues of possible damage to a patients intervening tissue [5], [10].

This paper demonstrates the application of a fully controllable electropermanent magnetic coupling system between a permanent magnet inside of the porcine stomach and an electropermanent magnet (EPM) for external manipulation. The current realization provides a mechanical working channel alleviating possible ambiguity in current procedures that necessitate trans-abdominal incisions, such as is typical in the placement of percutaneous endoscopic gastrostomy (PEG) tubes [23].

C. *PEG.*

PEG is a technique employed by surgeons to introduce an enteral feeding tube into the stomach via the abdomen. It is one of the most common techniques employed by clinicians in cases where patients are unable to feed themselves [24]. Due to the ambiguity of the current procedures significant complications can occur, particularly the laceration of organs such as the colon that are unknowingly present between the abdomen and stomach walls [25], [26]. Although the system may find application in a number of clinical settings (e.g., laparoscopic camera anchoring, tethering of clips etc.), the original aim of the EPM magnet developed in this work was to simplify coupling across the abdominal and stomach walls at the beginning of the PEG procedure.

II. Methods and Materials

The realization of a functional, switchable EPM for trans-abdominal magnetic coupling was subject to a number of design constraints:

1. The EPM and internal magnet should couple with sufficient force at distances appropriate to human intra-abdominal wall thicknesses (>2cm).
2. The magnetic flux permeating from the EPM should be able to be close to zero to facilitate decoupling.
3. The internal magnet should be endoscopically deployed.
4. The system should ideally be operated using one hand.

A. *Magnet Design*

Two magnets were used in the investigation. The internal magnet actuator (internal magnet) consisted of a Parylene-coated N52-grade neodymium-iron-boron ring with a residual magnetic strength of 1.48 Tesla (HKCM Engineering e.K, Eckernförde, Germany) shown in Figure 1. The ring's dimensions were 18mm OD, 13mm ID and 10mm H. The second, external magnet is an EPM as detailed in Figures 1 and 2

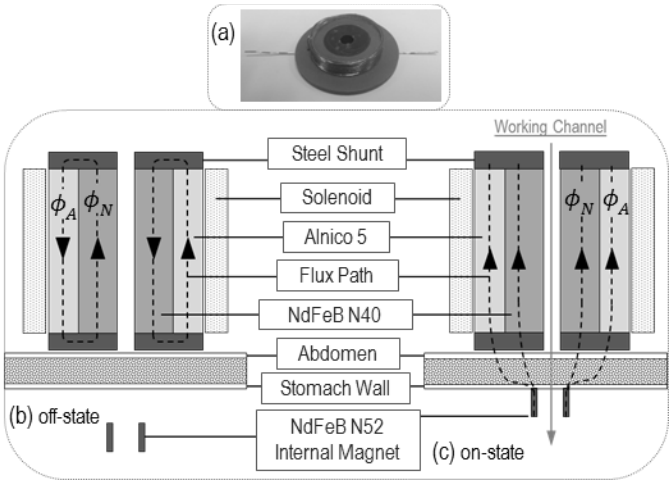


Fig. 2. (a) Photograph representing the layout of the EPM core with interior NdFeB ring, exterior Alnico 5 ring and solenoid all shown; (b) The external magnet relies on permanent electromagnetic (or electropermanent) magnet technology. In the off-state, by matching the materials carefully, the total flux (Φ_A being the flux component from the Alnico and Φ_N being the flux component from the NdFeB) is contained within the system via the two steel shunts and there is little or no coupling to the external magnet. In the on-state (c) a pulse of electrical current in the coil is used to flip the direction of magnetization of the Alnico but not the NdFeB material. The flux from the two magnetic cores are added together and couple with the internal magnet actuator. The external magnet can be turned back off by complimentary pulse of current in the opposite direction.

The EPM consists of a core of permanent magnet material contained within a solenoid. The permanent magnet core can

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either be either a volume of homogenous semi hard magnetic material (i.e., one with a relatively low value of magnetic coercivity) or more typically, an arrangement of two magnetic materials with significantly different values of coercivity. The EPM described consists of two concentric ringed cores shown in Fig. 2, composed of N40 grade neodymium-iron-boron and Alnico 5, each with approximate remnant flux densities of 1.26 Tesla (Ningbo Newland International Trade Co. Ltd, Ningbo, China). These cores are capped on either end by two annular ring 'shunts' made from low-carbon, ferromagnetic steel. A single current pulse in the coil aligns the dipoles in the Alnico with the NdFeB magnetization direction resulting in an addition of the flux from the two cores Φ_A and Φ_N, which emanates from the device in the on-state (Fig. 2 (c)) coupling to magnetic targets in the surrounding environment. A pulse in the opposite direction aligns the poles of the Alnico in opposition to the NdFeB and the flux is confined by the steel shunts, circulating within the system and rendering the effective external field of the device to be equal to zero in this, the off-state (Fig. 2 (b)).

