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Research Article

Novel *Ex Vivo* Stricture Model for Evaluation of Gastrointestinal Stent Migration

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Abstract

Background: The development of novel, high performance colonic stents requires in depth understanding of migration and perforation properties. The aim of this study is to establish a porcine *ex vivo* stricture model that could reliably assess stent migration and could guide the design and development of the next generation gastrointestinal implantable devices.

Methods: A simple *ex vivo* porcine stricture model was created and subsequently integrated into a newly designed dynamic testing apparatus that simulates gastrointestinal migration. We investigated the migration characteristics of six of the most commonly used colonic stents (WallFlex, Ultraflex, Ella, Choostent, Niti-S-D-type, Niti-S-ComVi). A total of thirty-six experiments were performed and the maximal pullout resistance force, the total migration energy, the migration initiation force and the time to migrate were recorded. All colon specimens were assessed for injury at the end of the experiments.

Results: Ultra flex achieved the highest maximal pullout resistance force (7.9±0.9N) and also required the largest amount of energy to migrate (168.3±30.5J). Alternatively WallFlex generated the least pullout energy (52.7±10J), but due to its elongation ability, it required the longest time to completely migrate (80.6±1.8sec). The non-covered Niti-S D-Type and the partially covered Niti-S-ComVi reached the highest force before the migration occurred (4.2N and 3.7N) and were associated with a subsequent colon perforation.

Conclusions: This is the first dynamic *ex vivo* animal model that closely simulates human colonic stricture and tests stent migration. This model could be a valuable tool to help understanding the process of migration and steer the development of modern stent technology.

Keywords: Colon stricture; *Ex vivo* porcine model; Stent migration

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Introduction

Colorectal Cancer (CRC) continue to be among the most common malignant diseases in the United States with over 134,000 new cases diagnosed annually including more than 95,000 colon and 39,000 rectal cancers [1]. Despite the progressive advancement in screening and therapy, colorectal cancer still remain the third most common cause of cancer related death in the US with approximately 50,000 deaths each year [1,2].

Over time, 7-29% of the patients with CRC will present with near complete or complete bowel obstruction that require rapid intervention such as emergency surgery with or without creation of colostomy. Unfortunately such invasive procedures result in an unacceptably high rate of morbidity (40 - 78%) and mortality (12 - 24%) [3]. In addition, colostomy in the elderly and frail patients has adverse effect on the quality of life with ostomy reversal in only half of the patients [4,5].

Self-Expandable Colonic Stents (SECS) as an alternative treatment for malignant colonic obstruction was initially described by Dohomoto in 1991 [6]. Within the last two decades colonic stenting gained popularity and was mainly used with two indications: as a Bridge to Surgery (BTS) or definitive therapy of palliative malignant strictures. Currently, only 12.1% of all colonic obstructions are treated with SECS, leaving the majority of the patients with only invasive surgical alternatives [7].

One of the main reasons for such low penetration into clinical practice is the underwhelming performance profile of the available colonic stents. Unacceptably high migration rates (10 - 11.8%) [3,8], excessive stiffness and lack of flexibility resulting in dangerous perforations (7.2-10.9%) are responsible for the high failure rates and justified skepticism among clinicians [9].

In order to develop novel colonic stents that can overcome the deficiencies of the currently available SECS, there is an acute need to develop testing models that could reliably evaluate and compare key stent characteristics.

The aim of this study is to establish a simple dynamic ex vivo colon stricture model that could be used for in depth investigation of the migration properties of SECS in the early phase of development. Better understanding of the various pullout forces associated with migration would help to guide the design of the next generation gastrointestinal implantable devices.

