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A Magnetic Retrieval System for Stents in the Pancreaticobiliary Tree

Pádraig Cantillon-Murphy*, Member, IEEE, Marvin Ryou, Sohail N. Shaikh, Dan Azagury, Michele Ryan, Christopher C. Thompson, and Jeffrey H. Lang, Fellow, IEEE

Abstract—Clinical endoscopic intervention of the pancreaticobiliary tree [endoscopic retrograde cholangiopancreatography (ERCP)] often concludes with the insertion of a temporary plastic stent to reduce the risk of post-ERCP complications by promoting continued flow of bile and pancreatic fluids. This stent is later removed once the patient has fully recovered, but today this necessitates a second endoscopic intervention. The final goal of this work is to obviate the second intervention. This is to be achieved by adding a magnetic ring to the stent such that the stent is removed using a hand-held magnet, held in a suitable position ex vivo. This paper details the design, optimization, and both ex vivo and in vivo testing of the magnetized stent and hand-held magnet, which has been accomplished to date. The optimized design for the hand-held magnet and the modified stent with a magnetic attachment performs in line with simulated expectations, and successful retrieval is achieved in the porcine ex vivo setting at 9–10 cm separation. This is comparable to the mean target capture distance of 10 cm between the entry point to the biliary system and the closest cutaneous surface, determined from random review of clinical fluoroscopies in ten human patients. Subsequently, the system was successfully tested in vivo in the acute porcine model, where retrieval at an estimated separation of 5–6 cm was captured on endoscopic video. These initial results indicate that the system may represent a promising approach for the elimination of a second endoscopic procedures following placement of pancreatic and biliary stents.

Index Terms—Biliary stent, magnetic retrieval, magnetic stent, pancreatic stent.

I. INTRODUCTION

WHEN the biliary or pancreatic ducts become occluded, the placement of a temporary, removable plastic tube (stent) facilitates bypass of the occlusion [1], [2]. Stents are also used for prophylaxis of post-endoscopic retrograde cholangiopancreatography (ERCP) complications following aggressive endoscopic manipulation of the pancreaticobiliary tree [3]. Typically, biliary and pancreatic stents are 4–6 cm in length and 1.6 mm (conventionally referred to as “5 French” (5 Fr), where the difference is a factor of π in diameter. Conventional stents for this purpose are commonly made of polyethylene or Teflon and often include barbs, flaps, or flanges at either one or both ends of the stent. These barbs are designed to prevent migration of the stent further up the duct (thus complicating retrieval) or premature escape from the duct. However, barbs are often removed by physicians prior to placement to accelerate the stent’s expulsion from the biliary tree.

Stents have a multitude of designs either to reduce migration and/or to assist in drainage. Stents have also been formed in expandable formations to assist with drainage capabilities [4]. Both biliary and pancreatic stents are usually designed to be inserted over an endoscopic guidewire and are pushed into position with the aid of a catheter. The stent is generally advanced endoscopically until about 1 cm of the stent extrudes from pancreaticobiliary system into the small intestine after placement. The placement procedure ends by the withdrawal of the guiding catheter, followed by the removal of the guidewire itself. Later removal of the plastic stent (typically 2 to 3 weeks after placement) requires at least one endoscopic procedure, and can involve surgical intervention in cases where a stent migrates and lodges in the pancreatic or biliary ducts. The attractive magnetic retrieval proposed here is equally applicable to pancreatic or biliary ductal stents.

The use of magnetic retrieval for in vivo bodies is not a new concept. The magnetic retrieval of foreign bodies in the esophagus, stomach, and duodenum was first proposed by Equen et al. [5] in 1957. More recently, foreign body retrieval in the gastrointestinal tract has been augmented by fluoroscopic imaging [6], [7]. Magnetized or magnetic stents have also been widely employed in coronary procedures, where stenting is used extensively in the carotid arteries [8]–[12]. Magnetic guidance has also been proposed for nasoenteral feeding tube placement [13], [14], where an external, hand-held magnet guides the feeding tube through the esophageal tract to the subject’s duodenum. Various magnetic stents and implants have also been proposed to trap magnetic drug-carrying nanoparticles in the human vasculature [15]–[20]. Additionally, navigation of larger ferromagnetic devices has been proposed [21], [22] using magnetic resonance imaging in the carotid arteries.

