Development of an Endoscopic Continuum Robot to Enable Transgastric Surgical Obesity Treatment

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Abstract. This paper presents the development of an endoscopic continuum robot for surgical obesity treatment using a transgastric approach. This proposed transgastric gastroplasty approach performs suturing and resizing of a stomach from inside, aiming at further reducing postoperative complications by avoiding the use of skin incisions. The presented design can be inserted into the stomach in a folded configuration and can be unfolded into a working configuration to perform surgical interventions. It uses sutures fabricated from pre-curved super-elastic NiTi (Nickel-Titanium) alloy to facilitate the motion of tissue penetration. Role of the NiTi needle is demonstrated in in-vitro tissue penetrating experiments, while deployment of this endoscopic robot was verified on the prototype.

Keywords: continuum robots, surgical robots, endoscopic robots, NOTES, obesity treatment.

1 Introduction

Obesity has become a public health concern in the United states and Europe because of its fast prevalence in the past decades [1, 2]. It is widely accepted that morbid obesity is often associated with diabetes, dyslipidemia, cardiovascular diseases, etc. Although various methods could be used for obesity control (e.g., behavior therapy and pharmacologic intervention), surgery remains the most effective treatment of morbid obesity [3]. Current surgical interventions mainly include i) gastric restrictive methods (e.g. Vertical Banded Gastroplasty, VBG [4], Laparoscopic Adjustable Gastric Banding, LAGB [5], Laparoscopic Sleeve Gastrectomy, LSG [6]), ii) malabsorptive procedures (e.g. jejunoileal bypass [7], Laparoscopic Roux-en-Y Gastric Bypass, LRGB [8]), and iii) combination of the two methods (e.g. VBG-RGB procedures [9]).

Although the surgical treatment is quite effective, it is only considered for patients with morbid obesity (Body Mass Index, BMI over 40 kg/m^2), because of high postoperative complication rates and many premature deaths even when most procedures were performed laparoscopically [3]. If the postoperative complications

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and premature deaths could be further reduced, surgical treatment for obesity might be applied to a greater population with mild obesity.

NOTES (Natural Orifice Translumenal Endoscopic Surgery) might be a way to further reduce postoperative complications. NOTES is a recent development after the minimally invasive laparoscopic procedures. It uses patient's natural orifices (e.g. vagina, esophagus and stomach, etc.) for surgical interventions [10, 11]. Recent clinical studies [12] and many animal studies [13] have shown NOTES effective in further diminishing postoperative complications. Encouraged by these results, a NOTES gastroplasty (it is transgastric in this case), which performs suturing and resizing of a stomach inside the stomach, could possibly greatly reduce the postoperative risks. Hence surgical treatment could be potentially offered to more patients with mild or moderate obesity.

An endoscopic continuum robot shown in Fig. 1 was designed and constructed to verify design concepts which could lead to the accomplishment of a NOTES gastroplasty.

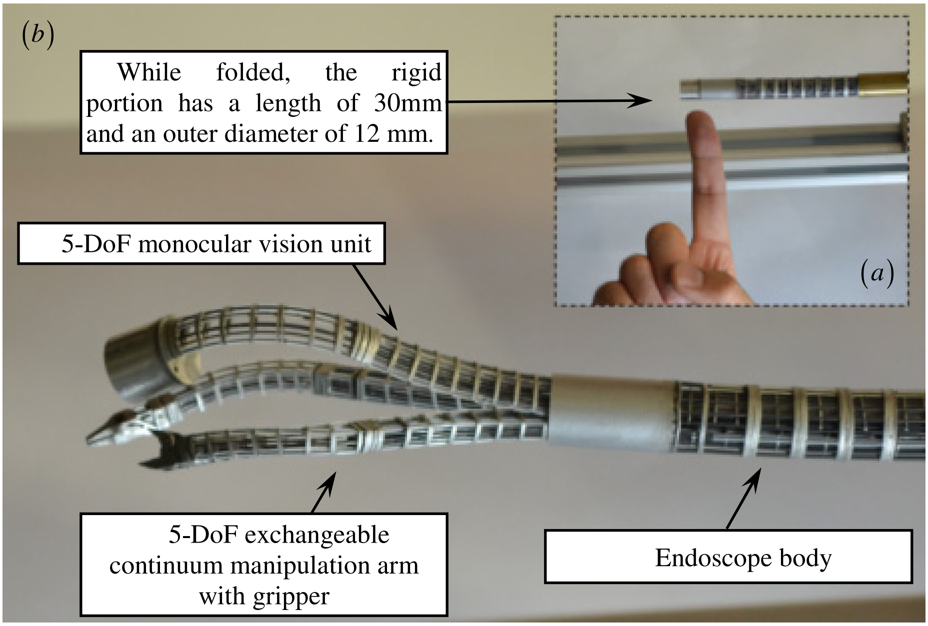

Fig. 1. Design of an endoscopic continuum robot for transgastric gastroplasty: (a) the folded configuration and (b) the unfolded working configuration

