Design of Continuum Robot With Variable Stiffness for Gastrointestinal Stenting Using Conformability Factor

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***Abstract*—Stent placement in the gastrointestinal tract has emerged as an effective method of therapy for intestinal obstruction. In fluoroscopic guided stenting, clinicians first insert a hyper-elastic guidewire, and a stent introducer loaded with a compressed stent is passed along the guidewire to the desired deployment site. However, the high bending stiffness of the loaded stent introducer tends to straighten the inserted guidewire at the tortuous region. To overcome this issue, tubes of various stiffnesses are repeatedly inserted and removed. To optimize the mechanical properties of the devices for successful GI stenting, the interaction between the device and the environment should be considered as a key factor. In this study, conformability factor, a new index that abstracts the physical interaction for GI stenting was proposed. Based on the conformability factor, we proposed design requirements for variable stiffness continuum robots for GI stenting. The *in vitro* stent deployment experiment result shows that the proposed instrument can successfully deploy the loaded stent introducer without exchanging multiple tubes.**

***Index Terms*—Biomedical applications of radiation, catheters, gastroenterology, manipulators, medical robotics.**

I. Introduction

Stent placement in the gastrointestinal tract (GI) has emerged as an effective method of therapy for acute abdominal obstruction. During the procedure, a self-expandable metallic stent (SEMS) is compressed into a narrow tube called stent introducer, and deployed at the stenosed lumen under endoscopic or fluoroscopic guidance [1].

Generally, during a fluoroscopy-guided GI stenting procedure, radiologists first insert a guidewire through the patient's mouth. When the guidewire, inserted through the esophagus, contacts the gastric wall, the tip of the guidewire bends by axial reaction force from the gastric wall and slips into the duodenum (see Fig. 1(a)). A catheter is slid over and along the guidewire to opacify (visualize) the area of interest by injecting a contrast medium (see Fig. 1(b)). Finally, the catheter is removed, and a stent introducer loaded with a stent is slid over and along the guidewire for stent deployment (see Fig. 1(c)). However, a stent introducer loaded with the compressed stent is stiff compared to the inserted guidewire. The stiff stent introducer passing along the curved path formed by the guidewire generates straightening torque and as a result, the guidewire cannot maintain its path to the stent deployment location (see Fig. 1(d)). This limits the stiffness of the stents that can be loaded into the introducer. While the stiffer stents with high expansion force, or with additional cover can provide better treatment of the stenosed lumen, they cannot be used.

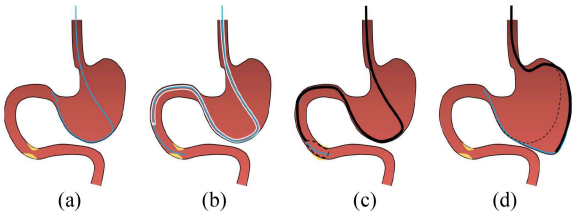

Fig. 1. Basic process of GI stenting procedure. (a) Guidewire (blue) is inserted (b) Catheter (white) is slid over (c) Stent introducer (black) is inserted for stent placement (d) Guidewire is straightened by stent introducer at tortuosity.

To resolve this issue, the percutaneous approach [2], [3], endoscopic guidance [4], and use of a guiding sheath [5] have been considered. The percutaneous approach requires incisions to insert a stent delivery tube, therefore, complications and infection risk increases [6]. Endoscopy is used to actively steer the guidewire through the working channel of the endoscope, eliminating the possibility that the guidewire becomes trapped in the GI tract. However, the method has some limitations, in particular, the discomfort caused by the endoscopy and an inability of the currently available large diameter stent introducers, which are designed for covered stents, to pass via the working channel [7]. The guiding sheath with a pre-curved tip can function as a supporting structure for the guidewire in the stomach during the stent introducer insertion. Although the usefulness of the guiding sheath in GI stenting was reported as a long-term retrospective study [8], delivering the stiffer or covered stents to the distal side of the duodenum is still limited because the guiding sheath can only reach the stomach.

Currently, for the best alternative solution, a soft guidewire is replaced by a super-stiff guidewire to maintain the curvature during the stent introducer insertion. In this process, multiple tubes (e.g., coil catheter and guiding sheath) are introduced, one over the other and then removed sequentially, gradually increasing the stiffness of the pathway until the stiff stent introducer can be passed without straightening the pathway [9], [10]. The repeated exchanging of the

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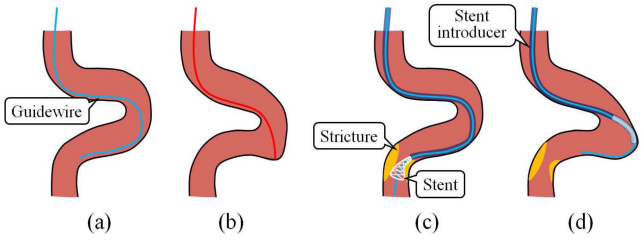

Fig. 2. Concept of conformability. (a) Soft guidewire is passing without tissue distension (b) Tissue distension increases when stiff guidewire is passing (c) Stent is deployed in appropriate position and direction when conformability is high (d) guidewire is moved by stent introducer in low conformability.

tubes is a time-consuming process, and radiation exposure increases with the number of fluoroscopic images taken to confirm the placement of each tubes. To decrease the number of tubes, a device that can maintain the pathway for passing tubes with a broad range of stiffness, is necessary.

