Jana Steger*, Anne Zimmermann, Thomas Wittenberg, Dirk Wilhelm

Electromagnets for an endoscopic anastomosis tool in the colon

Abstract: The goal of our research work is the development of a novel endoscopic anastomosis device for the colon. One of the main challenges in this context is the application of forces at the endoscope tip to rejoin the two bowel endings. Thus, we focus on a magnetic two-part compression implant approach. The implant halves are detached from the applicator units by means of electromagnets. In this contribution we present the results of our experiments to determine the implant design with special focus on tissue compression forces and the resultant electromagnet dimensioning to estimate size requirements of the application/detachment system. To achieve the targeted compression forces derived from literature, we used cubic N52 magnetized neodymium magnets[1] with a side length of 5 mm and mild steel screws. For these magnets, we evaluated a required electromagnetic repulsion force of 4.1 N. For the electromagnetic detachment system this led to the need for 166 windings for the coils on oral side, and 146 windings for the coils at the aboral side. Based on these requirements, a colonoscope diameter (~14 mm) increase of 10.6 mm on the oral side and of 12 mm on the aboral side due to the application device must be assumed. Nevertheless, this diameter still remains within the size range of other colonoscopic tools, such as e.g., circular staplers.

Keywords: Anastomosis, endoscopic intervention, magnets, electromagnets, colon
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1 Introduction

In the context of intraoperative trauma minimization, therapeutic endoscopy has become increasingly important in recent years. Procedures performed directly in the access lumen, such as endoscopic submucosal dissection in the colon, wound closure or the ablation of colonic polyps are already common clinical practice. For the last 15 years, procedures have been developed that even allow scarless surgical procedures in the abdominal cavity, and thus leaving the access lumen [1]. The basic prerequisites for performing such complex procedures are specialized endoscopic instrumentation and tools to support the surgeons. Due to the limited surgical space available and the high functional requirements, the technical challenges in developing such platforms are extensive. In 2006, the Society of American Gastrointestinal and Endoscopic Surgeons (AGES) published an overview of systems to further advance the establishment of surgical endoscopic techniques. A system for endoscopic anastomosis creation was considered particularly important. [2] Converntionally, gastrointestinal anastomoses are formed either by hand-suturing or stapling, these days. An alternative approach, however not widely established, are so-called compression anastomosis systems, which create an anastomosis by continuous pressure applied to the tissue between two connector halves. While the tissue grows together in one area of the joined intestinal endings, it becomes necrotic inside the lumen. By this means the compression implant is excreted.

Whereas hand suturing is complex in movement and hardly standardizable, and stapling requires high forces for plastic deformation of the titanium clamps, compression implants allow intuitive and force saving anastomosis formation just by joining two implant halves. However, in complex endoscopic interventions, the force application at the endoscope tip to pierce tissue or even only to join implant halves is a great challenge and limited by the forces which can be applied on long distances. Thus, self-assembling compression implants based on magnetic forces are gaining attraction.

2 State of the art

2.1 Magnetic anastomosis implants

Currently, two magnet-based implants are known to be in the clinical approval process.

Magnamosis™ (Magnamosis, Inc., San Francisco, CA) consists of two annular, polymer encapsulated neodymium-iron-boron magnets (Harrison Rings), available in two different magnetization strengths N35 and N50, which is designed to enable application purely via natural orifices. [3–6]

IMAS, incisionless magnetic anastomosis system (IMAS, GI Windows, West Bridgewater, MA, USA) and its predecessor *SAMSEN* are also two-piece implant systems comprising two neodymium-iron boron magnets encased in a biocompatible nitinol exoskeleton. Placed in the endoscope channel in a linear configuration, the implant halves are inserted into the body and released at the site of application in each of the two hollow organs to be connected. Due to the nitinol encapsulation, the magnets take on a predefined shape and connect due to the magnetic attraction forces. [7,8]

Thus, the magnet-based approach allows minimizing the compression forces to be realized at the endoscope tip for joining a two-piece implant. At the same time, the attraction forces require a high degree of manual control to avoid mispositioning and undesirable pinching of healthy structures in the organism.