In order to accomplish a transgastric gastroplasty, an endoscopic robotic device which could effectively perform suturing and knot tying in confined spaces will be needed. This robot could also be useful in other NOTES procedures to close incisions in walls of stomach or vagina. Previous studies showed that, if a traditional rigid circular suture is used, suturing (and knot tying) in confined spaces is still very difficult even when the task was assisted by robots [14-16] or it was manually performed using a specially designed endoscope [17]. The design shown in Fig. 1 was conceived to overcome these difficulties.

This design is inspired by the work done by Xu *et al* [18] where a robotic system is designed for SPA (Single Port Access) laparoscopic surgery. In the folded configuration, the current device would be easily swallowed by patients; after deployed into the stomach, the device can perform operational procedures in an unfolded configuration. The use of pre-curved NiTi needle is inspired by the work done by Webster *et al* [19, 20] and Dupont *et al* [21] where continuum robots made from pre-curved concentric NiTi tubes were studied for navigation and drug delivery.

Major contribution of this paper is the proposal of using continuum robots and pre-curved super-elastic suture to facilitate both suture penetration and knot tying. Minor contribution is the presentation of one possible design to realize this proposed concepts.

The paper is organized as the following. Section 2 presents design requirements and a new surgical concept on how a NOTES gastroplasty could be performed. System overview and detailed design descriptions are presented in Section 3. Prototype deployment are presented in Section 4 with conclusion and future work followed in Section 5.

2 Design Requirements and Surgical Concepts

A NOTES (transgastric) gastroplasty demands a endoscopic robotic device with the following capabilities:

1) The device should be foldable to facilitate its insertion into stomach through pharynx and esophagus. Gastroscopes from Olympus® have outer diameters from 11.3mm (GIF-1TQ160) to 12.6mm (GIF-XTQ160), while existing endoscopes for NOTES [17] usually have outer diameters from 14.3mm (Olympus "R" scope) to 18mm (USGI Transport scope). The presented design shall have a comparable or smaller diameter (currently 12mm).
2) The device can deploy itself into a working configuration for suturing, knot tying, ablation, etc.
3) Additional channels should be available for insufflation, manipulation tools for knot-tying, ablation, etc.
4) The device can be positioned and oriented to achieve suturing and knot tying within the entire stomach. This can be achieved by placing the device at the distal tip of an endoscope such as the ShapeLock® [22].
5) The device has a vision unit with integrated illumination.
6) The device is actuated by its actuation unit located outside patient's mouth.

Using such an endoscopic robotic device with these aforementioned capabilities, a transgastric gastroplasty can be achieved in many ways. One possibility is shown in Fig. 2. This endoscopic robotic device will firstly be inserted into the stomach. Medical balloons can be placed near pylorus so that the stomach can be sealed and inflated. After enough space is created, the device deploys itself into the working configuration to perform suturing. A lockable band could be attached to the inner wall of the stomach by multiple stitches. After the robotic device is retracted, the band can then be tightened and locked to create a small pouch to achieve the stomach resizing.

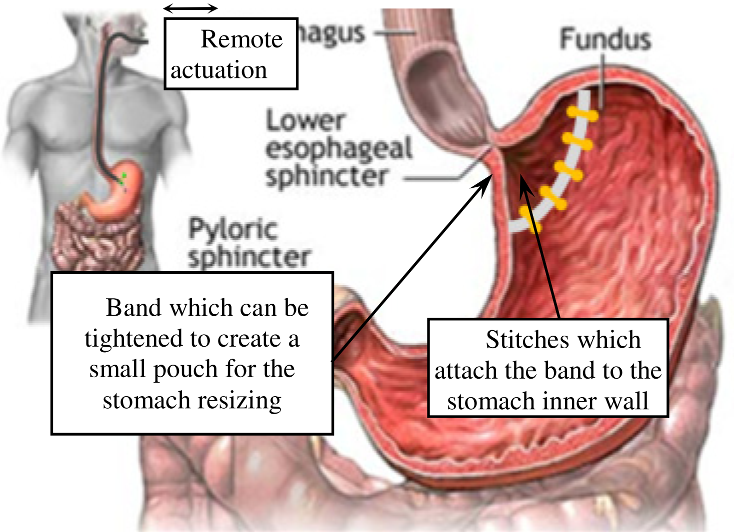

Fig. 2. Schematic drawing of a proposed new surgical concept for stomach resizing. The stomach diagram is from the University of Maryland Medical Center Encyclopedia.

