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A Novel Robotic Suturing System for Flexible Endoscopic Surgery

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Abstract—Perforations in flexible endoscopy are life-threatening. Defect closure or suturing in flexible endoscopy has long been a critical challenge due to the confined space of the access routes and surgical sites, high dexterity and force demands of suturing tasks, as well as critical size and strength requirements of wound closure. This paper introduces a novel robotic suturing system for flexible endoscopic surgery. This system features a flexible, through-the-scope, five-degree-of-freedom robotic suturing instrument. This instrument allows the surgeon to endoscopically manipulate a needle via a master console to create running stitches and knots in flexible endoscopy, which is not possible with existing devices. Successful ex-vivo trials were conducted inside porcine colons to show how surgical stitches and knots can be endoscopically created and secured in a completely new way. This new technology will change the way how surgeons close defects or perforations in flexible endoscopic surgery.

I. INTRODUCTION

Natural Orifice Transluminal Endoscopic Surgery (NOTES), since its advent in 2004 [1], has been recognized as a promising paradigm shift for minimally invasive abdominal surgery. Unlike conventional abdominal open surgery and the currently dominating laparoscopic minimally invasive surgery where incisions (either large or small, multiple or single) on the abdominal wall are always required, NOTES is a scarless endoscopic procedure that obtains access to the abdominal cavity through the body's natural orifice (mouth, anus, urethra, and vagina) and subsequently through an internal incision in the stomach, colon, bladder, or vagina. NOTES promises decreased postoperative pain, less need for postoperative analgesia, shorter hospital stay, faster recovery, and being "scar-less" on the abdominal skin. However, these potential benefits come with critical technical hurdles [2, 3]: (1) flexible instruments for safe access and high maneuverability but with large force outputs, (2) stability and triangulation for tissue manipulation, (3) spatially constrained access routes and operative workspaces, and (4) endoscopic closure of internal access incisions or wounds (the most critical barrier for NOTES [2, 4]). Generally, instruments for flexible endoscopic surgery need to be flexible and small to pass through narrow, tortuous access routes and meanwhile have high-level of stiffness, force capability, dexterity, and functionalities to perform tasks such as lifting/cutting/suturing which, in laparoscopy, are done with rigid, significantly larger laparoscopic tools. During the last decade, various novel instruments and techniques for NOTES and flexible endoscopic surgery have emerged [5, 6], including (a) specialized endoscope platforms: Transport Multi-Lumen Operating Platform and Cobra systems (USGI Medical, USA) [7], NeoGuide Endoscopy System (NeoGuide Systems, USA)

[8], R-Scope (Olympus, Japan) [9], Anubiscope system (Kar Storz, Germany), Direct Drive Endoscopic System [10] (Boston Scientific, USA); (b) Robotic endoscopic systems: MASTER system (EndoMaster, Singapore) originated from our research group [11], ViaCath system [12] (EndoVia, USA), and iSnake [13, 14]. These advances provide promising solutions for the above technical difficulties (1) to (3); however, safe and secure closure of defects or perforations still remains as a bottleneck challenge [2, 4, 15]. After completing a NOTES procedure, a safe and secure closure for the internal access incisions or planned perforations is a must to avoid continued leakage of fluids into the abdominal cavity with the risk of life-threatening complications, bacterial contamination, and peritonitis. In addition, defect closure in classical flexible endoscopy is also crucial. As reported in the literature [16, 17], full-thickness gastrointestinal defects are strongly associated with a high rate of morbidity and mortality, e.g., the mortality rates due to anastomotic leak after esophagostomy are between 30% and 60%. Nevertheless, developing a reliable and efficient endoscopic suturing device is challenging due to the confined space of access routes and target surgical sites, critical size and strength requirements of wound closure, and high dexterity and force demands of suturing tasks. All existing technologies (detailed in Section II) cannot avoid adopting irregular solutions, e.g., clips or fastening elements, while the gold standard of wound closure—suturing with stitches and knots—is most desirable.

