

# Advancement of Flexible Robot Technologies for Endoluminal Surgeries

*This article covers the key technical issues in flexible surgical robotics, such as manipulator design, modeling, and control, and it introduces emerging flexible technologies organized according to their target application in the endoluminal surgical field.*

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**ABSTRACT** | The trend of achieving minimal invasiveness in surgeries and recent technological advances in robotics have resulted in the emergence of flexible surgical robots. Such flexible robots can reach a surgical site via narrow and tortuous pathways, extending the reach of robotic surgery and potentially reducing the incision size. This review covers the key technical issues associated with flexible surgical robotics and introduces emerging flexible surgical robot systems organized according to their target applications in the endoluminal surgical field. Furthermore, the challenges and recent advancements in manipulator design, modeling, and control as well as the shape and force sensing of flexible robots are presented as key technical issues. Furthermore, the technical features and clinical values of emerging flexible surgical robot systems are introduced with their medical applications.

**KEYWORDS** | Continuum robot; endoluminal surgery; flexible robot technology; flexible surgical robot; hysteresis

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## I. INTRODUCTION

Surgery has evolved to provide better clinical outcomes for patients by enabling less complication and more effective surgical procedures. A notable trend in surgery is the pursuit of minimal invasiveness, which can be explained by the paradigm shift from an open surgery to a minimally invasive surgery (MIS). An MIS can be a multiport/single-port surgery or in a more exploratory manner, a so-called no-incision or no-visible-scar surgery using natural orifices. Such an MIS is advantageous to patients because it can reduce skin incisions, thereby reducing infection, postoperative pain, and recovery time while improving cosmesis.

Advances in technology, particularly the application of robotic technology to surgery, have played an important role in the realization and even expansion of such paradigm-shifting procedures in conjunction with a substantial effort on the part of surgeons. Although an MIS is beneficial to patients, it is difficult for surgeons because the surgery must be performed under the restricted vision obtained from a videoscope, which is a stick-like instrument exhibiting a lack of maneuverability, dexterity, and ergonomics that may considerably limit the surgeons' capabilities. The use of robotic technology provides surgeons with precise and dexterous instrument motion as well as intuitive and ergonomic manipulation. Thus, robotic assistance can expand the benefits of an MIS and enable new procedures.

The successful clinical adaptation of the da Vinci system by Intuitive (Sunnyvale, CA, USA) [1] demonstrated the clinical benefit of robotic surgery and thus catalyzed the development of surgical robots. Several similar multiport

robotic surgical systems with rigid and straight instruments having articulating tips have emerged in the last decade (emerging multiport laparoscopic robotic surgical system are summarized in [2]). The adaptation of such robot systems to single-port surgery has been encouraged, revealing limitations such as instrument collision and limited triangulation. This resulted in the development of next-generation robot systems specifically designed for single-port surgery, with a camera and elbow articulating instruments introduced through a single access port (da Vinci SP [3], SPORT<sup>1</sup> (rebranded as Enos) [4], and micro-IGES [195]). The instruments are inserted into the surgical site in a straightened shape and triangulation is formed using the elbow joint. This feature considerably improves accessibility with reduced instrument collision, particularly in confined spaces near natural orifices such as the oral cavity and rectum. The emergence of such robot systems effectively broadens the applicable surgical sites from abdominal incisions to passing through natural orifices.

The use of robotic surgical system in endoluminal surgeries is still limited because the use of a long and rigid instrument impedes the access to surgical sites through narrow and curved anatomical pathways in the lumen, such as the esophagus, stomach, colon, ureter, bronchial tubes, and arteries. Traditionally, a flexible endoscope is used to access and perform advanced therapeutic procedures in intralumens or endolumens. Transluminal approaches, such as natural orifice transluminal endoscopic surgeries (NOTESs), have also been attempted. However, performing complex surgical procedures such as tissue cutting or suturing is technically challenging due to limitations, such as the lack of instrument dexterity, no triangulation, and nonintuitive endoscope manipulation. Therefore, open or laparoscopic surgery is inevitable if a lesion requires complex surgical procedures that are not covered by the current endoscopic methods.

Such limitations of conventional endoscopes and widespread adoption of the MIS technology across surgical disciplines gradually push surgical robot systems to have flexible articulating endoscopes and instruments. Flexible robotic surgical systems have been actively developed in the last decade, demonstrating greatly improved accessibility and feasibility for completing surgical tasks with dexterity. In an ideal robotic surgical system, it would be extremely beneficial to have a flexible instrument that is small in size, flexible yet strong, and precisely controllable for successful clinical applications, as shown in Table I. Because flexible surgical robot technology is still in its infancy and its clinical validation is lacking, many research efforts are ongoing to improve the performance, validate the feasibility, and investigate the possible indications of a flexible surgical robot for endoluminal and transluminal applications.

In this review, we present key technical issues and recent advancements in the design, modeling, control,

<sup>1</sup>Trademarked.

**Table 1** Requirements and Technical Challenges Faced by Flexible Surgical Robots for Endoluminal Applications

Requirements	Technical challenges
Flexibility for access to the surgical site through narrow and tortuous routes via natural orifices	<ul style="list-style-type: none"> <li>Flexible guide tube (or endoscope) with excellent bending capability</li> <li>Complete integration of endoscopic functions in a limited overall diameter</li> </ul>
Dexterity, accuracy, and stability for performing surgical interventions in a confined space	<ul style="list-style-type: none"> <li>Multi-DoF flexible instrument with thin and compact size</li> <li>Instruments with flexibility but adequate payload/stiffness</li> <li>Surgical triangulation</li> <li>Precise control of long and thin flexible instruments</li> <li>Ergonomic and intuitive human-robot control interface</li> </ul>
Safe access to the surgical site and tissue manipulation	<ul style="list-style-type: none"> <li>Precise and reliable intraoperative shape sensing</li> <li>Tissue interaction force sensing and feedback</li> </ul>

and shape- and force-sensing ability of flexible surgical manipulators. Furthermore, we present the state-of-the-art comprehensive analysis of the technical features and clinical significances of flexible robotic surgical systems for endoluminal surgeries. The review is organized as follows. In Section II, the challenges and most recent developments with respect to each key technical issue of flexible surgical robots are presented. In Section III, a comprehensive analysis of flexible robotic surgical systems is provided based on their target application in the field of endoluminal surgery. In Section IV, a summary and an insight into the current and future state of flexible robotic surgical systems are provided.

The primary search terms for technical issues covered in this article are as follows: continuum surgical manipulator, variable stiffness surgical manipulator, payload of surgical manipulator, kinematic modeling of continuum manipulator, statics and dynamics of flexible surgical instrument, master-slave (M-S) control of flexible surgical instrument, hysteresis of tendon-sheath mechanism (TSM), hysteresis of flexible surgical instrument, shape sensing of flexible surgical instrument, force sensing of flexible surgical instrument, and haptic feedback of flexible robotic surgical system.

## II. KEY TECHNICAL ISSUES IN FLEXIBLE SURGICAL ROBOTS

### A. Manipulator Design

1) *Types of Flexible Manipulators*: Reviews of various types of flexible manipulators in medical robotics have been presented in [5] and [192]. From these reviews, we expanded the flexible manipulator design categories to include manipulators with continuous backbones, discrete backbones, hybrid backbones, soft robotics, and origami robotics. Robots with a continuous backbone (also known as continuum robots) use a continuous elastic backbone

bent via push–pull actuation, antagonistic pairs of wires, or shape memory actuators, as well as preshaped superelastic tubes. Recent progress in the flexible manipulator design includes compliant manipulators based on a notch flexure hinge [196]–[198]. Robots with discrete backbones are hyper-redundant serial manipulators that are driven via the push–pull antagonistic actuation of wires and use articulated linkages, pivots, and wire-compressed cams to form their structure. The driving cables are designed to always pass through the center of all joints to achieve a decoupled drive. Robots with a hybrid backbone manipulate objects by combining flexible elements (e.g., springs) and linkages. The entire body of a soft robotic manipulator is made of a soft material, such as silicon rubber, and is bent using a hydro/air pressure actuator. A comprehensive review of soft robotics for an MIS is presented in [6]. This type of flexible surgical manipulator is expected to be developed in the future due to its high compliance and safety inside the body; however, designs in which the flexible material deforms greatly require attention to the fatigue breakdown due to repeated use. An origami robot presents a potential solution to enhance the space efficiency and dexterity of a flexible manipulator. Few origami-based mechanisms have been proposed for flexible robotic surgical system applications, representing an opportunity for achieving a large workspace from an initially tiny structure [199]–[201]. In addition, it should be noted that long systems typically have a semirigid or flexible passive part near the base and flexible steerable segments near the distal part.

*a) Single-backbone versus multiple backbone manipulators:* Single-backbone flexible manipulators have one central structure that allows transmission elements and instrument channels to pass through. Multiple backbone flexible robots have multiple elements that run in parallel and are constrained to one another.

*b) Single instruments versus multiple instruments:* Simple surgical procedures in confined spaces are usually performed using a single instrument, whereas more complex surgical interventions will require several flexible arms and some triangulation.

*c) Extrinsic actuation versus intrinsic actuation:* Extrinsic actuation includes: 1) cable or tendon actuation; 2) superelastic push–pull rods; 3) magnetic steering; and 4) concentric tubes. Intrinsic actuation includes: 1) shape memory alloys and active polymers and 2) fluidic actuation.

There is a fundamental tradeoff between high flexibility and range of motion of instruments versus output stiffness and payload. An important part of the current research in the design of a flexible surgical instrument is concentrated on the enhancement of payload and stiffness.