This study examines the design and both ex vivo and in vivo testing of a modified stent suitable for the biliary and pancreatic ducts, which can be located and removed without endoscopic or surgical intervention (i.e., without using forceps or snares).
Instead, retrieval is by means of a ring of permanent magnetic material [neodymium–iron–boron (NdFeB)], which is fixed to the stent’s distal end and a large hand-held magnet. The magnetic ring is designed such that there is no occlusion of the stent associated with its magnetic properties, while the ring’s outer diameter (OD) facilitates endoscopic deployment. The proposed system is illustrated in Fig. 1. Rather than an ad hoc testing of various magnets, a careful analytical study was undertaken to optimize the design of the hand-held magnet. This is because, in order for the system to be ultimately successfully adopted into the clinical environment, the weight of the hand-held magnet should be an absolute minimum, thus, allowing ease of use, conceivably by non-clinicians. The stent retrieval mechanism proposed and investigated in this study somewhat resembles the nanoenteral feeding tubes approach of Gabriel et al. [13], [14]. Due to the confined space of the biliary and pancreatic duct, forceps and snares do not tend to be efficient or effective in vivo retrieval. Finally, the magnetic stent was endoscopically deployed in an acute porcine model and retrieved by means of the external hand-held magnet. Magnetic retrieval was recorded using endoscopic video.

A. Hand-Held Magnet and Stent Design

The dimensions of the hand-held magnet (ratio of height to diameter) was optimized for a fixed weight. Optimization was achieved by means of numerical simulation using MATLAB (Mathworks, Inc., Natick, MA). The hand-held magnet must be sufficiently lightweight to allow easy maneuvering in the vicinity of the patient once stent retrieval is required. This magnet will ultimately be maneuvered in skin contact with the patient’s stomach or side to retrieve the magnetic stent. Hand-held magnets of 2.27, 3.18, and 4.54 kg (5, 7, and 10 lbs) were investigated by means of numerical simulation. To maximize magnetic attractive forces while minimizing sharp edges and corners, a cylindrical, axially magnetized N-42 grade NdFeB hand-held magnet was proposed and simulated, where N-42 NdFeB is typically supplied with a remnant magnetization of $\mu_0 M_r$ near 1.3 T (KJ Magnetics, Jamison, PA) and $\mu_0 = 4\pi \times 10^{-7}$ is the magnetic permeability of free space. A range of hand-held magnet diameters was investigated up to 40 cm, where the corresponding magnet depth was determined by the fixed magnet weight; N-42 grade NdFeB has a density of 8.2 g/cm³. Attractive force to a magnetic ring was evaluated at 10 cm separation. A separation of 10 cm was found to be typical under fluoroscopic review of the distance from the hepatopancreatic ampulla to the closest cutaneous site in ten human patients at the Endoscopy Center, Brigham and Women’s Hospital, Boston.

The magnetic attachment to the stent consists of an axially magnetized cylindrical ring with an ID and OD, as shown in Fig. 1(b). The ID is chosen such that the attachment can be slipped over and adhered to the OD of the biliary or pancreatic stents (∼0.625 mm). Stents are categorized by length (from the distal end to the last barb) and external diameter so that a 5–3 stent has a 5 Fr (0.16 cm) diameter and 3 cm length to the last barb. The total length is approximately 4 cm. For the following simulated and experimental results, the ring’s OD is 3.175 mm (1/8”) and the ID is 1.5875 mm (1/16”) in each case, while the length is 6.35 mm (1/4”), unless otherwise stated. This OD was chosen to allow the magnetic stent to be deployed through the instrument channel of a standard endoscopic gastroscope.

