

A MAGNETIC COUPLING TO IMPROVE PLACEMENT OF GASTROENTERAL FEEDING TUBES

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Abstract: Percutaneous Endoscopic Gastrostomy (PEG) is a non operative endoscopic technique to place a transabdominal (from outside the abdomen through the gastric wall and into the stomach) gastric feeding tube. It is the preferred method of enteral feeding in patients who would otherwise have inadequate nutritional intake due to a number of underlying illnesses. During the PEG procedure, the feeding tube can deviate from its intended path, perforate organs and surrounding tissues leading to complications. We propose a novel technique to alleviate or eliminate these concerns using magnetic coupling. This technique forces the tube to pass through a specified path, compressing tissues between the gastric and abdominal walls such that the tube cannot deviate from its intended path. This modified PEG procedure could secure a safer tract for insertion, decrease procedural time and limit user variability, with hypothesised benefits including shorter procedural times and lower complication rates. The magnetic coupling mechanism has been modelled using analytical tools with experimental validation. The approach has been demonstrated in a bench-top anatomical model and may be of use in applications beyond the PEG procedure including endoscopic instrument positioning on the gastric wall.

1 INTRODUCTION

1.1 Enteral Nutrition Techniques

Enteral nutrition is a means of delivering nutrition to patients who would otherwise be unable to feed themselves for a variety of reasons: neurological impairment, dysphasia (difficulty in swallowing) after surgery, oral cavity tumours, anorexia, or as a preventative for aspiration pneumonia. There are a number of types of enteral feeding solutions used but the most common are nasogastric tubes (NGT) and gastroenteral tubes, placed using the percutaneous endoscopic gastrostomy (PEG) technique. While NGT nutrition is often preferred by radiologists, PEG is the preferred technique amongst gastroenterologists, endoscopists and surgeons (Ponsky, 1981) This is because PEG tubes are easier to tolerate, show better nutritional results and patients with PEG tubes have higher survival rates than those with NGT tubes, even when PEG tube patients are in more advanced stages of illness (Dwolatzky, 2001). However, PEG tube placement is not without complications including gastric perforation, tube

blockage, site infection, PEG tube dislocation and inadvertent puncture of peripheral organs such as the colon (Britton, 1997; Conlon 2004; Loser 1998). In this work, we are particularly interested in addressing the last of these complications: the inadvertent puncture of organs that can become sandwiched in between the gastric and abdominal walls during the placement of the PEG tube. Our solution is a simple magnetic coupling (*i.e.*, two apposing north/south magnetic surfaces) consisting in two permanently-magnetized rings which are initially coupled across the gastric and abdominal walls to provide a safe tract for subsequent passage of the gastroenteral feeding tube. Since coupling of the two rings only occurs inside a predeterminable distance, we hypothesise that this technique could be used as to improve feeding tube placement using the PEG technique by eliminating a significant complication.

1.2 Magnetic Coupling in Surgery

The use of magnets in minimally-invasive interventions has a long history. The magnetic retrieval of foreign bodies in the esophagus, stomach

and duodenum was first proposed as early as 1957 (Equen, 1957). More recently, magnetic coupling has been used for anchoring of magnetic instruments (Scott 2007), retrieval of stents (Cantillon-Murphy, 2010) and magnetic NGT guidance (Gabriel 2001) where an external, hand-held magnet guided the feeding-tube through the esophageal tract to the subject's duodenum. In this work, we extend that work to the use of magnetic coupling for providing a safe tract for transabdominal insertion of an enteral feeding tube.

1.3 Current PEG Technique

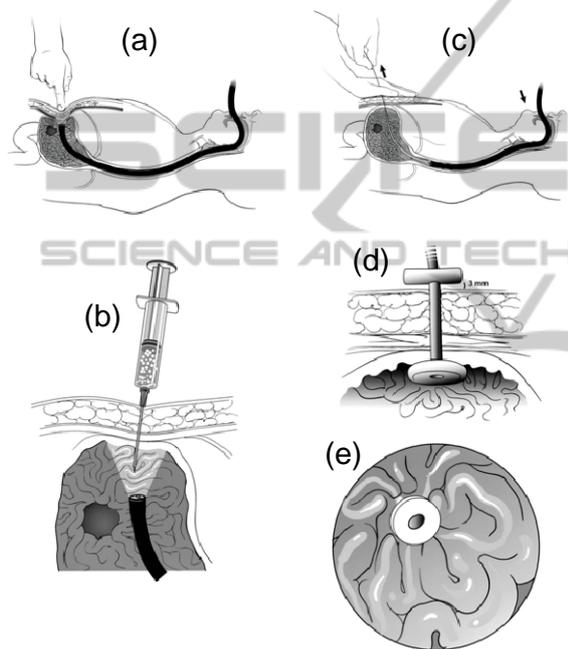


Figure 1: Outline of the current PEG tube placement procedure involving (a) endoscopic trans-illumination, (b) transabdominal needle perforation, (c) guidewire-introduced tube placement, (d) mechanical interlocking and (e) fixation (reproduced from Ponsky 2004).

