Exploring New Possibilities to Anchor a Colonic Stent

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Exploring New Possibilities to Anchor a Colonic Stent

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Preface

Colorectal cancer is the fourth most common sort of cancer in the world and the second in developed countries. Colonic obstruction is a complication of colorectal cancer. The tumor obstructs the colon blocking the pass of fecal contents. If the obstruction is not treated on time, this situation can lead to life-threatening complications. One of the current treatments, aimed to open a colonic obstruction, is called stent placement or stenting. During this medical procedure, a stent is inserted and deployed along the obstruction, re-establishing the normal pass of fecal contents. Despite its advantages, stent placement is related to a number of medical complications. The literature shows that the most common complication of colonic stent placement is migration. Until now, little was known about the factors that influence colonic stent migration. This paper investigated those factors and proposed possible solutions to prevent stent migration.

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Exploring New Possibilities to Anchor a Colonic Stent

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Abstract

Malignant colonic obstruction is a severe complication of primary colorectal carcinoma. Patients presenting this clinical condition develop tumors that obstruct the lumen of the intestinal tract. The treatment of this medical complication is aimed to re-establish the normal pass of fecal mass through the colon. One of the current treatments includes the insertion of a self-expandable meshed metal tube (stent) along the obstruction. By deploying the stent, the obstruction is opened, allowing the passage of fecal mass. Despite its advantages, stent placement is associated with a number of medical complications. The literature shows that colonic stent migration is the most common stent-related medical complication. This paper studies the factors that influence colonic stent migration and explores new possibilities to anchor a colonic stent to the bowel. In vitro experiments show that providing the colonic stent with an appropriate fixation mechanism, decreases the chance of colonic stent migration. The results suggest that the friction forces in the interface between the stent and the colonic wall increases, if the stent is provided with a fixation mechanism.

Keywords: Stent migration, fixation mechanism, microhooks, friction force.

1 Introduction

A tumor is a mass of abnormally and quickly growing cells, that can be benign or malignant. Benign tumors have uncontrolled cell growth, but without any invasion into normal tissues and without any spread. A malignant tumor is called cancer when tumor cells gain the propensity to invade other tissue (metastasis).

Malignant colonic obstruction is a severe medical complication of cancer. The tumor obstructs the lumen of the colon interrupting the normal pass of feces. The treatment of this medical complication is aimed to re-establish the normal pass of feces through the lumen of the colon. The selection of the treatment depends on a number of factors, such as the physical condition of the patient [14]. For patients in the end stage of the cancer, treatments are aimed to improve their “quality of life”. One of the current palliative treatments includes the insertion of a self-expandable meshed metal tube (stent) along the obstruction. By deploying the stent, the obstruction is opened, restoring the pass of feces [1, 4, 21].

This paper only focuses on colonic stents. The mechanical characteristics of self-expandable metal stents for colonic obstructions, are similar to those of the gastroduodenal and esophageal metal stents. Colonic stents only differ in length, diameter, and in the energy stored in the stent needed for deployment.

1.1 Colonic stent migration

Colonic stent placement was introduced in the 1990's [9, 13, 19, 22]. Since then, a number of studies have been carried out in order to assess the efficacy of colonic stenting as a palliative therapy [4, 6, 15, 16, 21]. The most common complication of colonic stent placement is stent migration, which occurs in almost 40 percent of the cases [1, 4, 12, 14, 21].

A number of studies suggest that stent migration mainly takes place as a consequence of food impact, tumor growth or shrink, and stent design [1, 12, 14]. However, there has been a lack of information about the factors that play a role in colonic stent migration. Hence, a structured strategy has not been introduced in stent designs to face stent migration. Most technical studies on stents analyze the properties and mechanical characteristics of metal stents [5, 10, 18], but do not provide solutions to problems related to their use, such as stent migration.

1.2 Goals

In order to find a solution for colonic stent migration, the goals of this paper are:

- To analyze the factors that influence colonic stent migration.
- To evaluate the possibilities for stent fixation to the colon by exploring new possibilities to anchor a colonic stent.
2 Factors that influence colonic stent migration

Four factors were identified as to be directly involved in colonic stent migration [14]: (1) Peristaltic contractions in the colon, (2) Feces passing and impacting the stent, (3) Change in tumor size, and (4) Mucus secretion. (1), (2), and (3) exert migrating forces to the colonic stent. (4) is considered a factor that reduces the friction forces in the interfaces stent-colonic wall, stent-tumor, and stent-feces.

In this section, a qualitative analysis of the migrating forces acting on the stent is discussed. In order to simplify this analysis, it is assumed that the stent is straight after deployment. In this situation, the migrating forces are parallel to the stent. Forces perpendicular to the stent do not directly influence stent migration; however, they influence the friction forces in the interface stent-colonic wall.

2.1 Effect of peristalsis

Peristalsis can be divided in three sort of contractions [2, 20]: rhythmic phasic contractions (RPCs), ultrapropulsive contractions (UPCs), and tonic contractions (TCs). The UPCs are further divided in high amplitude propagated contractions (HAPCs) and low amplitude propagated contractions (LAPCs). In all cases, the contractions are associated with full or partial closure of the lumen of the colon. The intensity of these contractions, their duration, and the distance of propagation vary for each of them.

The forces due to the peristaltic contractions can be represented as radial and longitudinal forces acting on the colonic wall. Manometric measurements of colon activity showed that the values of the contraction pressure of HAPCs are far higher than those of the other sort of contractions. The HAPCs have an average contraction pressure of 13.33KPa and an average propagation velocity of 1.1 cm/s [2]. The other contractions have a contractile amplitude in the range of 0.67 to 6.70KPa, with a very low propagation velocity. Since the effect of HAPCs is higher than the effect of the other contractions, it is considered that these other contractions do not contribute significantly to colonic stent migration. Consequently, the analysis only considers the effect of the HAPCs.

The forces due to the HAPCs do not only move the fecal mass towards the rectum, but will also push against the edges of the inserted colonic stent. In order to evaluate the effect of the contraction forces on the stent, two assumptions are made:

1. The contraction forces exerted on the body of the stent are not considered. The reasons for that are that along the tumor no peristaltic contraction takes place, and because it is assumed that the stent has a high radial stiffness designed to withstand tumor growth and bowel contractions.

2. Since the HAPCs propagate towards the rectum and because along the obstruction peristalsis is interrupted, the forces exerted at the proximal edge of the stent are considered to be stronger...
Factors that influence colonic stent migration

than those exerted on the distal edge of the colonic stent.

3. The effect of the peristaltic contraction in opposite direction to the HAPCs are assumed to be negligible.

The orientation of the forces exerted on the stent cannot be exactly estimated. Hence, a vector representation of the forces acting on the stent is used. For the analysis a two-dimensional model is considered. The forces exerted on the stent have radial (perpendicular to the stent) and/or longitudinal (parallel to the stent) components. It must be noted that the analysis of forces on the stent presented in this paper is considered in an early stage. Further research on this topic is needed.

