Multilevel Operation Strategy of a Vascular Interventional Robot System for Surgical Safety in Teleoperation

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Abstract-Remote-controlled vascular interventional robots have great potential for use in minimally invasive vascular surgeries in recent years due to their ability to reduce the occupational risk of surgeons and improve the stability and accuracy of surgical procedures. However, blood vessels will suffer from the damage caused by collision with medical instruments to some extent even though the surgeries are very successful. Moreover, when surgeons perform unsafe operations, the unsafe operations will not only seriously affect surgical safety (or even cause serious complications) but also restrict the continuity of operation. In this article, a multilevel concept for operating force is first introduced into surgical procedures as a reference for the choice and design of operation strategies. Based on this concept, a novel multilevel operation strategy is first proposed to reduce blood vessel damage, ensure surgical safety, and allow for continuous operation. This strategy can remind surgeons about the operative conditions in real-time, reduce collision to blood vessels, and eliminate unsafe operations online. A prototype was fabricated and calibrated through calibration experiments and the performance of the multilevel operation strategy was validated through in vitro and ex vivo experiments. Experimental results demonstrate the engineering effectiveness of the proposed method and motivate the need for further in vivo studies to evaluate improvement on surgical safety.

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Index Terms—Force feedback, minimally invasive vascular surgery, multilevel operation strategy, remote-controlled vascular interventional (VI) robot, surgical safety.

I. INTRODUCTION

R EMOTE-CONTROLLED vascular interventional (VI) robots have received increased attention and interest in the field of minimally invasive vascular surgery due to the potential benefits including X-rays protection, low workload, and high operation accuracy [1]. In robot-assisted minimally invasive vascular surgeries, the essential elements consist of three aspects: Robot systems, surgeons, and patients. All these three aspects need to be considered but only one or two of them were contemplated in existing research, and thus some issues remain as follows.

1) Blood Vessel Damage: Blood vessels suffer from the damage caused by collision with medical instruments to some extent even though the surgeries are very successful as the medical instruments travel through blood vessels [2]-[4]. The blood vessel damage includes internal bleeding, tears in the lining of arteries, and puncture [4]-[6]. Moreover, it is difficult for surgeons to accurately control the force of catheter/guidewire within a tiny and proper range and determine the collision states because of the limited perceptual resolution in force discrimination of hands (7-10% over a range of 0.5–200 N [7]) and small operating force during catheterization procedures (generally not exceed 3.2 N [8]). Thus, the blood vessel damage will increase for sure, and it will not be conducive for patients' quick recovery and may produce potential complications including thrombosis [5], [6].

2) Operation Safety: When surgeons perform unsafe operations on the master side (using a master manipulator), the remote-controlled VI robot will replicate the unsafe operations. An unsafe operation with great operating forces will seriously affect the safety of surgeries or even cause serious complications, such as vascular perforation [9].

3) Operation Efficiency: When surgeons manually control the robot to stop replicating unsafe operations, or surgeons stop to tackle emergencies during the surgeries, the continuity of operation will be restricted. Furthermore, additional requirements to prepare, assemble, or disassemble

1552-3098 © 2022 IEEE. Personal use is permitted, but republication/redistribution requires IEEE permission. See https://www.ieee.org/publications/rights/index.html for more information. equipment, either before or after the procedure, may add time and complexity to the surgical workflow.

The related research topics of remote-controlled VI robots can be divided into two types: Implementation of movements and guarantee of safe operations. Most research focuses on the implementation of movements, i.e., new mechanism design, which can enable catheters or guidewires to be operated with several degrees of freedom (DOF) [10]-[16]. As for the guarantee of safe operations, varied methods are proposed and integrated with robot systems, including image navigation [17], position control [18]–[19], motion compensation [20]–[21], force sensing [22], and force feedback [22]. Jayender et al. [17], [18] proposed autonomous robot-assisted insertion of an active catheter instrumented using image guidance and it can track the tip of the catheter and provide information on the location of the catheter. Moreover, they also presented a simultaneous force/position control method to ensure a safe and reliable catheter insertion. Kesner and Howe [20] presented a control-system compensation method to compensate for the fast motion of cardiac tissue using three-dimensional (3-D) ultrasound image guidance. The friction and backlash are identified in the control system and the movement of the catheter can be controlled accurately when complicated surgical tasks are performed in the beating heart. Cha et al. [22] developed a novel robotic system, which uses a steerable catheter and can measure the operating force and generate force feedback. However, these methods are all about the design or control of the robot system and they ensure operation safety by improving motion accuracy, operating force measurement accuracy, force feedback accuracy, and so on. Few studies focus on the online adjustment of operation strategy by considering the level of operating force and traumatic lesions of blood vessels caused by collision with medical instruments. In [23], a force control algorithm, which uses two control loops to track position and force profiles and desired torques for each joint, was presented to control the insertion force of a catheter. It can help the surgeon stop inserting the catheter into the body at any obstruction but does not contemplate the level of the operating force and the effect on surgeons. Therefore, these three remaining issues discussed above have not been addressed simultaneously. In our previous research [24]-[27], several types of remote-controlled VI robots were designed to operate catheters with two DOFs and generate force feedback. These robot systems can operate catheter and guidewire accurately and provide force feedback for surgeons but still fail to consider the damage to the blood vessels and the level of operating force. Moreover, we previously proposed a multimodal force feedback method that can enable surgeons to distinguish whether the proximal force exceeds the safety threshold of blood vessels or not more easily [28]. A mechanism was also developed to prevent inaccurate operation during surgeries [29]. However, these two methods are very straightforward, and they ensure surgical safety only in an independent way and lack a systematic consideration. They did not consider all the essential elements during procedures (robot systems, surgeons, and patients). By using these two methods, these three problems summarized abovementioned cannot be addressed simultaneously and effectively. The effectiveness and application scope of these two methods are limited.