Materials and Methods

Commercially available stents

Using our model we investigated the migration properties of wide range of the commercially available colonic stents introduced in Europe, Asia and the United States. Table 1 shows description of the various SECS including their type and physical dimensions. While the WallFlex (Boston Scientific, USA), Ultraflex (Boston Scientific, USA) and Niti-S D-Type (Taewong Medial, South Korea) are non-covered self-expandable metal stents, the body of the Niti-S ComVi (Taewong Medial, South Korea) is partially covered with ePTFE and the Choostent (M.I.Tech, South Korea) is completely covered with Silicone. SX-Ella BD (ELLA-CS, Czech Republic) is a non-covered, biodegradable colonic stent approved for use in Europe. To date, the colonic stents that are FDA approved in the United States are nitinol based, non-covered SECS. Figure 1 gives a photographic overview of the various stents used for the experiments.

Stent name	Manufacturer	Diameter body/ flare (mm)	Length (mm)	Stent Type	Delivery Mechanism (Fr)
WallFlex	Boston Scientific	25/30	60	Uncovered	10
Ultraflex	Boston Scientific	25/30	57	Uncovered	24
SX-ELLA BD	Ella-CS	25/31	60	Uncovered (biodegradable)	27
Niti-S D-Type	Taewong Medical	26	60	Uncovered	18
Niti-S ComVi	Taewong Medical	26	60	Partially Covered (ePTFE)	18
Choostent	M.I.Tech	22 /28	100	Covered (Silicone)	24

Table 1: Description of the tested colonic stents.

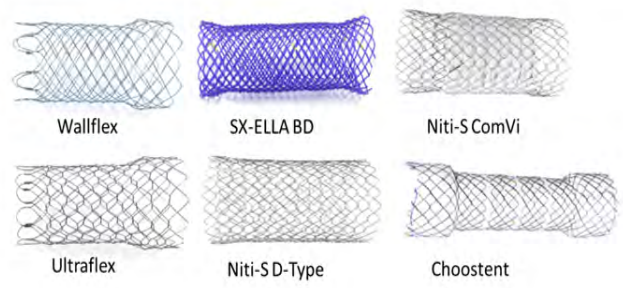
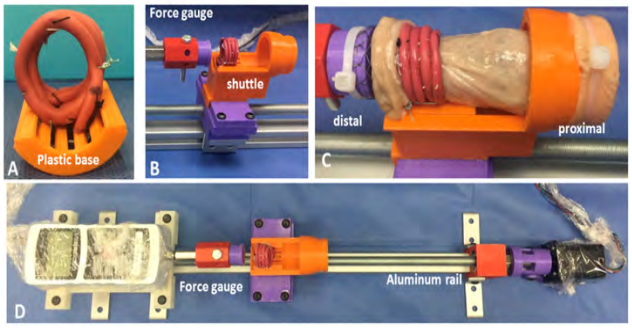


Figure 1: Photographic overview of the colonic stents tested in the study. Wallflex, Ultraflex and Niti-S D-Type are non-covered self expandable nitinol stents. Niti-S ComVi is partially covered with ePTFE and the Choostent is a segmented fully covered with silicone stent. SX-ELLA BD is a self expandable, biodegradable stent.

Ex vivo stricture model and testing apparatus

A 30mm long stricture was created using standard 8Fr latex Red Rubber catheter (Bard Medical). The stricture was created so that the initial (pre-deployment) inner diameter was 15mm. This diameter was selected in order to allow the easy passage of the various stent delivery systems (10 - 27 Fr). In addition, since the majority of the migration events occur immediately after or within the first days post deployment; we selected a stricture inner diameter that corresponds to partially expanded stents, which is the diameter within the first 24-48 hours after deployment [9].

After a 30mm long red rubber stricture was created, it was attached to a custom-designed, 3D-printed plastic base that was later integrated into the fixture of an automated shuttle system used for the migration experiments as shown on Figures 2 (A and B). This fixture features a proximal collar designed to secure the proximal end of the tissue and an attachment point for the base with the stricture at the distal end. The easily removable base with the attached red rubber stricture allowed for easy tissue exchange after each set of experiments. The tissue fixture was secured to a shuttle that rides on an aluminum rail. This shuttle was driven at a rate of 0.777mm/s by rotating a threaded shaft via a high-torque stepper motor and microcontroller (Arduino Uno R3).



