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Compliant and Flexible Robotic System with Parallel Continuum Mechanism for Transoral Surgery: A Pilot Cadaveric Study

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Abstract: As one of the minimally invasive surgeries (MIS), transoral robotic surgery (TORS) contributes to excellent oncological and functional outcomes. This paper introduces a compliant and flexible robotic system for transoral surgery, consisting of an execution part with flexible parallel mechanisms and a positioning part with a continuum structure. A pilot cadaveric study that mimics the procedure of the TORS using an intact cadaveric human head was conducted to evaluate the feasibility and efficiency of this robotic system. Both the initial setup time and the time cost by the robot to safely access the deep surgical area in the upper aerodigestive tract are shortened due to the enlarged workspace, compact structure, and increased flexibility. The proposed surgical robotic system is preliminarily demonstrated to be feasible for TORS, especially for the in-depth surgical sites in the upper aerodigestive tract.

Keywords: surgical robotics; flexible parallel mechanism; continuum robot; transoral robotic surgery; cadaveric study

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1. Introduction

Minimally invasive surgeries (MIS) are becoming promising trends in surgical procedures due to their advantages such as reduced trauma, less pain, and faster recovery [1,2]. Robot-assisted MIS technologies significantly enhance the surgeon's capacity by dexterous manipulators. In these technologies, the robotics for natural orifice transluminal endoscopic surgery (NOTES) procedures with less trauma have been playing an increasingly important role in recent years [3]; these include continuum manipulators [4] and flexible robots [5]. Transoral robotic surgery (TORS) as an emerging NOTES procedure allows for the resection of cancers from hard-to-reach areas of the upper aerodigestive tract to be completed via a transoral approach [6]. Compared with traditional therapies, e.g., open surgery, chemoradiation, or radiotherapy, TORS contributes to excellent oncological and functional outcomes, including increased survival rate, shortened hospital time, reduced dependence on temporary tracheostomy, and a faster-recovered swallowing function [7–10]. Unlike manual transoral surgery (TOS), a suspension laryngoscope, which has a high risk of incurring various complications [11], can be abandoned in a TORS procedure.

The first breakthrough of this technology was achieved when the TORS procedure was completed in animal models with the da Vinci surgical robotic system (Intuitive Surgical, Inc, Sunnyvale, CA, USA) in 2003 [12]. Two years later, TORS was successfully performed on a human subject using the same system [13], which obtained FDA approval in 2009. Since then, the clinical application of TORS in the management of head and neck cancers has expanded considerably [14]. However, bulky working arms, rigid and slender instruments, and limited dexterity at the distal end make visualization, exposure, and maneuverability in deep regions in the larynx challenging for multiarmed da Vinci Robotic systems (da Vinci S, Si, Xi). Thus, they are only applicable to the upper oropharynx. A more flexible single-port robotic system (da Vinci SP) was developed based on the da Vinci Si and Xi systems. Although the technical feasibility of this flexible system to safely access deep surgical sites in the upper aerodigestive tract, including the nasopharynx, oropharynx, larynx, and hypopharynx, was verified [15], more in-human trials are needed to evaluate its oncologic and functional outcomes before obtaining FDA approval. The Flex Robotic System (Medrobotics Inc., Raynham, MA, USA) is another system that received clearance from the FDA for TORS in 2015, which has been adopted to manage oropharyngeal tumors [16]. Nevertheless, broad cross-section [17], slow running speed [18], and small load capacity deteriorate its performance in TORS. Moreover, surgical instruments of this system are manually controlled, leading to lower levels of dexterity and manipulability [19].

In addition to these commercial systems, specialized designs have been developed for TORS. A 3-degree-of-freedom (DOF) articulating robotic forceps was devised for transoral laser microsurgery [20]. Nevertheless, high stiffness and limited flexibility make safe operation in a confined area significantly challenging for this device. Snake-like continuum robots, e.g., the multi-backbone continuum mechanism [21] and the concentric tube mechanism [22], feature a simplified structure, improved compliance, and increased flexibility, which have been employed to design transoral surgical robots. However, lower stiffness and complex modeling lead to reduced load capacity and motion accuracy. Moreover, these robots still rely on laryngoscopes to access the target sites. EndoMaster is a flexible robotic system originally designed for the endoscopic resection of gastrointestinal polyps and tumors and was recently utilized in a TORS cadaveric study [19]. Although it can access the target site in the oropharynx without the laryngoscope and demonstrates good flexibility and dexterity, an assistant was required to operate and position the flexible endoscope during the surgery.