*2) Stiffness Enhancement:* Endoluminal applications of flexible robotic surgical systems require a manipulator with both flexibility and high stiffness. To access an affected area via a long and curved pathway, the manipulator

should be flexibly bendable. A manipulator with a discrete or continuous backbone mechanism has flexible features that can greatly improve the access to an affected area that is difficult to reach using a conventional rigid manipulator. However, when performing surgical interventions, such as tissue resection and suturing, the manipulator should resist external load and maintain the desired distal-end pose to provide a stable surgical environment. In brief, the manipulator should be flexible enough to access the affected area but should stiffen after reaching the affected area. To address this tradeoff problem, methods for the stiffness enhancement of flexible manipulators have been studied for flexible surgical robot applications in the last decade. The major approaches can be classified with respect to the working principle for stiffness change: wire tension, friction or interlocking, and phase transition. A comprehensive review of the stiffness variable mechanism for flexible medical devices can be found in [7]. Hereafter, this review focuses on stiffness enhancement using wire tension, which has not been included in previous reviews, with an update of recent results obtained using known approaches.

*a) Wire tension:* Increasing wire tension has been proposed to enhance the stiffness of wire-driven flexible manipulators. Several studies [8]–[10] have proposed a discrete backbone manipulator with a rolling contact joint and parallel wire path. Because rolling contact joints allow the wires to dominate the stiffness of the manipulator, the stiffness increases with an increase in the initial wire tension. In addition, an energy-based optimization of the rolling joint geometry was proposed to minimize shape distortion against an external load applied to the end tip [10]. Moreover, several researchers attempted to improve manipulator stiffness with nonparallel wire paths. The distance between the wire hole and central axis was shortened to stiffen the distal end of a discrete backbone manipulator against lateral forces [11]. A convergent wire path for a continuum backbone manipulator was proposed to improve the stiffness against the lateral force applied at arbitrary points on the manipulator [12]. A tradeoff relationship was established between parallel and convergent wire paths against lateral force and moment applied to the distal end of a discrete backbone manipulator with a rolling joint. Then, a combination of parallel and convergent wire paths was suggested to increase the stiffness against both lateral force and moment [13]. These approaches can be simply and compactly integrated with flexible manipulators without any additional components. However, constant tension control is required to maintain stiffness in case of wire elongation or slack.

*b) Friction or interlocking:* The change in stiffness can be achieved via friction or interlocking between interacting structures (e.g., joints, layers, teeth, and granular material) that can be generated by an activation force, such as wire tension, pneumatic or hydraulic force, or electromagnetic (EM) force. To enhance the stiffness in a rigid state, a discrete backbone manipulator was proposed that involved a shape-locking mechanism using the coupling of

a mechanical latch activated via EM force [14]. In addition, new ideas based on a jamming transition have emerged recently. A combination of layer jamming and granular jamming has been suggested [15], and a fiber jamming transition that produces remarkable variable stiffness in long slender manipulators was proposed [16]. These approaches generally require additional mechanisms or a certain amount for interacting components; therefore, compact design should be considered to minimize the overall diameter of the manipulator and effectively secure the working channels for introducing surgical instruments when used as guide tubes.

c) *Phase transition*: A phase transition material, including electrorheological fluids, magnetorheological fluids, low-melting-point alloys, or thermoplastic polymers, can change the elastic property from a flexible to a rigid state. This property can be activated by heat, chemical reaction, or EM field. Several studies recently proposed the use of a low-melting-point alloy that presents a substantial stiffness variation (solid to liquid and vice versa) within a biocompatible temperature range (melting temperature of  $<50$  °C) [17]–[19]. Meanwhile, the use of thermoplastic material showed considerable stiffness enhancement, which is much stiffer than commercial endoscopes [20], [21]. Although the current achievable rate of stiffness change is encouraging, further technological advancements are required before the phase transition materials can be used in surgical situations, particularly those requiring rapid responses in case of an emergency because these mechanisms take several to tens of seconds to switch between phases.

3) *Payload Enhancement*: At the early stage of the emergence of flexible surgical robots for endoluminal surgery, flexible surgical instrument design mainly focused on a small and flexible instrument with a large range of motion and multiple degrees of freedom (DoFs). These flexible robots have improved dexterity considerably in endoluminal surgical interventions, such as endoscopic submucosal dissection (ESD). However, flexible surgical robot applications have been limited to surgical interventions that require only a small amount of force. This is because the payload capability of a flexible surgical instrument is greatly reduced due to its flexibility and small diameter, as surgical interventions must be performed in a confined intraluminal space, such as the esophagus, stomach, or large intestine. Thus, several mechanisms and methodologies for improving the payload of flexible surgical instruments have emerged in recent years.

The two fundamental factors related to the payload of underactuated flexible manipulators are the amount of wire tension and the moment arm at the pivot joint. Due to the limited wire strength and a large amount of elongation in the thin wire used in small-sized flexible surgical instruments, current research concentrates on increasing the moment arm of the manipulator. Several researchers have implemented a rigid connecting link or

rod between the joints of a discrete backbone manipulator to increase the moment arm at a pivot joint [22], [23]. In addition, a discrete backbone manipulator with a completely open-wire path between the joints and an auxiliary inner link was proposed [24]. The fully open-wire path provides an increased moment arm at a pivot joint, and the auxiliary link prevents an s-shaped deformation against an external load. Furthermore, gear-shaped links avoid shear slippage between joints. These approaches can efficiently increase the moment arm; however, they are applicable in a limited-bending DoF and the interference between protruding rods or wires and surrounding objects should be considered. As another approach, a joint design parameter optimization methodology was proposed for discrete backbone manipulators using rolling joints [25]. The moment arm in a given manipulator diameter is maximized by optimizing joint design parameters based on the moment equilibrium equation. In addition to increasing the moment arm, a rolling contact joint with a sandwiched spur gear contact surface and corresponding joint geometry optimization was devised to overcome sliding at the contact surface [26]. Furthermore, a wire-reduction mechanism was developed using a similar method with a movable pulley for high payload and stiffness while reducing actuating wire tension [27].

4) *Special Considerations in Manipulator Design*: Several considerations can be included in the design of driving mechanisms to enhance the safety, robustness, and precision of a flexible manipulator. Reducing the passive stiffness of a flexible manipulator can improve the safety of the human body. A torque limiter on an actuator can provide a completely free mode, an active drive mode, and a slipping mode under overload [28]. Furthermore, the driving-wire elongation should be adjusted to ensure long-term and robust control in a wire-driven flexible manipulator. An effective solution to deal with the wire elongation is applying a mechanism that can automatically adjust the extension of the driving wire without using any servo system [29]–[31]. In addition, the diameter and frictional resistance of the actuating cable must be reduced to smoothly insert a flexible and thin surgical robot into a place with a small radius of curvature. A special cable with a diameter of  $100\ \mu\text{m}$  and a special coating on the cable surface was developed for this purpose. A low friction microcable was used for flexible surgical robots in [30] and [31]. Later, this unique cable was commercialized by HI-LEX Corp and is now widely used.

The fabrication scheme is another issue that should be considered while designing a flexible manipulator. A comprehensive introduction of flexible surgical manipulator fabrication methods is described in [229]. The major fabrication methods for the prototyping of flexible surgical manipulators can be categorized into subtractive manufacturing and additive manufacturing. Typically used subtractive manufacturing methods include computerized numerical control machining, laser cutting, or wire

electrical discharge machining (EDM). The 3-D printing, including metal printing or laser sintering, is typically used for additive manufacturing. In general, compared with subtractive manufacturing, additive manufacturing provides superior resolution, accuracy, and mechanical properties, including strength and surface smoothness. Additive manufacturing has the advantage of its capability of realizing complex 3-D structures, such as multiple working channels or helical tendon paths. Therefore, researchers need to understand the characteristics of each fabrication method and consider using a suitable method according to the purpose, structure, material, and size of the manipulator.

## B. Modeling and Control

Modeling of flexible manipulator kinematics is directly dependent on the flexible manipulator's mechanical design: manipulators with a continuous, discrete, or hybrid backbone, single-backbone versus multibackbone manipulators [32], and single versus multiple instrument manipulators.

1) *Kinematics and Dynamics Modeling*: Discrete backbone manipulators are modeled as a series of rigid links connected using revolute or spherical joints with possibly some translation of the instruments and the main body. Therefore, classical Denavit–Hartenberg (D–H) kinematics modeling can be used. This method has also been used to approximate kinematic modeling of some continuum medical robots [24], [236], [237].

Continuous backbone manipulators usually comprise several flexible segments. The forward kinematic model of each segment consists of the pose of the backbone with respect to the arc length along the backbone and the actuator position for the segment. The most commonly used approach assumes a constant curvature of the segments where the pose of the backbone is given by the segment length and curvature and the angle provided by the actuation [33]. The constant curvature assumption enables continuum robot motion in free space assuming a uniform distribution of stress, i.e., in the case of tendon-driven mechanisms, a uniform tension is assumed in the cables. This model is efficient for diagnosis purposes in the case of classical flexible endoscopes. However, it does not allow the modeling of torsion along the backbone.

Variable curvature arc segments could also be used to improve modeling. The backbone pose evolves along the arc length according to differential equations with no known closed-form solution. Therefore, a numerical integration from base to tip of the manipulator must be performed.

Because applying analytical approaches for obtaining inverse kinematics solutions for continuum robots is difficult, due to their redundancy and nonlinear elastic nature, learning-based approaches have also been proposed to compensate for the reliability and complexity issues of analytical modeling [202], [203].

To consider interaction forces working on continuum robots, it would be necessary to use mechanics-based representations. Lumped-parameters mechanics models use discrete springs, dampers, and masses to approximate the response of a continuum robot to applied loads and actuation. Such a model is used to consider actuation elasticity [34] and friction [35]. Classical elasticity theories for long slender objects, such as beams, rods, or strings, are also used to model bending, torsion, shear, and extension of continuum robots. Cosserat rod theory, in particular, allows the consideration of external forces and moments via a set of ordinary nonlinear differential equations describing internal forces and moments coupled with material constitutive linear stress–strain laws [36]. The Cosserat rod theory provides the kinematics and dynamics models that are numerically solved with appropriate boundary conditions [37]. Based on the Cosserat rod theory, a mechanical model considering tendon interaction and external force [204] and a stiffness controller for a continuum robot [205] was developed.