Currently, the technique most commonly used for PEG tube placement is the so-called ‘pull’ technique, outlined in Figure 1. An endoscope is introduced into the patient’s stomach and a combination of trans-illumination (*i.e.*, shining the endoscopic lamp across the gastric and abdominal walls) and finger pressure is used to determine the site of closest contact (Figure 1(a)). The so-called ‘safe tract’ method involves insertion of a syringe of local anaesthetic which is blindly guided across the abdominal and gastric walls at the site of transillumination (Figure 1(b)). The site is catheterised and an endoscopic snare (introduced via

the endoscope’s instrument channel) is used to lasoo a guidewire which is pushed through the catheterised abdominal and gastric walls (Figure 1(c)). Removing the endoscope leaves the guidewire extending across the abdominal and gastric walls and out of the patient’s mouth. The guidewire then serves as the tram-line for the oral introduction of the feeding tube in advance of reintroducing the endoscope for inspection. The distal end of the feeding tube usually has a round bumper to prevent its escape through the gastrostomy (Figure 1(d, e)). The procedure ends when the portion of inserted feeding tube outside the abdominal wall is snipped, the nutrition sack is attached and the endoscope is removed. The external t-bar shown in Figure 1(d) sits above the skin and is designed to stop excessive tension and “buried ring syndrome” where the gastric wall grows over the tube thereby causing obstruction

1.4 Magnetic Coupling and PEG

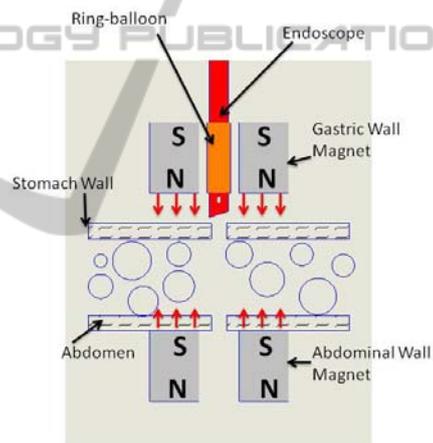


Figure 2: Magnetic coupling to aid in PEG tube placement.

Our approach is to augment the ‘safe tract’ approach shown in Figures 1(a) and (b) with a simple mechanism of temporary magnetic coupling across the abdominal and gastric walls, as shown in Figure 2. The magnetic coupling of two rings, one on the abdominal wall (external to the patient) and one on the gastric wall (endoscopically delivered) is the second step (*i.e.*, coming between Figures 1(a) and 1(b)) in a slightly modified PEG technique. However, once the coupling is in place, the result is that the relative positions of gastric and abdominal walls are fixed and sandwiched in place at a known minimum separation, as predicted by theory. Furthermore, coupling only takes place at a separation less than a critical maximum which can

be used as a check for inadvertent sandwiching of organs like the colon between the gastric and abdominal walls during the procedure.

2 METHODS

2.1 Magnetic Coupling Design

The critical component of the approach is the coupling of the two magnetic rings at a known and predictable distance of separation. To investigate, this dependence, the usual magnetic charge model was used to simulate magnetic mating of two permanently magnetised concentric rings (Furlani, 2001). Following the usual Coulombic Law formulation, the force vector exerted by 'magnetic charge', q_{m1} , on 'magnetic charge', q_{m2} is given by (1) where μ_0 is the magnetic permeability of free space ($4\pi \times 10^{-7}$ H/m) and \mathbf{r}_{12} is the displacement vector between q_{m1} and q_{m2} .