Current surgical robotic systems have distinct shortcomings and are only applicable for a small portion of head-neck surgery. To fully exert the advantages of TORS and expand its application scope, robotic surgical systems with comprehensively improved performance should be developed. This paper presents a flexible and compliant surgical robotic system based on the combination of the flexible parallel mechanism and the continuum structure. The clinical feasibility of the robot for TORS is verified through cadaver trials.

2. Materials and Methods

TORS is extremely challenging due to the deep, narrow, and tortuous anatomical structure of the upper aerodigestive tract. The surgical robotic system should satisfy the following requirements to meet the clinical requirements of TORS. First, the cross-section of the distal part of the robot should be within a circle with a diameter of 20 mm [23]. Second, the designed robot should have an adequate workspace and flexibility to transorally reach deeper anatomical sites in the larynx. Third, the designed robot should have proper compliance and adaptability to navigate the confined and complex anatomical structures in the oropharynx and larynx while minimizing postoperative complications. Fourth, two manipulators and one vision unit are essential for surgery. Manipulators should have enough dexterity, and load capability [24]. Furthermore, they should be equipped with different instruments for various tasks. For the vision unit, the angle of view should be independently controllable, making it more convenient for the operator to monitor both the surgical site and its surroundings.

2.1. System Overview

To address challenges imposed by TORS, a compliant and flexible robotic system with a parallel continuum mechanism based on our previous work [25] is proposed. As depicted in Figure 1a, the surgical robot consists of an execution part and a positioning part. The execution part (Figure 1b), containing one vision unit and two manipulators, provides visual feedback of the surgical site and complete surgical interventions under the control of surgeons. The positioning part (Figure 1c) is developed to increase the flexibility of the robot and facilitate the execution part to reach the more in-depth surgical site in the upper respiratory tract. It can generate a bending motion and a linear motion. The parameters of the designed robot are shown in Table 1. The robot can be easily mounted to a multi-DOF passive positioning arm due to its compact structure and lightweight. Consequently, this flexible and compliant robot satisfies the compatibility requirements of most operating theatres [26].