Control of flexible systems can be open/closed loop or a combination of both loops [38]. Open-loop control strategies are built on the assumption that a near-perfect kinematics model of a flexible robot is known and the control issue is providing a real-time inverse kinematics model. Because closed-form solutions to the inverse kinematics problem do not exist in general, there is a tradeoff between modeling complexity and real-time computation. Furthermore, several major uncertainties exist in flexible medical robotics, making open-loop control in a Cartesian space ineffective in practice. There are often poorly modeled friction forces, a large variable hysteresis, and a dead zone between actuator and end-effector motions, especially with TSMs. Another major issue is that the contact forces on the body of a flexible manipulator usually change its shape and position in space, making it impossible to know the position of the instruments inside the patient based solely on the positions of the actuators. The contact force on the instruments will also necessitate specific sensors if they are considered.

Consequently, practical approaches concentrate on closed-loop strategies to compensate for the uncertainties using extra sensing that are external to the robotic device, i.e., medical intraoperative images, and on shape, force, and haptic measurements. In the case of manually manipulated devices, feedback control is achieved by keeping the surgeon in the loop and/or using automatic control strategies under surgeon supervision.

For medical applications, flexible instruments are moved at a low speed and they have a small mass. Inertial effects are somewhat negligible compared with static friction and flexible energy storage. Therefore, dynamic modeling is generally not necessary and modeling is focused on kinematics and static deflection.

2) *Teleoperation and Automatic Control*: Flexible instruments with steerable heads and multi-instrument flexible

devices are difficult to control manually using a single operator. This justifies the roboticization of any device used in complex endoluminal surgeries.

M-S robotized systems are developed with several objectives in robotized surgery, e.g., (see the recent review [39]):

- 1) added dexterity at the instrument level;
- 2) multiple instrument manipulation by a single user;
- 3) motion scaling;
- 4) tremor filtering;
- 5) workspace limitations;
- 6) dynamical constraints;
- 7) force and torque limitations;
- 8) gravity compensation;
- 9) keeping the surgeon in the loop for safety and regulatory reasons.

These objectives are valid for rigid and flexible instrument telemanipulation. In the case of flexible instruments and endoluminal applications, manual procedures require extensive training and are usually limited in scope, requiring high proficiency to perform them and making robotized instruments necessary for routine clinical acceptance.

*a) M-S mapping strategy:* The goal of this strategy is to enable the surgeon to perform intuitive manipulations to reduce the learning curve and improve safety [40]. Poorly designed interfaces reduce the ergonomics for the surgeon and will hinder the acceptance of the robot [41]. Existing telemanipulated robots use either commercially available master interfaces or interfaces that were custom designed. When the operator moves the master interface, the measurements of the master joints are mapped into control commands for the slave robot actuators. The ergonomics of the M-S robotic system will depend on different factors:

- 1) geometry and kinematics of the main master interface controlling instrument motion;
- 2) mapping strategy between master joint measurements and slave instrument actuator control;
- 3) visual and sensory interface for the awareness of the surgical environment;
- 4) different command interfaces for activating specific features besides instrument motion, e.g., camera motion, instrument opening and closing, and energy device activation.

The learning curve will be reduced if the surgeon can easily build a mental picture of how the motion on the master interface side translates into the motion of instrument tip, e.g., a two-arm master interface will drive dual instrument systems, moving the instruments back and forth by moving the master arms back and forth, and rotating the instrument around an axis by rotating the master interface around an axis perceived as parallel through the visual interface. The surgeons feel as if they are moving the instruments inside the body by hand. It is required that both the master interface design and the mapping strategy allow slave motion control in the operating space [42].

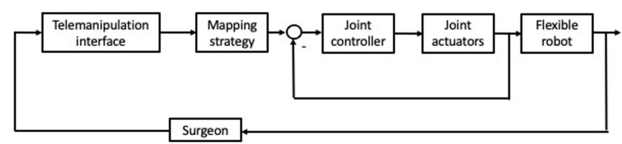


Fig. 1. M-S control loop.

The latter requires an inverse kinematics computation to be built into the mapping strategy (see Fig. 1).

For manipulability and motion scaling, it is essential that master interface motion avoids the interface singularity and the limit of its workspace. These considerations will require the development of specially designed medical robot interfaces rather than using all-purpose commercial products. The mental burden of the surgeon should be dedicated to performing the surgical act and not concentrating on which button to push, which pedal to activate, or which arm motion to perform.

Possible issues that need to be addressed through comparative testing when designing a master interface include the following [43]:

- 1) joint mapping versus position mapping in the task space;
- 2) large bending control (up to retroflexion);
- 3) a master interface with more DoFs than the slave instrument (usually three or four DoF per instrument).

*b) Automatic closed-loop control with telemanipulation:* In the case of a telemanipulated robot, the surgeon closes the loop by observing instrument displacements during surgery and working on the master interface to adjust their positions in real time (see Fig. 1). To improve the control performance, it is of interest to combine telemanipulation with automatic feedback control, assuming that the measurements of the position of the instrument tips can be performed in the operating space. In [44], breathing-induced motions of the liver were tracked via visual servoing combined with telemanipulation in the case of a robotized endoscope. If the telemanipulation interface allows haptic feedback, it is possible to constrain motions on the master side via haptic feedback when reaching the limit of the authorized workspace of the slave, assuming that measurements of the position of the instrument tips in the operating space are available. A recent review of haptic feedback in tele-operated robotic surgery is presented in [45]. Tactile feedback is more stable than force feedback but less transparent.

*3) Hysteresis Compensation of the TSM:* TSM is a common actuation method for achieving steerability in flexible surgical robots. This mechanism offers several advantages, such as flexibility, efficient transmission, and compact manipulator size. While a TSM-based manipulator has many advantages, its precise control is difficult due to the hysteresis caused by nonlinear friction between the

tendon and sheath, backlash, or a dead zone caused by tendon slackening and elongation. This contributes to the delay and degradation of control accuracy in conventional kinematic control models, limiting the performance of flexible surgical robots [46]. Flexible surgical robots for endoluminal applications are prone to hysteresis because their manipulators usually have a long and tortuous tendon configuration, leading to large friction force and wire deformation. Thus, considerable effort has been made to compensate for the effect of hysteresis using various approaches: offline and online compensations.

*a) Offline compensation:* In offline compensation, an analytical or data-driven hysteresis model is typically determined preoperatively and used to perform intraoperative hysteresis reduction without changing model's parameters. Several studies have proposed a static model that uses the Coulomb friction to overcome hysteresis [47]–[53]. In this model, tension propagation is represented by the friction coefficient and curvature radius of the sheath. Several mathematical models representing hysteresis behavior, such as the Bouc–Wen and Prandtl–Ishlinskii models, have also been proposed to deal with the dynamic characteristics [54]–[56]. Because these hysteresis models are complicated and contain several hyperparameters whose identification is complicated, more simplified models were proposed. These models include a positive inverse kinematic model based on offline learning of the hysteresis behavior of the instrument [57], a learning-based method for hysteresis modeling [58], [66], and a simplified piecewise linear model to identify backlash and dead-zone hysteresis using actuating motor current [59]. Although these offline approaches require no additional sensors and have low intraoperative computational cost, they have a common limitation that the compensation may be degraded if priori hysteresis characteristics are converted intraoperatively. This is mainly due to the change in tendon-sheath configuration. This has resulted in the development of active or adaptive models, such as a nonlinear model with adaptive parameters against time-varying sheath configuration [60], a backlash model considering tendon and sheath deformation [61], and an active model-based scheme estimating hysteresis model error using an unscented Kalman filter [62].

*b) Online compensation:* In online compensation, the pose of the flexible manipulator is usually measured or estimated using sensors or camera images. Feedback compensation is performed using the difference between the measured pose and the desired input pose. This method is more robust than offline compensation methods, regardless of the change in hysteresis characteristics. A fiber Bragg grating (FBG) sensor can be used to measure and compensate for the changes in the shape of the continuous backbone manipulator [63]. The use of an EM position sensor and closed-loop feedback in conjunction with a telemanipulation scheme has been proposed to compensate for hysteresis [64], [65]. However, these approaches require adding extra sensors to an instrument, which is challenging

due to the space limit and sterilization issues. Another promising method for the online compensation is to estimate the pose of a surgical instrument using the image captured by an endoscopic camera. The position estimation of a surgical instrument was performed by tracking a marker attached to the flexible surgical instrument, which compensates for the three-DoF hysteresis [66]. A learning-based pose estimation was proposed that used instrument images acquired from an endoscopic camera and compensated for the two DoF motion of a surgical instrument [67]. Furthermore, a robust hysteresis compensation for image occlusion was proposed by fusing the image information and kinematic information of a surgical instrument [68]. The nonlinear hysteresis behavior of a surgical instrument in a different tendon-sheath configuration was estimated using an instrument image obtained from an endoscopic camera [69]. Although the camera image-based pose estimation provides reasonable accuracy without using an additional sensor, performance degradation in the case of occlusion and low image quality need to be investigated further. In addition, hysteresis physiological motion was compensated using visual servoing for the two DoF of a flexible robotized endoscope [70], [71].

### C. Shape and Force Sensing

*1) Shape Sensing:* The inherent characteristics of surgical flexible manipulators, such as deformability, compliance, redundancy, and inevitable collision with surrounding tissue, make the accurate estimation of manipulator's shape and pose difficult using the kinematics and mechanics-based models. Furthermore, the application of this model-based approach is difficult due to uncertain model parameters and the effect of external loads, resulting in large changes in shape and kinematics. This leads to a lack of accurate position feedback and unsafe guidance of the flexible manipulator to the surgical site. Therefore, in addition to the conventional model-based approaches, an effort has been made toward the development of shape-sensing methods using various sensors. The emerging sensor-based approaches can be divided into three categories: optical-fiber sensor-, EM sensor-, and intraoperative image-based methods. These techniques are used not only for precise control but also for navigation and contact-force estimation of the flexible instrument used in endoluminal surgery. A comprehensive review of shape-sensing technologies is presented in [73]. This section briefly provides the basic principle and state-of-the-art updates with respect to each technology.