$$\mathbf{F}_{12} = \mu_0 q_{m1} q_{m2} / (4\pi \mathbf{r}_{12}^2) \quad (1)$$

One of the principal challenges in magnetic coupling is the inverse square roll-off in the force of attraction between magnetic components. We began by simulating the coupling forces between concentric mating magnetic rings using the open-source *Radia* (ESRF, France) add-on to *Mathematica 7* (Wolfram Corp., Champaign, Illinois). The magnetic force is found by discretisation of all the magnetic surfaces and integration of (1) over the nearby surfaces which are subject to the field (*i.e.*, the adjacent ring). The simulated results, shown in Figure 3 demonstrate the familiar inverse square relation between force and separation between the two magnetic rings (ignoring gravitational forces) as well as the force associated with coupling an external magnet to internal steel rings (SR1-SR3) of varying dimensions. Based on the investigations of Figure 3, we designed a coupling capable of magnetic mating across expected stomach wall thickness of 3-4 cm. Two permanent magnetic N52 grade neodymium-iron-boron (NdFeB) rings were purchased (26mm OD, 18mm ID and 25mm H) from HKCM Engineering, Germany, for subsequent testing (Figure 4(a)). In addition, a number of mild steel rings (EN3B grade mild steel) were fabricated of various wall thicknesses and lengths (Figure 4(b)). Because EN3B grade steel has significant paramagnetic properties (*i.e.*, it behaves magnetically in the presence of a magnetic field source such as a permanent magnet with magnetic susceptibility, $\chi \approx$

800), we also investigated the use of mild steel rings for use as the gastric wall magnet in Figure 2.

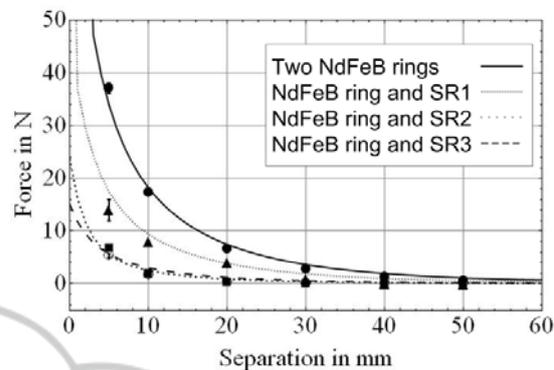


Figure 3: Force-separation characteristics between the N52 grade ring magnet and (i) a second identical magnetic ring (MR), and (ii) three stainless steel rings of varying thicknesses and lengths; SR1 with 26mm OD, 20mm ID and 25mm H, SR2 with 26mm OD, 20mm ID and 12.5mm H and SR3 with 22mm OD, 20mm ID and 12.5mm H. Gravitational forces are ignored.



Figure 4: The gold-plated N52 grade neodymium-iron-boron ring (a) and stainless steel rings of various thicknesses (b) which were used in subsequent testing.

2.2 Mechanical Design

The most significant challenge in implementing a magnetic coupling across the gastric and abdominal walls was the placement of the gastric wall magnet within the patient's stomach without any incision. Since the PEG procedure already involves the oral introduction of an endoscope, we used the endoscope as the vehicle to carry the gastric magnet into its final position. A number of approaches were considered including introducing the magnet in advance of the endoscope using a magnetised catheter. However, the technique that was found most satisfactory was spearing the ring with the endoscope's shaft with a radially-inflatable ring balloon between the endoscope and magnet, as shown in Figures 5 and 6. This approach had four significant advantages; (i) the magnet could be held in position on the endoscope's shaft by inflation of the balloon and released for coupling by deflation; (ii) inflation of the balloon beyond the ring OD

during oral insertion limited any possibility of tearing to the oesophageal wall upon introduction of the endoscope; and (iii) the magnet presented no visual impediment to the scope's field of view.

The ring balloon was constructed from a 51Fr (17mm) veterinary endotracheal tube (Jorgensen Laboratories, Colorado) which was chosen to fit snugly over a standard 12mm diameter endoscope (GIF Q20 by Olympus Inc., Japan). The balloon was lure-lock connected to a standard endovascular balloon inflator (Boston Scientific Corp., Massachusetts) which was used to inflate the balloon to a measureable pressure as shown in Figure 5(c).

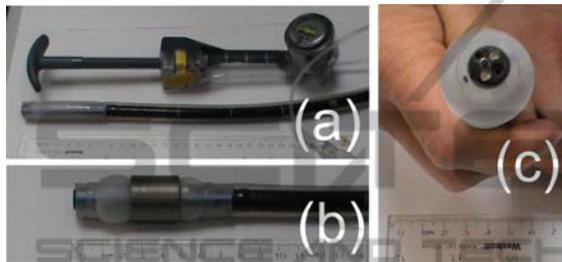


Figure 5: (a) An modified endotracheal tube was used as the ring balloon, fitting snugly over the 12mm endoscope. (b) When inflated, the balloon fixed the ring on the endoscope's shaft. (c) The balloon also minimised risk of tissue tearing due to the magnet's edges upon insertion of the endoscope.