3 System Overview and Design Description

The endoscopic stitching device in Fig. 1 was conceived to meet the requirements mentioned in Section 2. In the folded configuration, the device can be inserted into stomach through the esophagus. Its forward-looking vision unit could guide the surgeons through the insertion phase. In the stomach, the device first inflates the stomach to generate enough space for its unfolded working configuration. Suturing and knot-tying can then be performed. The deployment process is experimentally verified by the prototype shown in Fig. 10.

As shown in Fig. 1, the device consists of one 5-DoF (Degrees of Freedom) monocular vision unit and two 5-DoF snake-like exchangeable continuum manipulation arms with grippers. The continuum manipulator arm can be replaced by sensor modules (e.g. an ultrasound probe) or energy sources (e.g. a cautery).

Within the vision unit and the manipulation arms, there are continuum segments as shown in Fig. 3 and Fig. 4. A structural similarity shared by these continuum segments is that these continuum segments consist of a base disk, a end disk, several spacer disks and several backbones (made from super elastic nickel-titanium alloy). Backbones are attached to the end disks and can slide in holes of spacer disks and base disks. Synchronized pushing or pulling of these backbones deflect the segments into desired shapes. Actuation unit of these backbones will remain outside patient's month, as indicated in the inset of Fig. 2. Motion discrepancy caused by backlash or friction might be compensated as in [23]. Design considerations and solutions for critical components will be discussed as follows.

3.1 Vision Unit

CAD design of the 5-DoF monocular vision is shown in Fig. 3. Once inserted into stomach, the vision unit can be extended to provide space for the deployment of manipulation arms, as shown in Fig. 10.

As shown in Fig. 3, the vision unit consists of continuum segment I with three DoFs, segment II with two DoFs and the monocular camera head. Both segment I and segment II can bend sideward any direction, which is a 2-DoF bending motion. The additional DoF of the segment I is its variable length when extended from the endoscope.

CCD chip intended for the camera head is the chip CSH14V4R1 from NET Inc. with an outer diameter of 6.5mm. Since the diameter of the camera head is 12mm, only one CCD chip can be fitted in. If a smaller CCD chip can be used, the vision unit can be easily turned into a stereo vision. Camera field of view is also considered in the CAD model to make sure manipulation of the inserted arms will be seen.

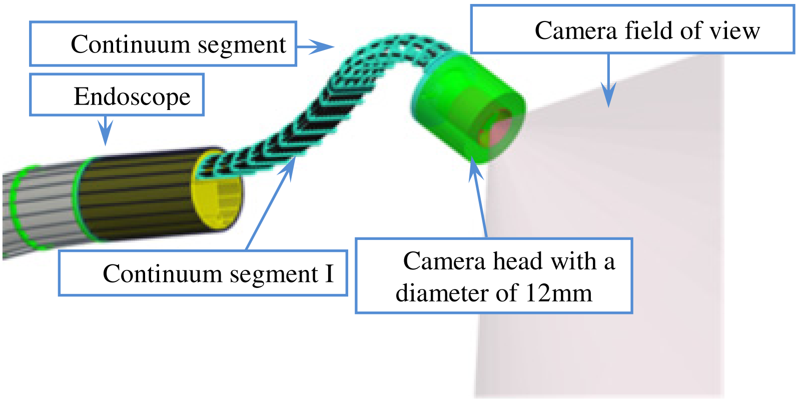

Fig. 3. The 5-DoF monocular vision unit

3.2 Continuum Manipulation Arms

CAD design of the 5-DoF exchangeable continuum manipulation arm is shown in Fig. 4. After insertion into one's stomach, the vision unit extends itself to provide space for the continuum manipulation arm to be deployed as shown in Fig. 10.

As shown in Fig. 4, the continuum manipulation arm consists of continuum segment I with three DoFs, segment II with two DoFs and a gripper integrated with a suture. Both segment I and segment II can bend sideward any direction, which is a 2-DoF bending motion. The additional DoF of the segment I is its variable length when extended from the endoscope.

Function of the suture will be detailed in the next session.