Figures 2(A-D): *Ex vivo* stricture and testing apparatus used for the migration (pull out) experiments. **A** - 30mm long red rubber stricture with inner diameter of 15mm, attached to a plastic 3D printed base. **B** - Introduction of the plastic base with the stricture into the fixture of the shuttle system. **C**- Attachment of 130mm fresh, distal porcine colon to the collar of the fixture. The distal portion of the previously deployed colonic stent has been attached to the static plastic extension of the force gauge. **D** - Overview of the automated migration (pull out) shuttle system without porcine tissue.

Next, a 130mm previously isolated segment of distal fresh porcine colon (24-48h between testing and tissue extraction) was introduced through the stricture and attached to the proximal end of the shuttle box as shown on Figure 2 C. The length of the bowel segment and the stricture was selected in order to allow each stent to extent at least 15mm beyond the proximal and distal end of the stricture once deployed.

The various stents were deployed, so that the stricture was located in the middle of the stent body. The distal end of each stent was secured to a 3D-printed plastic extension of the force gauge that remained static throughout the experiments. In such a way, by slowly and continuously advancing the shuttle with the attached stricture (along the aluminum rail), the various stents were "pulled out" from the stricture and the generated forces have been recorded. For maximal precision, the forces were measured using a high-accuracy, high-resolution force gauge (M5-20, Mark-10 Corporation, Copiague, New York, USA). In addition, software was used to collect real-time force measurements (MESUR™ Lite, Mark-10 Corporation, Copiague, New York, USA) at a pre-selected rate of 10 times per second. The comprehensive data was exported to Microsoft Excel (Microsoft Corporation, Redmond, WA) for further analysis.

Testing details

We performed six pull out trials with each of the six commercially available stents (total of 36 experiments). The porcine tissue was exchanged after every six trials so that fresh tissue was used for each of the various stents. Once the experiments were completed, each of the colonic specimens was carefully examined for damage and/or potential perforations. The results of the macroscopic tissue evaluation were recorded and all specimens were photographed if further review was deemed necessary.

The recorded forces

For each of the six stents, we recorded the maximum pullout resistance, the time for complete stent migration and also calculated the total energy required for the SECS to be completely displaced. The energy required for full stent migration was calculated for each stent using the definite integral approximation of the area under each mean force response curve. This definite integral was calculated using a midpoint rectangle method as follow:

$$\int_a^b f(x)\,dx = h\sum_{n=0}^{N-1} f(x_n)$$

Using this general formula, the areas of rectangular subintervals of equal widths under each mean force response curve were found and summed to approximate the area under each curve, as follow:

$$h\left[\left(\frac{F_0 + F_{0.1}}{2}\right) + \left(\frac{F_{0.1} + F_{0.2}}{2}\right) + \left(\frac{F_{0.2} + F_{0.3}}{2}\right) + \cdots + \left(\frac{F_{N-0.1} + F_N}{2}\right)\right]$$

Where h is the width of each subinterval, which corresponds to the sample rate of the test (0.1s), and F_0, $F_{0.1}$, $F_{0.2}$, etc. are the average forces measured at time points 0s, 0.1s, 0.2s, etc.

We reported the migration initiation force, which is the maximal force that was reached before the onset of migration. The migration initiation force was determined by finding an inflection point in the average pullout response curve for each stent. Each of these points represented the displacement and the force at which the initial increase of force changed from a largely linear response. It is hypothesized that this change indicates a transition from measurement of static friction force to kinetic friction force, which denotes the point at which the stent begins to migrate.

The inflection point for each stent was estimated by calculating the coefficient of determination, or R^2 value, for a linear regression of each response. The point at which this coefficient fell below 0.97 was considered the point at which the linear regression no longer fit the response sufficiently and was thus chosen as the inflection point.