3 RESULTS

3.1 Magnetic Coupling

The magnetic coupling force predicted by Figure 3 was experimentally investigated by compression and separation tests using a Stable Micro Texture Analyser (Godalming, UK). The resultant force - separation characteristic for the various rings are shown as datapoints on Figure 3.

To accurately predict the required force to couple the gastric and abdominal magnets in the presence of the inflated balloon, the axial force required to slide the gastric magnet off the inflated balloon was also investigated as a function of various balloon inflation pressures. This is an important parameter because, in the modified procedure, the magnetic coupling is mainly impeded by the frictional forces between the balloon and gastric magnet, which varies as a function of inflation pressure, and not gravitational force. The coupling distance (*i.e.*, critical distance at which mating occurs) between the various gastric magnets of Figure 3 and the NdFeB

abdominal ring magnet is shown in Table 1. These results correspond to the worst-case scenario where gravity acts axially against the magnetic coupling force. This is not unrealistic in a clinical setting where the PEG placement usually takes place while the patient lies on their back.

Table 1: Coupling Distance to NdFeB Ring.

	NdFeB	SR1	SR2	SR3
Coupling Dist (mm)	35±3	21±2	19±4	18±3

3.2 Procedural Testing



Figure 6: The procedure was demonstrated in a benchtop anatomical model for (a) endoscopic navigation imparment and (b) magnetic coupling before testing in the scaled plasticine gastric model for (c) navigation and (d) transgastric magnetic coupling.

The modified PEG procedure including magnetic coupling was experimentally demonstrated in a benchtop test using a simplified anatomical model, as shown in Figure 6(a) and (b). The magnetic coupling mechanism and 'steerability' of the endoscope in the presence of the balloon and ring magnet was then investigated using a *plasticine* gastric model (Figure 6(c) and (d)). In this investigation, the endoscope was advanced through a 2cm diameter rigid tube (simulating the oesophagus) into the model stomach. The endoscope was then flexed at approximately 30° to the horizontal to provide coupling to the external magnetic ring. Some manipulation of the endoscope's position was required before coupling was achieved. This was primarily due to the thick inner wall of the ring balloon. Coupling occurred at a separation of 3-4cm. After coupling, the gastric magnet was removed by reinserting the endoscope into the ring, inflating the balloon and removing the external magnetic ring.

4 DISCUSSION

In this study, we propose a simple yet novel mechanism that may reduce complications in the placement of gastroenteral feeding tubes. The technique relies on the temporary magnetic coupling of two rings, one in the stomach (which is endoscopically delivered) and a second external to the patient. We have successfully prototyped a preliminary proof-of-concept design which we investigated in the benchtop setting for technical feasibility. As indicated in Figure 3, the coupling compression forces are highly predictable. Also, depending upon the coupling ring materials, we have shown in Table 1 that the distance within which coupling occurs can be predicted. Based on expected gastric/abdominal wall separation of 3-4cm and the results of Table 1, it is clear that two N52 NdFeB rings represent the best opportunity for successful coupling. This modification may represent a significant advantage over current approaches where there is no knowledge of gastric to abdominal wall separation distance.

We have also identified a number of elements that need attention in advance of a pilot animal study, the most critical of which is the inner wall thickness of the ring balloon. The balloon is an excellent means to maintain the gastric ring magnet in position until coupling is needed. However, in the current embodiment, which uses a retrofitted endotracheal tube, the balloon wall thickness represents a significant enough impediment to manoeuvrability of the endoscope to be problematic. To alleviate this concern, we propose (i) to design and construct a customised ring balloon with minimal inner wall thickness and (ii) to consider the use of a bronchoscope (6-8mm OD) rather than an endoscope (12mm OD) for future investigations. A second refinement will involve the integration of a visual confirmation of mating (e.g., a light-emitting diode which turns on upon coupling) attached to the external magnetic ring unit. We are confident that with these modifications, an acute porcine survival study can soon be undertaken (Autumn 2011).

Finally, we note that this approach of transgastric magnetic coupling may have implications beyond that considered in this work. The use of transabdominal magnetic coupling for positioning of surgical instruments has already been elegantly demonstrated (Scott 2007). In this work, we propose a novel extension to that approach which uses the endoscope as the vehicle for introducing the gastric magnetic. This may have implications for recent

advances in minimally-invasive procedures such as natural orifice surgery and single-site laparoscopy, where a similar approach could be employed to tether endoscopic instruments to the gastric wall during procedures by means of gastric to abdominal wall magnetic coupling (e.g., a magnetic camera positioning system).

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