The resultant force exerted on the stent due to the HAPCs ($F_{HAPC}$) can be expressed as the sum of the forces exerted at the proximal end ($F_{p1}$) and distal end ($F_{p2}$) of the colonic stent (Figure 1):

$$F_{HAPC} = F_{p1} + F_{p2}$$  (1)

2.2 Effect of feces passage and impact

When feces hits the edge of the stent, the forces generated due to the impact will tend to move the stent in the same direction. When feces comes in contact to the inner part of the stent, friction forces in the interface stent-feces start to develop. If the friction forces in the interface stent-colonic wall are lower than the friction forces in the interface stent-feces, then the resultant force exerted on the stent will have the same direction as the feces movement.

Although feces impact and passage can cause stent migration, its real influence will depend on the consistency of the feces. If the feces has a very thin (liquid) consistency, e.g. like the effect produced by some laxatives, then its influence on stent migration is negligible. If instead, the feces has a hard consistency, then its influence on stent migration is important. The resultant force exerted on the stent ($F_{feces}$) due to the effect of feces passage ($F_{fp}$) and impact ($F_{fi}$) can be expressed as (Figure 2):

$$F_{feces} = F_{fp} + F_{fi}$$  (2)

2.3 Effect of change in tumor size

When cancer is still progressing, parameters such as tumor size, its growing location, and growing velocity are very difficult to predict. The same occurs when tumor shrink takes place (because of treatment such as radio- and chemotherapy). Due to these uncertainties, the effect of change in tumor size and its associated forces cannot be exactly represented in a model. However, it can be assumed that if tumor growth occurs, the tumor can push the colonic stent in two possible directions, i.e. either towards the rectum, or away from the rectum. When the tumor...
shrinks, the stent will further deploy until it reaches its final diameter. Therefore, tumor shrink results in lower pushing forces of the tumor to the stent, decreasing the resultant of all migrating forces. This is why this paper will only consider the effect of tumor growth.

If the tumor pushes the stent towards the rectum, the force exerted on the stent due to tumor growth will contribute to the effect of the previously discussed migrating forces. The resultant of all the migrating forces will then increase. If the tumor pushes the stent away from the rectum, then the force exerted on the stent due to tumor growth will help to prevent migration. However, if in this last case the force due to tumor growth is very high, then stent migration in the opposite direction of the fecal mass movement can take place.

The resultant force due to tumor growth ($F_{\text{tumor}}$) is the resultant of the pushing forces ($F_{t1}$ and $F_{t2}$) exerted by the tumor on the stent (Figure 3).

$$F_{\text{tumor}} = F_{t1} + F_{t2} \quad (3)$$

### Figure 3: Forces acting on the stent due to the effect of change in tumor size.

#### 2.4 Effect of mucus

The mucus is a viscous slippery secretion that is produced to moisten and lubricate the colonic wall, and to facilitate the passage of fecal mass. The mucus also protects the colonic wall against bacteria and the irritating action of the fecal mass present in the colon.

The layer of mucus present on the colonic wall will not directly exert any forces on the stent, as the other discussed effects do. However, the mucus does influence the action of those effects. The layer of mucus is responsible for a reduction of the friction forces present in the interfaces stent-colonic wall, stent-feces and stent-tumor in comparison to a hypothetic dry colonic wall. Because the friction forces in the interface stent-colonic wall and stent-tumor are reduced, the possibility of colonic stent migration increases. In the interface stent-feces, the reduction of friction forces decreases the risk of stent migration.

The mucus will influence the friction coefficient between the different interfaces, reducing the effect of the forces exerted on the stent. That influence is represented by $K_m$, which is considered constant in...
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Figure 4: Forces exerted on the stent by the different factors that influence colonic stent migration.

this analysis. Stent properties, such as the material of the stent, are also important to take into account, because they will influence friction in the interface stent-colonic wall. Therefore, expression (2) can be expressed as function of:

\[ F_{\text{faces}} = f(F_{f1}, F_{fp}, K_{\text{mucus}}, \text{stent properties}) \]  

(4)

The sum of all the effects describes their overall influence on stent migration (Figure 4). From the qualitative analysis performed in this paper, the resultant of the migrating forces on the stent \( F_r \) can be expressed as sum of each effect:

\[ F_r = F_{\text{HAPC}} + F_{\text{faces}} + F_{\text{tumor}} \]  

(5)

In order to prevent colonic stent migration, the friction forces present in the interfaces stent-colonic wall and stent-tumor \( F_{\text{friction}} \) must counteract the longitudinal component of the resultant migrating forces on the stent \( F_{rL} \). Therefore, if

\[ |F_{rL} - F_{\text{friction}}| \begin{cases} \leq 0 & \text{stent does not migrate} \\ > 0 & \text{stent migrates} \end{cases} \]  

(6)

3 Stent anchoring techniques

From a technical perspective, the migrating forces exerted on the stent need to be counteracted in order to prevent stent migration. Increasing the friction forces in the interface stent-colonic wall may be achieved by anchoring the stent to the colonic wall with a fixation mechanism.

3.1 Technical approach of the problem

In order to evaluate which possible fixation mechanisms can be used to fixate a colonic stent, it was decided to categorize the mechanisms in: (a) whether they use friction for fixation, (b) the technical domain to which they belong, and (c) whether they cause damage to the mucosa.

(a) Friction: This category considers whether the mechanism uses friction or another method to achieve fixation.

(b) Technical domain: This category indicates to which technical domain the fixation mechanism belongs. The considered domains include: (1) Mechanical fixation, (2) Magnetic attachment, (3) Chemical attachment, and (4) Thermal attachment.

(c) Damage to mucosa: This category indicates whether the fixation mechanism causes damage to the colonic wall. Tissue damage is considered here as any penetration caused to the colonic wall that can lead to bowel perforation (Figure 5).
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[Image of fixation mechanisms]

Figure 5: (a) Fixation to tissue with penetration. (b) Fixation to tissue without penetration.

3.2 Fixation mechanisms

In nature a number of organisms, such as the tape-worms, exists that are able to fixate to the wall of the gastrointestinal tract by using special fixation accessories [11]. Inspired by the fixation mechanism of those organisms and by the mechanisms found in the literature, this paper evaluates 14 different fixation mechanisms that can be used to anchor a colonic stent. Despite the large range of possible fixation mechanisms available in the technical domain, not all of them are apt to be used inside the colon. They must fulfill a number of conditions. The mechanisms are grouped in the categories described above:

(A) Without friction: Mechanical attachment

1. Microhooks
   Microhooks are small hooks or nails. This mechanism is inspired by the tapeworms that live in the intestine of infected humans. The microhooks of tapeworms penetrate the tissue up to the mucosa, where attachment takes place. Because penetration of the mucosa may lead to bowel perforation, the microhooks should not damage the colonic wall but deform it. In the colon, the mucus has a thickness of approximately 0.48mm. Taking this into consideration, it is suspected that microhooks with a height of 0.5-0.7mm will deform the mucosa without penetrating it (Figure 6).

2. Microexpansion anchor
   This mechanism works in the same way as the plugs used to attach a screw into a concrete wall. However, in this case the microexpansion anchor will not penetrate the colonic wall, but will press against and deform it. As with the microhooks, the height of a microexpansion anchor has to be approximately between 0.5-0.7mm (Figure 7).