In this article, to extend our previous research, we consider the essential elements during procedures and integrate them into robot design. We define the damage level of blood vessels and the level of operating force. Moreover, the force feedback for surgeons and the movement mode is graded according to the level of operating force. Based on these concepts, a novel operation strategy is proposed and a prototype is fabricated. The main contributions of this article are as follows.

- We introduce a multilevel concept for operating force into surgical procedures for the first time. This concept divides the operation state based on the operating force and can be used as a reference for the choice and design of operation strategies in robot-assisted surgeries and for formulating evaluation indexes for preoperative training and postoperative evaluation.
- A multilevel force feedback method is proposed to reconstruct force feedback for surgeons. It can remind surgeons about different operative conditions in real-time and remedy the limitation of perceptual resolution in force discrimination of hands.
- 3) A novel multilevel operation strategy integrated with mechanical protection on the slave side and force feedback warning on the master side, is proposed for the first time to reduce blood vessel damage, recognize, and eliminate unsafe operations online. This strategy can assist surgeons in determining the instrument collision states and implementing necessary auxiliary safe procedures. This strategy establishes a general framework for promoting safe operation during surgical procedures and provides a new potential paradigm for surgical safety.

The remainder of this article is organized as follows. Section II presents the system description of our remote-controlled VI robot. Section III describes the multilevel concept for the operating force and presents the multilevel operation strategy. Two calibration experiments of the movement protection mechanism are conducted in Section IV. In Section V, the performance of the multilevel operation strategy is evaluated through *in vitro* experiments. *Ex vivo* experiments are detailed in Section VI. Finally, Section VII concludes this article.

II. DEVELOPED INTERVENTIONAL ROBOT SYSTEM

The remote-controlled VI robot is a telerobotic system, and it is composed of a master manipulator and a slave manipulator. Fig. 1 shows the robot system overview. The master manipulator located outside the operating room (on the master side) captures the operations of surgeons while the slave manipulator mounted on the operating table (on the slave side) replicates the movement of surgeons. The slave manipulator measures the force of the catheter/guidewire during surgeries and the master manipulator generates the force feedback for surgeons at the same time.

To operate the catheter and guidewire respectively and reconstruct force feedback of the catheter and guidewire, two commercial haptic devices (Geomagic TouchTM X, 3-D Systems, Inc., USA) are used as the master manipulator (catheter haptic device and guidewire haptic device) [see Fig. 1(b)]. In our previous research, two prototypes were fabricated and validated through laboratory setting experiments and in-human



Fig. 1. Robot system overview. (a) Schematic diagram. (b) Master manipulator. (c) Slave manipulator.



Fig. 2. Schematic diagram of the multilevel concept for operating force.

experiments [30], [31]. As the robot proposed in [30] has more motion control parts and the extension can be implemented easily, it is selected for use in this article and the physical prototype of the slave manipulator is shown in Fig. 1(c). In this article, some components of this slave manipulator were redesigned and fabricated based on the proposed method.

III. MULTILEVEL OPERATION STRATEGY

A. Multilevel Concept for Operating Force

During surgical procedures, medical instruments interact with organs/tissues and the operating force of medical instruments varies. The operating force can reflect the collision conditions between medical instruments and organs/tissues, and thus, the value of operating force can be used as a criterion for evaluating the safety of surgical procedures. On the other hand, the hierarchical division applied to engineering is well known, such as hierarchical control [32] and hierarchical motion planning [33], and it has been used extensively for decades. In view of this, we reference the hierarchical division and introduce a multilevel concept for operating force is divided into three levels according to its value, and the schematic diagram is shown in Fig. 2. The red line represents the operating force during surgical procedures, such as the force of the catheter or guidewire. $F_{\rm E}$ refers to the

force of emergency level and it is the minimum threshold of serious damage (or serious complications) to organs/tissues; $F_{\rm L}$ means the force of less urgency level and it is the minimum threshold for the initiation of damage.

The surgical procedures can be divided into three operative zones based on the value of operating force: Safe zone, potentially unsafe zone, and unsafe zone.

- In the safe zone, the operating force is less than the force of less urgency level and the medical instruments have little damage to organs/tissues. The operation in this zone is called "safe operation."
- 2) In the potentially unsafe zone, the operating force is larger than the force of less urgency level but less than the force of emergency level. The medical instruments could damage the organs/tissues to some extent. The operation in this zone is called "potentially unsafe operation."
- 3) In the unsafe zone, the operating force is larger than the force of emergency level and the medical instruments will damage organs/tissues seriously or even cause serious complications. The operation in this zone is called "unsafe operation."

The design principles for operation strategy can be summarized in three items: Increasing "safe operations," reducing "potentially unsafe operations," and eliminating "unsafe operations." When the proportion of "safe operations" is improved in surgical procedures, the success rate of surgeries will increase. When "potentially unsafe operations" are reduced to some extent, it will be conducive for patients' quick recovery because of the reduced damage to organs/tissues. Besides, serious complications can be avoided by eliminating "unsafe operations" in real-time. However, operations in different operative zones have various characteristics. To ensure operation safety and reduce damage to organs/tissues, diverse operation strategies need to be designed for different operations. Generally, this multilevel concept for operating force can be used as a reference for the choice and design of various operation strategies for robot-assisted surgeries, and we will propose a novel operation strategy for the remote-controlled VI robot based on this concept.

B. Overview of the Multilevel Operation Strategy

To address the challenges described in Section I, we propose a multilevel operation strategy (see Fig. 3) based on the multilevel concept for operating force. In addition, we propose a multilevel force feedback method (MFFM) and it is integrated into the multilevel operation strategy. The MFFM can generate three types of force feedback based on the operative zones (see Fig. 2): General force feedback, magnified force feedback, and inactive force feedback.