*a) Optical-fiber sensor-based method:* Optical-fiber-based shape sensing uses scattered signals from multiple optical fibers to identify local curvature and twist and, thus, the shape of a given structure. Fibers are typically integrated alongside the shaft of a flexible body. This method has been widely used in flexible surgical robots due to their flexibility, small size, lightweight, immunity to EM interference, and biocompatibility. Optical-fiber-based

sensing technologies can be classified into FBG-based methods and light intensity modulation (LIM)-based methods. The research endeavors of each technology is presented in [73]. To measure the large bending of a flexible manipulator, a fiber-optic sensor with minute notches on its surface that do not interfere with manipulator motion was proposed in [74]. Moreover, some research groups have presented a helically wound FBG sensor that overcomes the limited stretchability to adapt to the large deformation of a flexible manipulator [75], [76]. The FDA-approved robot-assisted bronchoscopy Ion (Intuitive, Sunnyvale, CA, USA) uses optical-fiber sensors for sensing the shape of the robotic catheter. While previous research concentrated on the sensor design, several recent studies have focused on algorithms and methodologies to enhance the accuracy of shape sensing and distal-end position estimation. These algorithms have presented a data-driven learning-based approach [77], an updated shape reconstruction algorithm based on the error accumulation of a single-point recursive reconstruction algorithm [78], and an extended Kalman filter-based estimator that iteratively predicts and updates not only curvatures on the fiber but also the degree of its twist [79]. The fusion of fluoroscopy and FBG for 3-D shape reconstruction of a catheter has been proposed as well [206].

*b) EM sensor-based method:* Mutual induction- and EM sensor-based methods are capable of localizing EM receivers working within the tracking workspace produced by an EM-field generator. The small size of EM sensors and their freedom from line-of-sight constraints demonstrate unique capabilities for tracking and localizing flexible manipulators within lumen. Generally, multiple EM sensors are attached along a flexible instrument body and collaboration with kinematic models is encouraged to compensate for the discrete pose obtained using the distributed EM sensors. Recently, a continuum manipulator with an integrated small permanent magnet and a magnetic sensor was devised that did not require any other external detection platforms [80]. In addition, a fusion of EM tracking with fiber optical shape sensing for 3-D guidance was proposed [81], [207]. A commercialized robot-assisted bronchoscope (Monarch, Auris Health, USA) uses EM sensors for improving the stability of computerized tomography (CT) image-based navigation. Although there are advantages to this method, one challenging issue is its susceptibility to distortion in the presence of EM fields associated with metallic surgical tools in an operating environment.

*c) Intraoperative image-based methods:* Intraoperative image-based techniques enable direct shape measurements of flexible surgical robots. External imaging modalities, such as fluoroscopy and ultrasound, can be used to determine the shape of the flexible shaft (e.g., insertion tube). Knowing the shape and pose of the surgical instruments, particularly in endoluminal systems, can be useful for obtaining control feedback. This is usually measured using internal imaging modalities such as endoscope cameras.

Recently, an image-based shape estimation using convolutional neural networks has emerged for enhancing robustness in measuring complex articulated surgical instrument shapes [82]–[84]. In addition, a robust and fast regressor that estimates instrument kinematics directly from camera images was presented [85]. Although the image-based approach has demonstrated great potential for shape and pose sensing without the use of additional sensors, ensuring robustness in the face of occlusion requires further investigation. Thus, several approaches have emerged for a robust shape-sensing algorithm even if partial occlusion occurs. These approaches proposed a shape reconstruction method based on partial marker point position information [86] and an error compensation method based on machine learning and sampled EM tracking data [87].

*2) Force Sensing:* Some intrinsic features of endoluminal surgery require contact sensing between the instrument and organ, which is more important in an endoluminal surgery than any other surgery: 1) contacting organs is inevitable because the surgical instrument accesses the surgical site through long, narrow, and curved pathways; 2) surgical instruments are surrounded by relatively fragile organs, such as the esophagus, colon, blood vessels, and ureter; and 3) a camera is located at the tip of the endoscope or overtube and has a limited field of view such that the edge of the endoscope or the shaft of the triangulated surgical instrument cannot be seen from the camera. During manual endoluminal procedures, the surgeons can feel the touch with tissue through their hands. This haptic information is used in the perception of contact and tissue damage, which is directly related to the patient's safety. Therefore, the knowledge of the interaction force between instrument and tissue in a robotic surgical system is crucial. Although current flexible robotic surgical systems have not yet provided haptic or tactile feedback, several studies have been performed to measure the interaction forces (contact and gripping forces).

*a) Contact-force sensing:* This sensing principle can be classified into sensor-, camera image-, and model-based hybrid methods.

*Sensor-Based Method:* Major sensor-based approaches use a sensor attached to the distal end of surgical instruments, where the sensor directly interacts with the tissue. Then, the consequent output (voltage, current, impedance, resistance, and so on) is converted to contact force by considering the known mechanical properties of the sensor material. Several surgical instruments with a force-sensing capability have been developed based on the abovementioned sensor-based approaches [88]–[90]. The sensor types can be categorized as electrical [91]–[93] and optical [94]–[96].

Recently, the application of FBG sensors has been actively studied for direct and indirect force sensing at the distal end of a flexible instrument [110]–[112], [208]–[211]. In addition, research was conducted to guarantee isotropic resolution along each axis [212]. Moreover,



the use of optical fibers for both actuation and tension, shape, and force sensing of a continuum manipulator was presented. A model-based estimation method has been developed to simultaneously estimate the shape and tip force [213]. When sensors are directly embedded in a surgical instrument, maintaining a small size, ease of sterilization, and robustness are tasks that are still difficult to attain. Insertion force sensing is another application of the sensor-based approach. When axially moving a flexible instrument, the sum of the contact forces along the instrument body can be represented as an insertion (or resistance) force at the proximal side. Current approaches mostly use a force/torque sensor attached at the proximal part of the instrument for preventing insertion with excessive force [97], [98].

*Camera Image-Based Method:* The deformation of one of the interaction objects, i.e., the distal part of the surgical instrument or tissue, is estimated using camera image-based approaches. For example, the camera estimates the instrument deformation using LIM, and then, the contact force is derived with the known mechanical property of the instrument [95]. The principle of using the tissue deformation approach is based on estimating the amount of tissue deformation and then calculating the estimated contact force via the mechanical properties of the tissue. An *in vivo* measurement of tissue properties was proposed that used deep learning to learn contact case images and the contact force directly [99]. A detailed review of image-based tissue deformation estimation methods for estimating contact force is presented in [100]. Although current camera image-based contact-force estimation focuses primarily on rigid instruments, it can also be used on flexible instruments using the images obtained from endoscopic cameras or optical coherence tomography (OCT) catheters.

*Model-Based Hybrid Method:* The model-based hybrid method is applied for the contact sensing of the entire flexible body (e.g., the insertion tube) because the overall contact at the entire body is hard to determine due to the difficulty in applying sensors to all the contact points. Extracorporeal imaging devices, such as CT, ultrasound, OCT, or magnetic resonance imaging, are frequently used to obtain overall interaction features between tissues and a flexible body. The deformed shape is estimated using image processing techniques from the image data of the organ and surgical instruments. A model-based guidewire contact-force estimation algorithm with an extracorporeal image for overall deflection tracking of a guidewire is presented [101]. In [193], intrinsic force sensing was performed using joint-level information and modeling. Another study used the sensor-model hybrid approach to estimate contact forces along the catheter body [102]. Two sensors with multicore FBG fibers were used for shape sensing, and three-axis force sensors were used to sense forces at the catheter base. A pseudo rigid body model was used for modeling catheter deflection in static situations. If the catheter contact points are known,

all the contact forces at each contact position can be estimated.

Another model-based hybrid method is to estimate distal force based on the measured proximal force, such as driving-wire tension at the proximal end. Previous studies attempted to estimate distal-end tension using the proximal- and mathematical-tension transmission model [107], [214], [215]. However, modeling the force transmission of the flexible manipulator is challenging because of the complexity and shape-dependent characteristics of the transmission force. The shape of the flexible manipulator is unknown and varies during surgical procedures. Deep learning approaches have been proposed to solve the variance in the tension transmission model [108], [109]. Large datasets for training and errors that remain in the motion transition phase are the unresolved issues in the deep learning approach.

*b) Grip-force sensing:* The grip-force sensing method can be categorized as direct interaction sensing (between the gripper and the tissue) and indirect sensing, which measures actuation loads of the gripper.

*Tactile Sensor-Based Direct Sensing Method:* The main principle of direct sensing is to measure the interaction force between the gripper and tissue using a sensor attached to the gripper's jaw. A comprehensive review of tactile sensors for surgical applications is presented in [103]. It is stated that most studies have estimated sensor deformation in [103]; however, some studies have estimated surgical tool deformation. A microelectromechanical system (MEMS) endoscopic tactile sensor has been used to distinguish tissue stiffness [104] and multiple polyvinylidene fluoride (PVDF) films have been used to detect the large deformation of soft tissue. In another report, forceps' jaw integrated with a flexure hinge and capacitive sensing cells was proposed to achieve five-DoF force/torque sensing [105]. A previous study has tried to sense the gripping force using visual information [106]. A camera was used to observe the color change of a tactile sensor, which was then translated into a 3-D force. This sensor only works at the distal-end tip; therefore, it is unaffected by the structure of the instrument's backside (e.g., flexible tube). However, size constraints, sterilization, and repeatability issues should be considered for clinical applications of the sensor.