Data from all 36 experiments was recorded and exported to Microsoft Excel (Microsoft Corporation, Redmond, WA) for further analysis. Data were summarized as means ± Standard Deviations, if normally distributed, as medians with interquartiles, if abnormally distributed, or as frequencies (%) when appropriate.

Results

Maximum pullout resistance force

The mean maximum pullout resistance force that was reached during the experiments varied significantly between the six stents tested. The WallFlex (Boston Scientific, USA) exhibited the lowest maximal resistance force at 1.7±0.5N while the Ultraflex (Boston Scientific, USA) had the highest at 7.9±0.9 N. The completely covered Choostent (M.I. Tech, South Korea) and the partially covered Niti-S ComVi (Taewong Medical, South Korea) required higher pullout force than Wallflex, but less than the Ultraflex (4.5±0.3 N and 5.1±0.4 respectfully). The details of the mean maximum pullout resistance force are summarized in Table 2. The mean force response curve over time for each of the stents tested is shown on Figure 3.

Stent	Mean Max Pullout Resistance Force [N]	SD [N]
WallFlex	1.7	0.5
SX - ELLA BD	2.3	0.1
Choostent	4.5	0.3
Niti-S D-Type	4.6	0.2
Niti-S-Comvi	5.1	0.4
Ultraflex	7.9	0.9

Table 2: Results for the mean maximum (peak) pullout resistance force for each stent tested. SD -Standard Deviation.

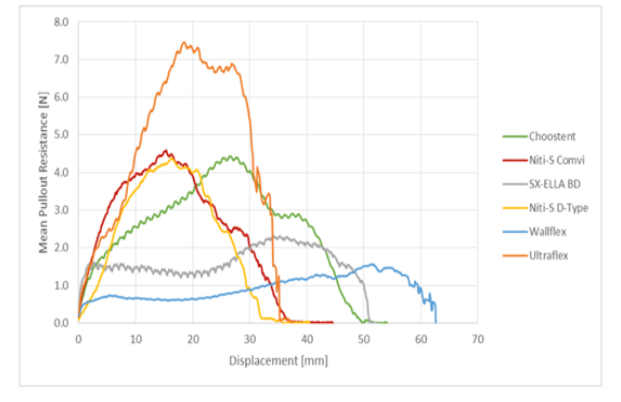


Figure 3: Graphic representation of the mean pullout resistance over time of all six commercially available colonic stents.

Total migration energy

The energy required for full migration of the various stents yields slightly different results when compared with the maximum pullout resistance force. While WallFlex again had the lowest total energy required to completely migrate the stent (57.2±10 N) and Ultraflex had the highest (168.3±30.5 N), the other stents varied in magnitude. The Choostent, despite being the longest of all tested stents, required less total energy in order to be completely displaced (133.0±3.6 N). Summary of the results is shown in Table 3.

Migration initiation force

After initiation of the experiments, the resistance force gradually increased until it reaches the so called "inflection point". The inflection point is where the pulling force of the stent starts to overcome the static friction of the stricture and the tissue. This is the point where the actual migration with stent displacement begins. Figure 4 shows a graphic illustration of the "inflection point" based on the mean force response from the six tested stents.

Stent	Mean Work to Pullout [J]	SD [J]
WallFlex	57.2	10.0
SX - ELLA BD	83.0	3.0
Niti-S D-Type	86.5	8.0
Niti-S-Comvi	104.5	9.0
Choostent	133.0	3.6
Ultraflex	168.3	30.5
SD - Standard Deviation; J - Joule.		

Table 3: Overview of the mean total energy required to completely migrate the various commercially available stents.