In this study, conformability factor, a new index that abstracts the physical interaction between a tube being inserted and the environment that it passes through during GI stenting, was proposed. Based on the conformability factor, we proposed design requirements for variable stiffness continuum robots for GI stenting. Section II presents a new index-based method for determining the bending stiffness that affects the interaction between the tubes and the GI tract. The detailed design, working principle, and the manufacturing method are given in Section III. Section IV presents the related validation experiment. Section V concludes this study with future works.

II. Concept Design of Variable Stiffness Stent Delivery Tube

A. Observations From GI Intervention Process

During the insertion of the guidewire, the guidewire should be soft enough such that it bends and 'conforms' to the shape of the stomach when it contacts the surface of the stomach, in order to safely make a turn around the stomach wall and proceed to the duodenum. If the guidewire is too stiff, it can perforate the stomach wall instead of sliding along the wall (see Fig. 2(a, b)). On the other hand, during stent deployment, the stiff loaded stent introducer passing along the soft guidewire straightens the guidewire in the curved pathway, causing the tip of the guidewire to move away from the desired position (see Fig. 2(c, d)). In this case, the guidewire needs to be stiff enough that the stent introducer 'conforms' to the shape of the guidewire as the introducer passes along the guidewire.

This observation leads to an idea that the relative bending stiffness between the tube being inserted and the environment that it passes through, for example, the bending stiffness between the guidewire and the gastric wall during guidewire insertion process, and between a stent introducer and a guidewire during stent deployment process, is important. In other words, the fundamental physical process that is repeated during the GI stenting procedure is the process of inserting one tube through another tube that serves as an environment which the inserted tube passes through. While the exact physical modeling for this process of inserting a tube through an environment during the GI stenting process will be complex, it can be abstracted as an interaction between the two elastic objects. Thus, the relative bending stiffness between the environment and the inserted tube will have a considerable influence on the outcomes of GI stenting.

B. Conformability Factor

When we investigate the GI stenting procedure from this perspective, the GI stenting process can be facilitated or prevented depending on how the interaction between the tube and the environment is controlled by choosing an appropriate bending stiffness of the tube. Based on these observations, we suggest a design variable called conformability that measures the relative ratio of bending stiffness between the environment and the inserted tube and how conformable one is to the other.

TABLE I
Bending Stiffness of Interventional Devices

Device	Bending stiffness (Nmm^2)
Soft guidewire (Φ0.89, Terumo, Ni-Ti)	1,957
Stiff guidewire (Φ0.89, Boston Scientific, steel)	6,256
GI Stent introducer	7,157
Coil Catheter (S&G Biotech)	4,721
Guiding Sheath (Φ6, PTFE)	12,944
GI Stent (S&G Biotech)	2,770 – 3,984

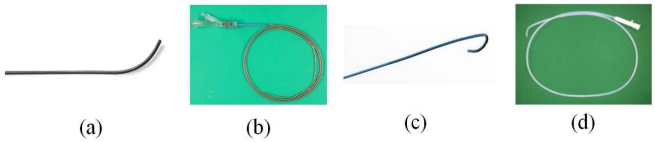

Fig. 3. Interventional devices for fluoroscopic-guided stent placement. (a) Soft guidewire (RADIFOCUS, TERUMO, Inc.) (b) Coil catheter (S&G Biotech, Inc.) (c) Super-stiff guidewire (Amplatz, Boston Scientific, Inc.) (d) Pre-curved guiding sheath (S&G Biotech, Inc.).

The conformability factor C between the environment and the inserted tube is defined as the bending stiffness of the environment normalized by the bending stiffness of the inserted tube, as follows:

$$C = \frac{EI_{ENVIRONMENT}}{EI_{INSERTED\ TUBE}} \tag{1}$$

where E is the elastic modulus and I is the area moment of inertia.