*Actuation Load-Based Indirect Sensing Method:* Another indirect sensing approach involves estimating the grip force using actuation loads, such as the compression force applied to the distal end of a sheath. Several studies have determined that the magnitude of compression on the sheath is equal to that of the tension on the tendon in the TSM. FBG sensors were incorporated at the distal end of a sheath to measure the driving-wire tension, which could be used to estimate the grip force [110], [111].

## D. Remaining Challenges

In addition to the abovementioned key technical issues, several challenges remain before successfully applying the

flexible surgical robots to clinical practice: instrumentation, visualization, and drape coupler design.

1) *Instrumentation*: Different instruments are required to perform various tasks, such as resection, dissection, ablation, retraction, suturing, and coagulation, which are usually required in a surgery. So far, most flexible surgical robots provide only a limited set of dedicated instruments, such as a grasper, monopolar scissors, and a cautery knife. An instrument design that considers the specific structural constraints of a flexible manipulator is desirable. For example, an end-effector should be designed to have a small diameter and a short length to ensure a smooth insertion through a small-diameter working channel (often shaped with a small bending-curvature radius).

In addition, a flexible instrument having a distal rolling motion is recommended as it significantly improves the dexterity. Most of the currently developed flexible instruments achieve the distal rolling motion by rotating a flexible shaft at the proximal end. However, it is difficult to obtain a precise distal rolling motion due to the backlash accumulation through the kinematic chain of distal joints of the instrument and the large friction between a flexible shaft of the surgical instrument and a working channel of the endoscope (or overtube). A flexible instrument having an independent rolling DoF at the distal end would be promising to obtain precise distal rolling motion [238], [239].

A flexible energy device incorporating advanced bipolar and ultrasonic technology would substantially broaden the application of a flexible surgical robot. However, it is often challenging to precisely control the energy transmission through a flexible medium. Recently, several studies have demonstrated the feasibility of developing dedicated instruments, such as suturing [231] and laser [232] devices.

2) *Visualization*: The challenges in visualization can be categorized based on the image quality and line of sight. High-definition 3-D visualization, such as in the da Vinci system, would be highly preferred by surgeons because of good anatomy identification with depth perception. However, due to the spatial constraint of endoscope or overtube, image quality is inferior in flexible surgical robots in general. Real-time super-resolution techniques [233], [234] would be promising to obtain higher resolution images from original lower resolution images. Real-time imaging and robustness against varying imaging conditions require further investigation.

In addition, the imaging axis of an endoscope camera is usually located in parallel with a surgical instrument. Because the surgical instrument is located within the line of sight, it may obscure the affected area. Therefore, there are restrictions in obtaining the desired surgical view, such as during laparoscopic surgeries. Some researchers have implemented additional DoFs to an endoscopic camera [156], [235]; however, there is a tradeoff between the entire overtube diameter and the space required for other

functionalities such as suction, irrigation, and additional instruments.

3) *Drape Coupler Design*: In general, for the ease of sterilization and versatility, a flexible robotic surgical instrument or an endoscope is designed in a form that is detachable from the driving unit of the robot. Therefore, a drape coupler should be placed between the interface of the surgical instrument and driving unit. In the drape coupler design, it is important to minimize the effect on precise instrument driving while ensuring the instrument's sterilizability, waterproofing, and insulation. In particular, because the articulation of a small-diameter surgical instrument is controlled only by a few millimeters of tendon driving, care should be taken to not cause any motion loss due to friction or backlash at the drape coupler. Design optimization is often required through many trials and errors.

### III. FLEXIBLE ROBOTIC SYSTEMS FOR ENDOLUMINAL APPLICATIONS















Since the late 1980s, pioneering research on flexible surgical robots has emerged as an M-S type active endoscope [113], [114]. Since 2000, starting with the first flexible endoscopic surgical robot, Micro Finger [30], [31], several flexible surgical robots have emerged in earnest. This section presents a comprehensive and state-of-the-art analysis of the technical features, advancements, limitations, and clinical achievements of the flexible robot systems organized according to their target endoluminal applications: gastrointestinal endoscopic surgery, ureteroscopic surgery, bronchoscopic surgery, and endovascular surgery. Table II presents a summary and comparison of flexible robot systems for endoluminal surgery. This review focuses on the robot systems whose feasibility and efficacy have been validated through *ex vivo* tests, *in vivo* animal trials, or human trials. Notably, several articles have been recently published in the medical field reviewing robotics applications for endoluminal and transluminal endoscopic surgeries [115]–[117], [189]. As a recent update in robotic vaginal NOTES, Hominis<sup>2</sup> (Memic Ltd., Or Yehuda, Israel) [230] attained the FDA approval in 2021.

#### A. Gastrointestinal Endoscopic Surgery










Gastrointestinal endoscopy is one of the most active fields in which surgical robot technology is applied. Thus, through robotic assistance, easier manipulation and dexterous instrument motion can be obtained, which are major limitations of the conventional gastrointestinal endoscope, to advance diagnostic and therapeutic procedures. The robotic assistance in gastrointestinal endoscopy is classified as follows: robotic insertion assistance and robotic surgery assistance. Among these technologies, this review particularly focuses on assistance from robotic systems for endoscopic surgery. These flexible systems commonly contain two articulating robotic instruments that

<sup>2</sup>Registered trademark.

**Table 2** Summary and Comparison of Flexible Robotic Systems for Endoluminal Applications

System		Clinical application	Manipulation type (mechanical (M)/robotic (R))	Endoscope (Guide tube) diameter/articulation DoF	Instrument diameter/articulation DoF	Approval	Technical advancement/limitation
COBRA (USGI Medical) (Image [120])		NOTES	A guide tube (M)/two instruments (M)	NA	NA	No	Shape-locking scope and triangulation/imprecise instrument control and impossibility of instrument change
R-Scope (Olympus) (Image [121])		GI surgery and NOTES	An endoscope (M)/two instruments (M)	14.3 mm/3	<2.8 mm/1	No	Instrument channels with vertical and horizontal motion/complex manipulation and poor instrument performance in retroflexion
DDES (Boston Scientific) (Image [123])		GI surgery and NOTES	An endoscope (M)/ two instruments (M)	16 mm / 2	4 mm/2	No	Ergonomic instrument driving handles/impossibility of retroflexion and limited triangulation
EndoSamurai (Olympus) (Image [126])		GI surgery and NOTES	An endoscope (M)/ two instruments (M)	15 mm/2	NA/2	No	Triangulation and driving handles with laparoscopic paradigm/difficulty in bending due to protruded arms and instrument motion delay
Anubiscope (Karl Storz/IRCAD) (Image [129])		GI surgery and NOTES	An endoscope (M)/ two instruments (M)	18 mm/2	<4.3 mm/1	CE	Distal-end mechanism for triangulation and ergonomic instrument driving handles/limited instrument DoF
Micro Finger (Nagoya University) (Image [227])		GI surgery and NOTES	An endoscope (M)/ two instruments (R)	Commercial endoscope	2.6 mm/2	No	The first prototype of a flexible surgical robot and thin instrument inserted through commercial endoscope channels/limited triangulation and force
ViaCath (Endo Via Medical) (Image [133])		GI surgery	An endoscope (M)/ two instruments (R)	Commercial endoscope	4.75 mm/4	No	Enhanced instrument articulation with two distal bending segments/difficult insertion into the GI track and insufficient instrument force
EndoMASTER (EndoMaster) (Image [138])		GI surgery, NOTES, and Transoral head and neck	An endoscope (M)/ two instruments (R)	12.6 mm/2 (Commercial endoscope)	<3.7 mm/4	No	Triangulation with an elbow joint and thin instrument inserted through commercial endoscope channels/retraction only with left arm, occlusion of instrument tip, and no service channel available during bimanual manipulation
FLEX (Medrobotics) (Image [141])		Transoral head and neck, GI surgery, and NOTES	An endoscope (R)/ two instruments (M)	15 × 17 and 18 × 28 mm <sup>2</sup> /2	3.5-4.0 mm/2	CE and FDA	Follow-the-leader mechanism for endoscope insertion, 3D HD vision, and laser instrument/limited endoscope bending angle, instrument torque, and grasping force
STRAS (Univ. Strasbourg) (Image [147])		GI surgery and NOTES	An endoscope (R)/ two instruments (R)	16 mm/2	3.5 mm/1	No	End-tip mechanism for triangulation, solo teleoperation/limited instrument articulation DoF, and endoscope length
RAFE (Kyushu University) (Image [151])		GI surgery	An endoscope (R)/ two instruments (R)	9.9 mm/2 (Commercial endoscope)	2.6 mm/2	No	Thin instrument inserted through commercial endoscope channel, solo teleoperation, and small radius of bending/limited triangulation and force
i2 snake robot (Imperial College London) (Image [191])		ENT surgery and GI surgery	An endoscope (R)/two instruments (R)	16 mm/6	3.8/5	No	Endoscope and instrument with high articulation DoFs, integration with industrial robot arm, and solo teleoperation/limited control accuracy and lack of axial rotation and translation of instrument
ROSE (Korea University) (Image [152])		GI surgery	An endoscope (M)/an instrument (R)	Commercial endoscope	16 mm/1	No	Master interface enabling simultaneous instrument control with endoscope/large robot arm, unsmooth roll motion, and protruding instrument during insertion
PETH (KAIST) (Image [154])		GI surgery	An endoscope (M)/an instrument (R)	Commercial endoscope	6 × 6 mm <sup>2</sup> /2	No	Flexible transmission part without interference to endoscope bending/large robot arm, protruding robot arm during insertion, and assistant for instrument manipulation