The attractive force was simulated using a magnetic charge model [23], where the pole faces (North/South) of both the hand-held cylindrical and stent ring magnet were quantized to represent surfaces with discrete magnetic facet charges. Each facet has an area of $dA_1$ for the hand-held magnet and $dA_2$ for the stent ring magnet, and the associated facet surface charges
\[ q_{m,1} \text{ and } q_{m,2} \text{ are given by (1)} \]
\[ q_{m,1} = \mu_0 M_r \, dA_1 \]
\[ q_{m,2} = \mu_0 M_r \, dA_2. \]  

The magnetic force between two magnetic facets charge is then given by (2), where the indexes 1 and 2 represent the hand-held magnet (index = 1) and the magnetic ring (to be attached to the stent) (index = 2), and \( r_{12} \) is the interface distance between faces
\[
F_m = \frac{1}{4\pi\mu_0} \frac{q_{m,1} \, q_{m,2}}{|r_{12}|^2}.   \]  

The total force \( F_m \) between the hand-held magnet and the magnetic stent attachment is due to the two pole faces (north denoted by +, and south denoted by −) of each magnet. The total force is then the sum of the integrands on the pole faces of each magnet with areas \( A_1^+ \) and \( A_1^- \) for the north and south faces, respectively, of the hand-held magnet, and areas \( A_2^+ \) and \( A_2^- \) for the north and south faces, respectively, of the magnetic ring. The interfaced displacement is now denoted \( r_{12} \), where the signs indicate which face is being considered (i.e., + for north, − for south)
\[
F_m = \frac{1}{4\pi\mu_0} \left( \int_{A_1^+} \int_{A_1^-} \frac{q_{m,1} \, q_{m,2} \, dA_1^+ \, dA_1^-}{|r_{12}^2|^2} \right. \\
+ \int_{A_2^+} \int_{A_2^-} \frac{q_{m,1} \, q_{m,2} \, dA_2^+ \, dA_2^-}{|r_{12}^2|^2} \right) .   \]  

For this study, symmetry assures that \( A_1^+ = A_1^- = A_1 \) and \( A_2^+ = A_2^- = A_2 \), while for the facet areas \( dA_1^+ = dA_1^- = dA_1 \) and \( dA_2^+ = dA_2^- = dA_2 \). For the facet charges, \( q_{m,1} = -q_{m,1^-} = q_{m,1} \) and \( q_{m,2} = -q_{m,2^-} = q_{m,2} \); Therefore, simplification of (3) is possible as given in (4).
\[
F_m = \frac{1}{4\pi\mu_0} \left( \int_{A_1} \int_{A_2} \frac{q_{m,1} \, q_{m,2} \, dA_1 \, dA_2}{|r_{12}|^2} \right).   \]  

The full summations are then given for the cylindrical coordinate system in (7), where + denotes the north pole face, − denotes the south pole face, index 1 indicates the hand-held magnet, and index 2 indicates the magnetic stent attachment
\[
F_m = \frac{1}{4\pi\mu_0} \left( 2\pi \sum_{i_{r,1}=1}^{N_{r,1}} q_{m,1} \, q_{m,2} \, \frac{dA_1 \, dA_2}{|r_{12}|^2} \right) .   \]  

\[
\sum_{i_{A_1}} = \sum_{i_{r,1}} \sum_{i_{A_2}} = 2\pi \sum_{i_{r,1}=1}^{N_{r,1}} .   \]  

For the hand-held magnet, the radial facet segment length was set to 1.25 mm, chosen as a tradeoff between time to run the simulation (<5 min) while remaining significantly larger than the shortest separation distance considered in simulation (>1 cm). Therefore, each iteration of $i_{r,1}$ corresponds to an 1.25 mm increment along the radial axis. Therefore, the total number of radial facets changes with hand-held magnet diameter (e.g., $N_{r,1} = 30$ for a 3.81 cm = $3r$" magnet diameter). For the magnetic ring of the stent, the radial facet segment length was set to 40 $\mu$m and $N_{r,2} = 20$ throughout, since only the ring’s length, and not its radii, change. In the case of the ring magnet, $i_{r,2}$ was iterated such that $i_{r,2} = 1$ corresponded to the inner radius of the ring (i.e., 1/16") and $i_{r,2} = N_{r,2}$ corresponded to the ring’s outer radius (i.e., 1/8").

This numerical model was then used to simulate 1) the force between the two magnets as a function of hand-held magnet diameter, as shown in Fig. 3 for various hand-held magnet weights, and 2) the force between the two magnets as a function of separation, as shown in Fig. 4, which was compared with experimental ex vivo results. The magnetic force on axially magnetized N-42 grade NdFeB cylinders of 1.5875 mm (1/16") ID, and 3.175 (1/8") and 6.35 mm (1/4") length due to a hand-held cylindrical magnet of increasing diameter and fixed weight was simulated by means of (7). For the hand-held magnet, N-42 grade NdFeB was also simulated and later used in experiment.

