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A Flexible Endoscopic Robotic Suturing System for Gastrointestinal Perforations: Animal Study

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INTRODUCTION

Gastrointestinal perforations may be caused due to complicated flexible endoscopic procedures such as Endoscopic Submucosal Dissection (ESD), Endoscopic Full-Thickness Resection (EFTR), and Natural Orifice Transluminal Endoscopic Surgery (NOTES). The most reliable approach of closing gastrointestinal perforations is by suturing which, however, is usually done through open or laparoscopic surgery. Suturing through flexible endoscopic procedures is highly desirable but challenging due to the confined space of the lumen and target area, high dexterity and force demands of suturing tasks, and critical size and strength requirements of the closure. Although two endoscopic defect closure devices exist on the market, i.e., Over-The-Scope Clip (OTSC, Ovesco Endoscopy Inc., Germany)[1] and OverStitich (Apollo Endosurgery Inc., US)[2], both devices are not for standard suturing due to the use of clips or fastening elements, and they are limited with large sizes and the lack of dexterity or tool triangulation.

We developed a flexible endoscopic robotic suturing system [3] which can endoscopically close gastrointestinal wounds with standard stitches and knots using a robotic suturing arm (Ø4.4 mm) and a grasping arm (Ø4.2 mm). Both arms are flexible, through-the-scope, and have five Degrees Of Freedom (DOFs). This paper presents an in-vivo test of this system suturing an incision on the rectum wall of a live pig.

MATERIALS AND METHODS

The two robotic arms, remotely controlled by a surgeon via a master console, can be inserted through the two tool channels of a customized endoscope which is controlled by an endoscopist. This through-the-scope feature enables tool exchange without withdrawing the endoscope during surgery. As shown in Fig. 1a, the suturing arm is a five-DOF grasper (gripping, yaw, pitch, roll, and translation) with two jaws. The double-point lancet needle (gauge 21, 10 mm long) can be inserted into the needle receiving holes on the two jaws. The needle can be switched between the jaws by a pair of tendon-sheath-driven locking blades (Fig. 1 b and c) which can be translated to engage or disengage with the notched slots (Fig. 1 b) on the needle tips. During suturing, the 10-mm-long needle is locked to one of the

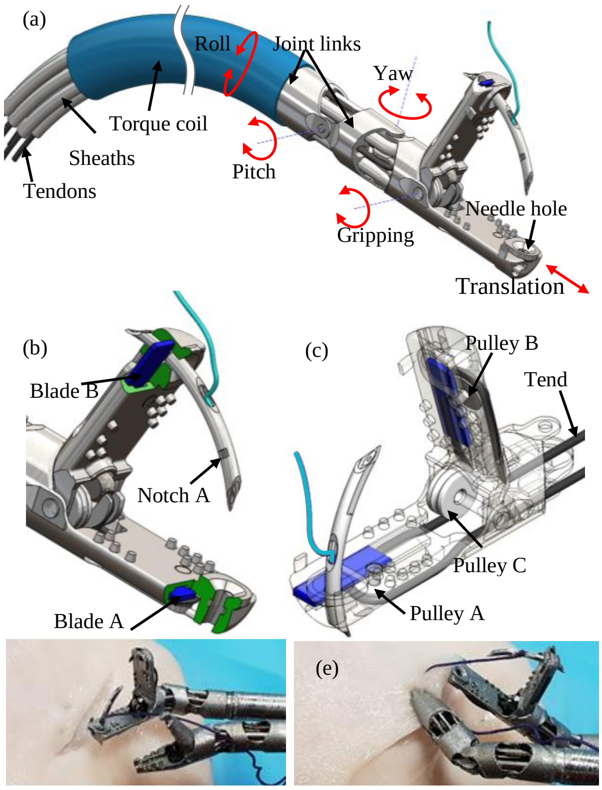

Fig. 1 (a) suturing arm; (b) needle and blade engagement, (c) tendon-controlled blades, (d)-(e) working prototype.

two jaws, resulting in a profile of the suturing device much larger than the endoscope tool channel(Figure 1a~c); thus, a nitinol guidewire was proposed to deploy the needle so that the suturing arm can be delivered through the endoscope channel [3]. The grasper arm is a simplified version of the suturing arm without the needle manipulation mechanism. The prototypes of the two arms are shown in Fig.1d-e.