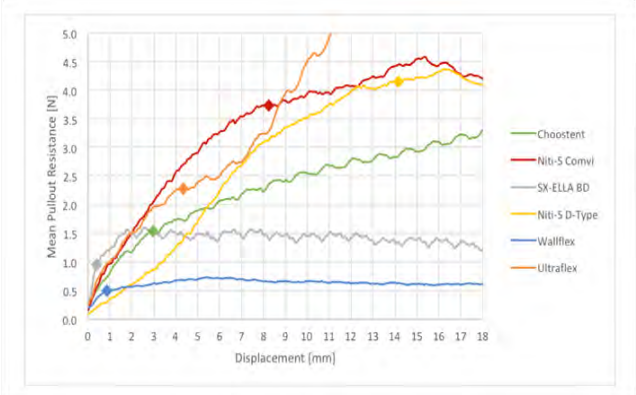


Figure 4: Portion of the mean force response curves showing the approximate "inflection point".

Stent	Distance to inflection point [mm]	Force reached at the Inflection point [N]
WallFlex	0.9	0.5
SX - ELLA BD	0.4	0.9
Choostent	3.0	1.5
Ultraflex	4.4	2.3
Niti-S-Comvi	8.2	3.7
Niti-S D-Type	14.1	4.2

Table 4: Migration Initiation Force. The various "inflection points" mark the time when the migration initiation force is large enough in order the stent migration to begin. The distance from testing start to the onset of the migration is shown below as well.

Migration time

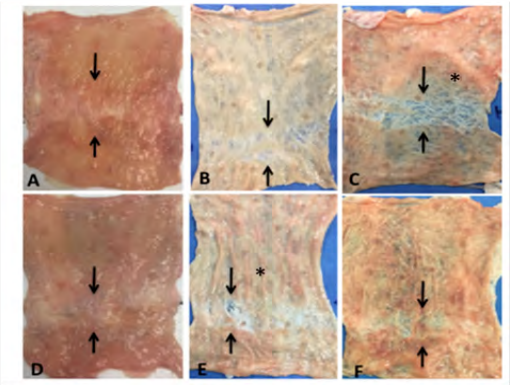
There was a substantial difference in the total time required for the various stents to migrate. While Wallflex reached the lowest maximal pullout resistance force (1.7±0.5 N), it was the SECS that required the longest time in order to migrate (80.6±1.8s). The non-covered, biodegradable SX-Ella BD stent shares structural similarity with Wallflex, especially in the way it gets compressed and elongates. As such, it required on average 70.2±0.7 seconds to migrate, closely following the time of the WallFlex colonic stent. On the opposite side of the spectrum is Ultraflex that appeared to be the stiffest and least probable stent to migrate, but once the migration occurred the stent was expelled the fastest among the other stents (48.1±2.6s). Description of the mean time to migrate among the various stents is shown in Table 5.

Stent	Mean Time to migration [s]	SD [s]
WallFlex	80.6	1.8
SX - ELLA BD	70.2	0.7
Niti-S D-Type	52.0	0.9
Niti-S-Comvi	57.7	3.1
Choostent	69.7	0.8
Ultraflex	48.1	2.6
SD- Standard Deviation, s-seconds		

Table 5: Overview of the mean time to migrate for the various colonic stents.

Tissue evaluation

After every set of experiments we exchanged the tissue and reviewed for potential damage and macroscopic signs of injury. Macro perforations were observed in two out of the six specimens (33.3%). The non-covered Niti-S D-Type (Figure 5C) and the partially covered Niti-S - ComVi (Figure 5E) caused injury to the colonic wall during the pull out experiments. The perforations occurred in the middle and/or at the end of the stricture. Photographic overview of the various specimens is shown on Figures 5 (A-F).



Figures 5(A-F): Post-experimental macroscopic evaluation of the porcine colon. The arrows mark the site of the stricture in each one of the individual specimen. **A**- Wallflex; **B** - Ella, **C** - Niti-S D-Type; **D** - Ultraflex; **E** -Niti-S.