In Fig. 3, when the remote-controlled VI robot is turned ON, the force of the catheter (F) is measured and compared to the force of less urgency level of blood vessels. If $F < F_{\rm L}$ (in the safe zone), surgeons will obtain the general force feedback, and the remote-controlled VI robot will keep performing surgical operations until the catheter reaches the target position. If $F_{\rm L} \leq F < F_{\rm E}$ (in the potentially unsafe zone), the magnified force feedback will remind surgeons about the existence of



Fig. 3. Flowchart of the multilevel operation strategy.

TABLE I
NOMENCLATURE OF THE MULTILEVEL OPERATION STRATEGY

Notation	Description
F	Force of the catheter
$F_{\rm L}$	Force of less urgency level of organs/tissues (blood vessels)
$F_{\rm E}$	Force of emergency level of organs/tissues (blood vessels)
$F_{\rm M}$	Force feedback generated by the master manipulator
$F_{\rm A}$	Clamping force applied by the clamp in AGM
$F_{\rm MF}$	Clamping force applied by the clamp at position A
$F_{\rm MB}$	Clamping force applied by the clamp at position B
$S_{\rm s}$	Linear displacement of the slave manipulator
$S_{\rm M}$	Linear displacement of the master manipulator

"potentially unsafe operations," and the motion reducing control will reduce blood vessel damage caused by the "potentially unsafe operations." If $F \ge F_E$ (in the unsafe zone), surgeons will be warned by the inactive force feedback, and the movement protection mechanism starts to eliminate the "unsafe operations" online. The movement protection mechanism can effectively eliminate "unsafe operations" via two mechanisms: An adjustable gripping mechanism (AGM) and a bimodal gripping mechanism (BGM).

As operations are divided into three types and appropriately dealt with different measures, the damage to blood vessels will be reduced significantly and the safety of operations will be improved greatly. Moreover, surgeons can keep performing surgeries (do not need to stop to tackle emergencies and prepare to reoperate again) when "potentially unsafe operations" are reduced and "unsafe operations" are eliminated online. Thus, this strategy can also allow for continuous operation and improve operation efficiency. The notations regarding this strategy are presented in Table I.

C. Design of the Movement Protection Mechanism

In order to increase operation safety, the movement protection mechanism is designed to have two mechanisms: AGM and BGM, which can ensure operation safety in various ways. Moreover, to improve the continuity of operation and correspond to the multilevel force feedback method and motion reducing



Fig. 4. Schematic diagram of the movement protection mechanism.

control method (detailed in Sections III-D and III-E), AGM and BGM are designed to have different working principles and be located at different axial positions. As shown in Fig. 4, AGM is mounted on a slider rail and, thus, it can move forward or backward. BGM fixed to the platform is located between AGM and blood vessels.

AGM can grasp or release the catheter during surgeries and thus can assist in delivering the catheter to the target position. The clamping force of AGM can be adjusted online based on different positions of the catheter in blood vessels, e.g., aortic arch, left common carotid artery, etc. When the force of the catheter exceeds the clamping force of AGM, the catheter will slide in AGM and cannot move forward. Therefore, it can prevent the catheter from damaging the blood vessels in real-time by adjusting the clamping force online.

Besides, if surgeons operate the catheter with "unsafe operations," BGM will also begin to run (grasp the catheter). It results in that the "unsafe operations" are eliminated online by preventing the catheter from moving forward. Moreover, the catheter can be pulled back at the same time and be operated again since BGM generates different clamping forces when catheters move forward and backward. Thus, surgeons can perform surgeries again without restarting the robot or manually pulling the catheter back offline on the slave side.

1) Adjustable Gripping Mechanism: In our previous research, we proposed a novel method to grasp the catheter/guidewire without damage to them by using a static connection principle and conical clamping method [24]. In this article, based on the conical clamping method, we propose a new principle to enable the robot to adjust the clamping force online. The principle of AGM is shown in Fig. 5. Two clamping blocks and a spring comprise the clamp. The clamp can move forward



Fig. 5. Principle of the adjustable gripping mechanism (AGM).



Fig. 6. (a) Cutaway diagram of AGM in the catheter manipulator. (b) Virtual prototype of the clamp in AGM.

or backward by the positioning mechanism with the lead screw. The lead screw can move in the horizontal direction when a motor drives it through a gear train. Therefore, the movement of the clamp can be controlled by the motor. The clamp can grasp the catheter with various clamping forces when the clamp is located at different positions in the horizontal direction. The various clamping forces are generated by different deformations of the spring.

The kinematic relations for AGM could be written as follows:

$$\Delta s = \frac{\Delta \varphi p}{i} \tag{1}$$

$$\Delta x = \Delta s \tan \theta \tag{2}$$

when Δs in (2) is substituted by (1) and (2) can be rewritten as

$$\Delta x = \frac{\Delta \varphi p \tan \theta}{i} \tag{3}$$

where Δs is the motion rise of the lead screw and clamp in the horizontal direction, $\Delta \varphi$ represents the change in rotation angle of the motor, p means the lead of the lead screw, i is the transmission ratio of the gear train, Δx is the change in axial motion of the spring, and θ indicates the angle of inclination for the interface between the fixed base and the clamp.

The clamping force generated by the clamp can be obtained by

$$F_{\rm A} = \mu k \Delta x. \tag{4}$$

Substituting (3) into (4) results in

$$F_{\rm A} = \frac{\mu k p \tan \theta}{i} \Delta \varphi \tag{5}$$

where F_A means the clamping force applied by the clamp in AGM, μ is the friction coefficient between the clamp and catheter, and k indicates the stiffness coefficient of the spring.

Therefore, the clamping force can be changed by adjusting the rotation angle of the motor, and various clamping forces will be set up during surgeries based on different positions of catheters in blood vessels. The virtual prototype of AGM is shown in Fig. 6.



Fig. 7. Principle of the bimodal gripping mechanism (BGM). (a) Clamp located at position A. (b) Clamp located at position B.