The conformability depends on which tube is chosen as the "environment" or the "inserted tube". For example, during the guidewire insertion, the gastric wall is the environment and the guidewire is the inserted tube, if the conformability is high, the guidewire will 'conform' to the geometry of the stomach (see Fig. 2(a)). On the contrary, the stomach is deformed when the stiff guidewire is inserted (see Fig. 2(b)). During the stent deployment, the guidewire becomes the environment and the stent introducer is the inserted tube. If conformability is high, the stent can be deployed in the appropriate position and direction as the inserted guidewire can maintain its shape while the stent introducer passes (see Fig. 2(c)). However, conformability decreases as the stent introducer becomes much stiffer than the environment and as a result, the guidewire is straightened by the stent introducer (see Fig. 2(d)).

To investigate the conformability factor of interventional devices for fluoroscopic-guided stent placement (see Fig. 3), the bending stiffnesses of the stents and stenting devices were measured using the 3-point bending test (see Table I). Through the measured bending stiffness of each device and stent, the conformability factor of different combinations for each step of typical GI stenting procedures is calculated and shown in Table II.

Based on the conformability analysis, stiffness requirements of a new device for GI stenting that can decrease the number of procedural steps and allow the use of stiffer stents with higher expansion forces were deduced and shown in Table II. When the soft tissue is considered as the environment and the inserting tube is the guidewire, the bending stiffness of the new device should be relatively low as the conformability factor is close to 1. On the contrary, when the

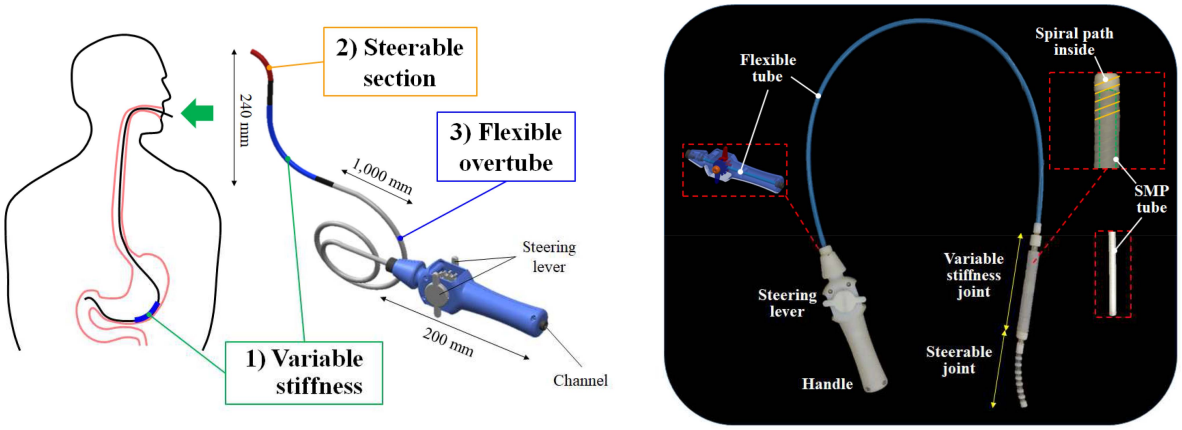

Fig. 4. Continuum robot for GI stenting. (a) Concept of continuum robot with three components: steerable joint, variable stiffness joint, and flexible overtube (b) Prototype of continuum robot.

TABLE II
CONFORMABILITY FACTOR OF GI STENTING DEVICES

	Environment	Inserting Tube	*C*
General process			
Step 1	Organ	Soft guidewire	-
Step 2	Soft guidewire	Coil catheter	0.42
Step 3	Soft guidewire	Stent introducer	0.27
Alternative solution (Current)			
Step 1	Organ	Soft guidewire	-
Step 2	Soft guidewire	Coil catheter	0.42
Step 3	Coil catheter	Stiff guidewire	0.75
Step 4	Stiff guidewire	Guiding sheath	0.48
Step 5	Stiff guidewire + Guiding sheath	Stent introducer	2.68
Stenting using a new device			
Step 1	Organ	Soft guidewire	-
Step 2	Soft guidewire	New device	**> 2**
Step 3	New device	Stent introducer	**> 2**

stent introducer is passing, the device (environment) should be stiff enough to maintain its shape. From this concept, a continuum robot for GI stent delivery should maintain a conformability factor higher than 1, desirably higher than 2, with the changing environment and tubes. This leads to the design requirements for a new device with variable stiffness.

III. CONTINUUM ROBOT WITH VARIABLE STIFFNESS

A. Design Requirements

The overall design concept was shown in Fig. 4(a). The design requirements of the continuum robot were considered based on the gastrointestinal system anatomy and the form factor analyses of the conventional devices for GI stenting, such as a guidewire, coil catheter, guiding sheath, and flexible endoscope. With the consideration of the upper gastric system anatomy [11], the new device was designed to be 1,200 mm in length and 5/7.5 mm in inner/outer diameter. Under these form factor constraints, the proposed device should have a variable stiffness joint that can maintain a conformability factor of 2. Thus, a variable stiffness mechanism satisfying the desired bending stiffness range (979–16,742 Nmm^2) was considered. A steerable joint was embedded to control the orientation of the tip when the variable stiffness joint is in the rigid state, which can achieve bi-curvature bending considering the GI tract anatomy. The steering capability enables delicate direction control during stent placement. The steering mechanism for the new device was selected under the consideration of the limited space in the tubular structure and the motion range. The pull-wire mechanism is advantageous in terms of simplicity and force transmission for far side actuation. Two sets of wires form an antagonistic pair.