We present a novel master-slave robotic suturing system for flexible endoscopic surgery (including NOTES). This system, fulfilling all the critical requirements for endoscopic suturing (detailed in Section II), features a suturing instrument and a grasper, both of which are flexible, robotically driven, five-degrees-of-freedom (DOFs), and through-the-scope. This novel suturing instrument allows the surgeon to make running stitches by continuously operating a needle to puncture tissue at desired positions and orientations and to tie surgical knots. The dexterous grasper facilitates stitch-making and knot-tying by manipulating tissue and suture threads, e.g., feeding tissue to the suturing arm and forming suture loops. With joints driven by tendon-sheath mechanisms (TSMs), the instruments are small and flexible enough to go through the tortuous tool channels of the endoscope and have sufficient dexterity and force capabilities for suturing. Suturing with this system is safe because the motion of the needle is well constrained by the dedicated suturing arm and the instruments are under the endoscopic vision and master-slave control of the surgeon.

In the following, Section II reviews existing endoscopic suturing devices based on seven requirements; Section III presents the system overview. In Section IV, the working principle and design of the suturing arm are detailed. Force capabilities of the instruments and ex-vivo trials are presented and discussed in Section V. Section VI concludes the paper.

II. CLOSURE DEVICES: REQUIREMENTS AND REVIEW

Existing devices for flexible endoscopic defect closure are evaluated in Table 1 based on the following requirements:

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(1) Triangulation—whether the device has the dexterity for triangulation instead of steering solely via the endoscope. Triangulation is important for functionality and efficiency.

(2) Through-the-Scope—whether the device is delivered to surgical sites via the endoscope’s tool channel. Through-the-scope tools are preferred for efficient tool exchanges.

(3) Running stitches—whether running stitches rather than interrupted stitches are created. Running stitches are preferred for better closure strength and easier defect management.

(4) Controlled/safe puncturing—whether there is a risk of puncturing other organs adjacent to the surgical site. Puncturing should be performed in a controlled manner where the needle /clip is in the sight line of the surgeon.

(5) Surgical knots—whether standard surgical knots can be created to secure the closure.

(6) Full-thickness—whether full-thickness closure can be achieved. Full-thickness is preferred for a wider range of surgical procedures and also for improved closure strength.

(7) Large-defects—whether the device can perform closure for relatively large defects (length ≥ 2 cm). Closure of large defects is preferred for a wider range of surgical procedures.

Seven types of devices are briefly discussed below.

Hemoclips. Hemoclips, delivered through the biopsy channel of an endoscope, are for the management of gastrointestinal bleeding and may be adapted for defect closure [18]. These clips are easy to use but limited with a small closing force and thus suitable to the mucosal layer only.

T-tags. In a T-tag opposition system, a needle catheter delivers two t-tags to the two sides of a defect, and a locking unit is used to secure the closure [19]. This approach has the risk of blind puncture, inadvertent penetration of surrounding organs and is not approved for clinic use.

G-Prox. The G-Prox tissue opposition system lifts a tissue fold and then punctures the tissue with a hollow needle which is preloaded with two expandable baskets connected by a suture. Once both baskets are released, pulling one end of the suture can approximate the tissue fold [20]. This technology is mainly used for weight loss surgery where the volume of the stomach is shrunk by creating tissue folds on the stomach wall.

Overstitch. Overstitch [21] can be mounted onto the endoscope tip. A curved needle punctures the tissue and passes the suture through. Once the tissue is cinched, the two T-tags on the suture are locked to secure the closure. An over tube is needed to deliver the device safely to surgical sites.

Over-The-Scope Clip (OTSC). OTSC [22] is a commercial large flexure clip mounted on a suction cap at the tip of an endoscope. Once released, the clip can cinch the defect edges that are suctioned into a cap. The clip can exert around 8-9 N force, but it may injure adjacent organs due to suction. Changing tools during the procedure is not convenient, and the location of the clip cannot be adjusted when mis-released.