Fig. 8. (a) Cutaway diagram of BGM. (b) Virtual prototype of the clamp in BGM.

The clamp can move forward or backward when the threaded sleeve rotates forward or reverses. In Fig. 6(b), the integrated gear has a wedge-shaped cavity and it can enable the four claws of the clamp to grasp and release the catheter (along the blue arrow) when the clamp moves forward or backward.

2) Bimodal Gripping Mechanism: We previously proposed a type of BGM in [29] that grasps catheters using an electromagnet and the conical clamping method described in [24]. To enable BGM to grasp catheters or guidewires much more reliably, we redesign BGM (especially the clamp and active base), and the principle and virtual prototype of BGM are shown in Figs. 7 and 8, respectively. Two clamping blocks and a spring comprise the clamp. The active base driven by an electromagnet can move downward and push the clamp. The electromagnet will generate different driving forces by setting various working voltages. Various clamping forces of the BGM can be produced as the electromagnet drives the active base with diverse driving forces. When the catheter moves forward, the clamp will be located at position A [see Fig. 7(a)]; when the catheter moves backward, the clamp will be located at position B [see Fig. 7(b)]. The clamping forces generated by the clamp can be obtained by

$$F_{\rm MF} = \mu k \delta \tag{6}$$

$$F_{\rm MB} = \mu k (\delta - b \tan \psi) \tag{7}$$

where $F_{\rm MF}$ represents the clamping force applied by the clamp at position A (catheter moves forward), $F_{\rm MB}$ is the clamping force applied by the clamp at position B (catheter moves backward), μ means the friction coefficient between the clamp and the catheter, k is the stiffness coefficient of the spring, δ indicates the motion rise of the active base in the vertical direction, b means the length of the gap between the active base and the clamp in the horizontal direction, and ψ is the angle of inclination for the interface between the active base and the clamp. $F_{\rm MF}$ and $F_{\rm MB}$ are clamping force of the catheter, so

$$F_{\rm MF} > 0, \ F_{\rm MB} > 0.$$
 (8)

Using (6)–(8) concludes that

$$F'_{\rm MF} > F'_{\rm MB}.$$
 (9)

When $F_{\rm MF}$ and $F_{\rm MB}$ are selected appropriately, surgeons cannot push the catheter forward but can pull the catheter back.

3) Integrated Solution: AGM and BGM can eliminate "unsafe operations" in different ways. To perform operations more safely and reliably, we integrated these two mechanisms and got an integrated solution (movement protection mechanism). Since the two principles have diverse application objects, one challenge is determining how to integrate them into a system. In view of the characteristics of these two principles, we design the arrangement of AGM and BGM, which fix AGM to a platform and set BGM on a slider rail (see Fig. 4). Additionally, the clamping forces generated by each mechanism at different blood vessel positions are set based on

$$F_{\rm MB} < F_{\rm A} < F_{\rm MF}.$$
 (10)

To integrate with our previous robot system, BGM is set inside the assistant grasping mechanism 1, and AGM is set inside the catheter manipulator [see Fig. 1(c)]. If the catheter is located in a blood vessel (e.g., left common carotid artery) at this time, $F_{\rm A}$ could be set equal to or less than the force of emergency level of the left common carotid artery (i.e., $F_{\rm A} \leq F_{\rm E}$). When surgeons perform "unsafe operations," the movement protection mechanism will start to protect the vessel against damage. During this process, surgeons cannot push the catheter forward and, thus, the "unsafe operations" are eliminated; at the same time, surgeons can pull the catheter back and, thus, surgeons can continue to perform surgeries (without restricting the continuity of operation). This is mainly due to the following three reasons. First, BGM can grasp the catheter and prevent it from moving forward because of $F_{\rm MF} > F_{\rm A}$. Second, the catheter will slide in AGM (i.e., stay static relative to the blood vessels) and cannot move forward while the catheter manipulator moves toward the blood vessels. This is due to $F_A \leq F_E$. Third, surgeons can pull the catheter back and prepare surgical operations again because of $F_{\rm MB} < F_{\rm A}$.

D. Design of the Multilevel Force Feedback Method

Force feedback is extremely important for minimally invasive vascular surgery because it not only allows surgeons to take full advantage of existing operational experience but also provides the operative conditions for surgeons. To make full use of force feedback and ensure "safe operations" more effectively, we propose the MFFM to reconstruct force feedback for surgeons. The method is designed based on the multilevel concept for operating force (see Fig. 2), and the equation of MFFM is

$$F_{\rm M} = \begin{cases} F & F < F_{\rm L} \\ F_{\rm L} + n(1 + \alpha \frac{\mathrm{d}F}{\mathrm{d}t} + \beta \frac{\mathrm{d}s}{\mathrm{d}t}) \left(F - F_{\rm L}\right) & F_{\rm L} \leq F < F_{\rm E} \\ F_{\rm T} & F \geq F_{\rm E} \end{cases}$$
(11)

where $F_{\rm M}$ means the force generated by the master manipulator, F is the force of the catheter measured by the catheter manipulator, n indicates the magnification times of the force feedback (n > 1), α is the regulation coefficient for force differential, β represents the regulation coefficient for displacement differential, s is the linear displacement of the master manipulator, and $F_{\rm T}$ indicates a constant force with high value set before surgeries.

According to the operating characteristics of different zones in the multilevel concept for operating force, the force feedback is divided into three types. Each type can be obtained by different equations. The descriptions for these types are as follows.

In the safe zone ($F < F_L$), to retain the existing experience of surgeons in surgical operation, the force generated by the master manipulator is the same as that measured by the catheter manipulator. This is the general force feedback.

