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Flexible robotic endoscopy for treating gastrointestinal neoplasms

Therapeutic flexible endoscopic robot

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Abstract

Therapeutic flexible endoscopic robotic systems have been developed primarily as a platform for endoscopic submucosal dissection (ESD) in the treatment of early-stage gastrointestinal cancer. Since ESD can only be performed by highly skilled endoscopists, the goal is to lower the technical hurdles to ESD by introducing a robot. Some such robots have already been used clinically, but they are still in the research and development stage. This paper outlines the current status of development, including a system by the authors' group, and discusses future challenges.

Key Words: Therapeutic flexible endoscopic robotic systems; Endoscopic submucosal dissection (ESD); Tissue triangulation.

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Core Tip: The current status and future issues in the new standardization that therapeutic flexible endoscopic robotic systems have brought to endoscopic submucosal dissection (ESD) and endoscopic full-thickness resection (EFTR) were outlined.

INTRODUCTION

Therapeutic flexible endoscopic robotic systems were initially developed as a platform for natural orifice transluminal endoscopic surgery (NOTES) ^[1, 2]. However, NOTES was not widely adopted as a treatment modality, so development shifted to endoscopic submucosal dissection (ESD), a highly complex, gastrointestinal endoscopic procedure that emerged as a treatment modality for early-stage gastrointestinal cancer. The authors' group has also developed a robotic system for ESD known as the Endoscopic Therapeutic Robot System (ETRS) ^[2, 3]. Various reviews have been published on this subject^[4-7]. This paper provides an overview, from the developers' perspective, of the current status and future issues in the development of a therapeutic

flexible endoscopic robot that can be adapted to ESD and to the next-generation Endoscopic Full-Thickness Resection (EFTR) therapy.

1. INTRODUCTION OF ROBOTICS TO ESD

2. A THERAPEUTIC FLEXIBLE ENDOSCOPIC ROBOT FOR PERFORMING ESD AND EFTR

1) MASTER (MASTER AND SLAVE TRANSLUMINAL ENDOSCOPIC ROBOT

2) ENDOMASTER EASE SYSTEM

3) ENDOLUMINAL SURGICAL SYSTEM

4) FLEX ROBOTIC SYSTEM

5) ENDOLUMINAL ASSISTANT FOR SURGICAL ENDOSCOPY

6) ENDOSCOPIC THERAPEUTIC ROBOT SYSTEM (ETRS)(FIGURE 1)

3. FUTURE ISSUES

1) LESION ACCESS

2) VERSATILITY WITH COST-EFFECTIVENESS

3) ARRANGEMENT OF OPERATORS

4) DEVELOPING AUTONOMY

Abbreviations

ESD: endoscopic submucosal dissection

NOTES: natural orifice transluminal endoscopic surgery

ETRS: Endoscopic Therapeutic Robot System

EFTR: endoscopic full-thickness resection

EMR: endoscopic mucosal resection

multi-DOF: multi-degree-of-freedom

MASTER: Master and slave transluminal endoscopic robot

EASE: Endoluminal Assistant for Surgical Endoscopy

EOR: Endoscopic Operation Robot

Introduction of robotics to ESD

ESD is a treatment modality that uses an electronic knife *via* the forceps channel of a flexible endoscope. First, an incision is made around the lesion (e.g., early-stage cancer) at submucosal depth, and then the lesion is dissected i from the wall of the digestive tract at the submucosal layer^[8-10]. ESD made it possible to perform en bloc resection of large lesions, which could not be done with the conventional endoscopic mucosal resection (EMR) modality. However, the procedure was very difficult and time-consuming because incision and dissection were performed by counter traction, which was achieved only by manual manipulation of the angle and axis of a single flexible endoscope. This was an opportunity for the introduction of robotics. ENDOSAMURAI was developed for use with NOTES^[11]. The system is equipped with two arm forceps that resemble hands at the tip of a flexible endoscope, with grasping forceps serving as the left hand and knife forceps as the right hand. Each element of the procedure, such as incision, dissection, and hemostasis, is intuitively performed by grasping and pulling with precise tissue triangulation^[11]. The arrival of ENDOSAMURAI marked the beginning of the development of a therapeutic flexible endoscopic robot for performing ESD and EFTR^[12]. Specifically, the shift from counter traction with a single flexible endoscope to tissue triangulation with two robotic arm forceps was a major contribution of robotics to ESD and other highly challenging endoscopic procedures.