**Table 2** (Continued.) Summary and Comparison of Flexible Robotic Systems for Endoluminal Applications

K-FLEX (KAIST) (Image: Permission from KAIST)		GI surgery and NOTES	An endoscope (R)/two instruments (R)	17 mm/4	3.7 mm/2	No	Double-bending endoscope, payload enhanced instruments, and solo teleoperation/limited triangulation and large bending radius of endoscope
ColubrisMX ELS system (Colubris MX) (Image [156])		GI surgery	A guide tube (R)/a camera (R)/two instruments (R)	22 mm/2	6 mm/4	No	Articulating camera for angled view, triangulation using elbow joint, and solo teleoperation/large guide tube diameter
Roboflex Avicenna (ELMED) (Image © 2020 ELMED Medical Systems)		Renal stone removal	A ureteroscope (R)	Commercial ureteroscope	NA	CE	Compatible with various commercial ureteroscopes and integrated irrigation control/limited ureteroscope translation range and no robotic assistance for basketing
MONARCH (Auris Health) (Image © 2022 Auris Health, Inc.)		Lung biopsy and renal stone removal	A bronchoscope (R)/a sheath (R)	(Scope) 4.2 mm/2 (Sheath) 6.0 mm/2	NA	FDA	Integrated electromagnetic navigation guidance, enhanced scope steerability, and tension relaxation during withdrawal/risk of electromagnetic interference
ION (Intuitive) (Image © 2022 Intuitive Surgical)		Lung biopsy	A catheter (R)	(Catheter) 3.5 mm/1	NA	FDA	Optical fiber-based shape-sensing catheter/absence of direct camera vision during the use of biopsy needle
Sensei X (Hansen Medical) (Image [228])		Endovascular surgery	A catheter (R)/a sheath (R)	(Catheter) 8 F/2 (Sheath) NA/1	NA	FDA	Highly flexible catheter with small bending radius and tactile vibration/large size and relatively long setup time
Magellan (Hansen Medical) (Image [32])		Endovascular surgery	A catheter (R)/a sheath (R)/a guidewire (R)	(Catheter) 6 F/2 (Sheath) 9.5 F/1	NA	CE and FDA	Enhanced steerable active catheter and detection of excessive driving wire tension/lack of haptic feedback
R-One (RoboCath) (Image © 2018 Robocath, Inc.)		Endovascular surgery	A guide wire (R)/a balloon/stent catheter (R)	Commercial guide wires and catheters	NA	CE	Compatible with market leading guidewires and catheters/NA
Corpath (Corindus) (Image © 2022 Corindus, Inc.)		Endovascular surgery	A catheter (R)/a balloon/stent catheter (R)/a guidewire (R)	Commercial catheters	NA	FDA and CE	Manipulation of all interventional devices, procedural automation, and teleoperation/lack of catheter articulation and loss of tactile feedback

are attached to the exterior of a flexible endoscope or introduced through the endoscope channels. The instruments (even the endoscope) are either operated manually or teleoperated using a commercial or customized master device. Bimanual surgical manipulations, such as tissue traction while cutting, suturing, and knot tying, are now possible using the two articulating instruments. One such system is currently commercially available and many others have been demonstrated to be feasible and benefiting in preclinical or clinical trials. These systems were initially developed as a “mechanical system” in which the endoscope and surgical instruments were manually manipulated by two operators using a mechanically connected handle or knob. The technology then advanced to the “robotic M-S system,” which allows the teleoperation of the endoscope or surgical instruments for achieving improved intuitiveness, ergonomics, precision, and with fewer operators.

#### 1) Mechanical System:

a) *COBRA*: *COBRA* from USGI Medical (San Clemente, CA, USA) comprises a shape-locking scope and three independent arms added at the distal end of the scope. The scope provides shape-locking capability

using friction between serially connected links that are activated by applying wire tension. The scope can provide a flexible state during insertion and then be locked into a rigid configuration to provide a stable platform for surgery [118], [119]. The three independent arms are dedicated to a camera and two surgical instruments, providing an endoscopic triangulation for achieving traction and countertraction and maintaining the visualization of the surgery area without moving the optics when the instruments are moved. Complex tasks performed using *COBRA*, such as suturing and suture-tying, have been reported to be difficult in the laboratory due to the limitations of imprecise cable-driven controls and the impossibility of changing instruments during surgery [120]. No further preclinical or clinical results have been reported.

b) *R-Scope*: The *R-Scope* developed by Olympus (Tokyo, Japan) is the first generation of a mechanically operated therapeutic endoscopic system that modifies a standard dual-channel therapeutic scope for advanced endoluminal resection and NOTES [120]. This system has a double bending scope in which the primary flexure can be locked by increasing the actuation wire tension and a

second flexure can be freely positioned. The system has two instrument channels that can be moved independently of the scope: one for lifting forceps that can be moved vertically to lift the mucosal area and the other for lifting electric knives that can be moved horizontally. The scope and two instruments can be manipulated by rotating the dedicated knob at the control body. The system was initially tested for gastric ESD in both animal and clinical studies. However, the results were less than optimal, with perforations in ~20% of both cases, mainly because of the lack of proficiency of the operator [121]. Following a clinical study with gastric ESD for superficial gastric neoplasm, the results showed comparable en-bloc resection, complications, and local recurrence results with conventional ESD, as well as a considerably short operation time [122]. The limitations of the system are that the controls are quite complex and difficult for a single operator to handle and poor instrument performance in retroflexion.

c) *Direct-drive endoscopic system*: Direct-drive endoscopic system (DDES) developed by Boston Scientific (Marlborough, MA, USA) is a manually driven, multitasking platform aimed at endoluminal [123] and NOTES applications [124]. This system comprises a rail platform and a flexible articulating guide sheath that can be articulated in two directions by manipulating familiar endoscopic controls and locking them into the desired shape. Each instrument comprises an ergonomic drive handle that is connected to a long flexible shaft with a specified end-effector at the distal tip. The handle transmits the operator's hand motion to the instrument tip, which has seven DoFs in total, including additional two DoFs provided by the guide sheath. *Ex vivo* and *in vivo* animal tests suggested that the DDES can perform complex nonsurgical tasks, including endoscopic mucosal resection, full-thickness suturing, and knot tying.

d) *EndoSAMURAI*: EndoSAMURAI developed by Olympus (Tokyo, Japan) is an endoscopic multifunctional system for conducting intraluminal and transluminal therapies. The system consists of three components: a flexible endoscope, two independent articulating working arms with surgical end effectors, and an operator interface. Because the flexible endoscope is steerable and lockable, it can provide system stability. The two working arms with five DoFs are connected at the tip of the flexible endoscope and provide triangulation with an elbow-like function. The ergonomic laparoscopy-like operator interface mechanically transmits the movement of the operator's hands to the two working arms. When compared with a conventional endoscope, the system demonstrates improved accuracy and reduced procedure time in complex endoscopic tasks, such as endoscopic full-thickness resection [125], [126]. It was also possible to perform an anastomosis of the small bowel with acceptable quality and within a reasonable time [157]. Basic surgical tasks, such as cutting, suturing, and knot tying, were performed with precision and efficacy comparable to that

of the laparoscopic instrumentation, although more time was required [127].

e) *ANUBISCOPE*: ANUBISCOPE<sup>1</sup> was originated through a collaboration between Karl Storz (Tuttlingen, Germany) and IRCAD (Strasbourg, France) and is a CE-marked surgical endoscopic platform for performing endoluminal and transluminal surgeries [128]. The system has a flexible four-way endoscope whose distal part opens like a clamshell to place the distal part of instruments and offers surgical triangulation. The instruments have an articulated distal part and allow three DoFs, each of which is manually manipulated via two-handle interfaces that also control the activation of the instrument end effectors. ANUBISCOPE requires two operators: one for the main endoscope and one for the instruments. The total number of DoFs amounts to 10:3 DoFs for each instrument and four DoFs for the main endoscope (two at the tip and two by moving the base). Initial animal and clinical studies were performed to validate the feasibility of the system for NOTES. In a swine model study, the system successfully performed a total mesorectal excision (TME) using a transanal approach and rigid surgical instruments [129]. Following a human trial, a successful transvaginal cholecystectomy with a good prognosis was reported [130]. Then, the system was evaluated for colonic ESD using a porcine model. The findings showed that ESD was feasible with less perforation and a shorter dissection time than conventional ESD, indicating promising aspects in terms of the system's safety and effectiveness [131]. The system was then advanced to a robotic M-S system called STARS [132] (see Section III-A2).

## 2) Robotic M-S System:

a) *ViaCath*: The ViaCath system by EndoVia Medical (Norwood, MA, USA) is a first-generation teleoperated robot for endoluminal surgery [133]. The system comprises a master console with haptic interfaces, slave-driving mechanisms, and long-shafted flexible instruments that run alongside a standard gastroscope or colonoscope. The two distally articulated robotic instruments are advanced compared with the endoscope, enabling a bimanual manipulation of tissues. Together with a positioning arm, the instrument provides a total of seven DoFs within the visual field of the endoscope. Several *ex vivo* and *in vivo* animal trials revealed that the system is feasible. The instruments and overall system were used appropriately to allow mucosal resection and basic suturing in the stomach and colon. A second-generation system was designed to overcome limitations such as difficulty of inserting the endoscope into the gastrointestinal tract and insufficient instrument manipulation force.

b) *EndoMASTER*: EndoMaster is a robot-assisted surgical system originally designed at Nanyang Technological University [134], [135] for performing NOTES. The first applications were endoscopic resection of gastrointestinal

polyps and tumors [136], [137]. EndoMaster incorporates two robotic arms (a grasper and a probe for monopolar diathermy) into the end of a flexible endoscope, improving maneuverability, with two arms allowing nine degrees of movement and triangulation. This enables fine manipulation and dissection of tissues. A small-scale preclinical human trial was performed where complete resection of gastric neoplasms was conducted with no complications in all patients [190]. The latest version of the EndoMaster EASE System completed a colonic ESD without perforation in a porcine model [216]. A clinical trial on the treatment of colorectal lesions began in May 2020 and was completed in December 2021. Notably, cadaver studies have also been conducted for transoral applications [138].