This suturing system was tested via an in-vivo study on a live pig (about 70 kg) with ethical approval (NO.: INH2018/017). The setup of the animal study is shown in Fig. 2. A colonoscope was inserted into the rectum of the pig under general anesthesia. A 10 mm submucosal incision was cut in advance. Then, the robotic arms were inserted to the incision site through the two working channels of the colonoscope. The needle was deployed

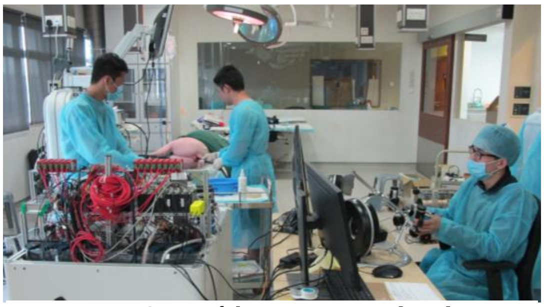

Fig. 2 Setup of the in-vivo animal study

through a nitinol guidewire. Four running stitches were made for the incision, followed by a Surgeon's Knot by passing the needle through suture loops. Stitching and knot-tying were intuitively teleoperated by the operator via the robotic system through the master console. The suture was then cut; the needle and the instruments were withdrawn through the endoscope channels. The pig was euthanized after the procedure.

RESULTS

It took around 3 minutes to deploy the needle and withdraw the guidewire. Fig. 3 shows the suturing process. The suturing arm on the right pointed the needle tip to the desired stitching point (Fig. 3b) and to the suture loop (Fig. 3d). Meanwhile, the grasper on the left helped lift and feed the tissue to the suturing arm as well as handling the suture thread. By translating the two arms into opposite directions, the knot was securely tightened (Fig. 3e). After the closure, the suture was cut, and the needle was completely released from the suturing device and subsequently taken out by the grasper. The times spent on stitches and knot (three throws) were 11 mins and 4 mins, respectively.

DISCUSSION

The needle locking mechanism was reliable and ensured successful needle switching during the trial. When the needle penetrated through tissue, the rotating jaw always had a snapping motion and the needle tip became visible, both of which indicated that the needle was ready to be switched. The needle could then be easily switched by pressing the associated button on the handle of the right haptic device. This approach made needle manipulation easy. In this trial, the robotic grasper played an important role in lifting and feeding the tissue to the suturing arm as well as handling the suture thread. The cooperation between the two arms made suturing more natural and intuitive. The five DOFs of the two arms were vital for tool triangulation which naturally suits suturing tasks while other existing devices [1-2] have only one arm without triangulation. In particular, the rolling DOF ensured that the grasper/needle could grasp/puncture tissue edges at any desired orientations, which is necessary for incisions with random orientations. Moving the tip of the endoscope was occasionally needed to help the arms reach the suture or tissue in difficult scenarios. The through-the-scope feature is particularly useful when a new needle needs to be used for additional stitches. The feasibility of deploying the needle using a nitinol guidewire was also confirmed robust. Suturing in this trial took much longer time than previous ex-vivo trials [3] because of the limitation of

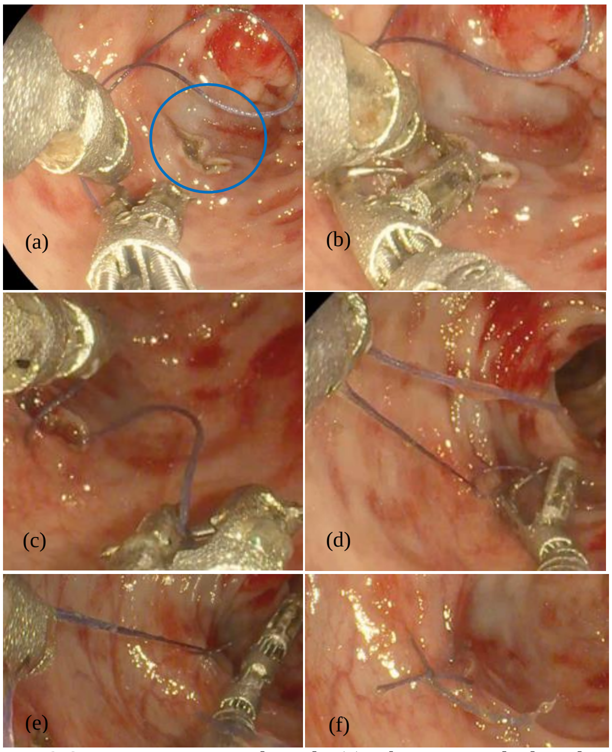

Fig. 3 Suturing process and result. (a) robotic arms deployed at the incision site (the blue circle); (b) driving the needle through the tissue; (c) four stitches made; (d) creating knots by passing the needle through suture loops; (e) securing the knots by translating the robotic arms into opposite directions; (f) suture was cut, and incision was closed.

the system in sealing insufflation gas. The time can be significantly shortened with proper insufflation. The jaws, with unilateral opening, can be opened with 78 degrees and thus the suturing device can maximally bite tissue with 3.4mm thickness while the thickness of stomach and colon tissue is normally within 3mm. Further development with bilateral opening jaws can enhance the reach of the instruments, and thicker tissue would be handled easier.

This in-vivo trial confirms that the system can be used to endoscopically make standard stitches and knots (not possible with existing devices) in a realistic surgical scenario. It is expected that this system be used to close defects or perforations in ESD, EFTR, and NOTES, etc.

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