The finite element method for modelling the design or rare earth permanent magnet devices has proven to be valid and a cost-effective method to optimize designs and identify problems prior to construction [27]–[29]. Design of the magnetic system presented was performed using incremental finite element analysis using the FEMM 4.2 software [30]. The inner diameter of the working channel was fixed to 8mm based on current PEG tube diameters [26], the maximum height and diameter of the system were fixed to 60mm and 40mm respectively, based on weight and acceptable distance from the abdomen for tools in the working channel. An automated batch simulation was performed varying all other dimensions with different selected magnetic materials to find the most appropriate geometry of the system. Each geometry was simulated and tested for holding force using a block integral of force on the internal magnet, at a distance of 25 mm in both the off-sate and on-state. All systems with zero holding force in the off-state were considered and the geometry with the maximum force in the on-state was chosen. The resultant optimized EPM dimensions were 40mm outer diameter (OD), 8mm inner diameter (ID) and 60mm height (H) with resultant volumes of 3.95 x 10^{-5} m^3 for Alnico and 3.26 x 10^{-5} m^3 for NdFeB (a ratio of 1.21:1) determined as optimum from the batch simulations. The device, which weighed approximately 1.5kg, was connected to a power supply for on/off operation. The external magnet incorporated a Hall Effect magnetic field sensor which indicated by a lighted LED on the top surface of the magnet when coupling had occurred to the internal magnet.

B. Electronic Control

The on/off control of the EPM is controlled via current pulses to the solenoid. To fully demagnetize and re-magnetize the Alnico 5 volume, a saturating magnetic core intensity of 3-5 times its 55 kA/m coercivity is required throughout the entire volume [31]. Based on simulations performed in FEMM, a current pulse with a peak of 20A using 740 turns of AWG20 copper wire is required.

The transitory pulse, control of the magnetic field and the large inductance of the solenoid (~14mH, 3.9Ω) facilitates the use of an undriven, RLC circuit to deliver the required energy. 4.4mF of electrolytic capacitance is used to give an approximately critically damped response with a damping factor of 1.16, ensuring sufficient pulse width to ensure no undesirable oscillation in the induced magnetic field. Capacitors are charged directly from a bench top power supply via a current limiting power resistor. Pulse polarity and switching is facilitated by a simple H-Bridge circuit using four, discrete power MOSFETS (IRF640NPBF from International Rectifier, El Segundo, CA). Control of the H-bridge was achieved using an ATTINY13 microcontroller unit (Atmel Corp., San Jose, CA). Total galvanic isolation between the low voltage control circuitry and the high voltage H-bridge circuit is achieved using optocouplers and isolated point of load DC/DC converters thus ensuring maximum safety to the operator in the clinical environment.

With respect to heating of the coil from the induced current pulse, assuming that all of the energy from the capacitor is discharged through the coil and neglecting any cooling effects from the coil geometry, the maximum heat increase of the solenoid is 0.3K for a single switching pulse. The switching cycle is intended to be on the order of minutes thus heating effects can be neglected.

III. Experimental Techniques and Results

A. Bench top evaluation

The system was evaluated in the bench top setting to investigate the maximum coupling distance achievable with the system in the on-state and the minimum decoupling distance achievable with the system in the off-state; the experimental setup is shown in Fig. 3. The purpose of the test was to define a working range of intra-abdominal thicknesses for the system.

Maximum-coupling-distance was defined as the largest vertical distance which the EPM was able to lift and hold the internal magnet (weight 9g) via attractive magnetic force from a rest position. Minimum-coupling-distance was defined as the minimum vertical distance between the EPM and the actuator at which the attractive force was not sufficient to lift the actuator from a rest position.

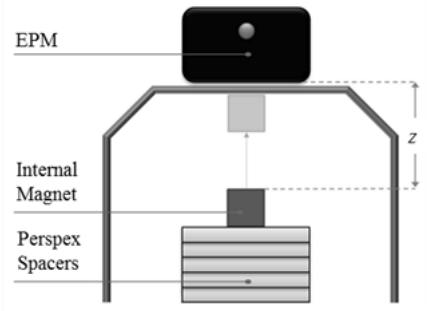


Fig. 3. Bench top evaluation experiment for defining coupling range.