c) *FLEX robotic system*: The FLEX<sup>2</sup> robotic system by Medrobotics Corporation (Raynham, MA, USA) was originally developed as a highly articulated robotic probe (HARP) [139] for intrapericardial applications. The system was extended for conducting transoral and transanal endoluminal procedures. A robot-assisted flexible endoscope (RAFE), compatible flexible instruments, and a steering console comprise the system. In contrast to a traditional flexible scope, the FLEX scope comprises two linkages: one leading and one distal. The robot is driven in a follow-the-leader manner, which has a considerable advantage in entering a flexible path. The articulating instrument provides four DoFs, including two directional bendings that are manually controlled by an operator using a handle connected to the flexible shaft of the instrument. Preclinical cadaver studies in a larynx surgery as well as a nasopharynx surgery demonstrated the system's advantages in reaching and visualizing the surgical site, which cannot be achieved using standard rigid instruments [140], [141]. During its initial clinical study, the system had shown promising results for use in transoral surgical procedures in the pharynx and larynx [142], [143]. It received the European CE mark and FDA clearance in 2014 and 2015, respectively, for transoral procedures. The system was then applied to transanal access to the colorectal anatomy and demonstrated successful local excisions and full-thickness suture closure of rectal defects in the cadaveric and porcine models [144]. The system received FDA clearance in 2017 for use in colorectal endoscopic procedures. Follow-up cadaveric trials were investigated to explore the possible surgeries, reporting feasibility in various colorectal surgeries such as transanal TME (taTME) [144] and transvaginal rectopexy [145].

d) *Single access and transluminal robotic assistant for surgeons*: Single access and transluminal robotic assistant for surgeons (STRAS) by the University of Strasbourg, ICube Laboratory, is a robotized M-S adaptation of ANUBISCOPE by Karl Storz [132], [146], [147]. On the slave side, the STRAS system involves the motorization of ten DoFs of the main endoscope and its two instruments, i.e., two DoFs for the distal part of the main endoscope, two DoFs for the platform supporting the base, and three DoFs for each instrument. The motorization is designed so that

the system can be manually introduced into the patient and then attached to the supporting platform. The motorized instruments are introduced separately into the main endoscope working channels, and their bases are attached to the endoscope holder. The instruments can be easily removed during the procedure. The first STRAS system was manipulated using two Omega 7 master interfaces from force dimension [132]. Later, a customized master device was designed for better ergonomics [146], [147]. The master console comprises two mobile handles that are kinematically similar to the system's two instruments for intuitive manipulation, while the four DoFs of the main endoscope are controlled by small thumb joysticks on both handles. The M-S system STRAS has been extensively tested in *in vivo* animal studies for ESD [146], [148], [194]. It showed better performance with fewer complications than manual procedures [146], [147], [194].

e) *Robot-assisted flexible endoscope*: The RAFE platform developed by Kyushu University (Fukuoka, Japan) is designed for ESD. The concept of the platform is to use commercially available standard endoscopes that are similar to a previously developed flexible surgical robot [31]. The endoscope is driven with all of its DoFs using the extrapolated motor unit. The platform contains two articulating instruments with two bending DoFs. One is inserted through a built-in channel of the standard endoscope and the other is inserted through an additional tube attached to the tip of the endoscope. The platform was originally developed as a mechanical system in which both endoscopes and instruments were controlled by a mechanically connected knob or handle [158] and then transformed to a fully motorized system where the endoscope and two instruments were remote controlled [149]. *Ex vivo* studies using a porcine stomach demonstrated that the platform allowed a novice to perform procedures more easily and quickly than conventional ESD [148], [149], [150]. The safety and efficiency were validated from *in vivo* porcine colonic ESD, and the platform allows a reduced perforation rate and shortened resection time [151].

f) *i<sup>2</sup> Snake robot*: The *i<sup>2</sup>* Snake robot developed by Imperial College London is an endoscopic surgery system specially designed for ear-nose-throat (ENT) surgeries and ultimately endoluminal surgeries [191]. This system comprises a KUKA LBR iiwa arm, a snake-like robotic endoscope equipped with a camera, a light source, and two flexible robotic instruments. The robotic endoscope provides a six-DoF bending and can, therefore, fully perform retro-flex and form s-shapes. It is attached to an industrial robot arm (KUKA LBR iiwa) that provides various control modes: compliant positioning, teleoperation, and collision prevention modes. A handheld master interface with EM sensor-based position/orientation tracking provides teleoperation of the robot arm, endoscope, and instruments. The system was proven to be functional in a laboratory experiment [191]; however, no further preclinical or clinical studies have been reported.

g) *Robot for surgical endoscope*: Robot for surgical endoscope (ROSE) by Korea University, Seoul, South Korea, is an endoscopic assistive robot arm for ESD that can be attached or detached at the distal end of an existing general-use endoscope. It comprises a four-DoF articulating robot arm with a grasping end-effector that is teleoperated by a surgical assistant via an interface console. Because it lifts the mucosal flap dissected earlier during ESD, this robot arm allows operators to see more of the dissection area. A pilot *in vitro* study using an extracted porcine stomach showed great improvements in reducing perforation during ESD among unskilled operators [152]. These findings suggested that the assistive robot arm could help improve surgical safety. The *in vivo* study reported a substantial increase in dissection speed, especially in novice surgeons [153].

h) *Portable endoscopic tool handler*: The portable endoscopic tool handler (PETH) by the Korea Advanced Institute of Science and Technology (KAIST), Daejeon, South Korea, is an articulated robotic arm that can be attached to a commercial gastroscope or colonoscope [154]. This robot arm has two DoFs for bending and a commercial endoscopic instrument, such as forceps, that can be introduced through a working channel made inside the robot arm. The robot arm can be teleoperated by an endoscopist or an assistant using the thumbstick controller. In an *ex vivo* test using the porcine stomach, a counteraction method employing the PETH system considerably improved dissection speed and reduced blind dissection by enhancing direct visualization of the submucosal plane [154]. *In vivo* gastric ESD was performed using the porcine model, and the result presented successful application of the system in conventional ESD procedures performed at various lesion locations.

i) *K-FLEX*: K-FLEX by KAIST proposed a flexible endoscopic surgical robot featuring a payload-enhanced flexible manipulator [10]. The K-FLEX system comprises a flexible overtube, two surgical instruments, a driving part, and a master device. The overtube has four DoFs for bending at the distal end, allowing retroflexed and cobra-shaped bending. The design parameters of a discrete link comprising the overtube were optimized to achieve the maximum distortion resistance; thus, the overtube overcame shape distortion and deflection during payload handling. The surgical instrument adopted a special joint mechanism that constrained the redundancy of the discrete links mechanically using an auxiliary link to enhance the payload [24]. Intuitive teleoperation was provided by the master device, which was kinematically similar to the surgical instrument. Several benchtop tests revealed that the K-FLEX could perform endoscopic procedures with less fatigue and faster learning compared with a conventional gastrointestinal endoscope [155]. ESD was performed using an extracted porcine stomach and the results demonstrated faster precut and dissection compared with the conventional endoscopic procedure performed by an expert endoscopist. Additional *ex vivo* and *in vivo* animal

trials were conducted to investigate potential applications of the system, and the results indicated the feasibility of tissue cutting and suturing in gastrointestinal surgeries and single-port surgeries. The next version for commercialization is now under development by EasyEndo Surgical (Daejeon, South Korea).

j) *ColubisMX ELS system*: The ColubrisMX ELS system developed by ColubisMX (Houston, TX, USA) is a flexible endoscopic robot system specially designed for a transanal surgery. This system comprises a four-DoF steerable overtube called Colubriscope, a three-DoF videoscope that can be introduced through a channel of the overtube, and two robotic effector arms deployed through an overtube channel. The overtube and two arms can be teleoperated by the console surgeon using the delta-robot-based master interface. The overtube itself is flexible to be delivered transanally to the proximal colorectal affected area. It permits rotation along its long axis, allowing the surgeon to approach any lesion regardless of orientation within the lumen. An initial preclinical evaluation using an *ex vivo* porcine colon revealed that the tasks of partial-thickness disk excision and closure were successful [156]. The system is currently being evaluated for transanal endoluminal procedures in a phase-II FDA study in the USA.

## B. Ureteroscopic Surgery

Robotic assistance is being applied to the flexible ureteroscope mainly for renal stone treatment. A major limitation of conventional flexible ureteroscopy in renal stone removal is the surgeon's fatigue caused by a nonergonomic posture, which can result in an injury to the surgeon as well as a potential decrease in surgical efficiency and safety. Therefore, the robot systems include robotized ureteroscope manipulation, which aims to provide surgeon ergonomics as well as precise ureteroscope manipulation with less radiation exposure during the surgery. The system typically comprises a slave robot arm with a mounted commercial flexible ureteroscope and an operator's console for telemanipulation of the endoscope and instruments.

1) *Roboflex Avicenna*: Roboflex Avicenna<sup>1</sup> developed by ELMED Medical Systems (Ankara, Turkey) is the first commercially available robot-assisted flexible ureteroscope system specially designed for kidney stone treatment. This system comprises the surgeon's console with an integrated touch screen and two joystick interfaces as well as a flexible ureterorenoscopy manipulator. The handpiece of the robotic arm can hold a variety of commercial ureterorenoscopes. The surgeon works from the console in an ergonomic position, controlling two joysticks to manipulate the scope's rotation, deflection, and in-and-out movement. Activation of fluoroscopy and laser firing is integrated into the system via pneumatically controlled 2-ft pedals. Furthermore, the infusion speed of the irrigation fluid can be adjusted together with a motorized insertion and retraction of the laser fiber. The initial clinical study demonstrated that the system can successfully apply all

modern flexible ureteroscope techniques and protocols, such as laser dusting and extraction of larger fragments, with a positive impact on ergonomics and less radiation exposure to the surgeon [159]. The safety and efficacy of the system were demonstrated via additional clinical studies [160], and the overall surgical outcomes, such as stone-free rate, treatment time, and intraoperative complications, were relatively similar to those of the conventional procedure [161]. Recent consecutive cases have revealed successful use of the first generation of robotic systems in endourologic stone surgery, indicating that the performance of the robot is comparable to that of a conventional flexible ureteroscope with optimal ergonomics, preserving the surgeon's endurance in long-term surgeries [162]. The system received a CE mark in 2013, and the FDA approval is pending.