NDO Plicator. NDO Plicator uses a special overtube with preloaded T-tags [23]. However, the distance between two T-tags is not adjustable, and thus the closure strength is limited. Moreover, the plicator can only deliver one single stitch each time and needs to be withdrawn for re-loading.

Endocinch. Endocinch [24] sucks tissue into a suction chamber mounted on the distal tip of the endoscope. Then a needle with suture punctures through the suctioned tissue to deliver a stitch. Nevertheless, adjacent organs may be sucked and sutured by accident.

Table 1 Features of the instruments for defect closure

	Clip [18]	T-Tag [19]	G-Prox [20]	Over-Stitch [21]	OTSC [22]	Plicator [23]	Endo-Cinch [24]
Triangulation	×	×	×	×	×	×	×
Through scope	✓	✓	✓	×	×	×	×
Running stitches	×	×	×	✓	×	×	×
Safe puncture	✓	×	✓	✓	×	✓	×
Surgical knots	×	×	×	×	×	×	×
Full-thickness	×	✓	✓	✓	✓	✓	×
Large defect	✓	✓	✓	✓	×	✓	✓

To summarize, instruments described in [18-20] can be desirably delivered through endoscopes, but the closure is achieved through interrupted stitches and secured by clips[18], tags[19], or self-expanding baskets[20]. Moreover, these devices also have problems such as too weak and narrow tissue opposition [18], blind needle puncture [19], and bulky sizes [20]. The OverStitch system [21] (Apollo Endosurgery, Inc, USA) is capable of generating running stitches but is large in size and needs to withdraw the endoscope for tool exchange. Note that all the devices [18-24] are not able to do triangulation or steer on their own, i.e., they heavily rely on the endoscope for steering, which complicates the procedures and requires highly delicate operation from the surgeon.

III. SYSTEM OVERVIEW

The robotic system is designed with a master-slave architecture, i.e., the surgeon at the master console controls the robotic slave arms at the surgical site. As depicted in Figure 1, the system consists of a master console for the surgeon, a robotic workstation, two slave robotic arms (a suturing arm and a grasping arm, detailed in Section IV), a flexible endoscope operated by an endoscopist, and other standard endoscopic units such as an imaging processor, light source, insufflation machine, and suction machine. The master console mainly includes two Omega 7 haptic interfaces (Force Dimension Inc., Switzerland) which enable the surgeon to remotely control the two robotic arms (left and right) with haptic feedback. Receiving commands from the haptic interfaces, the motors in the robotic workstation drive the two dexterous slave robotic arms. When needed, the endoscopist assists the surgeon by steering/moving the endoscope to desired surgical areas. Vision feedback from the endoscope is provided to the surgeon and endoscopist.

As shown in Figure 2, the workstation consists of two controller boards connecting to a computer, two DC motor blocks, two motorized translational sliders with another DC motor and a pair of gears stacked on each slider, other electronic components (e.g., IO boards, power suppliers, and drivers), and an adaptor which the endoscope can be plugged into. The software and controller in the computer process signal communication between the master console and the robotic workstation. Each DC motor block, with eight DC motors (2657W024CR, Faulhaber Inc, Germany), actuates the joints of the respective slave robotic arm through stainless steel TSMs (Asahi Inc., Japan). In the DC motor block, there is also a load cell (LTH 300, Futek Inc., USA) for each TSM to

Figure 1. System Overview.

Figure 2. Robotic workstation with two through-the-scope robotic arms in the endoscope

sense the actuation forces. Each linear slider (EZ limo, Oriental Motor Co., Japan) move the associated robotic arm forward or backward. Meanwhile, the DC motor and gears on the slider can rotate the robotic arm along its longitudinal axis. The endoscope² has two customized tool channels large enough for two robotic instruments and one normal channel for $\varnothing 2.5$ mm manual endoscopic. The two robotic instruments go through the tool channels of the endoscope and thus can be swapped for tool exchanges without withdrawing the endoscope during surgery, which significantly simplifies the procedure. The suturing arm ($\varnothing 4.4$ mm) is dedicated for suturing, e.g., positioning and driving the needle to puncture tissue; the grasping arm ($\varnothing 4.2$ mm) manipulates tissue and suture thread to facilitate suturing. The grasping and suturing arms are arranged on the left and right in the endoscope (for right-hand users), respectively, considering that suturing requires more complicated manipulation than grasping. This arrangement can be reversed for left-hand users if needed.