The approach of our endoluminal, end-to-end electromagnet based anastomosis system presented below is intended to provide greater flexibility and control during placement and during detachment and reattachment of implant to applicator.

3 Material and Methods

3.1 Mechanism

The proposed anastomosis system comprises two application units (oral and aboral) mounted on the tip of an endoscope. Both units include electromagnets that are controlled extracorporally by the surgeon. The implant includes a permanent magnetic (PM) component (oral) and a soft magnetic (SM) component (aboral). The permanent magnet causes magnetization, which is responsible for implant closure and compression of the intervening tissue. While on the oral side we have monolithic cores, the cores of the aboral electromagnets are divided into two segments. One segment is firmly connected to the coil in the applicator unit, the second core segment is part of the implant and protrudes from the implant into the electromagnet. All coils of each of the two applicator heads are connected in series. An external control unit is used to switch on the coils of the oral and aboral applicator head separately for accurately adjustable time periods.

The applicator is inserted into the colon with the mounted implant parts and the bowel endings are attached to the oral and aboral applicator units. By bringing the intestinal margins of the bowel endings together the implant is closed, and the intestinal tissue is thereby compressed. The closed implant is deposited first orally, then aborally by actuating the electromagnets and the endoscope with the applicator is withdrawn from the colon.

The oral implant includes four neodymium magnets surrounded by polymer encapsulation and connected by bars. For the aboral implant, four mild steel screws are used for the first prototype approach (Figure 1) with an M4 thread, also interconnected by polymer segments. The cores of the aboral electromagnets are M4 screws as well, and those of the oral one M3 screws.

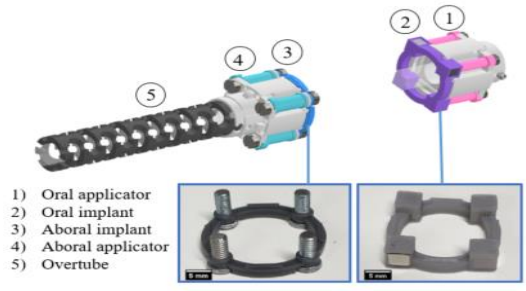

Figure 1 Schematics of the proposed anastomosis device and implants.

4 Results

4.1.1 Implant dimensioning

We investigated the correlation between the magnetic attraction force of different neodymium-iron-boron magnets and a soft magnetic counterpart with respect to an increasing distance between the components. We decided for the strongest magnet, which remains within the feasible size range for NOTES-application systems. This was a cubic N52 magnetized neodymium magnet[1] with a side length of 5 mm, emitting a magnetic flux density of 1.42-1.47 T. The attraction force distance correlation for a permanent magnet with soft magnetic bodies of 6.8 mm (head diameter of a M4 screw) is assessed in Figure 2 to derive the influence of a polymeric sheath of 0.6 mm wall width and two layers of colon tissue compressed between magnetic elements on the attraction forces.

***Corresponding author: Jana Steger:** Research group for Minimally invasive Interdisziplinary Therapeutical Intervention, Klinikum rechts der Isar of TUM, Munich, Germany
Anne Zimmermann: Chair for Visual Computing, FAU Erlangen, Germany
Thomas Wittenberg: Chair for Visual Computing, FAU Erlangen, Germany
Dirk Wilhelm: Clinic and Policlinic for Surgery, Faculty of Medicine, Klinikum rechts der Isar of TUM, Munich, Germany

[1] https://www.magnethandel.de/neodym-magnete-5-5-5-mm-n52#tab-description; last accessed:08.04.2021