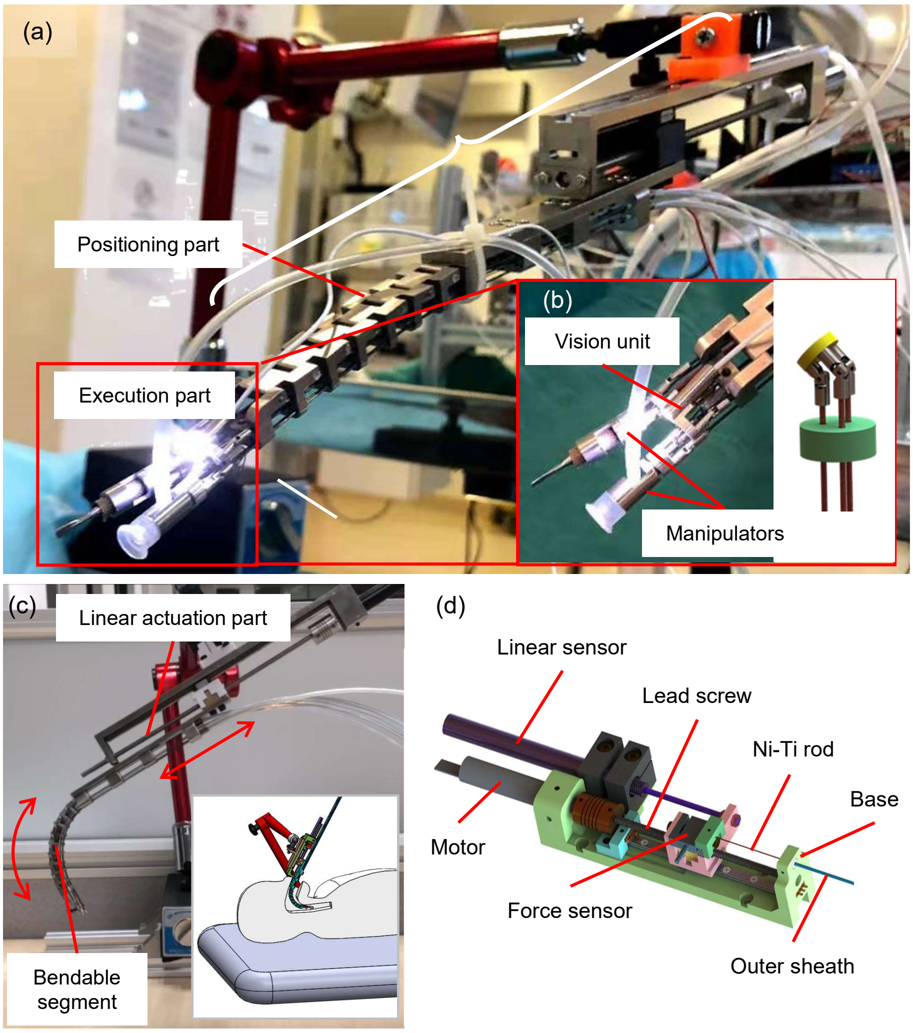

Figure 1. Overview of the surgical robot. (**a**) Prototype. (**b**) Execution part. (**c**) Positioning part. (**d**) Part of the actuator to drive one Ni-Ti rod.

The execution part comprises two flexible manipulators and a vision unit. The independently controllable vision unit is placed above the manipulators to improve ergonomics and provide a surgeon with more intuitive control of surgical instruments. Different surgical instruments could be equipped to the distal end of the manipulator. In this work, one vacuum suction was employed for grasping and one monopolar electrotome was utilized for cutting. The manipulator and the vision unit are developed based on a flexible parallel mechanism [27–29]. Super-elastic Nitinol (Ni-Ti) rods are used instead of rigid parts. Each flexible parallel mechanism contains a moving platform, a base platform, and three uniformly distributed serial chains. Each serial chain comprises a Ni-Ti rod and a universal (U) joint. The prismatic (P) joint is formed by passing a Ni-Ti rod through a hole in the base platform. By pushing/pulling the Ni-Ti rod, this mechanism can achieve 2 bending DOFs and 1 translational DOF.

Table 1. Parameters of this Flexible and Complaint Robotic System.

Parameters	Value	Units
Total DOF of the robot	11	-
Dimension of the robot	$200 \times 50 \times 46.5$	mm
Weight of the robot	480	g
Maximum bending angle of the positioning part	180	deg
Maximum translational displacement of the positioning part	200	mm
Maximum bending angle of the manipulator	45	deg
Maximum translational displacement of the manipulator	20	mm
Maximum load capacity of the robot	8.06	N
Materials	Stainless steel, nitinol alloy, and polylactic acid	-
Operating mode	Master–slave teleoperation	-

Compared with traditional parallel robots and other designs using the Ni-Ti rod, distinctions of this flexible mechanism are embodied. Firstly, slender and super-elastic NiTi rods are employed to replace rigid links and complex components of traditional parallel robots, e.g., spherical joints and hinge joints, contributing to a simplified structure, downscaled size, and reduced manufacturing cost. Secondly, Ni-Ti rods offer increased compliance, flexibility, and adaptability for this flexible mechanism, which are of great importance for surgical robots in terms of safety. Thirdly, compared with other mechanisms employing Ni-Ti rods/tubes [21,30], this flexible parallel mechanism features improved ergonomics and dexterity due to the universal bending motions and smaller bending radius, which are important for the surgical robot to achieve dexterous motions in narrow and confined surgical areas.

The positioning part, with a bendable segment and a linear actuation part, is designed to facilitate the execution to reach the more in-depth surgical site in the upper aerodigestive tract. The bendable segment is the part that will bend and travel across the oral cavity to reach the surgical site in the larynx. The continuum structure, which features improved compliance and adaptability [23], is employed in this design [31]. Several rigid vertebrae, which contain a number of guide holes, are sequentially connected to form a series of revolute joints. Ni-Ti rods are used to actuate the bending motion. The casing tubes of the Ni-Ti rod are fixed to the bendable segment via screw joints, which can be conveniently taken down and replaced. To guarantee the compactness of the structure, Ni-Ti rods and electrical cables of the execution part traverse these guide holes and are connected to the actuators, power supplies, and display devices. The interference between the bendable segment and the manipulator can be eliminated by the compensation method proposed in [26]. In addition, the positioning accuracy of the manipulator when the robot is in different bending states is acceptable for TORS. The linear actuation part can provide an additional translational DOF. The lead screw is connected to a motor via an elastic coupling. The bendable segment is fixed to the slide block by screw bolts. Thus, the linear motion of the bendable segment part is controllable.