Maximum-coupling-distance achieved was 82mm. The minimum-decoupling-distance achieved was 20mm. This

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corresponds to the minimum distance achieved between the internal magnet and a solid piece of mild steel, indicating that the attraction in the off-state is exclusively due to the field from the internal magnet.

B. Field experiments

To investigate the ability to reduce any magnetic pollutant whilst not in use, the field generated by the system in the on-state and off-state was measured. A GM-08 hand held gaussmeter (Hirst Ltd., Cornwall, United Kingdom) was used. The meter is calibrated for ±1% accuracy at 20°C with a sensitivity of 0.1 mT. Three tests were performed on separate days following a separate cycle of magnetization and demagnetization on each day. The experimental results are plotted in Fig. 4 and compared with the FEMM simulations. The mean of the absolute error between the simulation and experimental results is 0.58 mT with a standard deviation of 1.08 mT. The peak field strength measured in the on-state was 69 mT, the peak field strength measured in the off-state was 13.75 mT.

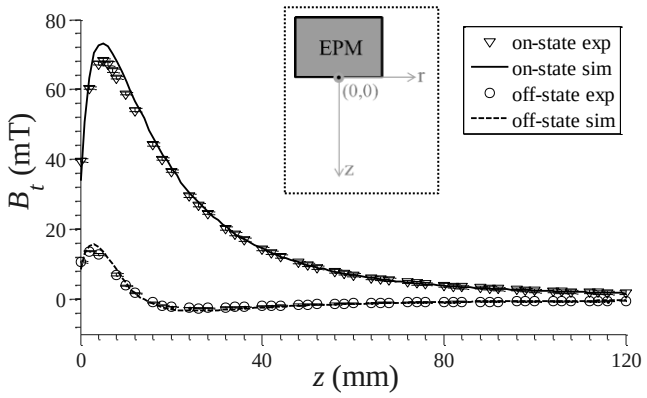


Fig. 4. Graph demonstrating tangential flux at a vector along the axis of the EPM (r = 0), as per convention described in the inset figure. The plot shows simulation and experimental data for the device in the on-state and off-state.

C. Force experiments

To characterize the coupling distances of the system, the coupling forces over distance between the EPM and the internal magnet actuator in both the on-state and off-state was investigated. This was realized using a TA.HD*Plus* Texture Analyzer (Texture Technologies, Hamilton, MA) fitted with a 5 kg load cell. The system was controlled using a desktop computer running Texture Exponent v3.2. The EPM was clamped in place and the actuator was connected to the load cell via a Delrin hanger. The separation distance between the EPM and actuator was progressively increased and the associated tensile force was measured on the load cell. The results from this experiment were compared with results from a finite-element-analysis simulation using FEMM 4.2. These are presented in Fig. 5 where good correlation is seen between the finite element analysis simulations and experimental results. An effective range of 20mm – 82mm is confirmed with a force of 0.09 N (~9g) measured on the actuator at displacements of 19.4mm in the off-state and 84.1mm in the on-state. The maximum coupling distance achieved using the actuator with a total of 39g weight (including actuator weight) was 47.6 mm compared to the maximum achieved by the MAGS system of 47.8 mm.

As discussed in the Introduction, one of the major issues with using permanent magnets for trans-abdominal coupling is the inherent 'fixed' magnetic strength of a particular piece of magnetic material. This is at conflict with the variance in intra-abdominal thickness that exists in human anatomy and will result in either magnets that are too strong, increasing the risk of tissue damage, or magnets that are too weak, leading to poor coupling.

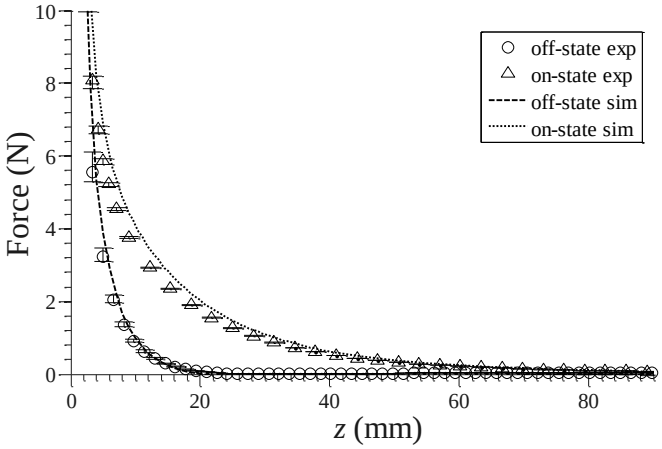


Fig. 5. Graph showing force on the internal magnet against displacement from the EPM. Five separate experiments were performed for both the on and off-state; resulting in the mean, maximum and minimum forces measured at each point.