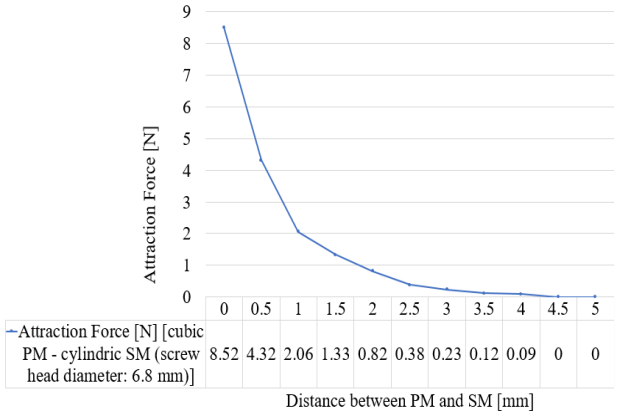

Figure 2 Change of magnetic attraction force over an increasing distance (paper) between a cubic N52 magnetized permanent magnet (PM-Neodymium-iron-boron) and a cylindric soft magnet (SM) (diameter: 6.8 mm; height: 2.45 mm)

4.1.2 Applicator dimensioning

Based on the implant's required compression force specifications and with respect to the tight size restrictions, we started with a first approach to define the design of the electromagnets accordingly. The diagram (Figure 2) shows that for a permanent and soft magnet (M4) pairing, with a 0.6 mm encapsulation wall thickness around the permanent magnets, a repulsion force of about 4.1 N is required to overcome the attraction between soft magnetic core of the electromagnet and the permanent magnet attached to it (oral side). The PM magnetizes the SM, which is why we assume this as minimally required repulsion force as well on the aboral side.

The coil bodies of the oral and the aboral implant carrier units were determined to have a maximum length of 15 mm (winding length of $l_{coil\ winding} = 13$ mm), which resulted as a trade-off between maximizing the electromagnetic force and the restrictions due to limited space in surgical environment. For the electromagnetic cores, soft magnetic mild steel screws with a standard M3 thread for the oral applicator, and standard M4 thread in the aboral applicator are supposed to be used in the first proof of concept prototype (magnetic permeability range $\mu_{r_{min}} = 100$; $\mu_{r_{max}} = 800 - 2000$) [9]. Operating the coil with a current flow of 3 A and a voltage of 24 V, the required winding amount to reproducibly repel an encapsulated cubic permanent magnet from an electromagnet was assessed by the following equations. For the magnetic field constant, we inserted $\mu_0 = 1.2566{*}10^{-6}$ $[\frac{N}{A^2}]$, for the coil length $l = 13$ mm, for the minimal core permeability $\mu_r = 100$ and for the core radius $R_{oral} = 1.5 * 10^{-3}[mm]$ (screw body diameter M3) and $R_{aboral} = 2.0 * 10^{-3}[mm]$ (screw body diameter M4). The magnetic strength [9] of a cylindric electromagnet is calculated by equation 1:

$$H = \frac{n*I}{l} \quad \textbf{(1)}$$

For the magnetic flux density we use equation 2 [9], based on which the magnetic force equation 3 (derived and simplified from [10]) can be determined.

$$B_{oral/aboral} = H * \mu_r * \mu_0 \quad \textbf{(2)}$$

$$F = \frac{1}{\mu_r * \mu_0} * A_{pole} * B^2 \quad \textbf{(3)}$$

The electromagnetic pole area is calculated by equation 4 with 5 and 6:

$$A_{pole} = R^2_{oral/aboral} * \pi \quad \textbf{(4)} \text{ with}$$

$$R_{oral/aboral} = R^{core}_{oral/aboral} + \frac{n_{oral/aboral}}{n_{layer}} * d_{wire} \quad \textbf{(5)} \text{ and}$$

$$n_{layer} = \frac{l_{coil\ winding}}{d_{wire}} = \frac{13\ [mm]}{0.3\ [mm]} = 43.3 \quad \textbf{(6)}$$