A therapeutic flexible endoscopic robot for performing ESD and EFTR

In this section, systems that achieve tissue triangulation with multi-degree-of-freedom (multi-DOF) robotic forceps and have been implemented for ESD and EFTR in animals or animal organs are reviewed, along with a discussion of the clinical application of some systems.

MASTER (Master and slave transluminal endoscopic robot)

MASTER (Endomaster Pte Ltd., Singapore, Singapore) was developed mainly by the University of Singapore and was the first robot to clinically implement ESD for early-stage gastric cancer^[13-15]. Grasping forceps and knife forceps with 7 DOF were fixedly mounted in the two forceps channels of an Olympus GIF-2T240 endoscope, and they could be manipulated by computer control using a dedicated master device. Submucosal dissection was made possible by good tissue triangulation, but other procedures such as marking and peripheral incision were performed separately using a conventional flexible endoscope, which necessitated repeated replacement of the flexible endoscope. The system also needed another endoscopist to operate the flexible endoscope itself. This system has been implemented for EFTR of the stomach using live pigs^[16].

Endomaster EASE system

The fixed configuration of the two robotic forceps in the old MASTER system made it impossible to exchange forceps, whereas a notable improvement of the next-generation MASTER systems was that the two grasping and knife robotic forceps could now be inserted and removed. The dedicated flexible endoscope has three channels: two for robotic forceps and one for surgical instruments. The addition of rotation, insertion, and removal capabilities to the operations of the robotic forceps themselves resulted in 9 DOF and made the system more intuitive and easier to operate^[17]. This system was initially implemented in colorectal ESD using live cows, and is now being applied in a clinical setting^[18]. Insofar as the flexible endoscope itself is not robotically operated and requires another endoscopist, there are no major changes in this regard.

Endoluminal Surgical System

The Endoluminal Surgical System (ColubrisMX, Inc., Houston, TX, USA) consists of a scope called a Colubriscope, robotic forceps inserted into the scope, and an operating console for the forceps^[19, 20]. The Colubriscope has an external diameter of 22 mm and four channels: two for robotic forceps, one dedicated camera channel and one surgical

instrument channel, as well as a separate dedicated channel for air supply and degassing. Unlike other robotic systems that have a camera function in the flexible endoscope itself, a single camera scope can be inserted into the Colubriscope's forceps channel, allowing independent adjustment of the field of view. Another advanced feature is the use of robotic grasping forceps in the left hand to obtain good tissue triangulation while using built-in powered scissors in the robotic forceps of the right hand to perform incision and dissection by means of hot dissection. This feature also has potential for use in procedures other than ESD. This system is also noteworthy in that it allows suture manipulation using both left and right robotic grasping forceps, and it is capable of EFTR. ESD and post-resection suture have been performed 20 times using porcine colons^[19].

Flex Robotic System

Flex Robotic System (Medrobotics Corporation, Raynham, MA, USA) is a master-slave robotic system ⁵ approved by the United States Food and Drug Administration in 2017 as a robotic system for head and neck surgery^[21, 22]. This perfected system has two forceps channels (left and right) on the outside of the flexible endoscope, through which dedicated forceps are inserted to allow operation with both hands. Two forceps can be selected from several types, such as grasping, electric scalpel, and powered scissors, to perform incision, dissection, resection, suturing, and so forth. The flexible endoscope itself can also be remotely operated, allowing almost all operations to be performed by a single endoscopist sitting at a dedicated console. The implementation of ESD in bovine colon has shown that even a surgeon inexperienced in ESD can easily master this technique^[21]. However, because this system is designed for head and neck surgery, the external diameter of the flexible endoscope is too large for insertion into the upper gastrointestinal tract, and, with a length of 25 cm, it cannot be used for deep lesions in the colon either.

² **Endoluminal Assistant for Surgical Endoscopy**

The Endoluminal Assistant for Surgical Endoscopy (EASE; ICube Laboratory, Strasbourg, France) is a master-slave robotic system developed as a successor to the

ISIS-Scope/STRAS system (Karl Storz, IRCAD, Tuttlingen, Germany)^[23, 24]. It has two channels for robotic forceps and a channel for conventional surgical instruments, and through robotic control of the grasping and knife forceps, it can be used to perform mucous membrane incision and submucosal dissection with precise tissue triangulation. Submucosal local injection is also possible by inserting a syringe needle through the channel for conventional surgical instruments. The flexible endoscope itself can also be operated by a joystick, allowing almost all procedures to be performed by a single endoscopist sitting at a dedicated console. ESD of the colon has been achieved in live pigs^[24].