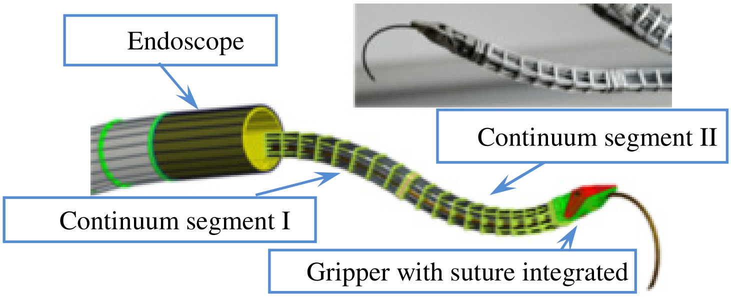

Fig. 4. The 5-DoF exchangeable continuum manipulation arm with a gripper attached and a NiTi suture embedded: the inset shows the prototype

Within all the segments, significantly redundant backbones are used in order to increase the stiffness of the continuum arms.

3.3 Super-Elastic Nickel-Titanium Suture

Key innovation introduced in this paper is to fabricate the suture using super-elastic nickel titanium alloy to facilitate tissue penetration. When a traditional rigid circular suture is used, suturing motion involves a distal rotation along an axis normal to the suture plane, passing through the suture's center. Using a pre-curved super-elastic NiTi suture could greatly simplify this tissue penetration motion. When the suture is housed in a rigid housing as shown in Fig. 5, the pre-curved super-elastic NiTi suture will be forced straight; when the suture is pushed outwards, it will bend back to its original circular shape, penetrating tissues in a circular path to facilitate the tissue penetration motion.

The NiTi suture will be housed in the rigid gripper during insertion of the endoscopic robotic device. Since the length of this rigid components is limited, the size of the suture can then be determined. According to literatures (e.g. [24]), super-elastic NiTi alloy usually has an elastic strain ranging from 4% to 6%. If a 4% strain is allowed,

$$\varepsilon_{strain} = r_{needle} / R_{suture} \leq 4\% \Rightarrow r_{needle} \leq 0.04 R_{suture} \quad (1)$$

Where r_{needle} is the radius of the needle's round cross section and R_{suture} is the radius of the suture.

If a 3π/4 suture with a length of 20mm will be used,

$$3\pi R_{suture} / 4 = 20mm \quad (2)$$

$$R_{suture} = 8.49mm \xrightarrow{r_{needle} \leq 0.04 R_{suture}} r_{needle} \leq 0.34mm \quad (3)$$

In the design and in the in-vitro tissue penetrating experiments, a NiTi tube with an outer diameter of 0.69mm is then used. Although this selection does not comply with Eq. (3) strictly, strain slightly over 4% usually still falls in the elastic region for super-elastic NiTi alloy.

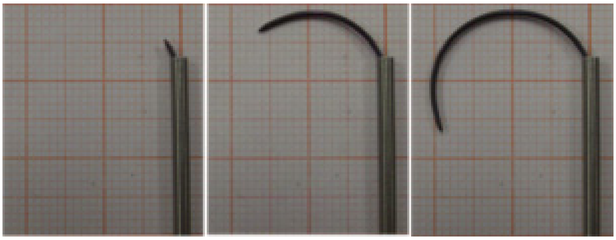

Fig. 5. A Ø0.69mm suture made from pre-curved NiTi alloy: it bends back to its original circular shape after released from a straight rigid housing. The suture's radius is about 9mm. Thinnest grids in the background are 1mm x 1mm.

The idea of using a NiTi suture to facilitate tissue penetration is also validated by an in-vitro experiment on a porcine model as shown in Fig. 6: (a) the suture housing approached the tissue and (b) then pushed against the tissue; (c) the NiTi suture was pushed out to start the penetration; (d) and the suture generated a circular cutting path; (e) it was shown this penetration could grip enough tissue; (f) the suture could be retracted back to the housing to carry out a second penetration.

Using a pre-curved super-elastic NiTi suture only simplifies the motion tissue penetration. To achieve a complete stitch, a suture thread should be guided through the tissue as well. The proposed idea is to insert a thread through channel in the NiTi suture which is made from a tube. As shown in Fig. 7, one end of the thread is hung outside the suture. During tissue penetration, the thread will be brought through the tissue by the non-cutting edge of the suture tip. After penetration, the thread will be picked up by the other manipulation arm, before the suture is retracted. After the suture is retracted, the thread is left through tissue and ready for knot tying.

