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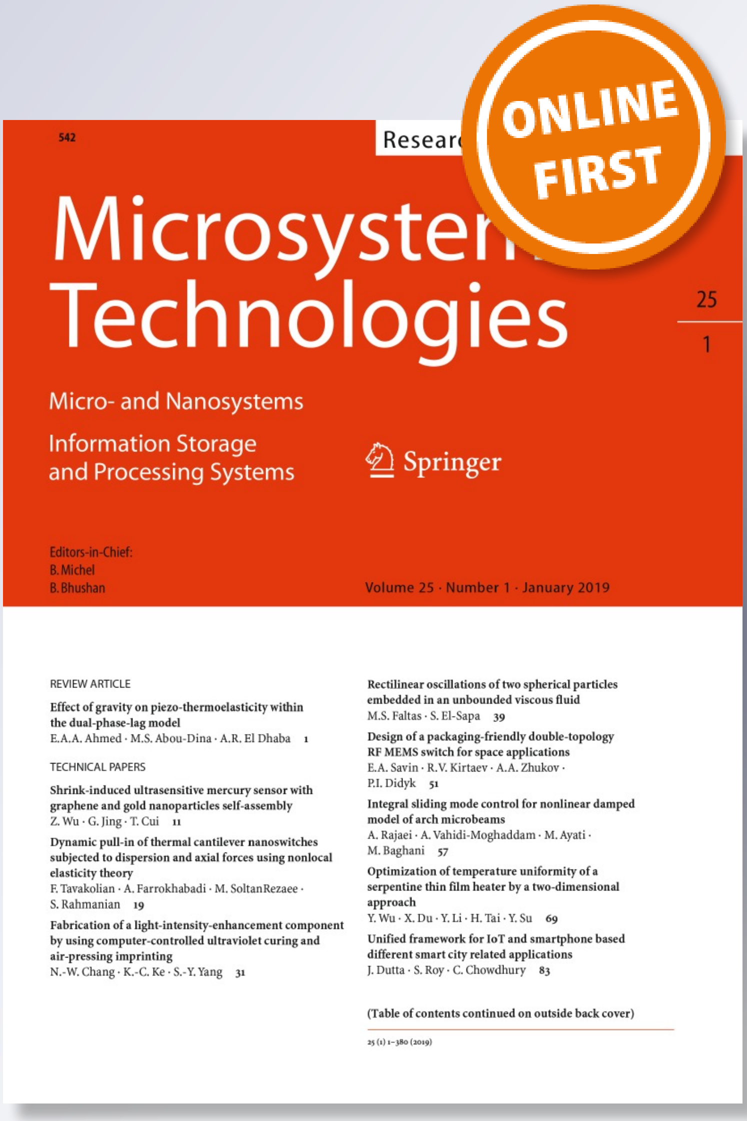

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TECHNICAL PAPER

Design and evaluation of sensorized robot for minimally vascular interventional surgery

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Abstract

Remote-controlled vascular interventional robots (RVIRs) are being developed to reduce the occupational risk of the intervening physician, such as radiation, chronic neck and back pain, and increase the accuracy and stability of surgery operation. The collision between the catheter/guidewire tip and blood vessels during the surgery practice is important for minimally invasive surgery because the success of the surgery mainly depends on the detection of collisions. In this study, we propose a novel sensing principle and fabricate a sensorized RVIR. The proposed sensorized RVIR can accurately detect force and reconstruct force feedback. The performance of the proposed sensorized RVIR is evaluated through experiments. The experiment results show that it can accurately measure static force and time-varying force. Subtle force changes caused by changes of movement direction in surgeries can also be detected. In addition, the proposed sensorized RVIR has higher operation efficiency than our previous prototype.

1 Introduction

Minimally vascular interventional surgery inserting special slender instruments through small skin incisions is widely used due to the least possible damage to healthy organs and tissues. However, the specific surgical procedure and small work space have caused several difficult problems for surgeons, such as the heavy radiation protection garments, back pain, and chronic neck (Klein et al. 2009), as well as the partial protection for the radiation (Whitby and Martin 2005). Therefore, the development of the surgical support devices with the application of robot technology are in demand (Taylor and Stoiariovici 2003). Remote-controlled vascular interventional robot (RVIR), allowing the surgeons to be released from radiation and heavy radiation protection garments, has become a growing interest in the field of minimally vascular interventional surgery.

Four main commercial remote-controlled vascular interventional robots have been developed by Corindus Vascular Robotics, Hansen Medical, Catheter Robotics Inc., and Stereotaxis Inc., respectively (Faddis et al. 2002; Schiemann et al. 2004; Saliba et al. 2006; Khan et al. 2013; Riga et al. 2013). Fukuda et al. used a linear stepping mechanism to achieve linear movement of the catheter and developed a system allowing magnetic tracking (Arai et al. 2002; Tercero et al. 2010). Park et al. (2010) introduced a novel catheter navigation system, which controls catheters by electromechanical actuators in the slave manipulator and provides force feedback by a master manipulator. A remote catheter navigation system developed by Thakur et al. (2009), is composed of a catheter sensor measuring motion of an input catheter and a catheter manipulator manipulating a patient catheter. Some other research groups have also been devoted to the study of RVIRs (Beyar et al. 2006; Cercenelli et al. 2007; Jayender et al. 2008; Marcelli et al. 2008; Fu et al. 2009; Srimathveeravalli et al. 2010; Wang et al. 2010; Kesner and Howe 2011; Meng et al. 2013; Feng et al. 2015; Tavallaei et al. 2016).