3. Micro interlocking
   This mechanism uses two different sub-mechanisms for fixation. The first sub-mechanism must be inserted and fixated to the colonic wall before stent placement. When the stent is put in place and deployed, the second sub-mechanism (which is attached to the stent) will “click” into the first one (Figure 8).

4. Form fixation
   This mechanism uses the predetermined form of the colon for fixation. This mechanism is a stent that (after deployment) has the same form as a part or the entire colon (Figure 9).

5. Spacer
   This mechanism fixates by expanding its spacer, which is in contact to the colonic wall. The spacer pushes tissue apart, generating forces in the interface between the spacer and the colonic wall.
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wall. Due to these forces, the spacer does not open its jaws further (Figure 10).

Figure 10: Spacer mechanism

6. Clamp
This mechanism uses the same configuration and principle as the spacer, except that here, the tissue is squeezed between the jaws of the clamp mechanism. The clamp mechanism exerts strong local pressure at opposed surface points of the colonic wall. An example of this mechanism are the jaws of a “laparoscopic grasper” used to grasp organs (Figure 11).

Figure 11: Clamp mechanism

7. Suction cup
This mechanism uses the principle of attachment by suction. The attachment depends upon the creation of reduced pressure in the space between the suction cup and the colonic wall. The stent has to be provided with suction cups of a very small size (Figure 12).

Figure 12: Suction cup mechanism

8. Microhook-suction cup
This mechanism combines microhooks and suction cups and follows the same principle used by tapeworms (Taenia Solium) for attachment to the intestine of their hosts. First, the microhooks are fixated to the colonic wall and then the suction cups follow, in order to stabilize the attachment (Figure 13).

Figure 13: Microhook-suction cup mechanism

(B) Without friction: Magnetic attachment

9. Magnet
This mechanism uses the principle of magnetism to attach two surfaces. The principle consists of implanting “magnetic seeds” into the colonic wall. Then, once the stent has been placed and deployed, the stent is attracted to the seeds, staying at the inserted position (Figure 14).

Figure 14: Magnet mechanism

(C) Without friction: Thermal attachment

10. Fusion of tissue to the stent wire
This mechanism uses heat to fixate the stent to the bowel. By heating the stent and putting it in contact to the colonic wall, the stent will burn into the tissue (Figure 15).

Figure 15: Fusion mechanism
(D) With friction: Chemical attachment

11. Adhesive polymer
   This mechanism uses chemical bonding principles for fixation to the colonic wall. The adhesive polymer chemically bonds to the mucus of the colonic wall [7].

![Figure 16: Adhesive polymer mechanism](image)

12. Adhesive polymer-microhook
   This mechanism combines the adhesive polymer and microhooks mechanism. First, the colonic wall is covered with a polymer. Then, the stent, which contains the microhooks, is attached to the polymer. The microhooks only penetrate the polymer layer leaving the colonic wall intact (Figure 17).

![Figure 17: Microhook-polymer mechanism](image)

13. Adhesive polymer-micro interlocking
   This mechanism combines the interlocking mechanism and the adhesive polymer. The colonic wall is first covered with the polymer. Then, one of the sub-mechanisms of the interlocking mechanism is attached to the polymer and the other to the stent. Once the stent is deployed, the interlock sub-mechanisms will attach to each other. No penetration through the colonic wall takes place (Figure 18).

![Figure 18: Polymer-interlocking mechanism](image)

(E) With friction: Mechanical attachment

14. Increase of surface contact
   This mechanism uses the principle of increasing the surface of the stent in contact to the colonic wall. In this way the friction forces in the interface stent-colonic wall will increase (Figure 19).

![Figure 19: Increase of surface contact](image)

3.3 Design requirements

The following design requirements must be fulfilled by each mechanism to be apt for colonic stent fixation. They consider the design objective (long term attachment) and a number of boundary conditions:

- Is the fixation mechanism suitable for long term attachment?
  Stent placement is performed to re-establish lumen continuity in the obstructed bowel. It is therefore required that the stent accomplishes that function for a long period. This period is set by the life expectancy of the patient. The prognosis of patients in the end stage of colorectal cancer is approximately 1 to 12 months [1, 12, 21]. Thus, if the stent does not migrate during 12 months, it performs satisfactorily. If it does migrate, then stent-related medical complications can occur [14].

- Is the fixation mechanism small and simple to construct?
  The undeployed stent and its incorporated fixation mechanism must be smaller than 3.3mm in diameter. In that way, the whole stent assembly is able to pass through the lumen of a standard colonoscope. Furthermore, to reduce cost and make it commercially interesting, the fixation mechanism must be small and simple to construct.

- Does the fixation mechanism allow peristalsis to continue in healthy tissue?
  The fixation mechanism should minimally interfere with the normal physiological functions of the healthy colon, such as peristalsis [14].
• Does mucus secretion not interfere with fixation?
  Mucus is constantly secreted to protect and lubricate the colonic wall. This criterion evaluates whether the fixation mechanism is expected to work satisfactorily despite the fact that mucus is secreted.

• Is the chance of bowel perforation negligible when using the fixation mechanism?
  Tissue damage is considered here as any wound caused to the colonic wall that results in penetration. Tissue penetration can lead to bowel perforation.

3.4 Evaluation and selection

Table 1 shows the result of the evaluation using the design requirements described above. Since the fixation mechanisms have not been experimentally tested, the result of the evaluation concerns the expected behavior of each fixation mechanism. In the table, the following nomenclature has been used:

(+) The design requirement is met.

(-) The design requirement is not met.

(?) There is uncertainty about the outcome.

Using Table 1 a selection was made of fixation mechanisms that meet the design requirements best: 1) Microhooks, 2) Adhesive polymer, 3) Increase of surface contact, and 4) Form fixation. These fixation mechanisms were broadly analyzed in order to assess their expected behavior in the colon. After this analysis, one fixation mechanism will be selected for further experimental studies:

• **Microhooks** provide a good fixation to the colonic wall. An advantage of using microhooks is that this mechanism generates high friction forces on a small surface, limiting its interference with the normal functions of the healthy colon. This is in contrast to other fixation mechanisms such as form fixation or increase of surface contact, where a large surface of the stent is needed. Because of the size of microhooks, the risk of bowel perforation is low. Until now, the exact immune response and damage to the colonic wall that microhooks will induce is unknown. Microhooks have been used before for locomotion in the colon [17]. Damage to the colonic wall was not documented in that paper. Further studies on this matter should be performed.

• **Form fixation** uses one or more curvatures of the colon for fixation. In the case a stent uses one curvature of the colon for fixation and has the tendency to become straight, then stent migration or bowel perforation is likely to occur. In the case a stent uses two or more curvatures of the colon for fixation (distal and proximal to the obstruction), then migration is not likely to occur but the risk of bowel perforation is still present. In general, it is not easy to access the part or entire colon distal to the obstruction and visibility is only limited to fluoroscopy. If a stent holds the form of the curvature of the colon without tending to become straight, then stent placement along the obstruction and one curvature of the bowel (proximal to the obstruction) should be sufficient to avoid stent migration. There are a number of disadvantages with the use of form fixation: (1) because a longer stent is inserted in the colon, the pain sensation of the patient will increase. (2) the stent has to be precisely placed along the curvature of the colon, which is a complex task because of the limited visibility. (3) the stent will interfere with peristalsis in the healthy colon.