While the model assumed concentric and perpendicular alignment between the hand-held magnet and the magnetic stent, there is no guarantee that this will be the case in clinical testing. However, the retrieval system does not necessarily need to be entirely blind. For example, if upon placement of the stent, a fluoroscopic image of the patient is obtained (this is often obtained in any case for diagnostic purposes), a patch or similar marker could be attached to the patient’s skin indicating the closest cutaneous surface perpendicular to the magnetic stent.

The closest “off-the-shelf” N42 NdFeB cylinder was purchased (KJ Magnetics, Jamison, PA) with dimensions of 7.62 cm (3") in diameter and 5.08 cm (2") in length, and weighing approximately 1.74 kg or 3.84 lbs. The magnet is coated with a 50 $\mu$m Ni–Cu–Ni layer for oxidation protection. This was the hand-held magnet used in all subsequent experiments.

The attractive force between a cylindrical hand-held magnet and the same magnetic ring was evaluated, again with reference to (7), but by using the diameter of the purchased hand-held magnet (7.62 cm). The force as a function of separation between the distal face of the magnetic ring and nearest face of the hand-held magnet is shown in Fig. 4, where the two magnets are coaxial and centered at $r = 0$. Simulated results for the force
were obtained for three different lengths of magnetic rings: 6.35 (1/4""), 9.525 (3/8"), and 12.7 mm (1/2"). In each case, the ring’s ID is 1.5875 mm (1/16") and the OD is 3.175 mm (1/8").

B. Ex Vivo Testing

The force was then evaluated experimentally for each of the three ring lengths as a function of separation from the hand-held magnet. This was achieved by suspending the magnetic ring from a simply supported thin aluminum beam (72" long, 1/2" wide, and 1/16" thick, F.D. and Sons Hardware, Chicago, IL). An initial calibration of the beam deflection, $s$ versus point load $p$, at the beam’s center was undertaken, and using a least-squares fitting algorithm, the calibration yielded an analytical expression for the beam deflection as a function of known load $s(p)$. The inverse relation [i.e., $p(s)$] was used to measure the force of attraction between the hand-held magnet (at a distance $s$) and the magnetic ring’s closest face using the three different ring lengths already simulated. The results for mean and standard deviation of the force are shown in Fig. 4, where the error bars corresponding to the standard deviation were found from five iterations of each experiment.

Close agreement was observed between the simulated and experimental data while the beam deflection remained a linear function of loading.

Capture distance using the purchased hand-held magnet was measured in the ex-vivo porcine ampulla, as indicated in Fig. 5. Magnetic rings were attached to standard pancreatic stents using medical-grade adhesive (Loctite 4541 PrismGel, Henkel Corp., Düsseldorf, Germany). Three different magnetic rings were attached to GPSO-5-3 and GPSO-5-5 Geenan pancreatic stents (Cook Medical, Bloomington, IN) (9.5 (3/8”), 12.7 (1/2”), and 15.9 mm (5/8") long) as indicated in Table I and shown in Fig. 5 with the GPSO-5-3 stent. The effect of the barbs on capture distance was also investigated. In each case, the magnetic ring overlapped with 1/16” of the stent’s plastic length, as indicated in Fig. 5; therefore, the overall extension to the stent’s original plastic length was slightly less than that of the attached magnetic ring. The stent was then manually inserted into the porcine ampulla such that the magnetic attachment protruded from the insertion point (see Fig. 5). Then, the hand-held magnet approached the stent such that the stent was approximately centered with the hand-held magnet’s center along the line of approach. Capture was achieved once the stent had completely left the duct having been pulled into the hand-held magnet. Mean capture distance is recorded over five iterations in Table I for each of the magnetic rings attached, where the asterisk * indicates the use of 5–5 rather than 5–3 pancreatic stents.