² This endoscope is customized by EndoMaster Pte. Ltd., Singapore, for commercial purposes. No detailed information is permitted to be disclosed in this publication.

IV. WORKING PRINCIPLE AND DESIGN

A. Working principle of the suturing arm

Figure 3 illustrates the working principle and design of the suturing arm. The arm is essentially a 5-DOF grasper with a double-pointed lancet needle (gauge 21) that can be swapped between the two jaws. The needle tips can be inserted into the needle holes on the jaws for a certain depth by closing the jaws. The needle and needle holes are curved with a radius the same as that (9 mm) of the needle's motion trajectory (rotation around the gripping axis) to minimize forces required to penetrate tissue and to reduce tissue trauma. There is a notched slot 0.11 mm depth on each end of the needle. On each jaw, there is a locking blade that slides forward or backward to engage or disengage with the notched slot of the corresponding end. The needle can be locked to one of the two jaws and swapped between the jaws using the locking blades inside the jaws. As shown in Figure 3b, Blade B is at its distal position and is engaging with the corresponding notch B of the needle. In this case, the needle is fixed to the upper jaw. Blade A on the lower jaw is at its proximal position and thus allows the needle to go into the needle hole on the lower jaw when the puncturing motion of the suturing arm is triggered. Similarly, in another case (Figure 3c), blade A is engaged with notch A of the needle, locking the needle to the lower jaw. When a wound edge is placed between the jaws, by closing the two jaws, the needle is driven to penetrate through the tissue, guiding the suture on the needle through the tissue. After swapping the needle to the other jaw, a stitch is made; repeating this process will form running stitches on the tissue.

Figure 3d shows how the tendons are looped around the pulleys and control the movement of the blades. The blades are laser welded to the tendon, and pulling one end of the tendon will engage one blade with the needle and simultaneously dis-engage the other blade with the needle. Three rotatable pulleys are employed to decrease the friction on the tendon: one on the rotating axis of the upper jaw, one on the upper jaw, and the third one on the lower jaw. These pulleys are crucial to ensure the durability of the tendon which would otherwise be worn out quickly and breaks. Note that the tendon is looped in such a way that the movements of the blades are coupled, i.e., moving one blade forward would move the other backward, and vice versa. This coupled motion ensures that one end of the needle is fixed on one jaw while the other end is released on the other jaw, and vice versa. The movements of the blades are controlled by two button switches on the handle of the right haptic device.

Figure 3e shows the details of the needle. There are a flat surface and a shoulder on each end of the needle. The flat surface prevents the needle from rotating in the needle hole which also has a flat surface, so the needle can accurately point to the opposite needle hole. The shoulder precisely defines the insertion depth of the needle so that the needle arrives at the designed locking position after puncturing.

B. Degrees of freedom

Surgical suturing requires high maneuverability of the suturing instrument because the needle needs to be positioned at desired locations to puncture tissue with proper orientation and the suture needs to be guided to desired positions and shapes to facilitate tying knots. As shown in Figure 3a, The suturing arm is composed of a tubular torque coil, two tubular articulated pivot joints, two suturing jaws, a needle, two

Figure 3. Suturing arm: (a) Overview; (b)-(c) switching needle between two jaws (with section views to expose locking blades); (d) tendon route and blade movement; (e) features of the needle; (f)-(g) stitching process.