The latter one describes the number of windings per single layer. By inserting equations 1,2,4,5,6 into 3 and transforming, we obtain equation 7. By solving equations 8 and 9 for $n_{\frac{oral}{aboral}}$, the required winding amounts for electromagnets on both sides are calculated.

$$0 = \frac{d_{wire}}{n_{layer}} * n_{\frac{oral}{aboral}}{}^2 + R^{core}_{\frac{oral}{aboral}} * n_{\frac{oral}{aboral}} - \frac{l}{l} * \sqrt{\frac{F}{\pi * \mu_0 * \mu_r}} \quad \textbf{(7)}$$

$$0 = 6.98{*}\ 10^{-6}\ [mm] * n_{oral}{}^2 + 1.5{*}\ 10^{-3}\ [mm] * n_{oral} - 0.44\ [\text{mm}] \quad \textbf{(8)}$$

$$n_{oral} = \frac{-1.5*10^{-3}\ [mm] + \sqrt{(1.5*10^{-3}\ [mm])^2 - 4*6.92*10^{-6}\ [mm]*(-0.44\ [mm])}}{2*6.98*10^{-6}\ [mm]} = 166$$

$$0 = 6.98{*}\ 10^{-6}\ [mm] * n_{aboral}{}^2 + 2.0{*}\ 10^{-3}\ [mm] * n_{aboral} - 0.44\ [\text{mm}] \quad \textbf{(9)}$$

$$n_{aboral}\ \frac{-2.0*10^{-3}\ [mm] + \sqrt{(2.0*10^{-3}\ [mm])^2 - 4*6.92*10^{-6}\ [mm]*(-0.44\ [mm])}}{2*6.98*10^{-6}\ [mm]} = 146$$

We derive that for the oral side we need approximately 166 windings, and for the aboral side 146 windings.

5 Discussion

The implant design was derived with respect to the technical specifications of the implant system *Magnamosis* [11], in order to achieve similar tissue behaviour in terms of healing, necrotization and implant excretion (after 7-18 days) [4]. The Harrison Rings reach a mean compression force of 4.35 N with a 95% confidence interval of [3.78 N - 4.93 N] for side-to-side anastomoses, a mean compression force of 2.41 N with [2.10 – 2.73 N] for end-to-side anastomoses, and a mean compression force of 1.48 N with [1.11 N -1.86 N] for end-to-end anastomoses. For compressed colon wall thicknesses of about 1 mm, we can achieve the targeted compression pressure

for end-to-end anastomoses. Fisher assessed the bowel wall thicknesses between 1.1 to 2.6 mm (μ = 1.8 mm) for the colon ascendens, 1.0-2.3 mm (μ = 1.6 mm) for the transverse colon and 0.9-2.6 mm (μ = 1.6 mm) for the descending colon [12]. Therefore, we conclude a further need for minimization of the polymer sheath wall thickness, to be able to compress even thicker tissue in the implant gap.

Furthermore, with equation 10,

$$d_{coil} = 2 * (R^{core}_{\frac{oral}{aboral}} + \frac{n_{oral/aboral}}{n_{layer}} * d_{wire}) \quad \textbf{[10]}$$

an outer coil diameter of 5.3 mm is calculated for the oral side and of 6 mm for the aboral side. To create a stable anastomosis, our implant is supposed to comprise 4 magnets, which results in a colonoscope diameter (~14 mm) increase of the application device of 10.6 mm on the oral side, and of 12 mm on the aboral side. Comparing these values to circular staplers (being the current reference systems) with head diameters in the range of 21 to 34 mm [13], our prototype is still in an acceptable range. Nevertheless, further investigations will focus on the implant and applicator configurations with several magnetic elements and the assessment of mutual influences. Furthermore, the overtube, attached to the application device, must be extended to cover the entire endoscope length (~1.0-1.5 m), to be able to be applicable within the entire colon.

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