A second experiment was performed using the same equipment to demonstrate the controllability of the system to maintain a particular force over a wide range of coupling distances. Fig. 6 shows the force versus distance of the system, following magnetizing current pulses of varying peak values. To demonstrate the controllability of the system, a horizontal dashed line is shown corresponding to a nominal holding force of 0.5N simulating coupling with an in vivo instrument weighing approximately 50g.

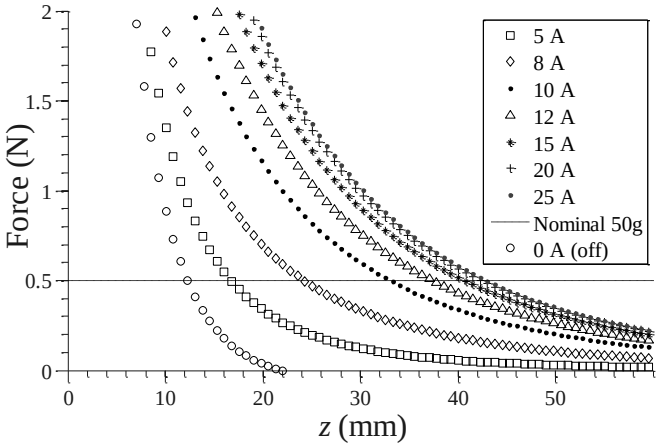


Fig. 6. Graph demonstrating controllability of a stable magnetic coupling force. The contours show the force decay over distance for the system following varying current pulses. The solid, horizontal line is used as an example to demonstrate the ability of the system to sustain a continuous force of 0.5N (approximately 50g) over a wide range of coupling distances.

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The plot shows that by adjusting the magnitude of the peak magnetizing current the system can maintain a coupling force of 0.5N over a separation of 15.7mm to 43.1mm. Clearly, the minimum coupling distance is constrained by the strength of the magnetic material used for the internal magnet. Decreasing the strength of the magnetic material used for the internal magnet will also decrease the lower constraint of the working range.

D. Pre-clinical evaluation

The pre-clinical evaluation of the system was achieved in the porcine model under full anesthetic and tracheal intubation. The investigation was approved by both the Irish Department of Health and UCC animal experimentation ethics committee. The model was a female Landrace pig weighing 18.1kg and was sedated for the duration of the procedure. A canuala was inserted into an ear vein and the animal was anesthetized with a bolus, followed by a continuous infusion of sodium pentobarbitonel (induction 30 mg/kg, dose to effect; with maintenance of 6 mg/kg/h i.v.). End-tidal carbon dioxide, arterial blood pressure, pulse oximetry and core body temperature were monitored using a SurgiVetAdvisorVital Signs Monitor (Smiths Medical, Dublin). The animal was euthanized immediately following the procedure by anesthetic overdose.

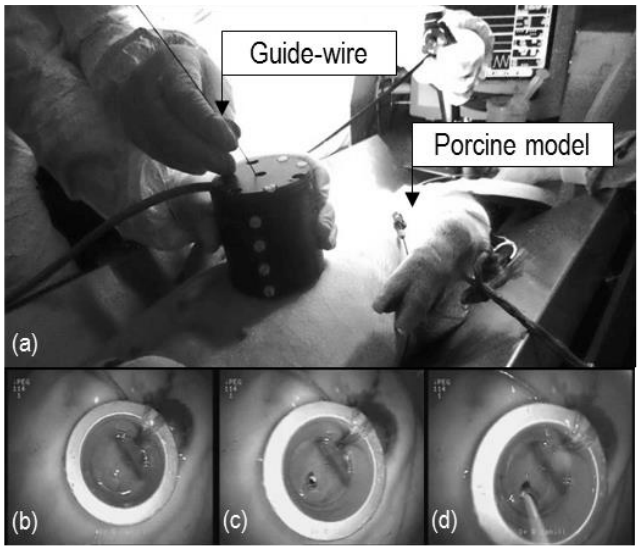


Fig. 7. In vivo experiment; (b) the internal magnet is coupled with the EPM; (c) percutaneous puncturing using a Tuohy needle is guided via the working channel of the coupled EPM/internal magnet (d) A guidewire is introduced and endoscopically snared, the guide wire can be seen being delivered externally in (a).