ComVi, F – Choostent.* - perforated specimens

Discussion

Stent migration is among the most commonly encountered complications in patients with GI obstruction. The reported migration rates vary significantly depending on the stent design and mechanical characteristics (1-12.5%) [10-15]. In this study, we established a novel porcine model of colonic obstruction that could be used to assess the migration properties and test the performance of novel GI stents. The ability to perform such testing especially early in the development will allow for timely design alterations with subsequent significant cost savings. To our knowledge, this is the first *ex vivo* model that dynamically tests the anti-migration features of SECS. In addition, we investigated the migration profile of the most commonly used colonic stents in Europe, Asia and the United States.

The colonic stricture models introduced to date involve mostly small animals such as rabbits, rats or sheep fetus used to evaluate bowel obstruction and atresia [16-24]. Those models mostly focus on the pathophysiology involved in colonic obstruction rather than evaluation of the mechanical properties of the various stents. Recently published literature presented *in vivo* colonic stricture model tested in mongrel dogs over several weeks [25,26]. The authors used non-absorbable synthetic mesh and rubber bands to wrap the descending colon of the animals in order to simulate the disease process. Using a canine model, Park et al., compared the migration rates of two covered colonic stents currently available for use only in Asia and Europe [25]. Such animal model could be a valuable tool in the assessment of the mechanical characteristics of SECS, however the time and costs invested in planning and performance of those experiments is substantial.

The ability to reliably guide the stent design, select the most optimal materials and test the migration properties early in the development is a "must" on the path of designing a novel high-performance gastrointestinal stent. Large animal studies should be reserved for late in the process, once the stent structure has been adequately validated in a reliable *ex vivo* model.

The significant advantage of an *in vitro*/*ex vivo* migration models has been proven in the development of vascular stents [27-30]. Such models were used to develop and pioneer abdominal aortic aneurysm stent grafts more than two decades ago. Secure proximal fixation of aortic stents is the key for long-term success. Failure to provide adequate fixation and the potential for graft migration are associated with catastrophic events. While the world of vascular stent grafts significantly evolved over the years, the development of sophisticated, high performance colonic stents is still in its early phase.

In order to test the validity of our novel colonic stricture model, we used a wide variety of currently available colonic stents used in human clinical practice. We investigated the migration properties of non-covered nitinol stents (WallFlex, Ultraflex, Niti-S D-Type), partially covered (Niti-S ComVi), completely covered (Choostent) and a biodegradable stents (Ella BD).

Generally, there are two main types of forces responsible for the adequate fixation of colonic stent to the wall of the intestine: the outward radial force and the friction of the stent wall towards the wall of the colon. The various stent designs address and alternate one or both of those characteristics. The results of our study illustrate how the stent design differences translate into higher or lower probability of the stent to migrate.

The stent behavior could be characterized based on their recorded force response curves (Figure 3). For instance, the WallFlex (Boston Scientific, USA) and the SX-ELLA (ELLA-CS, Czech Republic) stents are similar in their full-length braided constructions. Their responses during migration were similar as well, with a short increase to a plateau region followed by a marked increase in resistance force as the proximal stent end passed through the stricture. The structural similarity of WallFlex and SX-Ella is also responsible for the elongation capability of those stents resulting in the highest times required to migrate the stents (80.6s and 70.2s respectively).

Alternatively, the Niti-S D-Type and Niti-S ComViCOMVI Colonic Stents (Taewoong Medical, South Korea) have similar unfixed cell structures with weaving constructions and their force response curves are also comparable to one another. The close physical dimensions of those stents also contributed to their similar force responses with consecutive effect on the tissue (more pronounced than the WallFlex and SX-ELLA).