locking blades on the jaws, and eight TSMs. It has five DOFs, i.e., roll, translation, yaw, pitch, and gripping, which ensures sufficient dexterity for the suturing arm to reach its surrounding target tissue by itself without having to steer the endoscope and also to triangulate with the grasper arm on the left side. The translation and roll of the suturing arm are driven by the motorized slider and the motor/gears on the slider, respectively; all other DOFs are driven by TSMs. All the TSMs are inside the torque coil and the two tubular joints distally extends from the torque coil. The torque coil is flexible in bending but stiff in twisting and thus can go through

the tortuous path of the endoscope tool channel and meanwhile allows the arm to roll along the longitudinal axis and to transmit torques. The whole instrument can be translated within the tool channel of the endoscope by pulling or pushing the torque coil. The two joints links, with pivot joints on them, permit the device to be steered up/down (pitch) and left/right (yaw). The two jaws can be opened or closed for gripping. Two TSMs are used for each DOF of pitch, yaw, and gripping and also for the locking blades for bidirectional control. The diameters of the sheath and tendon for the suturing jaws are 0.96 mm and 0.5 mm, respectively, while those for yaw and pitch are 0.86 mm and 0.42 mm, respectively. TSMs have the high force-transmission capability and are flexible, compact, and reliable and thus were selected for this system which works in tortuous, confined GI tracts.

C. Dual-arm suturing

During suturing, the grasper arm on the left can help manipulate the tissue and suture thread. This grasper arm has the same joints and DOFs as the suturing arm but with teetted jaws for grasping and securing the tissue and suture from any directions without slip. The grasper arm can reach and retract tissue that is far from the suturing arm and then feeds the tissue to the needle tip of the suturing arm, which helps prevent blind puncturing to undesired adjacent organs or tissue (a critical problem of T-tag systems and suction-based systems). When tying knots, the grasper facilitates suture manipulation, e.g., forming suture loops, tightening knots, etc. The collaboration of the two dexterous arms mimics the surgeon's two hands, which significantly improves the capability of the suturing system. Figure 6f-i shows an example stitching procedure: the grasper firstly lifts and feeds the tissue to the suturing arm which subsequently punctures the tissue; the needle is then switched to the other jaw which steers to pull the needle and suture through the tissue.

Note that all the five DOFs of the grasper are driven by the actuation module (motor block and translational sliders) on the left side of the robotic workstation. Only six motors in the left motor block are needed to drive the grasping arm's joints. The diameters of the sheath and tendon for the gripping arm are 0.96 mm and 0.5 mm, respectively.

D. Tying surgical knots

Tying surgical knots is the standard of securing stitches in surgery. Various types of knots are used in surgery, but forming a loop and passing the needle through the loop are two critical procedures for knot tying. The dexterity of the two robotic arms makes these procedures possible. Figure 4 shows the schematic process of tying a Surgeon's Knot using the two robotic arms. An overhand knot is created in (a)-(c) first, followed by a double overhand knot formed in (d)-(e) and subsequently a surgeon's knot in (g)-(i). In this process, the two arms work together to form a loop through which the needle can be passed. Passing the needle through the loop is simple and efficient with the suturing arm. Stretching the two ends of the suture with the two arms in opposite directions will generate tissue apposition; then, surgical knots can be created.

E. Needle deployment

During suturing, the 10-mm-long needle is always locked to one of the two jaws (as shown in Figure 3a-c), resulting in a profile of the suturing device much larger than the tool channel of the endoscope; therefore, the suturing arm cannot

Figure 4. Tying a Surgeon's Knot using the two robotic arms

Figure 5. Needle deployment

be delivered or withdrawn through the tool channel with the needle standing between the two jaws. Thus, a simple, effective approach was employed to deploy the needle.

As illustrated in Figure 5, the two jaws are completely closed upon delivery (with a gap equal to the outer diameter of the needle), and the needle is not locked to any jaw but lies in-between the two closed jaws. A $\varnothing 0.12$ mm super-elastic nitinol guiding wire (breaking load: 19.6 N) goes through the inner lumen of the needle and the two needle holes on the jaws, both ends of the wire are extended to the proximal side