A previously proposed internal magnet delivery system [32] was used for internal magnet delivery whereby the internal magnet was deployed by positioning the magnetic ring over an annular balloon, fabricated in-house, which was attached to the distal end of a slim 6mm endoscope (BF-1T160 from Olympus Corp.). The deployment of the internal magnet into the animal's stomach was supplemented using a suture fastened to the magnet ex vivo. This was necessitated by an unexpectedly narrow porcine esophagus which resulted in moderate resistance in passing the internal magnet through the lower esophageal sphincter.

Successful coupling and decoupling between the external EPM and internal magnet was easily achieved in vivo at a variety of angular displacements between the internal magnetic ring and EPM. Following coupling, the working channel produced between the EPM and internal magnet was used for percutaneous puncturing using a Tuohy needle (18 Fr). A flexible guide wire was trans-abdominally inserted via the magnetic working channel and snared via the channel of the endoscope before being retracted back through the esophagus mimicking the beginning of a PEG feeding tube placement procedure as shown in Fig. 7. A visual inspection of the coupling site using the endoscope determined that some bruising of the stomach tissue had occurred.

IV. Discussion

In this paper we have demonstrated a novel and innovative method marrying the advantages of permanent magnet and electromagnetic technology in a single device for use in surgical and endoscopic anchoring. The approach is successfully demonstrated in vivo in the porcine model with similar coupling performance with a 39g payload to that reported by the MAGS team. Coupling distances in the study are clinically significant and may represent a key enabler for progress in magnetic anchoring beyond current norms. In addition, a number of limitations presented themselves during the in vivo study. A small animal resulted in an esophagus which was too narrow for facile deployment of the internal magnet. This was overcome by augmented leveraging of the internal magnet by guidewire deployment. A second finding was that the force from the external magnet was too strong for the intra-abdominal thickness of the particular porcine model. This resulted in bruising to the inside of the stomach. To address this issue, the experiments shown in Fig. 6 were subsequently undertaken. A high degree of control over the strength of the EPM was subsequently established by varying the current pulse magnitude, resulting in a magnetic coupling system that can be tailored to particular intra-abdominal thicknesses or specific tool weights.

Due to the relatively large size of the colon [33]–[35] and the close correlation between abdominal wall thickness and BMI [36], future iterations of the device should seek to magnetize the EPM to a value such that coupling only occurs at a known minimum displacement between the internal magnet and EPM. This may alleviate the risk of pinching the colon in between the stomach and abdomen wall, thus reducing the possibility of adverse events during PEG tube placements.

As discussed in the introduction, in addition to an aid for PEG procedures, the device may also find applications in the area of minimally invasive surgery. As the number of ports used for a surgery is being reduced down to one or even zero (with natural orifice methods) some fundamental problems are encountered. Restrictions in instrument manipulation and difficulties in obtaining good triangulation between an image source, instrumentation and the operating area have become

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increasingly prevalent due to the 'inline' nature of entry to the operating area. A coupling system such as the one presented could facilitate better triangulation by allowing separation of in vivo instruments without further incisions.

The concentric, annular ring design of this device has facilitated in vivo confirmation of the ability to provide magnetically coupled working channels to aid percutaneous intra-abdominal access, such as in reverse trocar and PEG placement. However, this shape does not lend itself to maximization of possible field strength for a given volume. This is due to the demagnetization effect of the shape of the Alnico and also the inherent loss in effective flux linkage coupling area. Future work will focus on combining the demonstrated controllable field with a more ideal geometry to increase the possible coupling forces in the clinically relevant range. Further investigation into the use of high permeability shielding to both reduce the magnetic pollution during on-state operation and also increase the strength of the field in the active area of the device will also be pursued

V. Conclusion

This work may represent a key enabler for progress in magnetic coupling in surgery and endoscopy beyond the current state of the art which relies on permanent magnets. Permanent magnets present beneficial weight to magnetic strength ratios and zero power dissipation and have so far become the prominent method of trans-abdominal coupling. However the: inability to switch the coupling magnetic field off and on, lack of control and the effects of unwanted magnetic 'pollution' in an operating room setting have mitigated against their widespread use.

The use of electropermanent magnetic technology in this study addresses these issues and should provide a platform from which a smarter, controllable method of magnetic coupling can be achieved over the range of clinically relevant trans-abdominal thicknesses thus facilitating improved anchoring performance, versatility and reliability

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