Among all six stents Ultraflex (Boston Scientific) reached the highest maximal pull out resistance force (7.9±0.9 N) and also required the highest total energy to migrate (168.3±30.5 J). Based on the results of our testing, this is the least likely stent to migrate. However, once the migration process began, it took the least amount of time for complete displacement. Those results were expected considering that Ultraflex colonic stent is relatively stiff and does not elongate due to the type of chain link of the nitinol wires. As such, it is non-compressible and exhibits the highest outward radial force among the tested stents. This is also evident based on the stent's delivery system; In order to load Ultraflex, the manufacturer folds the stent within the large (24 Fr) delivery sheath. In addition, Ultraflex has large gaps between the stiff nitinol wires that allow the colonic mucosa to prolapse and further fixate the stent to the colon wall. While the high outward radial force does stabilize the stent and helps to prevent migration, it is a risk factor for perforation.

On the other side of the spectrum, Wallflex achieved the least maximal pullout resistance (1.7±0.5 N) and required the lowest total energy for complete migration (57.2±10 N). It is an easily compressible stent resulting in significant elongation. Among all six stents, it required the highest time to completely migrate (80.6±1.8s).

In addition to the outward radial force provided by the nitinol wires, the length of the stent, in particular the size and the type of the surface are key in defining the ability of a stent to resist migration. Based on our results, the maximum pullout resistance force was not necessarily related to the total energy required for full migration. The Choostent (M.I. Tech, South Korea) with a tested length of 100mm required much higher total energy to pullout when compared to the Niti-S ComVi (testing length 60mm) despite having quite similar maximum pullout resistance forces.

The flare is an important feature that helps for proper stent positioning during the deployment. In addition, the flange contributes to the anti-migration features of the various SECS. Figure 3 shows how after the pullout resistance force reached an initial plateau, later in the migration process there is a local maximum corresponding to the flare. Those are most pronounced in the curves of the Wallflex and the SX-Ella stents. Further testing is needed in order to better quantify the contribution of the flare as an anti-migration stent feature.

The post experimental assessment of the tissue identified micro/macro perforations caused by the non-covered Niti-S D -Type (Figure 5C) and the partially covered Niti-S -Comvi (Figure 5E). Those two stents reached the highest forces before the onset of the migration (Table 4). The migration initiation force at the previously described inflection point was 3.7N for the Niti-S ComVi and 4.2N for the Niti-S D-Type stent. This force is an important measure since it represents the resistance that the stent has to overcome in order to start migrating. The higher the migration initiation force, the higher the pressure generated in the colonic wall and respectfully the higher the likelihood for injury and perforation. As such, both the Niti-S ComVi and the Niti-S D-Type caused a perforation during the experiments.

Based on our observations we do not claim causation but rather a possible correlation that has to be taken into account during the development of new stents. Further and more detailed experiments will be needed in order to better understand the relationship between tissue injury and maximal force reached at the time when the migration begins.

A number of limitations mitigate the power of our conclusions. There are differences in the function and physiologic response when testing *in vivo* colon and *ex vivo* colonic model. The lack of motility and muscle tone in addition to the lack of obstruction physiology of an *ex vivo* model will likely affect the migration of the various stents. However, our intent was not to substitute an *in vivo* colonic stricture model, but rather to develop a simple, reliable and easy to assemble *in vitro* tool that could help better understanding migration and efficiently guide the early GI stent development. The ease and accessibility of fresh porcine tissue makes our novel-testing model an attractive alternative that could be used repeatedly to test various stent characteristics and result in significant decrease of developmental time and costs.

In conclusion, our stricture model is the first dynamic *ex vivo* animal model that closely simulates human colonic stricture and tests stent migration. This model could be a valuable tool to help understanding the process of migration and steer the development of modern stent technology.

Authors Contributions

All of the listed authors contributed substantially in the design, development and execution of the experiments. Dr. Miroslav Peev designed the study, performed the experiments and wrote the manuscript. Russell Corwin, Andrew Harvey, Matthew Baird were closely involved in the design and development of the testing apparatus and also in the execution of the experiments. Dr. Jeffrey Milsom and Dr. Frederick Cornhill supervised the performance of all experiments and also the completion of the manuscript.

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