of the suturing device and can be pulled by hands. With the needle lying between the two jaws, the suturing device with the outer nitinol wire is small enough to be delivered through the tool channel of the endoscope. After reaching the surgical site, the jaws are open, and the two ends of the nitinol wire are pulled so that the needle is deployed to stand in-between the two open jaws (Figure 5b). Closing the two jaws would force the needle into one of the needle holes (Figure 5c), and the corresponding locking blade is then advanced forward to lock the needle (Figure 5d). After that, with one end being released, the thin wire is withdrawn from the endoscope by pulling the other end of the wire, and the suturing device is ready for stitching (Figure 5e). If the endoscope route is too tortuous, the guiding wire may be cut at the distal end using an endoscopic scissors through the manual tool channel, and then the two proximal ends are pulled out. When knots are tied, the suture is cut using an endoscopic scissors; the needle can then be unlocked from the suturing arm and subsequently taken out from the needle hole and withdrawn by the grasper. Finally, the suturing arm can be withdrawn.

For needle deployment, the robotic grasper can grip the suture and push it forward to ensure the needle is in desired orientations for deployment (not always necessary). Note that there is a gauge 25 SSL316 tube in the lumen of the needle, as shown in the enlarged view of the needle tip in Figure 3c. The nitinol wire goes through the gauge 25 tube, and the suture is securely fixed in the clearance between the two tubes. This arrangement ensures that the suture is not affected by the nitinol wire during needle deployment.

F. Dimensions and design considerations

The length of the needle is 10.0 mm; the lengths (measured with respect to motion axis) of each joint link, lower jaw, upper jaw of the suturing arm are 6.0 mm, 15.6 mm, and 10.6 mm, respectively. The length of each joint link, lower jaw, and upper jaw of the grasper are 6.0 mm and 14.2 mm, 9.0 mm, respectively. Table 2 shows the motion ranges of the master and slave manipulators. The joint angle ranges for the grasping and suturing arms are the same because of the same joint designs. These dimensions were determined mainly based on four factors: (1) maneuverability in tortuous GI tract, e.g., endoscope configuration with 65 mm bending radius; (2) workspace, e.g., a cylindrical space with at least 25 mm diameter for each arm, (3) maximum tissue thickness (3 mm) to be punctured for suturing, (4) stability of the needle in the needle holes and the sharpness of the needle. The rolling ranges of the instruments are not limited, which allows the user to roll the instruments as much as needed.

The needle was manufactured out of gauge 21 stainless steel 316 (SSL316) tube using wire electrical discharging machining; the joint links and jaws of the arms were 3D printed through Direct Metal Laser Sintering using SSL316 powder.

It is worthwhile mentioning that the suturing principle of swapping a needle between two jaws is similar to that of the laparoscopic suturing tool—Endo Stitch by Medtronic, USA. However, Endo Stitch is a rigid and large ($\varnothing 10$ mm) manual tool that is only for laparoscopy. The suturing instrument developed in this study, however, is a much smaller ($\varnothing 4.4$ mm), dexterous (5-DOF), and flexible (driven by flexible TSMs) robotic instrument which is suitable for flexible endoscopy and NOTES.

Table 2 Motion ranges.

	Slave	Master
Gripping	$[0, 78]^\circ$	$[0, 28]^\circ$
Left/right	$[-83, 83]^\circ$	$[-80, 80]^\circ$
Up/down	$[-83, 83]^\circ$	$[-40, 80]^\circ$
Translation	$[0, 90] \text{ mm}$	$[0, 110] \text{ mm}$

V. TESTS, RESULTS, AND DISCUSSIONS

A. Force capabilities

The force capabilities of the joints of the suturing arm and grasping arm were measured and are presented in Table 3. Since the friction force of TSMs heavily depends on the accumulated angle of sheath configuration, the measurement was done with the flexible portion of each instrument being looped one round, i.e., 360 degrees of accumulated angle on the TSMs. This angle is considerably large for both gastric routes and colonic routes in NOTES and flexible endoscopy. The maximum actuation forces on the proximal end of the tendons were limited to 90 N to ensure the durability of the tendons. The distal output forces of the robotic arms were measured by a load cell at the tips of the end-effectors. Many factors contribute to the output force differences of these joints, e.g., lengths of force arms, friction between sheaths and end-effectors, and uneven radial distributions of the TSMs. The suturing arm output smaller forces mainly because it contains two more sheaths than the grasping arm and it is 1.4 mm longer than the grasping arm.