C. In Vivo Testing

Subsequent endoscopic deployment of the stent, complete with a 9.5-mm magnetic ring attached, was demonstrated in the live porcine model, as shown in Fig. 6. A 38.7-kg Yorkshire male pig was the subject of a standard ERCP procedure. A protective overtube was inserted into the esophageal tract and a standard
gastric endoscope (Olympus Optical Co. Ltd, Tokyo, Japan) advanced through the stomach into the first portion of the small intestine. A Hydra Jagwire (Boston Scientific Corp., Natick, MA) was placed deep into the biliary tree following endoscopic localization of the ampulla. This guidewire served as the tramline for the endoscopic introduction of the magnetic stent. A magnetic stent comprising a modified 5–3 Geenan pancreatic stent with a 9.5-mm-long magnetic ring attached was back loaded through the instrument channel of a standard gastric endoscope such that the guidewire ran through the stent’s lumen. The endoscope was reintroduced in vivo along the guidewire, and a customized stent introducer (Cook Medical, Bloomington, IN) was used to push the magnetic stent into position in vivo. After placement, the magnetic portion of the stent still extended from the ampulla. The guidewire was removed while the pusher remained in place, maintaining the stent’s position within the biliary tree. After removal of the guidewire, the endoscope was slightly withdrawn so as to maintain line of sight with the stent at the ampulla. The hand-held magnet was then introduced external to the animal and, after some cutaneous massage, was able to withdraw the magnetic stent from the biliary tree into the small intestine. Magnetic retrieval was achieved at an estimated separation of 5–6 cm and the retrieval was captured on endoscopic video.

III. DISCUSSION

The overriding goal of this study was to evaluate the feasibility of a magnetic stent retrieval system using an external hand-held magnet to remove stents from the pancreaticobiliary tree. In particular, the study sought 1) to propose optimal geometries for the hand-held and stent magnets; 2) to evaluate the required attractive force by means of numerical simulation and experimental investigation; and 3) to test the design in both ex vivo and in vivo porcine models. Due to differences in anatomy, the distance in capture distances for human versus porcine in vivo experiments could be up to 5 cm, where the distance will increase in human subjects.

A target capture distance of 10 cm between the external hand-held magnet and the stent magnet was identified from review of fluoroscopic imagery in human patients. For the stent magnet, the ID and OD were constrained by the plastic stent diameter and the instrument channel of the standard gastroscope, respectively. Therefore, magnetic rings with ID of 1.5875 mm (1/16") and OD of 3.175 mm (1/8") were used throughout. Various magnetic ring lengths were investigated (9.5, 12.7, and 15.9 mm). The optimized hand-held magnet was a cylindrical permanent magnet of 11.3 cm diameter, 4.3 cm long, weighing 7 lbs with a maximum simulated force of 31.4 mN due to magnetic attraction at 10 cm for the 12.7-mm ring magnet. The experimental performance of the closest commercially available cylindrical magnet was then evaluated. It had dimensions of 7.62 cm in diameter and 5.08 cm in length, weighed 3.84 lbs, and consisted of N-42 grade, axially magnetized NdFeB. The ring magnets attached to the plastic stents were of similar magnetic material. The performance of this hand-held magnet in retrieval of the magnetic stent in the ex-vivo porcine model, as given in Table 1, indicate that capture distance is dependent on 1) the length of the magnetic ring attached to the stent and 2) the presence of barbs on the stent, but does not vary significantly with the length of the plastic portion of the stent. While the ex vivo experiment cannot accurately represent the in vivo compressive forces acting on the stent within the biliary tree, which arise due the surrounding anatomy in vivo, it should also be considered that the lubrication of the biliary tree associated with the ex vivo experiments is expected to be significantly reduced compared to that in the live animal. This hypothesis was subsequently validated, at least in animal studies, by successful retrieval at an estimated separation of 5–6 cm in the in vivo porcine model. Human trials will be needed to test this hypothesis in vivo.

Extensive ex vivo tests have shown that the absence of barbs is critical to successful capture with the hand-held magnet, where capture distance increased from 2.5 ± 0.1 cm with stent barbs intact to 9.0 ± 0.3 cm after their removal for the 9.5 mm magnetic ring, the corresponding decrease in the required magnetic attractive force at capture is over an order of magnitude (680 mN versus 59.2 mN), where the decrease in resistance is due to the elimination of the stent barbs. Similar results were obtained independent of plastic length and magnetic ring length. The primary finding is that a smooth, barbell stent is optimal for capture with a hand-held magnet at the target distance of 10 cm.