In the potentially unsafe zone ($F_{\rm L} \leq F < F_{\rm E}$), the force feedback is called magnified force feedback. It is obtained by adding the force of less urgency level of blood vessels and amplification equation. Actually, force and displacement are the most important parameters and they can reflect the operative conditions. They have a certain relationship but not a linear relationship. Therefore, both force and displacement are integrated into the amplification equation. In this amplification equation, the force differential can reflect the characteristics of force changes, while the displacement differential can reflect the characteristics of linear displacement changes. These characteristics will remind surgeons about the operative conditions in real-time. When the force or the linear displacement changes dramatically, the master manipulator will generate a large and rapidly changing force. These characteristics are magnified by using the magnification factor n, and thus, surgeons can be effectively reminded. They remind surgeons that 1) the operations are with the potentially unsafe zone, 2) the operations will cause damage to blood vessels, and 3) necessary operations need to be performed to avoid further damage to the blood vessels.

In the unsafe zone $(F \ge F_{\rm E})$, the force feedback is set to a large value. This is the inactive force feedback. The inactive force feedback can remind surgeons about unsafe operations and prevent them from pushing the catheter forward.

E. Design of the Motion Reducing Control

To reduce the damage caused by "potentially unsafe operations" and "unsafe operations" more reliably, we also propose the motion reducing control to change the corresponding relation between the linear displacement of the master manipulator and that of slave manipulator. When $F > F_L$, the motion reducing control starts to run and the equation of the motion reducing control is

$$S_{\rm S} = S_{\rm M} - \gamma (F - F_{\rm L}) \tag{12}$$

where $S_{\rm S}$ is the linear displacement of the slave manipulator, $S_{\rm M}$ means the linear displacement of the master manipulator, and γ is the regulation coefficient between linear displacement and force.

By using the motion reducing control, the linear displacement of the slave manipulator will be slightly reduced compared to



Fig. 9. (a) Experimental set-up for the calibration of AGM. (b) Experimental set-up for the calibration of BGM.



IV. CALIBRATION EXPERIMENT OF THE MOVEMENT PROTECTION MECHANISM

Two types of experiments were carried out to calibrate the movement protection mechanism. Experiment I is used to establish a functional relationship between clamping forces and motor rotations for AGM. Experiment II is used to establish a functional relationship between clamping forces and working voltages of the electromagnet for BGM.

A. Experimental Set-Up

The experimental set-up for Experiment I is shown in Fig. 9(a). A catheter (VER135°, Cordis Corporation, USA) mounted on the force sensor was grasped by AGM (set inside the catheter manipulator). The clamping force of AGM was altered by changing the rotation angle of the motor (see Fig. 5). The clamping force was measured by a force sensor (Gamma, ATI Industrial Automation, Inc., USA). We changed the rotation angle of the motor with a 1°-increment from 0° until the clamping force was about 2 N. In every measurement taken at 1° increment, we pulled the catheter manipulator in the horizontal direction until the catheter slid relative to AGM. The rotation angles of the motor and the maximum readings of the force sensor were then recorded. Ten cycles of repetition were carried out for each measurement.

In Experiment II, the experimental set-up is shown in Fig. 9(b) and the force sensor and catheter in Experiment I were also used in this experiment. The clamping force of BGM was altered by adjusting the voltage of the electromagnet. The working voltage of the electromagnet was changed from 24 V, with 0.3 V decrements, until the clamping force was 0 N. We pulled the force sensor in the horizontal direction (catheter moved forward) until the catheter slipped relative to BGM. The maximum force and the voltage of the electromagnet were then recorded.



Fig. 10. (a) Relationship between clamping forces and angles for AGM. (b) Relationship between clamping forces and voltages for BGM.

Experiments with each working voltage of the electromagnet were conducted ten times. Similarly, we pushed the force sensor in the horizontal direction (catheter moved backward) until the catheter slipped and recorded the working voltages and forces.

B. Experimental Results and Discussion

In Experiment I, the average clamping forces of AGM under different rotation angles of the motor were recorded and shown in Fig. 10(a). In this figure, the red dots represent the clamping forces of AGM (i.e., F_A). In Experiment II, the average clamping forces of BGM under different working voltages of the electromagnet were recorded and shown in Fig. 10(b). When we pulled or pushed the force sensor under the same working voltage of the electromagnet, the clamping forces of BGM were different [demonstrated in (6) and (7)]. As shown in Fig. 10(b), the red dots represent the clamping forces of BGM when the catheter moves forward (i.e., $F_{\rm MF}$); the blue dots represent the clamping forces of BGM when the catheter moves backward (i.e., $F_{\rm MB}$).

In order to establish a functional relationship between output forces (i.e., F_A , F_{MF} , and F_{MB}) and controlled variables (i.e., rotation angles of the motor and working voltages of the electromagnet), discrete data points in Fig. 10 were fitted into curves by using the curve fitting in MATLAB. The fitted curves can be expressed through polynomial equations

$$F_{\rm F} = \sum_{i=0}^{n} \zeta_i \chi^i \tag{13}$$

where $F_{\rm F}$ is the fitted value of the output force, ζ indicates the coefficient of the polynomial equation, and χ is the controlled variables. Based on this polynomial equation, a curve expressing the functional relationship between clamping forces of AGM and rotation angles of the motor was established and shown in Fig. 10(a), and the equation of this curve is written as

$$F_{\rm A} = \sum_{i=0}^{5} m_i \phi^i \tag{14}$$

where F_A means the clamping force of AGM (the unit of the force is mN), and ϕ is the rotation angle of the motor (the unit of the angle is degree). Similarly, curves representing the functional relationship between clamping forces of BGM and working voltages of the electromagnet were established and shown in Fig. 10(b), and the equations of these two curves can

			Value-i			
Notation	5	4	3	2	1	0
m_i	-4.5429×10^{-4}	3.4882×10^{-2}	-9.2893×10^{-1}	1.0896×10	-4.4588	-2.3978
n_i	-1.1568×10^{-1}	1.1010×10	-4.1266×10^{2}	7.5896×10^{3}	-6.8089×10^4	2.3743×10^{5}
p_i	1.9929×10^{-1}	-1.8581×10	6.8528×10^{2}	-1.2494×10^{4}	1.1275×10^{5}	-4.0329×10^{5}

TABLE II COEFFICIENTS OF THE FITTED POLYNOMIAL EQUATIONS



Fig. 11. In vitro experiments. (a) Experimental set-up. (b) Human body model.

be expressed as

$$F_{\rm MF} = \sum_{i=0}^{5} n_i V^i \tag{15}$$

$$F_{\rm MB} = \sum_{i=0}^{5} p_i V^i \tag{16}$$

where V is the working voltage of the electromagnet. The unit of the voltage is V and the unit of $F_{\rm MF}$ and $F_{\rm MB}$ is mN. All coefficients of (14)–(16) are shown in Table II.