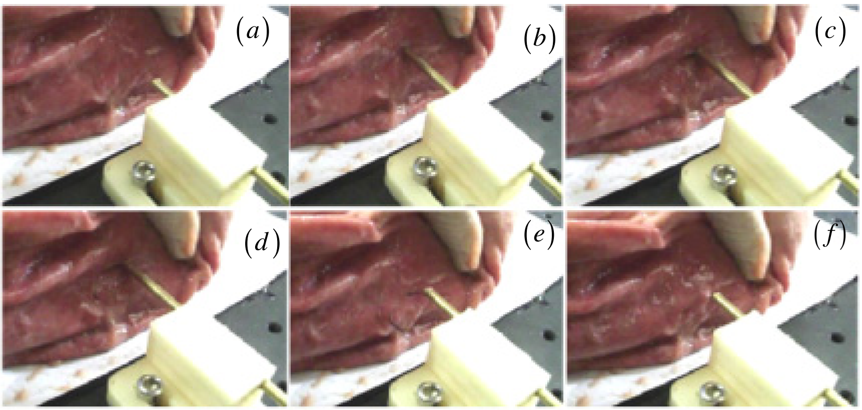

Fig. 6. In vitro tissue penetrating experiments: the Ø0.69mm NiTi suture penetrates and grips a porcine stomach wall

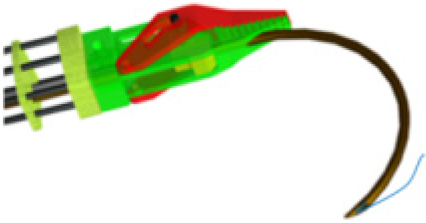

Fig. 7. The suture thread passes through the channel in the NiTi suture

3.4 Knot Tying Using the Manipulation Arms

Each continuum manipulation arm has five degrees of freedom while during knot tying, a point on a thread will need to follow a spatial curve which only requires three degrees of freedom. With proper dimension synthesis, knot tying could be realized.

Comparable results have been reported in [15] where continuum robots with similar structures realized knot tying, as shown in Fig. 8. These results combined with the results from Section 3.C proved that the proposed robotic device could realize endoscopic suturing hence potentially suitable for transgastric surgery of stomach resizing.

Workspace analysis and instantaneous kinematics of such a continuum manipulation arm are available in [15, 18].

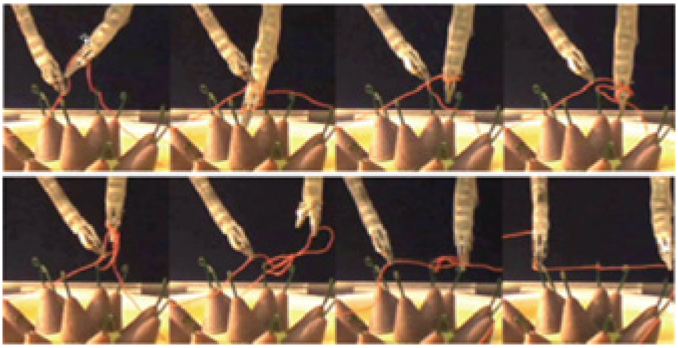

Fig. 8. Knot tying was achieved by continuum robots with similar structures as in [15]

3.5 Actuation Unit

The presented endoscopic continuum robots have 15 DoFs for the monocular vision unit and two manipulation arms. Each arm also has two addition elements to drive which are the NiTi suture and the gripper.

Due to the limits on the budget, the actuation unit was not motorized yet. All the actuation, including pushing and pulling of all the backbones, sutures and grippers, are all currently manual. Fig. 9 shows the endoscopic continuum robot assembled with the manual actuation unit.