B. Fabrication

A variable stiffness tube was fabricated using a 3D printable shape memory polymer (SMP). SMPs can maintain arbitrary shape with frozen strain by phase transition. This characteristic is suitable for designing devices with specific form factor limitations in medical applications. Polyurethane-based SMP filament (Kyoraku, Japan) with glass transition temperature of 55°C and maximum strain variance of 400% was used to fabricate a tubular joint with an off-the-shelf 3D printer (Prusa i3 MK3S, Prusa Research, Czech). The bending stiffness of the SMP joint (Outer diameter: 7.5 mm, inner diameter: 6 mm) was 119 Nmm^2 in the soft state and 34,408 Nmm^2 in the rigid state. This satisfies the conformability requirements for the continuum robot for GI stenting. To trigger the phase transition by raising the temperature, a silicon tube that can circulate cold or warm water was overlapped onto the SMP tube. The outer silicon tube consists of a dual spiral path that was made by a multi-layer molding process and an inner sheath (PTFE). The water is circulated inside the PTFE tube using a DC pump. The steerable joint was made of silicone rubber (KE-1606, Shin-Etsu, Japan) by the molding process. Rigid parts (including a handle) that fix and connect all components are fabricated by a high-precision 3D printer (Objet 260, Stratasys, U.S.). The steering wires (Flexinol, Dynalloy, U.S.) are passed through the backbone rings and fixed to the distal tip. Fig. 4(b) shows the prototyped continuum robot for GI stenting.

IV. EXPERIMENTS

To validate the feasibility of the prototyped continuum robot, variable stiffness characteristics were tested with an actual GI stent delivery process. When the SMP joint is in the soft state, bending configurations are determined by two joints (see Fig. 5(a, b)). As illustrated in Fig. 5(c), with the SMP joint in the rigid state, an S-curve configuration can be achieved by tension in the opposite direction. However, when the SMP joint is in the soft state, steerable sections are straightened by the stent introducer with a loaded stent (see Fig. 5(d)). When the SMP joint is deactivated, the GI stent can

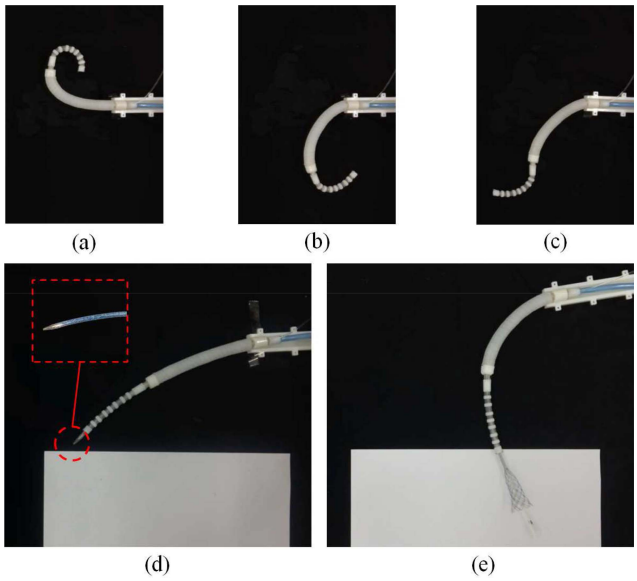

Fig. 5. Manipulation test using continuum robot. (a) Bending with SMP joint in soft state (b) Lower bending motion (c) Upper bending with SMP joint in rigid state (d) SMP joint in soft state are straightened by stent introducer loaded with stent. (e) Stent is deployed with desired curvature (SMP joint is in rigid state).

be successfully deployed with the desired direction, as exemplified in Fig. 5(e).

V. Discussion

This study proposed a new design principle for GI interventional devices. The proposed index, conformability factor was used to design an optimized tube that can be used in GI stenting procedures. A continuum robot with variable stiffness for GI stenting was designed and prototyped with consideration of the conformability factor. The *in vitro* stent deployment experiment result shows that the proposed instrument can successfully deploy loaded stent introducers without exchanging multiple tubes. The proposed robot will function as a guiding manipulator for GI stenting with high conformability.

Future works related to this involve:

- modify the conformability factor for multi-curvature
- investigate bending stiffness of the soft tissue
- in-vivo test using the proposed continuum robot.

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