### C. Bronchoscopic Surgery

Emerging flexible robot systems for bronchoscopic surgery mainly target lung biopsy. Due to the narrow and complex anatomical structure of airways, it is difficult to precisely and safely reach the lesion located at the peripheral of airways during traditional manual lung biopsy. Therefore, surgical robot systems aim to improve lesion targeting precision and safety. For this purpose, the systems feature a bronchoscope with enhanced articulation and an integrated navigation system that guides the bronchoscope pathway inside the airways. A previous review of currently available two robotic surgical systems for bronchoscopic surgeries: Monarch<sup>1</sup> and ION<sup>1</sup> is presented in [172].

1) *Monarch*: The Monarch platform developed by Auris Health (Redwood City, CA, USA; in 2019, Johnson & Johnson acquired Auris Health) is a robotic bronchoscope system with integrated electromagnetic navigation (EMN) guidance. The platform comprises a scope with pitch-and-yaw articulation, two robotic arms driving the scope, a handheld thumb stick-based controller, an EMN system with an EM field generator, and reference sensors. The scope allows four-way steering with 180° scope-tip deflection in any direction, providing enhanced endoscopic control and reaching in the peripheral airways. Furthermore, it provides automatic tension relaxation during scope retraction and driving tension monitoring for safety features [163]. An integrated navigation software provides automatic path planning to the lesion based on a reconstructed 3-D virtual lung model, and the scope is then applied to the lung model using EM position sensing. Cadaveric studies demonstrated improved accessibility of the peripheral airways [164] and successful biopsying of the simulated peripheral pulmonary lesions [165]. Initial clinical trials indicated that the platform is safe, with the initial diagnostic yield and complication rates comparable to those of the existing technologies, and that it is technically feasible for diagnostic bronchoscopy [166], [167]. The most recent clinical trial demonstrated the feasibility and safety of robotic bronchoscopy for patients

with peripheral pulmonary lesions. Confirmation of lesion localization occurred in 96% of patients, with a comparable observed adverse event rate with conventional bronchoscopy [168]. The platform received FDA approval for use in diagnostic and therapeutic bronchoscopic procedures in 2018.

2) *ION Robotic Endoluminal System*: The ION robotic endoluminal system by Intuitive (Sunnyvale, CA, USA) is a robotic catheter featuring shape-sensing technology that provides positional and shape feedback regarding the catheter. The system comprises a robotic articulating catheter that can bend up to 180° in any direction and has an integrated shape-sensing fiber that runs along the length of the catheter. It also includes a removable video-scope inserted into the catheter, a planning station, and a controller with a trackball and scroll wheel. The navigation software realizes a 3-D virtual airway reconstruction and automatically presents a pathway to the target area. This is followed by registration of the 3-D airway model and the catheter using position information obtained from the shape-sensing fiber, instead of EM position sensing. In a cadaver study, the system demonstrated the potential of robotic bronchoscopy to precisely reach, localize, and puncture small nodules in the periphery of the lung [169]. The first human trial demonstrated great promise for the safe and effective sampling of small peripheral pulmonary nodules, with an overall diagnostic yield of 79.3% and no device-related adverse effects [170]. The latest clinical study reported promising results, including diagnostic accuracy with an overall diagnostic yield of 92% and a very low complication rate [171]. The system acquired FDA clearance in minimally invasive biopsy in the peripheral lung in 2019.

### D. Endovascular Surgery

Flexible surgical robot technologies have also seamlessly transitioned to endovascular surgery. Despite technological advancements in endovascular surgery, remaining limitations, such as the reliance on lesion location, vascular tortuosity, operator technique, and a lack of precise positioning of intravascular instruments, considerably impede successful surgical outcomes. Therefore, robot systems have been developed to provide precise guidewire and catheter control, allowing ease in reaching difficult lesions. The resulting efficiency can potentially decrease fluoroscopy times, thus reducing radiation exposure to both surgeon and patient.

1) *Sensei X*: Sensei developed by Hansen Medical (Mountain View, CA, USA) is designed to facilitate control and allow precise positioning of catheters within the cardiovascular system. This system comprises a remote catheter manipulator, a workstation, a steerable guide catheter, and a sheath. A physician controls the guide catheter and sheath via an M-S electromechanical system [217]. The later generation of the Sensei system,



Sensei X, has an artisan extended catheter, which provides 270° bending with a small bending radius. Sensei X has several features: the tip of the catheter can be moved in three dimensions via remote control and is coupled to a robotic navigation system that measures the forces at the distal tip. These haptic vibrations are then translated to the user via the controller [218]. The safety and effectiveness of Sensei X for treating atrial fibrillation were evaluated. The outcomes demonstrated that the complications and recurrence rates using the robotic system were comparable to those of manual ablation, while the amount of radiation exposure was considerably lower with robotic assistance [219]–[223]. The FDA approval and CE mark were obtained for the system in 2007.

2) *Magellan*: *Magellan*<sup>1</sup> by Hansen Medical (Mountain View, CA, USA; Hansen Medical was acquired by Auris Health in 2016) is a redesigned robot mainly for conducting peripheral endovascular intervention. The main components of the system include a robot arm that manipulates steerable catheters and standard guidewires and an operator's console that allows remote control of the robot arm. Unlike the standard precurved catheters, the steerable catheters of the system enable 360° rotation and 180° multidirection articulation, allowing surgeons to change the shape and stiffness of the catheter within vessels [173]. The operator's console is situated away from the radiation source. A phantom study revealed a decrease in catheter–tissue contact [174] as well as a decrease in vessel trauma caused by the catheter touching the vessel wall [175]. Clinical trials showed the feasibility of the system where fenestrated endovascular repair (FEVAR) was completed without postoperative complications. These findings also indicated the possibility of simplifying complex endovascular tasks and reducing radiation exposure to the operator [176]. Navigation in iliofemoral arteries was successfully performed with ease, regardless of the operator's experience, and no access site complications occurred [177]. The use of the system was promising during thoracic endovascular aortic repair and resulted in considerably less embolization because the active maneuverability and control of the robotic catheter are likely to reduce collisions against the vessel wall [178]. The system received a CE mark in 2011 and FDA 510(k) clearance in 2012 for navigating guidewires and robotic catheters in peripheral vessels.

3) *R-One*: *R-One*<sup>1</sup> by RoboCath (Rouen, France) is a robotic assistance platform for intervention in cardiology. The robot comprises a radio-protected control unit and a robotic unit. The control unit enables surgeons to remotely control a guidewire and a catheter in a radio-protected environment. The robotic unit enables a motorized operation of market-leading guidewires and catheters [224]. Until now, no reports have been published on the results of clinical studies. RoboCath announced the successful completion of the first robotic coronary angioplasties in Africa, China, and several European countries between

2019 and 2021 [225]. In addition, RoboCath completed its last patient enrolment for a European clinical study of robot-assisted percutaneous coronary intervention (PCI) in 2021 [226]. RoboCath attained a CE mark for intervention in cardiology in 2019.

4) *CorPath*: *CorPath* developed by Corindus Vascular Robotics (Waltham, MA, USA; Corindus Vascular Robotics was purchased by Siemens in 2019) consists of an articulated arm with a robotic drive mechanism and a single-use cassette that overlays on the robotic drive. The operator cockpit includes a joystick and touchscreen controls. The robotic drive enables the manipulation of all interventional devices, including a guidewire, guide catheter, and balloon/stent catheter, with the motions of advance, retract, and rotation. It can advance or retract precisely in 1-mm increments and rotate the guidewire or guide catheter in 30° increments, allowing more exacting steerability, helping maintain the wire and catheter in the center of the vessel lumen, and avoiding vessel wall trauma [179]. Clinical studies of PCIs [180]–[182] and peripheral vascular interventions [183], [184] showed promising feasibility and safety with high procedural success, a substantial decrease in the radiation exposure to both operator and patient, and similar major adverse cardiac events to conventional surgeries, but no adverse events related to the robot. Furthermore, the system was successfully used in the case of below-knee interventions [185], renal artery interventions [186], and therapeutic neuroendovascular interventions [184]. Recently, a remote PCI was successfully conducted by an operator who was 20 mi away from the patient and no procedural complications or adverse events occurred [188]. In 2018, FDA granted the system 510(k) clearance for use in peripheral vascular interventions. In 2019, Corindus received a CE mark for neurovascular interventions.

#### IV. CONCLUSION

Along with the commercial success of the da Vinci laparoscopic robotic surgical system, there have been several flexible robotic surgical systems aimed at performing endoluminal surgery. However, technical difficulties regarding dexterous motion in the curved and narrow space inside the lumen need to be addressed. This article reviewed state-of-the-art research activities to overcome these technical challenges, such as the design of overtubes and small instruments that are flexible while being strong enough to perform surgical tasks as well as addressing control issues and the motion compensation of long-wire tendon-driven instruments and shape and force sensing of flexible surgical instruments.

If these research results are applied to flexible surgical robots, this new technology will impact two medical fields: robotic surgery and endoscopy. Surgeons will gain more widely applicable robotic solutions with less or even no incision through endoluminal, transluminal, and extraluminal approaches. Meanwhile, endoscopists will be able to

perform more advanced endoscopic diagnoses and endoscopic tumor resections with the help of dexterous surgical motion and navigational assistance. The advanced endoscopic surgical robot will standardize surgical outcomes across the surgeon's endoscopy skills and the difficulty level of the surgery. These advanced robots will also boost the development of new surgical instruments including flexible energy devices, such as laser, cryogenic, and electrical devices. Flexible surgical robots will essentially provide the benefits of robotics to new surgical areas that

were previously out of reach of conventional the rigid-type laparoscopic robotic surgical systems. ■

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