• **Adhesive polymer** has a great potential to be adequate as a fixation mechanism to anchor a colonic stent [7, 8]. It would probably not damage the colonic wall and it can also be easily incorporated to a colonic stent as a cover layer. Moreover, this layer can help to prevent tumor ingrowth. In the case of a medical complication, the stent could be removed by breaking the chemical bondings between the adhesive polymer and colonic wall. However, adhesive polymers are not yet suitable for long term fixation of a stent to a colonic wall. Further research on this topic is needed.

• **Increasing the surface contact** between the stent and the colonic wall can lower the risk of migration. This means that the length of a stent (longer than strictly necessary to open the obstruction) is inserted in the colon of the patient. Although increasing the surface contact will increase the friction forces in the interface stent-colonic wall, it is not known whether that will be enough to counteract the migrating forces present in the colon. A disadvantage of an increased surface contact is that a longer stent will interfere with peristalsis in the healthy colon and will increase the pain sensation of the patient. Further research is needed to know the exact influence on the friction forces.
Table 1: Evaluation of the Fixation Mechanisms.

<table>
<thead>
<tr>
<th>Fixation Mechanism</th>
<th>Technical Domain</th>
<th>Friction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microhooks</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Microexpansion</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Microinterlocking</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Spacer</td>
<td>-</td>
<td>+</td>
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<tr>
<td>Clamp</td>
<td>+</td>
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<tr>
<td>Suction cup</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Adhesive polymer</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Adhesive polymer-microhook</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Fusion of tissue to the stent wire</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

Note: + indicates a positive feature, - indicates a negative feature.
In this paper it was decided to perform a number of experiments with one of these fixation mechanisms to investigate whether its use would prevent colonic stent migration. Form fixation and increase of surface contact have not been chosen because these possibilities increase the pain sensation of the patient.

Furthermore, because they cover a longer part of the colon, they will interfere more with the normal functions of the healthy colon. Since adhesive polymers are not yet suitable for long term fixation of a stent to the colonic wall, this possibility was not selected. The use of microhooks will be investigated further, because microhooks probably generate high friction forces on a small surface and they satisfy the design requirements.

4 Experiments with anchoring techniques

Three experiments were performed to investigate whether microhooks can be used as a fixation mechanism.

4.1 Experiment 1

Experiment 1 was divided in 2 similar experiments. In Experiment 1.1 different wire mesh configurations were used, whereas, in Experiment 1.2 also Velcro was tested. In both cases the friction forces in the interface stent-colonic wall were measured.

- To analyze the static friction forces of different mesh configurations.

Hypothesis

The use of a mesh configuration results in higher friction forces in the interface stent-colonic wall than the use of a wire configuration parallel to the pulling direction.

Methods and materials

In Experiment 1.1 the colon of one pig was used. The colon was delivered in a physiological solution the day before the experiment took place. The physiological solution prevented colon corruption. The colon was stored in the refrigerator of the laboratory at 6°C until the experiment took place. During the experiments, the segments of the colon that were not used were held at low temperature by surrounding a bucket (containing the colon) with blocks with ice. The laboratory where the experiments took place has a conditioned environment. Its room temperature was 23°C.

The structure shown in Figure 21b was used to simulate the wire mesh configurations of a colonic stent. The friction forces of the three different wire mesh configurations were measured and compared. The material used to simulate the wire mesh structure of a stent was stainless steel of 0.4mm in diameter and the distance between the wires was 5mm (similar to the Wallstent of Boston Scientific). A 80mm long segment of the colon was opened longitudinally, fixed to a square plate (made of foam used for packing purposes) turned around and placed on the wire mesh configuration (Figure 22). The structure containing the different wire mesh configurations (Figure 21) was fixed onto the platform of a tensile testing machine (Zwick 1484). The plate was then loaded with 100g and connected via a thread and a pulley of negligible friction to the force sensor of the tensile testing machine. The load applied on the plate represented the intra-abdominal pressure of the human colon [7].

In this experiment, six square plates (40x40mm each) were used, two per wire configuration. The first plate was tested 3 times on the wires with one segment of the colon. After these three measurements, the wires were cleaned to have similar initial conditions on the surface of the wires. Then the second plate was covered with a new segment of the colon and was also tested three times on the wires. This procedure was repeated for the square mesh and rhombus mesh. For this experiment, six 80mm long segments of the colon were used. In total, 18 values of static friction force were recorded in Experiment 1.1, six values per wire mesh configuration. In
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order to record possible bowel perforation and to see tracks left by the wire mesh configurations, microscopic observations of the colon were taken.

Results of sub-experiment 1

Figure 23 shows the maximum static friction forces measured during Experiment 1.1. Measurement 1 shows the results of the first measurement of each plate, Measurement 2 the second, and Measurement 3 the third.

The maximum static friction force of the wires was 0.30N; the maximum static friction force of the square mesh was 0.68N; and the maximum static friction force of the rhombus mesh was 0.85N. Bowel damage was not observed under the microscope.

Conclusion of Experiment 1.1

The results of Experiment 1.1 verified the hypothesis. The rhombus mesh generated values of static friction force in the same magnitude as the square mesh. The wires generated a lower static friction force. This means that the square or rhombus mesh can be used as mesh configuration for a stent because they generate higher friction forces than wires.

Experiment 1.2

The experimental setup developed by Dodou et al. [7] was adapted to perform Experiment 1.2 (Figure 24). Two kinds of Velcro were used for this experiment: (1) regular Velcro, and (2) diaper Velcro (Figure 25). These materials were selected because they have similar characteristics as microhooks and because of their availability and low cost. The goals of Experiment 1.2 were:

- To analyze the static friction forces generated by Velcro.
- To compare the static friction forces between the Velcros and the rhombus mesh structure.
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Figure 24: Experimental setup used in Experiment 1.2. The microhooks (Velcro) are located at the bottom of the plate, which is in contact to the colon.

Figure 25: (a) diaper Velcro, and (b) regular Velcro.

Hypothesis

1. A Velcro will generate more static friction forces in the interface stent-colonic wall than a rhombus mesh.
2. Diaper Velcro will generate more friction forces in the interface stent-colonic wall than regular Velcro

Methods and materials

In Experiment 1.2 the colon of one pig was used. The pig used in this experiment was the same as the one used in Experiment 1.1. The handling, conservation and preparation of the colon followed the same protocol as in Experiment 1.1.

For Experiment 1.2, the mesh configuration with the best results in Experiment 1.1 (rhombus mesh) was selected as reference because of its similarity to a standard stent. The size of the plates was doubled (40x80mm) in order to observe under the microscope whether they cause damage to the colonic wall. It was suspected that the smaller plates of Experiment 1.1 limited the observation of such possible damage. In this experiment two 100mm long segments of the colon were used for each plate. The load applied on the plates was again 100g. The experimental setup used in Experiment 1.1 was repeated for the rhombus mesh. The results obtained with the rhombus mesh was compared to the results obtained with the plates containing the two kinds of Velcro (Figure 26).