In this design, the flexible 3-PU parallel mechanism-based manipulator is combined with the continuum structure to form a novel hybrid mechanism. There is no influence caused by the position part on the DOF or the motion range of the manipulator due to the super-elasticity of Ni-Ti rods. The Ni-Ti rods serve as the elastic backbone for the bendable segment, which can provide significantly improved flexibility and adaptability to guarantee adequate safety when the robot is traversing the narrow, long, and confined lumen in the upper aerodigestive tract without increasing the complexity or the dimension of the robot. Therefore, the surgical robot developed using this hybrid mechanism can satisfy the design requirements imposed by TORS in terms of size, workspace, flexibility, compliance, and dexterity.

The actuation system comprises 9 identical small actuation units, 1 large actuation unit, and 3 controller boards (SIMLAB, Zeltom Co., Ltd., Belleville, IL, USA). The small actuation unit employs the modular design concept, which utilizes a relatively motor (RE13, Maxon motor Inc., Sachseln, Switzerland) to control the motions of the execution part, and each can control the pushing/pulling of one Ni-Ti rod. Moreover, the number of small actuation units can be conveniently adjusted as required. The large actuation unit adopts a motor to control the bending motion of the robot.

As shown in Figure 1d, three notable modifications have been made compared with our previous work [25]. Firstly, a force sensor is attached between the Ni-Ti rod and the slide block, which measures and records the actuation force acting on the Ni-Ti rod. Secondly, the outer sheath is fixed to the base of the actuation unit using a set screw, which can be conveniently adjusted or replaced. Thirdly, linear sensors are added, which can provide the absolute position and send position feedback to the controller to further increase the positioning accuracy of this part.

2.2. Cadaveric Trials

Cadaveric trials have been designed and conducted to evaluate the feasibility of this flexible and compliant surgical robot operated in a master-slave teleoperation mode. Figure 2 shows the experimental setup. A cadaveric head from a man aged 45, which contained intact tissues in the oropharyngeal region and had never had any surgeries in this area, was utilized as the subject. A retractor kept the mouth open and left enough space for the robot. The surgical robot was mounted to a multi-DOF magnetic base holder so that the position and orientation of the robot could be quickly adjusted as required. Operators can steer the surgical robot using two haptic devices (3D Systems, South Carolina, CA, USA), connected to the PC via ethernet at the master side. The controller, implemented in MATLAB/Simulink, processes command signals from the haptic devices and sends corresponding control signals to the motor control boards via serial communication. These controller boards control the actuation units to generate actuation force to drive the robot at the slave side to complete desired motions. The vision unit in the execution part can provide visual feedback to the operator. The surgical instruments are controlled by the buttons, which are carefully devised and fixed to the handle of the haptic devices.

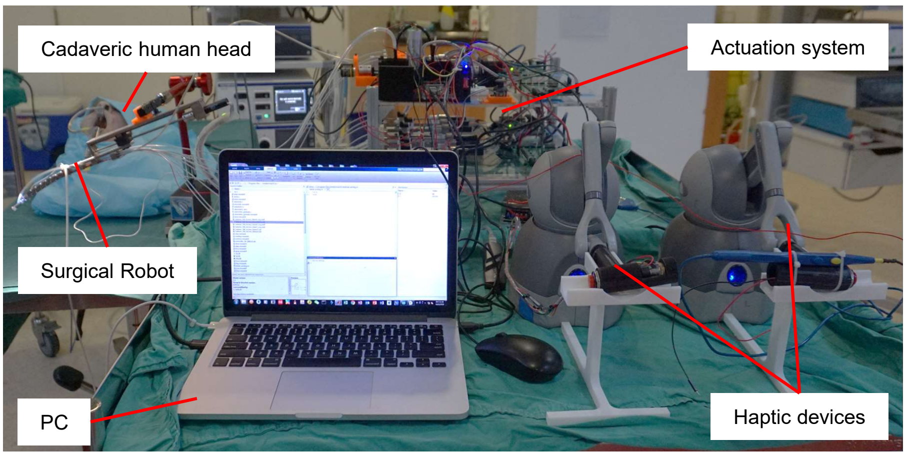

Figure 2. Experimental setup of the cadaveric simulations.