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Meanwhile, in our previous research, some novel active catheter systems with a miniature force sensor mounted on the catheter tip have been developed, which can realize linear and rotary movements of catheters accurately (Guo et al. 1995, 2008, 2016). Moreover, several kinds of RVIRs were designed, which can operate the catheter with 2-DOF, measure the proximal force and realize the force feedback accurately. Two semi-active haptic interfaces were developed as master consoles, and a catheter operation training system integrating a virtual reality simulator and a haptic device was also designed to train new surgeons (Bao et al. 2016, 2017, 2018a, b; Yin et al. 2016; Guo et al. 2018; Xiao et al. 2011; Zhao et al. 2018).

When commercial catheters (passive catheters) are used in minimally vascular interventional surgery, catheters and guidewires are both needed and are simultaneously operated by the intervening physician. Both the support of the catheter and the navigation of the guidewire are needed to direct the catheter/guidewire through vessels in the body; especially in the narrow vessel branch, it would be particularly difficult to navigate without such cooperation. The operation process wherein catheters and guidewires are both needed and are simultaneously operated, was defined as the cooperation of catheters and guidewires in our previous research (Bao et al. 2018a). Therefore, a lack of cooperation of catheters and guidewires poses a significant challenge for complex surgeries. However, few researchers have studied interventional robots based on the cooperation of catheters and guidewires (Srimathveeravalli et al. 2010).

To address these challenges, we proposed two novel solutions and fabricated two novel RVIRs (called RVIR-CI and RobEnt) (Bao et al. 2017, 2018a, b). The experimental results demonstrated that they can accurately operate the catheter and guidewire, and successfully complete complex surgeries with the cooperation of catheters and guidewires. Moreover, an in-human experiment was conducted to evaluate the performance of the RobEnt. The experiment results show that the RobEnt has good safety and reliability and can be used in clinical surgeries (Bao et al. 2018a, b). However, the RobEnt cannot provide force feedback and thus it will be a great challenge in telesurgery because the success of the surgery mainly depends on the force feedback (Yin et al. 2016). Force measurement is vital to obtain force feedback because the measured force serves as the foundation for generating force feedback. In addition, the catheter/guidewire should be disengaged easily from the RVIR for repair or sterilization in clinical operation. However, the easy disengagement of the catheter/guidewire has a serious impact on the force measurement.

In this paper, to extend our previous research, we propose a novel sensing principle and fabricate a sensorized RVIR. The main contribution of this paper is that the novel principle provides a reference for design of accurate force measurement in clinical operation. The proposed sensorized RVIR can allow for easy disengagement of the catheter/guidewire without reducing the accuracy of force measurement. The sensing unit in the sensorized RVIR is validated through experiments at the instrument level. Moreover, the sensorized RVIR is evaluated via experiments using a human body model in the actual surgical robot operating environment. In addition, operation efficiency of the proposed sensorized RVIR is evaluated through contrastive experiments.

The rest of this paper is organized as follows. The development of the proposed sensorized RVIR is presented in Sect. 2. Section 3 presents evaluation experiments including verification of the sensing unit, verification of the sensorized RVIR, and operation efficiency of the sensorized RVIR. The discussion on the experiments is described in Sect. 4. Finally, the conclusion is given in Sect. 5.

2 Design of the sensorized RVIR

2.1 Overview of the RVIR

The RVIR was designed as a telerobotic system, which is composed of a master controller and slave manipulator. These two components work together to realize the operation of the catheter and guidewire. The schematic diagram of the system, displaying the workflows and interactions of different components is shown in Fig. 1. As shown in Fig. 1, the master controller takes advantage of the surgeon's existing dexterity skills by obtaining the operational information imparted by the surgeon. This operational information includes the linear motion (x_h) and rotary motion (θ_h) of surgeon's hands. Then the operational information is preliminarily processed and transmitted as x_{mh} and θ_{mh} to the control unit on the master side. The other control unit on the salve side exchanges signals with the control unit on the master side and transmits the processed