The experiments with Velcro were performed using the experimental setup shown in Figure 24. The microhooks of the diaper Velcro had a height of approximately 0.4mm. The height of the regular Velcro was approximately 1mm. A plate (40x80mm) covered with Velcro was turned around and placed on top of the colon. The plate was then loaded with 100g and connected via a thread and a pulley of negligible friction to the force sensor of the tensile testing machine (Zwick 1484).

In this experiment, three square plates (40x80mm each) were used, one for the rhombus mesh, one for the regular Velcro, and one for the diaper Velcro. The first plate was tested three times on the rhombus mesh with one segment of the colon. After these three measurements, the rhombus mesh was cleaned to have similar initial conditions on the surface of the rhombus mesh. Then the same plate was covered with a new segment of the colon and was also tested three times on the rhombus mesh. To test the regular Velcro a 100mm segment of the colon was fixed onto the pad of the structure shown in Figure 24. The plate with the regular Velcro was tested three times on this segment. This procedure was repeated with a new segment of the colon after cleaning the plate covered with regular Velcro. The diaper Velcro was tested following the same procedure.

For this experiment, six 100mm long segments of the colon were used. In total, 18 values of static friction force were recorded in Experiment 1.2. In order to record possible bowel perforation and to see tracks left by the rhombus mesh and Velcro, microscopic observations of the colon were taken.

Results of Experiment 1.2

Figure 27 shows the static friction forces measured during Experiment 1.2. Measurement 1 shows the results of the first measurement with each segment of the colon, Measurement 2 the second, and Measurement 3 the third.
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The maximum static friction force of the rhombus mesh was 0.92N; the maximum static friction force of the regular Velcro was 0.97N; and the maximum static friction force of the diaper Velcro was 1.41N.

A uniform distribution of the mucus around the diaper Velcro was observed (Figure 28). In contrast to that, on the plate with regular Velcro, mucus was accumulated in different parts and in small amounts. In Experiment 1.2, bowel damage was not observed under the microscope.

Discussion Experiment 1

Although the results of Experiment 1 showed low values of static friction forces for the wire mesh configurations and Velcro, the use of a diaper Velcro will increase the friction forces with a factor of 1.5 with respect to the rhombus mesh. Since the plates used in Experiment 1 had a small surface, it is not known whether an even larger plate surface will increase the difference between the more significant. Further research is necessary on this topic.

The diaper Velcro gave the highest friction and showed a uniform distribution of the mucus around the microhooks, which may also have influenced the friction forces. This suggests that the friction forces also depend on other factors, such as adhesion. Further research is needed to evaluate the factors that are responsible for generating friction forces in the interface stent-colonic wall.

Experiment 1.2 showed that the size and shape of the microhooks influenced the friction forces in the interface stent-colonic wall. In Experiment 2, the influence of shape and size were explored further.

4.2 Experiment 2

For Experiment 2 three kinds of microhooks were used: (1) bent microhooks, (2) straight microhooks, and (3) diaper microhooks (Figure 29). The material used to represent the microhooks was again Velcro. The goal of Experiment 2 was:

• To analyze the influence of the shape and size of the hooks on the friction forces in the interface stent-colonic wall.

Hypothesis

The friction forces in the interface stent-colonic wall will be higher for the straight and diaper microhooks, with small and sharp ends, than for the bent microhooks.

Methods and materials

In Experiment 2 a new colon of one pig was used. The handling, conservation and preparation of the colon followed the same protocol as in Experiment 1.

The experimental setup was the one used for Experiment 1.2 (Figure 24). For this experiment, 3 plates (40x80mm) were used, one covered by bent microhooks, one covered by straight microhooks and one covered by diaper microhooks. Again the load applied on the plate was 100g. The three kinds of microhook had different characteristics. The bent microhooks were represented by regular Velcro, of
Experiments with anchoring techniques

Figure 29: (a) bent microhooks, (b) straight microhooks, and (c) diaper microhooks.

the same characteristics used in experiment 1. The height of the bent microhooks was approximately 1mm and their tips were bent (Figure 29a). The straight microhooks were represented by regular Velcro. The tips of the regular Velcro were cut to give the microhooks a sharp shape. The height of the straight microhooks was approximately 0.45mm (Figure 29b). The diaper microhooks were represented by diaper Velcro. The shape of diaper microhooks differs from the other two microhooks. Their tips have a circular shape with imprinted grooves. The height of the diaper microhooks was approximately 0.4mm (Figure 29c).

For this experiment, three square plates (40x80mm each) were used. To test the regular Velcro, a 100mm long segment of the colon was fixed onto the pad of the structure shown in Figure 24. The plate with the regular Velcro was tested four times on this segment. This procedure was repeated with a new segment of the colon after cleaning the plate covered with regular Velcro. The straight Velcro and the diaper Velcro were tested following the same procedure.

For this experiment, six 100mm long segments of the colon were used. In total, 24 values of static friction force were recorded in Experiment 2. In order to record possible bowel perforation and to see tracks left by the Velcro, microscopic observations of the colon were taken.

Results of Experiment 2

Figure 30 shows the friction forces measured during Experiment 2. Measurement 1 shows the results of the first measurement with each segment of the colon. Measurement 2 the second, Measurement 3 the third and Measurement 4 the fourth.

The maximum static friction force of the bent microhooks was 0.99N; the maximum static friction force of the straight microhooks was 1.42N; and the maximum static friction force of the diaper microhooks was 1.34N. Bowel damage was not observed under the microscope.

Conclusion Experiment 2

The hypothesis was verified. From these results can be concluded that small and straight microhooks generate higher friction forces in the interface stent-colonic wall than longer bent microhooks.

Straight and diaper microhooks created similar friction forces. Both microhooks have similar length and small and sharp tips. The bent microhooks clearly generated lower friction forces.

Discussion Experiment 2

The higher friction forces generated by straight and diaper microhooks suggest that: (a) The sharpness of microhooks may have provided better contact to the colonic wall, resulting in better fixation, and (b) the better mucus distribution around straight and diaper microhooks may have entrapped the mucus providing a better fixation.

Although the form and size of the microhooks influence the static friction forces in the interface stent-colonic wall, it is not known whether other factors,
such as the number of microhooks on the surface or the geometry of the plate, influence static friction forces as well. This will be studied further in Experiment 3.

4.3 Experiment 3

The difference in friction forces between diaper and straight microhooks was negligible in Experiment 2. Since there were problems with the availability of diaper microhooks, it was decided to perform Experiment 3 only with the straight microhooks. Three plate geometries containing the microhooks were used: (1) full plate, (2) plate with holes, and (3) plate with windows (Figure 31). The differences between the plate geometries is explained later. The goal of Experiment 3 was:

- To analyze the influence of the geometry of a plate covered with microhooks on the friction forces in the interface stent-colonic wall.

![Figure 31: Plates used in Experiment 3: (a) full plate, (b) plate with holes, and (c) plate with windows.](image)

**Hypothesis**

The reduction of the number of microhooks on the plate, due to the holes, will reduce the friction forces in the interface stent-colonic wall.