Like current TORS [32,33], the cadaver trial using the developed surgical robotic system comprises 4 stages: the initial setup, the target location, the surgical operations, and retraction. The initial setup is essential to all robotic surgeries. Since the robot has 11 DoFs and a large workspace, its initial setup becomes relatively simple, consisting of two steps. Firstly, the prototype of the developed robot is fixed by a multi-DOF magnetic-based holder and moved near the cadaver head. Secondly, the position and orientation of the robot are adjusted via the holder. The execution part of the robot is inserted into the oral cavity with the distal end facing the throat, and the tilt angle of the robot is around 80° relative to the horizontal plane, as depicted in Figure 3a.

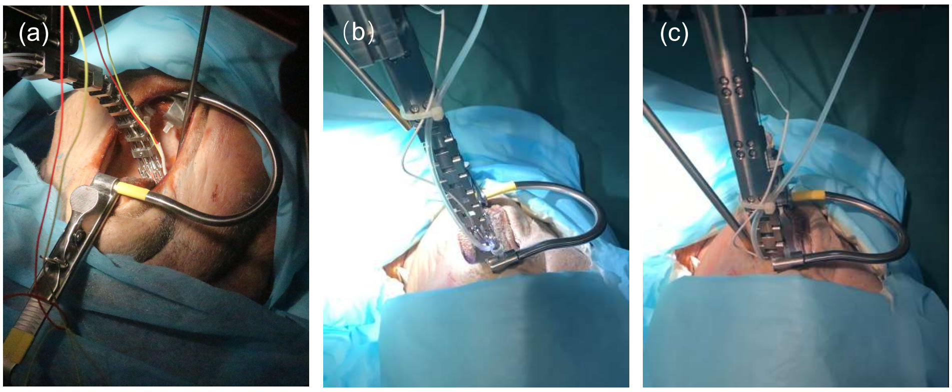

Figure 3. Experimental results of the cadaveric simulations. (**a**) Initial setup. (**b**) Initial state. (**c**) Final state.

In this cadaver trial, the initial setup was repeated by five operators, and the completion time of each was recorded. In the stage of the target location, the operator at the master side manipulated the haptic device to steer the robot to transorally reach the larynx, which was selected as the target surgical site. The bendable segment of the robot bent and advanced under the control of the operator. This stage ended when the manipulator touched the vocal cord. The initial and final states of this step are illustrated in Figure 3b,c, respectively. To evaluate the robot's efficiency at safely accessing the target surgical site, three amateurs, who each had thirty minutes to practice operating the robot, were tasked with navigating to the target location from the same initial start location. Each participant repeated the experiment three times. The time cost of each case was recorded. After reaching the target surgical site, two manipulators were teleoperated by the operator via two haptic devices to complete the surgical operation.

Figure 4a–h demonstrates the operation process of two manipulators in the cadaver trial, including the grasping and cutting. In the process of grasping, the left manipulator equipped with a vacuum suction was steered to adjust its orientation, as shown in Figure 4a,b. After that, it was controlled to approach and slightly contact the target tissue using the suction cup, as shown in Figure 4c. Finally, the vacuum suction was started to grasp the tissue, which was retracted to facilitate the cutting process, as shown in Figure 4d. In the cutting process, the right manipulator, which was equipped with a monopolar electrotome, was firstly manipulated to adjust its position and orientation relative to the left manipulator, as shown in Figure 4e,f. Then, the monopolar electrotome was used to cut the grasped tissue (Figure 4g). To cut the target tissue, the right manipulator was controlled to rotate around the left manipulator, as illustrated in Figure 4h. Finally, after the resection was complete, the robot was controlled to return to its initial state.