Table 3. Force capabilities of the robotic arms (Unit: N)

	Suturing arm	Grasping arm
Gripping	3.8	4.9
Left	3.2	3.8
Right	2.8	3.7
Up	2.8	3.1
Down	2.4	3.2

Tests have also been done to measure the required force to puncture explanted colon and stomach tissue using the suturing arm. For tissue thickness ranging from 0.5 mm to 3 mm, the required puncturing force at the distal end ranges from 1.1 N to 3 N. Note that these data are given only to confirm the puncturing capability of the suturing arm, more accurate data need to be measured in future in-vivo animal trials and human trials because in-vivo tissue can be punctured more easily than ex-vivo tissue.

B. Ex-vivo trials

An ex-vivo trial is presented here to demonstrate the capabilities of the system (refer to the supplementary video). The trial was done in an enclosed environment where the endoscope was inserted into the lumen of an inflated porcine colon. A 15-mm incision was cut before suturing. A 13-mm 3-0 Vicryl suture was used. Four stitches, two on each side of the incision, were firstly made, followed by a Surgeon's Knot. The endoscopic vision was provided to the operator.

Figure 6 shows the endoscopic views of the suturing process. Figure 6b, c are for stitching, and Figure 6d, e are for knot-tying. As can be seen, the suturing arm on the right can accurately point the needle tip to the desired stitching point (Figure 6b) and to the suture loop (Figure 6d). Meanwhile, the grasping arm on the left played an important role in lifting and feeding the tissue to the suturing arm as well as handling the suture thread. By translating the two arms into opposite directions (e.g., forward and backward), the knot was securely tightened (Figure 6e). The whole process took around eight minutes, with four minutes for the four stitches and four

Figure 6. Endoscopic views of the suturing process in an inflated colon.

minutes for the Surgeon's Knot (three throws). We found that puncturing tissue with the needle on the lower jaw is much more efficient than puncturing with the needle on the upper jaw because the needle can then be taken through the tissue by opening the upper jaw and steering the arm up (pitch). When puncturing with the needle on the upper jaw, the needle has to be taken out by steering the arm down which is, however, constrained by the colon's bottom wall. Although the two robotic arms are dexterous in their quite large workspaces, the auxiliary movement of the endoscope does help. However, different from existing devices that mainly rely on the endoscope for movements, these two robotic arms complete their tasks mainly with their own movements. Another main difference between this proposed suturing system and other existing devices is that suturing is done by two arms with triangulation which naturally suits suturing tasks while other devices have only one arm without triangulation. This made suturing with this system much easier and more intuitive than suturing with other devices. In summary, this trial demonstrates how defects in the gastro-intestinal tract can be endoscopically closed with running stitches and knots, which is not possible with existing closure devices.

In this trial, gas insufflation was used since the colon was not fully perforated. In case of perforations, a deployable "tent" [25] may be used to maintain the suturing workspace.

VI. CONCLUSIONS

This paper presents a novel robot-assisted endoscopic suturing system with two small, flexible, and dexterous robotic arms to overcome the critical challenges of defect closure in flexible endoscopic surgery and NOTES. The dedicated suturing arm ensures efficient and reliable manipulation of the needle, and the grasping arm assists the former by feeding tissue and handling suture threads. With the collaboration between the two robotic arms, running stitches and surgical knots can be created endoscopically in a way that is not possible with existing devices in the literature.

Ex-vivo trials have demonstrated the potential of the system in applications of NOTES and flexible endoscopy (e.g., suturing for Endoscopic Submucosal Dissection or Endoscopic Full-Thickness Resection). In-vivo animal studies will be conducted to further the proposed flexible endoscopic suturing technology.

Haptic feedback to the operator will be helpful for suturing and knot-tying. Approaches [26, 27] to sensing the distal forces on TSMs will be integrated into the system.

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