**Methods and materials**

The setup used in this experiment was the same as used in Experiment 2. Three different square plates (40x40mm) were used in Experiment 3. Each plate was loaded with 100g. In the case of a full plate, a square plate was completely covered with microhooks. In the case of a plate with holes, a square plate was perforated with square holes of 6x6mm. The rest of the plate was covered with microhooks. The distance between the holes was 6mm, leaving 5mm distance at the borders of the plate. In the case of a plate with windows, a square plate was covered with microhooks following the same pattern as the plate with holes. Only the microhook layer was perforated, not the plate.

Tests on the same intestinal segment reduces the amount of mucus on it, making the comparison between measurements very difficult. In order to increase the number of measurements and to avoid the use of the same intestinal segment, seven 100mm long consecutive colonic segments of the same pig were used for each plate.

First the full plate was tested one time on a 100mm long intestinal segment of the colon. Then, the plate with holes was tested one time using a new 100mm long colonic segment. After that, the plate with windows was tested one time using a new 100mm long colonic segment. All the plates were then cleaned to have similar initial conditions for the next series of measurements. This procedure was repeated six times, making a total of 21 values of static friction forces. In order to record possible bowel perforation and to see tracks left by the microhooks, microscopic observations of the colon were taken.

**Results of Experiment 3**

The results given in this section were evaluated using the Wilcoxon rank sum test of Matlab. The data obtained from the experiments with the full plate was compared with the data from the other two plates. The test showed that data obtained for the full plate and plate with holes are significantly different (h=1, p=0,0005). The same result was observed between the full plate and the plate with windows (h=1; p=0,0012). The test also showed that the data obtained with the plate with windows and the plate with holes were not significantly different (h=0, p=0,8048).

Figure 32 shows box plots and the friction forces measured during Experiment 3. The average static friction force of the full plate was 1,04N; the average static friction force of the plate with holes was 1,39N; and the average static friction force of the plate with windows was 1,46N. Bowel damage was not observed under the microscope.

**Conclusion Experiment 3**

The hypothesis was falsified. The reduction of the number of microhooks did not reduce the friction forces in the interface microhooks-colonic wall. On the contrary, reducing the number of microhooks led to an increase of the friction forces.

Similar friction forces were obtained with the plate with windows and with holes. These were higher than the friction forces generated by a full plate. This means that the geometry of the plate, which contains
the fixation mechanism, influences the static friction forces in the interface stent-colonic wall.

5 Conclusion

In this paper, data available from the literature was gathered and organized to analyze the factors that influence colonic stent migration. It turned out that four factors influence colonic stent migration: (1) peristalsis, (2) feces passage and impact, (3) change in tumor size, and (4) mucus secretion. By means of a qualitative analysis of these four factors, the forces acting on the stent were represented in a formula. If the friction forces in the interface stent-colonic wall are less than the resultant of the migrating forces on the stent, then stent migration will take place.

By evaluating possible fixation mechanisms, four fixation mechanisms were found suitable to anchor a colonic stent: (1) microhooks, (2) form fixation, (3) adhesive polymer, and (4) increase of surface contact. The microhook mechanism was selected for further experimental research.

Experiments with different kinds of microhooks and wire mesh configurations were performed and their values of static friction forces compared. The results showed that microhooks generated higher static friction forces than a wire mesh configuration. When comparing different kinds of microhooks (bent, sharp and diaper), it was noticed that the size and form of the microhooks also influenced friction. Small and straight microhooks generated larger friction forces than bigger and bent microhooks. The results also showed that a plate covered with microhooks and with holes or windows on its surface generated larger friction forces than a plate fully covered with microhooks.

Notwithstanding its limitations, this study shows that incorporating a fixation mechanism to a colonic stent decreases the chance of colonic stent migration.

6 Discussion and future research

An interesting outcome of the analysis of forces in the colon is that the combination of peristalsis and mucus secretion is primarily responsible for stent migration. Peristalsis generates high migration forces and because of the mucus, the friction forces in the interface stent-feces are reduced, decreasing the resultant of all migrating forces further. Therefore, the holes in the plate will probably play a major role in vivo experiments.

One of the reasons why the plate with windows generated higher friction forces could be attributed to the fact that the plate was in direct contact to the colonic wall. The foam of the plate may have contributed to the increase of the friction forces. If microhooks are incorporated on a metal stent, the effect described above will not take place.
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follow.
This study showed that microhooks are a possible solution to prevent colonic stent migration. Further research needs to be done in order to determine the optimal size and shape of the microhooks, the material used for the microhooks, the exact geometry of the surface of the stent to be covered by the microhooks, and the techniques to manufacture microhooks and to incorporate them to the stent.

This paper is limited to the study of the problems regarding colonic stent migration. However, stent placement is also associated with other stent related medical complications that were out of the scope of this paper. Lazarte Araoz [14] gives an overview of stent related medical complications of current metal stents, as well the requirements that a metal stent should fulfill for adequate performance. To complete all the characteristics that the "ideal stent" should have, a number of studies should be performed to find solutions regarding all stent-related medical complications.

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Appendix A

Tapeworms

A.1 Introduction

This Appendix describes tapeworms: parasites that attach to the bowel of animals and humans. It also handles the symptoms of the parasitic infection, and the ways in which parasites attach to the intestine of humans.

A.2 General description

Tapeworms are a group of parasitic worms that live in the intestinal tract of some animals. A number of them can also infect humans. The two most common species found in humans are the pork tapeworm (Taenia Solium) and the beef tapeworm (Taenia Saginata). Tapeworm infection (cestodiasis) occurs most commonly after eating raw or undercooked meat or fish that contains the immature form of the tapeworm (Figures A.1 and A.2). Tapeworms attach to the bowel of their host by using their organs of attachment that they carry in their scolex (Figure A.3). Some tapeworms, such as the Taenia Saginata, only use four suckers for attachment. Taenia Solium uses, besides the four suckers, two rows of rostellar hooks that anchor in the bowel of the host.

A.3 Pathology

Adult worms are found in the small intestine of their hosts. These parasites are usually well tolerated by the host or asymptomatic. The clinical manifestations of infection with adult tapeworms may cause nausea or vomiting, appetite loss, abdominal distress, indigestion, anorexia, nausea, localized pain, diarrhea, and weight loss [3]. Moderate eosinophilia (white blood cells that are responsible for combating infection by parasites in the body) may develop. A disturbing manifestation of Taenia Saginata infection is the active crawling of the parasite out of the anus. Rarely, intestinal perforation may occur from the scolex of Taenia species. Because of its limited contact with the epithelial lining of the bowel, adult tapeworm induces little host bowel inflammatory response. Taenia Solium shows a small focal cellular infiltrate or chronic enteritis (inflammation of the small intestine). The sucking action
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Oncospheres develop into cysticerci in muscle.

Oncospheres hatch, penetrate intestinal wall, and circulate to musculature.

Humans infected by ingesting raw or undercooked infected meat.

Cattle (T. saginata) and pigs (T. solium) become infected by ingesting vegetation contaminated by eggs or gravid proglottids.

Eggs or gravid proglottids in feces and passed into environment.

Figure A.1: Cycle of infection of tapeworms in humans. Adapted from [2].