V. PERFORMANCE EVALUATION OF THE MULTILEVEL OPERATION STRATEGY

A. Experimental Set-Up

The experimental set-up evaluating the performance of the multilevel operation strategy is depicted in Fig. 11. The force of the catheter was measured by the catheter manipulator. A position sensor (Polaris Vicra, NDI, CA) was used to measure the linear displacement of the catheter and a grating scale (JCXE-DK, Guiyang Xintian Optech Company, Ltd, CN) was used to measure the linear displacement of the catheter manipulator. Meanwhile, the linear displacement signal of the operator was captured by the haptic device [part of the master manipulator, shown in Fig. 1(b)]. The force feedback that surgeons obtained is the output of the haptic device. A human body model (General Angiography Type C, FAIN-Biomedical, Inc. JP) was used to simulate the surgical environment [see Fig. 11(b)]. In the experiments, the catheter was located in the aortic arch and would be operated along the operation route. The target point is the intersection of the aortic arch and brachiocephalic artery. Operators operated the master manipulator on the master side, and the catheter manipulator replicated the movement of the surgeon on the slave side. The operator completed the operation with and without the proposed method. After these operations, to

familiarize with the proposed method, the operator continued to practice by operating the robot. Then, the operator completed the same operation with the proposed method along the operation route. Ten volunteers were involved in these experiments and each volunteer repeated the operation ten times.

Different forces of emergency level and less urgency level needed to be selected before experiments were conducted. Unfortunately, to our knowledge, there is no report indicating the forces of emergency level or less urgency level of blood vessels. However, in our previous research [30], experiments were carried out in the human body model [see Fig. 11(b)] and the forces of the catheter and guidewire were recorded. Since the performance evaluation experiments for the proposed operation strategy were conducted with the same experimental environment [in the human body model in Fig. 11(b)], we took the experimental results in [30] as reference for the determination of the operating force level. Bao et al. [30] showed the maximum operating force of the catheter in the aortic arch and left subclavian artery varies, and they are lower than 1.1 N. Actually, the forces of emergency level are larger than the operating forces of the catheter. Therefore, the forces of emergency level for each experiment were selected as follows: $F_{\rm E} = 0.1$ N, 1.4 N, 1.7 N. The forces of less urgency level were selected by $F_{\rm L} = 0.8 F_{\rm E}$ for the present, i.e., $F_{\rm L} = 0.88$ N, 1.12 N, 1.36 N. The clamping force applied by the clamp in AGM was set equal to the force of emergency level ($F_{\rm A} = F_{\rm E}$). α and β are set according to that the force and the displacement differential have the same proportion in the amplification equation of MFFM [see (11)]. Some other parameters for each experiment were calculated by (10)–(16) and they are shown in Table III.

B. Experimental Results

Three operations were selected and shown in Fig. 12. Each figure includes the linear displacement of components (haptic device, catheter manipulator, catheter), the force of the catheter, and the force feedback. The linear displacement error and force feedback error during these operation processes were calculated and shown in Fig. 13. The maximal average displacement error between the haptic device and the catheter manipulator is 0.241 mm; the minimal average displacement error is 0.038 mm. The maximal average force feedback error is 60.23 mN; the minimal average force feedback error is 44.88 mN. The statistics of these operations, including the average time of every operator, the total time and the number of operations in different operating zones, were recorded and shown in Fig. 14.

	$F_{\rm E}$ / N	$F_{\rm L}$ / N	F_{T} / N	п	$\alpha / s \cdot N^{-1}$	$\beta / s \cdot m^{-1}$	$F_{\rm A}$ / N	$\phi/^{\circ}$	$F_{ m MF}$ / N	$F_{\rm MB}/{\rm N}$	V/V	$\gamma/\mathrm{mm}\cdot\mathrm{N}^{-1}$
Experiment I	1.1	0.88	3	3	0.2	0.015	1.1	21.85	1.36	0.64	17.6	4.03
Experiment II	1.4	1.12	3	3	0.2	0.015	1.4	25.32	1.62	1.08	19.8	4.03
Experiment III	1.7	1.36	3	3	0.2	0.015	1.7	28.64	1.89	1.37	22.6	4.03
3 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5	p B C 2 3 Time (s) (a)	<u>E</u>	90 75 0 15 0 5 90 90 90 90 90 90 90 90 90 90 90 90 90	$\begin{array}{c} 3 \\ -5 \\ 2.5 \\ 0 \\ 2.5 \\ 0 \\ 2 \\ 0 \\ 1.5 \\ 0 \\ 0 \\ 1 \end{array}$	atheter edback heter manipulat heter beter B 2 3 Ti	cD E		50 25 0 15 15 0 25 0 15 0 25 0 25 0 0 0 0 0 0 0 0 0 0 0 0	- Force- cathete - Force feedbac - Disp- catheter - Disp- haptic d - Disp- catheter	r manipulator evice A 2 3 Time (s) (c)		90 75 60 15 0 5

TABLE III PARAMETERS FOR EACH EXPERIMENT IN PERFORMANCE EVALUATION

Fig. 12. Operating data during the processes with three different forces of emergency level. (a) $F_{\rm E} = 1.1$ N. $F_{\rm L} = 0.88$ N. (b) $F_{\rm E} = 1.4$ N, $F_{\rm L} = 1.12$ N. (c) $F_{\rm E} = 1.7$ N, $F_{\rm L} = 1.36$ N.