The second finding of the ex vivo testing is the increase in capture distance achieved by increasing the length of the magnetic ring attachment. In the absence of barbs, the addition of an extra 3.175 mm (1/8") length of magnetic material to the original 6.35 mm (1/4") length resulted in an increase of ∼9% in capture distance (10 cm versus 9 cm), and an associated reduction in the required magnetic attractive force (44.1 mN versus 59.2 mN). However, subsequent increases in magnetic ring length to 15.9 mm caused no increase in capture distance. It is thought that as the ring attached to the stent is increased, the face closest to the hand-held magnet becomes increasingly dominant in determining capture. While longer magnetic rings result in a larger capture distance, they are expected to have two undesired results in subsequent survival studies: 1) the stent is heavier and, therefore, more likely to fall into the small-bowel prematurely and 2) there is increased risk of occlusion or blockage of the small intestine due to the magnetic body in the lumen. For these reasons, rings not exceeding 12.7 mm length will be used in future survival studies. Increases in the length of the plastic portion of the stent resulted in no change (for the 9.5-mm-long ring) or little (∼10%) for the 12.7-mm ring attached) decrease in capture distance. This is most likely because tissue friction in the pancreaticobiliary tree is most pronounced at the ampulla from where the stent protrudes and friction is not as significant further up the duct.

The endoscopic deployment of the magnetic stent was largely uneventful. Total procedure time was on the order of 30 minutes where this was largely spent on localization of the ampulla by endoscopic visualization. This step is frequently time consuming in ERCP procedures. However, subsequent deployment, withdrawal of the endoscope and retrieval of the magnetic stent were surprisingly straightforward. Clearly, the estimated separation distance of 5–6 cm upon retrieval was less than that expected.
in the human anatomy. However, the successful demonstration in the porcine model supplies evidence that the procedure may indeed obviate the need for a second endoscopic procedure to remove pancreatic and biliary stents in vivo.

IV. CONCLUSION

The goal of this study was to design an optimized magnetic retrieval mechanism for pancreatic and biliary stents with a magnetic attachment, and to test the resulting design in the ex vivo porcine model. Successful retrieval of the magnetic stent at a target distance of 10 cm from the external hand-held magnet requires a smooth plastic stent with no barbs. In this case, a magnetic attractive force of approximately 69 mN was sufficient to overcome the tissue friction associated with capture from the pancreaticobiliary duct using a 12.7-mm-long magnetic stent ring and the hand-held magnet in this study. This force decreased to 41 mN when the magnetic stent ring was extended to 15.9 mm in length.

While the results of this preliminary analysis and experimentation are encouraging, it remains to be seen how the system will perform in in vivo porcine survival trials, which will begin in 2010 and subsequent human pilot studies. The primary questions to be answered by these studies are 1) whether plastic stents without barbs will remain in place over the time periods of interest (typically 3–days) and 2) if tissue friction in the human model will differ significantly from the ex vivo porcine model, thus, resulting in more or less difficulty in stent retrieval. Smooth stents are not unprecedented in the clinical setting, where physicians routinely remove barbs for accelerated stent extrusion from the pancreaticobiliary tree. However, it remains to be seen how barbless stents and the addition of the magnetic attachment will affect premature extrusion in the porcine model. Pending these important investigations, the current results point to a promising and cost-effective method that has potential use in stent retrieval within the pancreaticobiliary tree.

REFERENCES


Padraig Cantillon-Murphy (M’03) received the B.E. degree in Electrical and Electronic Engineering from the University College Cork, Ireland, in 2003, and the M.S. and Ph.D. degrees from the Department of Electrical Engineering and Computer Science, Massachusetts Institute of Technology (MIT), Cambridge, in 2005 and 2008, respectively. His doctoral thesis examined the confluence of magnetic resonance imaging and magnetic nanoparticle dynamics. Since 2008, his postdoctoral research has been concerned with the role of magnetism in minimally invasive procedures, in collaboration with Brigham and Women’s Hospital, Boston. He is currently a Postdoctoral Research Fellow in the Research Laboratory of Electronics, MIT, Cambridge, and also a Research Fellow at Brigham and Women’s Hospital, Boston, MA.
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