Figure A.2: Diagrammatic section of a larval and adult parasite in the intestinal wall of a mouse [3].
of the scolex appears to have relatively limited immunogenic effect. The long life span of the worm suggests the absence of an effective inhibitory mechanism. Intestinal blockage or penetration has rarely been reported. Humans infected with these parasites are treated efficiently with drugs that attack and kill the parasite [3].

In contrast to humans, hamsters and mice infection with adult Taenia Solium show host reaction to the attachment process (Figure A.4 and A.5). In contrast to humans, hamsters and mice are not a natural host of adult Taenia Solium; humans are. As a result, an inflammatory (immunological) reaction occurs in which:

- Normal shape of the mucosa is lost.
- Edema appears (accumulation of serous fluid in tissue).
- Loss of villi structure takes place (stunted and deformed villi).
- Scarce macrophages rises, i.e., an increase of plasma cells, lymphocytes, fibroblast, and others, only in the location of the attachment.
- At the location where the scolex is attached, the host tissue exhibits various degrees of cell lysis and necrosis of epithelial and submucosal cells.

These facts indicate that the immune response of the hamster is stronger than the of humans, because hamsters are not the final natural host of these kinds of parasites.
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Figure A.4: Scanning electron micrograph (SEM) of a metacestode removed from an immunized mouse. The figure shows that the tapeworm caused an immune response to the host. Inflammatory cells can be seen scattered among the hooks (H), on the suckers (S), and on the strobilar tegument (ST) [5].

Figure A.5: A higher image magnification of the region [8] shown in Figure A.4. An intense inflammatory reaction completely covers the head of the parasite [5, 6].
Appendix A: Tapeworms

The immunological reactions showed in hamsters and mice intestine suggest that a similar reaction could affect humans. However, due to the effective inhibitory mechanism of the parasites in humans, those effects are minimized.

A.4 Description of the fixation mechanisms used by tapeworms

Tapeworms attach to the bowel of their host by using the organs of attachment found in their scolex, at the head of the parasite (Figure A.6). In this section the attachment mechanisms of Taenia Solium and Taenia Saginata are studied. Since Taenia Solium has both sucker cups and hooks, the definitions given in this section are referred to this parasite. The mechanism for sucker attachment applies for both parasites. The Taenia Solium has two posterior suckers and two anterior suckers. These four suckers are approximately 0.5mm in diameter. In addition to this, it has a rostellum that contains two circular rows of hooks. The mechanisms of hook and sucker attachment that Taenia Solium uses to fixate itself to the bowel are explained in the next sections.

![Figure A.6: Organs of attachment of Taenia Solium.](image)

A.4.1 Mechanism of hook attachment

The head of the scolex has a muscular rostellum (see Figure A.6) on which the strong hooks are arranged in two overlapping circles with the hooks staggered. There are in total approximately 22-32 hooks (11-16 hooks per row). The length of the hooks varies from 0.1 to 0.4mm. In order to attach itself to the bowel of its host, Taenia Solium first uses its hooks. The hooks anchor the worm to the epithelium of the intestinal wall. For this purpose, the hook arrangements are moved by special antagonist hook muscles [7]. The entire array of hooks is moved as a consequence of the contractions of the rostellum. The hooks are pressed into the intestinal wall, penetrating the first layer of the intestinal wall (mucosa), thus limiting its damage. In order to understand the procedure of hook attachment, this process is divided in three steps: (a) hook rotation, (b) hook translation and penetration, and (c) hook anchoring:
(a) Hook rotation

When the parasite is about to attach its hooks to the intestinal wall, it first rotates them in such way that the hooks will point towards the tissue, as shown in Figure A.7.

![Figure A.7: Hook rotation.](image)

(b) Hook translation and penetration

Once the hooks have been rotated, they will be moved by rostellum contraction towards the surface of the intestinal wall. In this process the hooks are pressed into the surface penetrating it superficially (Figure A.8).

![Figure A.8: Hook translation and penetration.](image)

(c) Hook anchoring

After penetrating the intestinal wall, the parasite pulls its hooks down to reinforce its attachment (Figure A.9).

![Figure A.9: Hook anchoring.](image)
A.4.2 Mechanism of sucker attachment

Once the parasite has anchored its hooks to the intestinal wall, sucker attachment takes place to stabilize the attachment. The suckers are suction organs that appear in fourfold. The attachment depends on the creation of a reduced pressure in the space between sucker and intestinal wall. That is, a force is exerted in order to increase the volume of the cavity between the sucker and the intestinal wall. Taenia Solium applies this force by muscular contraction, arranged so that it draws the center of the cup away from the surface while the edges remain seated. The edges must not collapse during this process in order to guarantee the attachment (Figure A.10).

$P_1 = \text{Pressure in intestinal wall (iw)}$

$P_2 = \text{Pressure between membrane and iw}$

Figure A.10: Mechanism of sucker attachment.
Appendix B

Colon motility

B.1 Introduction

Colon motility is a very important function of the large intestine. Colon motility consists of a number of different kind of contractions. From an engineering perspective, bowel contraction can be explained as the generation of forces that leads to bowel occlusion. This Appendix describes the different sort of contractions present in the colon and their possible influence on colonic stent migration.

B.2 Definition

Colon motility is defined as the capability of contracting bowel segments of the large intestine to carry out its main functions. Those functions include absorption of water, some electrolytes, bacterial metabolites, short chain fatty acids, net distal propulsion of contents, and storage of fecal mass for later evacuation.

B.3 Classification of bowel contractions

There are three different kind of colonic contractions (Table B.1): (a) Rhythmic phasic contractions (RPCs), (b) Ultrapropulsive contractions (UPCs), and (c) Tonic contractions (TCs). The intensity of these contractions, their duration, and the distance of propagation vary for each of them [1, 8]. In all cases, the contraction is a full or partial closure of the lumen of the colonic wall. From an engineering point of view, the closure of the lumen of the bowel can be represented as radial contractile forces. This results in pushing forces that are exerted on the feces, moving it towards the rectum for evacuation.

B.3.1 Rhythmic phasic contraction (RPC)

The RPCs cause mixing, agitation and slow distal propulsion of the bowel contents. The RPC is a colon event that constantly takes place along the large intestine. The contractile amplitude of RPCs ranges between 5-50mmHg (0,67-6,7KPa) [1].
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Table B.1: Classification of peristaltic contractions present in the large intestine.

<table>
<thead>
<tr>
<th>PERISTALTIC CONTRACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NON-PROPAGATING CONTRACTIONS</td>
</tr>
<tr>
<td>Rhythmic Phasic Contractions (RPCs)</td>
</tr>
<tr>
<td>Mixing Forces</td>
</tr>
<tr>
<td>Agitation Forces</td>
</tr>
<tr>
<td>Distal propulsion forces</td>
</tr>
<tr>
<td>PROPAGATING CONTRACTIONS</td>
</tr>
<tr>
<td>Ultrapropulsive Contractions (UPCs)</td>
</tr>
<tr>
<td>High Amplitude Propagated Contractions (HAPCs)</td>
</tr>
<tr>
<td>Low Amplitude Propagated Contractions (LAPCs)</td>
</tr>
<tr>
<td>Caudal mass movement forces</td>
</tr>
<tr>
<td>Enlarge RPC and UC contractile forces by reducing lumen diameter</td>
</tr>
</tbody>
</table>

B.3.2 Ultrapropulsive contraction (UPC)

When feces has to be propelled rapidly without regard for digestion or absorption, UPCs take place. This motor function is achieved by two types of UPCs: (a) High Amplitude Propagated Contraction (HAPC), and (b) Low Amplitude Propagated Contraction (LAPC) [1, 8]. The HAPCs are two to four times larger in amplitude and four to six times longer in duration than the maximum amplitude and duration of RPCs [8]. Manometric measurements of colon activity showed that the values of HAPCs have an average contraction of 100 mmHg and an average propagation velocity of 1.1 cm/s [1]. Because of their long duration, the HAPCs simultaneously contract a 20- to 30-cm-long segment, which increases the efficacy of the propulsion by reducing the chance of any feces being left behind. Figure B.1 shows the contraction of the colon due to HAPCs.