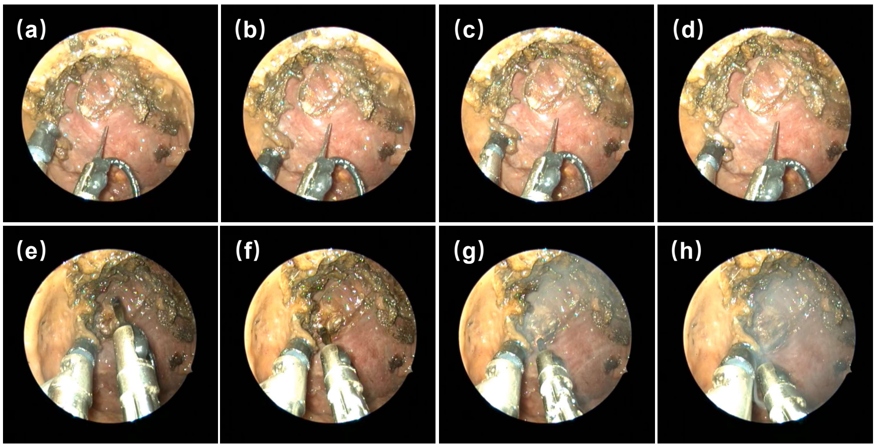

Figure 4. Endoscopic view of manipulators during the cadaver trial. (**a**–**d**) The left manipulator is equipped with vacuum suction to grasp the target tissue. (**e**–**h**) The process of the right manipulator equipped with the monopolar electrotome to cut the target tissue.

3. Results

The average time cost by this robot to complete the initial setup was 110 ± 32 s. The proposed surgical robotic system achieved excellent stability and maneuverability in the master–slave teleoperation mode. The average navigation time across all trials was 130 ± 35 s. The robot's efficiency in terms of access to deeper areas in the larynx was significantly increased, mainly due to the reduced size, enhanced flexibility, and improved compliance of the bendable segment. The motion of the stage of the surgical operation was not affected by the bending motion of the bendable segment. In addition, the tailor-made vacuum suction provided stable grasping and effective protection of the target tissue throughout the process, which is verified to be a feasible alternative to replace the traditional forceps. Additionally, surrounding tissues were well protected during the trials, which verifies the safety requirements of TORS.

4. Discussion and Conclusions

This paper introduces a compliant and flexible surgical robotic system with a parallel continuum mechanism for TORS and focuses on a pilot cadaveric study.

The cross-section of the bendable segment, which will enter the surgical area, is within a circle with a diameter smaller than 20 mm. In contrast, the da Vinci and the Flex surgical systems have diameters larger than 25 mm. The reduced dimension, increased flexibility, and improved adaptability can alleviate the injury caused by the collision between the robot and surrounding tissues. This surgical robot can easily bypass the epiglottis and cover most areas of the upper respiratory tract. After reaching the target area, manipulators can complete a series of surgical operations with the proposed master–slave teleoperation mode.

The cadaver results show that the proposed robot is easy to set up and use. Operators can quickly grasp the manipulation skills and complete the TORS procedure on the subject as demanded, during which the adjustment of the position and orientation can be achieved using the proposed master–slave control algorithm instead of additional assistants. The average time for the robot steered to the vocal cord (transorally approach) is slightly longer than the result obtained in [25]. However, this result is still shorter than the time cost of the Flex surgical system (218 s) [34]. Consequently, the developed surgical robotic system can satisfy all the clinical requirements and is well-suited for TORS.

Parts of the robot that directly contact the human tissues are made of autoclavable material and can stand the strict sterilizing requirements of the surgery. The carefully designed clamping device is for single-use, disposed of together with the surgical instrument to prevent cross-infection. To further increase the safety of this surgical robotic system, sterile wraps will be employed to cover the robot. In general, the designed robot meets the safety requirement of TORS.

Although the developed surgical robotic system achieved good performance in the cadaver trial, several deficiencies should be remedied before this robotic system can be applied in clinical applications. A rotational DOF should be added to the positioning part, contributing to the robot's further increased flexibility and applicability. More surgical instruments, e.g., various forceps, scissors, and electrotomes compatible with this surgical robot, should be designed to enable this robotic system to complete more extensive surgical operations. The vision unit was rarely used in the cadaver trial due to the extremely confined working environment, which can be simplified in the future design to further reduce the robot size. A new surgical aspirator was utilized to remove the smoke generated during the electrical cauterization, which often blocked the view of the endoscope and affected the operations of the manipulators in the cadaver trial. A built-in air channel can resolve this issue, which can also be used to clean the lens of the endoscope.

Future works mainly focus on the improvement of the stability and functionality of the robot. The clinical feasibility of this surgical robot system should be further verified with more animal trials and in-human experiments.

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Abbreviations

The following abbreviations are used in this manuscript:

MIS	Minimally invasive surgery
TORS	Transoral robotic surgery
TOS	Transoral surgery
FDA	Food and Drug Administration
DOF	Degree of freedom
Ni-Ti	Nitinol

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