Fig. 13. (a) Linear displacement error. (b) Force feedback error.



Fig. 14. Statistics for operations. (a) Average time. (b) Total time of every type of operation with and without using the proposed method. (c) Number of operations in different operating zones.

C. Discussion

In Fig. 12, the operation can be divided into five parts: Parts A, B, C, D, and E. Parts A and E are with the safe zone; parts

B and D are parts of the potentially unsafe zone; part C is with the unsafe zone. Due to the displacement reduction by using the motion reducing control and movement protection mechanism, the curves of the displacement of the catheter manipulator, haptic device and catheter do not coincide completely in Parts B–E. The displacement curve of the catheter is below that of the catheter manipulator; the displacement curve of the catheter manipulator is below that of the haptic device. These three curves are the same in shape and tendency and, thus, the surgeon can reconstruct the mapping relationship between the catheter and the haptic device by using X-ray images.

As shown in Fig. 13(a), the linear displacement errors for different operators vary greatly. As the proposed robot is a telerobotic system, the delay of information transmission between the haptic device and the catheter manipulator inevitably exists. Every operator pushed the catheter with a different velocity, and thus some operations produced larger errors with higher operating velocities [12]. Similarly, the delay of information transmission also had an impact on force feedback [see Fig. 13(b)]. However, no significant difference between force feedback errors occurred because the change in operating force was not as dramatic as that in the displacement.

In Fig. 14(a), the average operating time with and without the proposed method has similar values for some operators, while other operators needed more time using the proposed method. This is mainly because the proposed method (especially the force feedback) is a little different from the existing operation method, and the operators did not adapt to the new method. On the other hand, after adapting to the proposed method, the skilled operators spent almost the same or even less operating time compared to using the existing method. As shown in Fig. 14(b), the time spent in "unsafe operations" decreases significantly when the proposed method was used. Besides, the number of operations in the unsafe zone also decreases with the proposed method [see Fig. 14 c)]. However, the operating time and the number of operations in the potentially unsafe zone increase. When the operator operated the catheter with a large force and



Fig. 15. Set-up for *ex vivo* experiments. (a) Three types of pig blood vessels. (b) Aortic arch with an introducer sheath placed in a transparent container.

the operation would enter the unsafe zone, the proposed method reminded the operator with the magnified force feedback. The operator then changed the operation mode or stopped pushing the catheter forward, and thus, the operations that were about to become "unsafe operations" were transformed into "potentially unsafe operations." With the decrease in the number and time of "unsafe operations," the damage to blood vessels will be greatly decreased and the safety of the procedure will be significantly improved. Besides, the reduced number and time of the "unsafe operations" result in fewer emergencies, and thus, the continuity of operations will also be increased.

Various blood vessels possess different safety thresholds and, thus, these three experiments were conducted with different forces of emergency level. The experiments demonstrated good performance of the multilevel operation strategy. The proposed operation strategy works not only for the catheter but also for the guidewire, and they would have similar performances. Moreover, this strategy can also be used as an operation method for the rotary displacement of catheter/guidewire by changing some parameters, for example, replacing the force with torque and replacing the linear displacement with rotary displacement.

VI. EX VIVO EXPERIMENTS

A. Experimental Set-Up

To test the operating performance difference between in vitro experiments and actual applications and verify the possibility of clinical application of the proposed multilevel operation strategy, ex vivo experiments were carried out in pig blood vessels. Since the difference in the proportions of elastin and collagen results in blood vessels with various mechanical properties [34], three types of pig blood vessels, i.e., aortic arch, left brachial artery, and left subscapular artery [see Fig. 15(a)], were used to simulate human blood vessels. They were acquired from a food supplier and there is no ethics required. As shown in Fig. 15(b), the blood vessels filled with water were placed in a transparent container. One side of the blood vessels was sealed by using wires and the other side was fixed on the container. An introducer sheath inserted into the blood vessels was mounted on the sidewall of the container. All the blood vessels were bent into an arc to simulate the curved shapes of some real human blood vessels, e.g., the aortic arch, and form an obstacle to the advancement of catheters. These experiments had the same experimental set-up and operating procedures as those in Section V. Ten operators,



Fig. 16. Operating forces in three types of pig blood vessels. (a) Aortic arch. (b) Left brachial artery. (c) Left subscapular artery.

including six experienced operators (interventionalists) and four inexperienced operators, were involved in the experiments, and each operator repeated the operation ten times. The catheter, passing through the introducer sheath, was positioned near the curved shapes of the blood vessels and operated by the robot. Operators pulled, pushed, or rotated the catheter and let it enter the curved shapes of the blood vessels. These operations were performed with and without the proposed multilevel operation strategy.

B. Experimental Results and Discussion

Based on the successful completion of experiments using the proposed method, there are similar operating characteristics between the operations conducted in these three types of blood vessels. Compared to the in vitro experiments in Section V, these ex vivo experiments also have similar operating characteristics as well as the statistics for operations. We think this is due to the working principle of the proposed method, which determines the selection and implementation of different strategies (various working modes shown in Fig. 3) according to $F_{\rm L}$ and $F_{\rm E}$. The mechanical properties of blood vessels, e.g., Young's modulus, hardness, etc., only affect the magnitude and direction of the operating force under the same operating displacement and are not used as input parameters of the proposed method. Since the operating data in these experiments was similar to that in the human body model, it will not be repeated here. Besides, to show the changes of operating forces in blood vessels of different mechanical properties, the operating forces during the operations conducted by using and not using the proposed method in three different types of blood vessels were selected and shown in Fig. 16. The selected experiments using the proposed method have the same parameters as experiment II in Table III. Fig. 16 indicates that the increase in the operating force is not inhibited without using the proposed method. This uninhibited force would cause a certain degree of damage to blood vessels and even cause serious complications. On the other hand, with the proposed method, the operating force can be restrained within a relatively safe range, and thus, not only the operation safety can be ensured, but also the damage to blood vessels can be reduced.