B.3.3 Tonic contraction (TC)

A tonic contraction is a sustained increase in tone that may last for several minutes to several hours. Tone is defined as the normal state of elastic tension or partial contraction in resting muscles of the intestine [4]. The precise role of tone in the bowel motor function has not been well defined, but it is thought to enhance the efficacy of RPC and UC by narrowing the lumen [1].

B.4 Measurement of bowel contractions

Given the complexity of colonic motor activity and its anatomic conformation, it is not surprising that there is not yet an “ideal” technique for measuring colonic activity. However, a number of techniques have been developed to record human colonic
motility for extended periods of time (24 hours or more). Pancolonic manometry has been used to evaluate colonic motor activity over the entire length [1].

Bassotti and Crowell [1] described a technique to measure colon activity. They divided the colon activities into two groups: (a) segmental activity, which corresponds to the RPCs, and (b) propagated activity, which corresponds to the UPCs. In their experiments, Bassotti and Crowell [1] showed that the RPCs have contractile amplitude that generally fall within a range of 5 to 50 mmHg (0,67 to 6,7KPa). These contractions have been recorded at a frequency of 3 contractions per minute (cpm). The UPC contractile patterns are the minority of all contractions, yet an important one. The LAPCs have been recorded as propagated waves with an amplitude ranging from 5 to 40 mmHg (0,67 to 5,3KPa). The data on LAPCs suggest that they occur 60 times per day and that the frequency increases after meals. A number of studies showed that the LAPCs are associated with transport of colonic contents and with the passage of flatus [1]. The HAPCs represent an infrequent event in humans, appearing on average 6 times/day, with an average amplitude of 100 mmHg (13,3KPa). Most of the HAPCs propagate towards the rectum. In a few subjects, HAPCs have been observed propagating in a retrograde fashion, usually in the distal sigmoid colon. Table B.2 shows the data recorded by Bassotti and Crowell [1] in which the average value of HAPCs in the different segments of the large intestine are given.

<table>
<thead>
<tr>
<th>Colon segment</th>
<th>Amplitude (mmHg/Kpa)</th>
<th>Duration (s)</th>
<th>Propagation velocity (cm/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascending</td>
<td>114,7/15,3 ± 6/0,8</td>
<td>15,9 ± 0,9</td>
<td>1,8 ± 0,1</td>
</tr>
<tr>
<td>Transverse</td>
<td>109,6/14,6 ± 6/0,8</td>
<td>14,6 ± 0,8</td>
<td>1,1 ± 0,1</td>
</tr>
<tr>
<td>Descending</td>
<td>117,6/15,7 ± 7/0,9</td>
<td>13,9 ± 0,7</td>
<td>1,0 ± 0,1</td>
</tr>
<tr>
<td>Sigmoid</td>
<td>95,3/12,71 ± 5/0,6</td>
<td>13,0 ± 0,7</td>
<td>0,8 ± 0,1</td>
</tr>
</tbody>
</table>
Appendix C

Factors that influence migration

Table C.1: Factors that influence colonic stent migration and the forces associated with each of them.
Appendix D

Layers of the colonic wall

Figure D.1: Layers of the colonic wall.
Appendix E

Experiments

Figure E.1: The temperature of the bucket, containing the colon of a pig, is held low by using blocks with ice.

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Figure E.9: Friction forces recorded during Experiment 2 for the bent microhooks.
Figure E.10: Friction forces recorded during Experiment 2 for the straight micro-hooks.
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Figure E.11: Friction forces recorded during Experiment 2 for the diaper microhooks.
Figure E.12: Friction forces recorded during Experiment 3 for the full plate completely covered with microhooks.
Figure E.13: Friction forces recorded during Experiment 3 for the plate with holes.
Appendix E: Experiments

Figure E.14: Friction forces recorded during Experiment 3 for the plate with windows.
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Figure E.15: Pictures of the material and equipment used.
Figure E.16: Mucus between microhooks windows and holes of the plate.

Figure E.17: Tracks left by different fixation mechanisms.
Appendix F

Conceptual design

F.1 Introduction

This section introduces a conceptual design regarding the use of microhooks as a fixation mechanism to prevent colonic stent migration. During this research, a number of ideas were conceived but not further investigated due to limitation of time. Those ideas could be used as inspiration for future research.

F.2 Concept 1

The stent is coated with a layer of plastic along its entire length. On this layer microhooks are incorporated. Holes in the surface of the stent allow the pass of mucus and increase friction forces in the interface stent-colonic wall (Figures F.1).

![Concept 1 Diagram]

Figure F.1: Concept 1.

F.3 Concept 2

In this second concept a stent is covered with circular rings that contain microhooks (Figure F.2). These circular rings also have square holes on its surface to increase the
static friction forces in the interface stent-colonic wall.

Coated ring containing the microhooks

Figure F.2: Concept 2.

F.4 Additional ideas

- The microhooks can also be used for drug delivery directly to the tumor. If the microhooks are coated with a drug, patients can be treated locally (e.g. chemotherapy).

- When the stent is used for benign tumors, then the microhooks should be made of a biodegradable material to allow stent extraction.
Appendix G

Metal stents

This section shows a number of stents used in different medical applications. Figures G.1 to G.4 show stents used for duodenal, esophageal, colonic and other medical applications.

Figure G.1: Stents for duodenal applications: (a) Pyloric stent Y2C of Stentech, and (b) Wallstent of Boston Scientific.
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Figure G.2: Stents for esophageal applications: (a) Y3L of Stentech, (b) Wallstent of Boston Scientific, (c) Ultraflex of Boston Scientific, (d) Z-Stent fully coated of Cook, (e) Z-Stent with uncoated flanges of Cook, and (f) Z-Stent with anti-reflux valve of Cook.
Figure G.3: Stents for colonic applications: (a) Colo-rectal stent X3L of Stentech, (b) Colo-rectal stent Y4L of Stentech, (c) Colonic Z-stent of Cook, (d) Ultraflex of Boston Scientific, (e) Colo-rectal stent Y2C of Stentech, and (f) Wallstent of Boston Scientific.
Figure G.4: Stents for different medical applications: (a) Biliary stent Y2B of Stentech, (b) Wallstent RX biliary endoprosthesis of Boston Scientific, and (c) Urethral stent Y1L of Stentech.
Bibliography