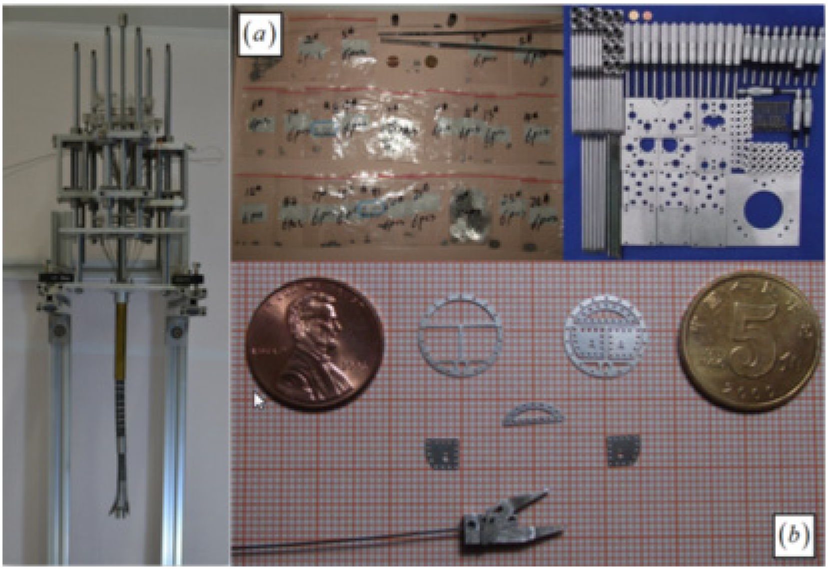

Fig. 9. The endoscopic continuum robot assembled with the manual actuation unit: (a) all the components of the endoscopic continuum robots and (b) a few components with respect to US and Chinese coins on a piece of graph paper

4 Experimental Validation of the Prototype

Motivation of this presented work is to valid a few design concepts: i) suture made from super-elastic NiTi alloy could facilitate the tissue penetration, ii) the current design can enter the stomach in a folded configuration and then be deployed into a working configuration. Other functionality, such as ability of tying a knot, has been proved by previously published results.

While the tissue penetration has been demonstrated in Fig. 6, the deployment of this endoscopic device is shown in Fig. 10: (a) after the endoscopic device is inserted into a stomach in a folded configuration, (b) the monocular vision unit starts extend itself, (c) after the vision unit is extended to the intended length, the vision unit starts to bend sideward and (d) reaches a desired pose; space is generated so that (e) continuum manipulation arms can be inserted; (f) the two manipulation arms can be inserted individually or together; (g) after the two arms are fully inserted, the arms can be actuated to (h) form various poses for surgical interventions. Since the actuation unit is not motorized, poses in Fig. 10 are all generated by manually actuating the backbones of the continuum segments. The exchangeable manipulation arm can also be replaced by sensor modules (e.g. an ultrasound probe) or energy sources (e.g. a cautery).

Preliminary tissue penetration experiments were also carried out on a porcine model using the current prototype, as shown in Fig. 11

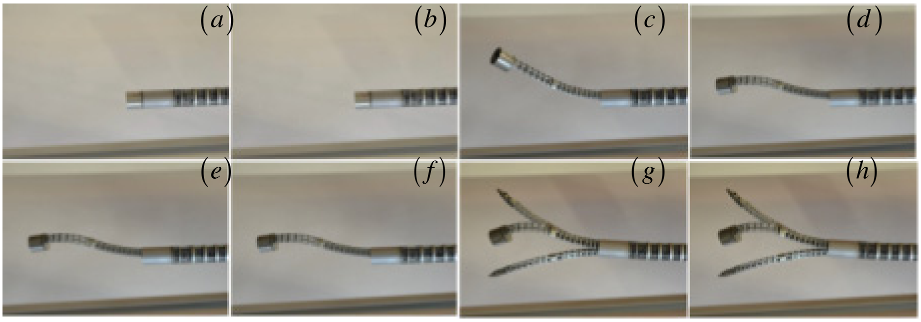

Fig. 10. Deployment of the endoscopic robotic device

Fig. 11. Preliminary tissue penetration experiments using the presented prototype

5 Conclusion and Future Work

This paper proposed a design of an endoscopic robotic device for transgastric surgical obesity treatment. This proposed transgastric gastroplasty using a NOTES approach performs suturing and resizing of a stomach from inside, aiming at further reducing postoperative complications hence making surgical obesity treatments available for a bigger population with mild obesity.

The prototype of this endoscopic continuum robot was constructed to verify the proposed ideas, which is a updated version of the design presented in [25]. Experiments showed that the current design can be inserted into the stomach in a folded configuration and can be unfolded into a working configuration to perform suturing and stitching. It uses pre-curved super-elastic NiTi alloy suture to facilitate the motion of tissue penetration. Suture thread can also be delivered through the hollow suture since the suture is made from a tube. Since knot tying had been realized by a laryngoscopic robot with similar structure as shown in Fig. 8, conclusion can be extended that the current design potentially has all the desired capabilities to perform a transgastric stomach resizing.

Future work regarding this design includes i) motorizing the actuation unit so that knot tying can be actually verified using the current prototype; ii) investigating control algorithm using inverse kinematics so that master controllers, such as the Phantom Omni® devices from the Sensable Inc., can be used to control this endoscopic robot.

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