3 Endoscopic therapeutic robot system (ETRS) (Figure 1)

The endoscopic therapeutic robot system (ETRS) is a master-slave robotic system developed by the authors' group exclusively for ESD^[3]. We started by developing a platform to remotely control movements of the endoscope itself, which we named the Endoscopic Operation Robot (EOR)^[25-29]. The current third-generation EOR is equipped with two-way haptic feedback functions that provide haptic feedback (force sensation) via the master unit while transmitting a force equal to that applied by the operator on the master unit to the endoscope tip, and all scope operations can be performed one-handed^[27, 28]. We then developed a master-slave system capable of remotely operating three different endoscopic instruments (grasping forceps, knife forceps, and injection-needle catheters), and we have combined this with the improved EOR version 3 (Figure 2) to create a novel gastrointestinal endoscopic robot in which all operations are completely remote-controlled. All procedural elements required for ESD, such as incision, dissection, submucosal local injection, water jetting, air supply, aspiration, and lesion recovery, can be performed by a single endoscopist sitting at a console. ESD has been performed in a resected pig stomach^[3].

Future issues

ESD was a procedure that could only be performed by highly skilled endoscopists, but therapeutic flexible endoscopic robotic systems allow less-experienced endoscopists to perform ESD by tissue triangulation using both hands to manipulate two multi-DOF

robotic arm forceps. However, compared to the perfected surgical robots as exemplified by da Vinci, there are still many issues that need to be addressed at the research level before wider general clinical application.

Lesion access

As just one example, ESD is intended to treat lesions in the upper gastrointestinal tract as far as the duodenum and lesions in the lower gastrointestinal tract as far as the cecum. Each robotic system must be able to easily reach the lesion site so that it can adequately fulfill its potential. Current systems are still inadequate for accessing lesions, mainly because the scope cannot be operated over a sufficient length.

Versatility with cost-effectiveness

Dedicated ESD and EFTR robots are not cost-effective in terms of system scale because they tend to be large and complex. The Flex Robotic System was developed for head and neck surgery and has been applied to colorectal ESD, but this system should be further developed so that it can be adapted to other diseases. Many of the systems introduced allow the replacement of robotic forceps. However, by expanding the robotic forceps options and forceps channels so that complex sutures and anastomoses can be performed at will, there is also room for development that extends the application of these systems to areas where flexible endoscopes are superior to rigid endoscopes, such as thoracic and intra-abdominal surgery. Nevertheless, all procedures must be performed within the caliber of a gastrointestinal endoscope, so greater development within these fine size constraints is required.

Arrangement of operators

The ETRS developed by the authors' group enables a single endoscopist sitting at a console to perform all the procedures required for ESD, although there are many other issues. Many of today's flexible endoscopes require assistants for their operation, and when complex, coordinated operation by two or more operators is required, and the hurdle for standardized operations becomes high. We think that assistants should perform only the minimum necessary operations, such as changing forceps, and a single endoscopist should be able to perform as much of the surgery as possible.

Developing autonomy

The purpose of the surgical robotic systems currently used clinically is to provide operational support to surgeons, and not to operate autonomously. If a robot were to be perfected as an operational support robot, we think it could be implemented clinically. For example, the Smart Tissue Autonomous Robot (STAR), which was developed as an autonomous surgical robot, is already performing automated intestinal anastomosis in live pigs^[30]. Autonomous support was introduced into surgical robotic systems along with the establishment of phased objectives that must be met, in the same way that levels have been set for automated driving in automobiles^[31]. I think this should begin with autonomous optimization of the surgical field so that the surgeon can always operate under an optimal surgical field.

CONCLUSION

Therapeutic flexible endoscopic robotic systems are being developed for ESD and EFTR, and while some have been used clinically, most systems remain in the research and development stage. These robotic systems are expected to offer numerous advantages to surgeons, but a number of issues will need to be overcome before there is wide-spread application in clinical settings.

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