In these experiments, water was used to simulate the blood and it might produce different effects on the operating force since the water has a lower viscosity than blood. This effect is not that serious and is the same as the effect of vascular materials on the operating characteristics, which would not be used as the input parameters of the proposed method. So we think this substitution could be feasible. Moreover, as discussed before, although these pig blood vessels are slightly different from human blood vessels in anatomical structures and mechanical properties, these differences would not affect the operating characteristics seriously. Therefore, we believe these differences are acceptable to replace human blood vessels with pig blood vessels for performance evaluation of this proposed method, and the proposed method applies to blood vessels of different materials and structures, including various blood vessels of different patients.

Additionally, in the proposed multilevel operation strategy, the operating force is determined according to the operational requirements of the specific clinical operation, which can be a proximal force (measured at the end of the catheter, outside the blood vessels) or distal force (measured at the tip of the catheter, in the blood vessels). In the in vitro and ex vivo experiments, the proximal force was used as the input of the proposed strategy. Since the catheter tip is in direct contact with the blood vessel, the distal force can better reflect the collision conditions between the catheter and blood vessel and be used as the ideal input of the proposed strategy. However, commercial catheters/guidewires are currently unable to measure the distal force because the use of catheters/guidewires with force sensors at the tip will be limited for use in some surgeries, such as the cerebral vessels. The catheter/guidewire with force sensors at its tip has a current inside and larger size and, thus, it will not be safe for operation in cerebral vessels. Therefore, at present, we evaluated the performance of the proposed method by using the proximal force, and this substitution will not affect the significance and performance evaluation of the proposed method. Some researchers tried to obtain the distal force without installing the force sensor at the tip and the distal force could be predicted through kinetic models [35] and deep learning [36]. Lai et al. [37] developed a small force sensor to detect the distal force of tendon-sheath mechanisms using fiber Bragg grating. With the force prediction accuracy and safety guaranteed, these methods will potentially integrate with the proposed method. Moreover, if some other vascular interventional robots with the distal force measurement are developed, this proposed method could also be applicable.

Clinical studies will be needed to accurately estimate the values of the forces F_L and F_E . We hypothesize that the three zones can be defined based on several clinical indicators, such as the vascular perforation force and the degree of damage to blood vessels. The best solution is to establish a comprehensive evaluation system composed of vascular perforation force, the thickness of blood vessel damage, and some other clinical indicators. If we take the vascular perforation force as an indicator, clinical research could be carried out as follows. Vascular perforation force can be used as F_E and F_L can be determined according to F_E , elastic modulus, thickness, Poisson's ratio, and other physical parameters of the blood vessels. Vascular perforation force and related physical parameters of the blood vessels are able to be preliminarily determined during blood sampling and could be further refined based on the physical examination data of patients, including age, gender, blood pressure, and so on. Additionally, vascular perforation force can be refined according to the types and thickness of blood vessels. On the other hand, when the clinical data is insufficient, smaller values could be selected for the parameters in the proposed method, e.g., F_L and F_E . The reduced value would decrease the operation efficiency slightly but could ensure the operation safety. This would make a balance between insufficient clinical data and operation safety and efficiency. As is often the case when new technologies emerge, it will take significant clinical tests with various users and cases to adequately determine the associated parameters, and then users will maximally benefit from this technology. Furthermore, this proposed method would motivate the need for further in vivo studies to evaluate improvement on surgical safety.

VII. CONCLUSION

In this article, a multilevel concept for operating force was proposed and a multilevel operation strategy was presented based on this concept. This strategy established a general framework for promoting safe operation during surgical procedures and provided a new potential paradigm for surgical safety. Based on the framework, this article developed specific operating methods for use in vascular interventional surgeries, including the movement protection mechanism, multilevel force feedback method, and motion reducing control. A prototype was fabricated and integrated with the previous robot. Calibration experiments, in vitro and ex vivo experiments, were carried out, and the results demonstrated the effectiveness of the proposed operation strategy. Generally, a remote-controlled VI robot would have the following potential advantages when the proposed multilevel operation strategy is used. First, it could potentially minimize damage to the blood vessels and might restore the patients to health more quickly. This strategy would remedy the limitation of perceptual resolution in force discrimination of hands both in the traditional invasive vascular surgeries and current robot-assisted surgeries. Second, some serious complications could be avoided online by recognizing and eliminating "unsafe operations." Finally, operation efficiency would be improved because surgeons can complete surgeries without restricting the continuity of operation. We may argue that 1) the multilevel operation strategy might be suitable for use in actual surgical operations to improve surgical safety and 2) the multilevel concept for operating force could be used as a reference for the choice and design of operation strategies in some other robot-assisted surgeries, and for formulating evaluation indexes for preoperative training and postoperative evaluation, or for the design of some other different operations in minimally invasive vascular surgeries, such as the rotary displacement of catheters or guidewires.

However, several limitations existed in this article. First, the thresholds of blood vessels should be selected based on clinical data. Second, the regulation coefficients of the force and displacement differential in the amplification equation of MFFM need to be optimized through comparative experiments. Third, an appropriate filter function should be selected and evaluated to smooth the MFFM and the motion reducing control. If an abnormal force value occurs (e.g., extremely large force) in the force of the catheter, it will be magnified several times by the MFFM and, thus, it will affect the surgical operation. In the future, we will overcome the limitations mentioned above and validate the multilevel operation strategy through *in vivo* experiments.

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