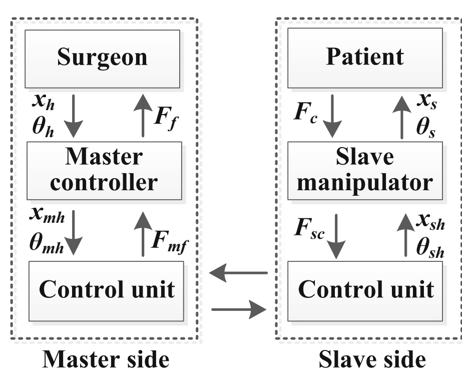

Fig. 1 Schematic diagram of the system

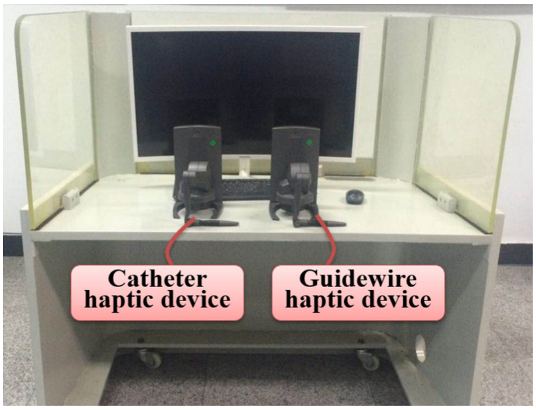

Fig. 2 Master controller, including a catheter haptic device and a guidewire haptic device

operational information (x_{sh}, θ_{sh}) to the slave manipulator. The slave manipulator then operates the catheter/guidewire (x_s, θ_s) to realize the surgical operation. In the process of this movement information exchange, the master controller and slave manipulator are connected through a local network, and a PID controller is used to complete the precise and stable control of the movement. Similarly, the force of catheter/guidewire (F_c) is captured by the salve manipulator, and then it is preliminarily processed and transmitted as F_{sc} to the control unit on the slave side. After the signal exchanges between the two control units, the processed information (F_{mf}) is transmitted to the master controller. Then the master controller generates the force and the surgeon will obtain the force feedback (F_f). The master controller is shown in Fig. 2.

2.2 Sensing principle

The collision between the catheter tip and blood vessels during the surgery practice is important in minimally invasive surgery. Few RVIRs provide force feedback to the operator; most of these robots use friction wheels to capture proximal force (Beyar et al. 2006; Fu et al. 2009; Feng et al. 2015). However, it is difficult to accurately measure the proximal force because the slippage between the friction wheels and catheter/guidewire exists when the friction wheels are used to realize proximal force measurements. To accurately measure the force of the catheter/guidewire, we proposed the use of the static connection method instead of the dynamic connection method (Fig. 3) (Bao et al. 2016). As shown in Fig. 3, a grasper is used to grasp the catheter/guidewire in a static manner, and the sensor is statically and directly linked with the grasper. Moreover, the catheter/guidewire can be grasped by using conical clamping principle. Therefore, the catheter/guidewire is effectively grasped and the force can be measured accurately.

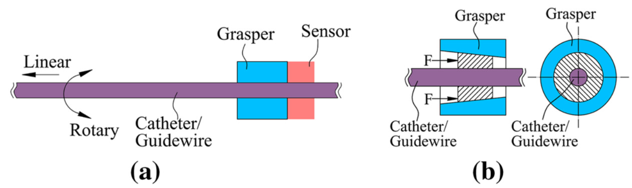

Fig. 3 The principle of force measurement: **a** the sensor linking with the grasper statically and directly, **b** the grasper grasping the catheter/guidewire by using conical clamping principle (Bao et al. 2016)

However, when the static connection method is used to capture the force of catheter/guidewire, two challenges exist.

(1) The grasper links with sensor statically and directly, while the catheter/guidewire needs to both move and rotate during surgeries. Moreover, the rotation of catheter/guidewire is driven by motor. Therefore, the rotation of catheter/guidewire and the connection between catheter/guidewire and motor will have a serious influence on the force measurement.

(2) Sterilization is directly related to the success of surgeries, and incomplete sterilization will increase the risk of infection, or even cause medical accidents. Therefore, it should permit easy disengagement of the catheter/guidewire from the RVIR for repair or sterilization.

To address these two challenges, we propose a novel sensing principle shown in Fig. 4. A ball spline is used to link the motor with the gear train, and the gear train connects with the catheter/guidewire by using a grasper. The ball spline can transmit the torque almost without restriction in linear direction, and thus the effect of the rotation of catheter/guidewire will be eliminated. The force of catheter/guidewire can be obtained by

$$F_{CG} = F_S + F_1 + F_2 \tag{1}$$

where F_{CG} is the force of catheter/guidewire, F_S is the measured force of force sensor, F_1 is the friction force generated by the linear slide, and F_2 is the friction force generated by the ball spline. Since the friction force can be

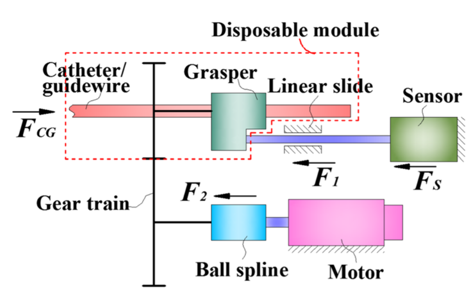

Fig. 4 Novel sensing principle for measurement and sterilization

regarded as a constant, we can measure the force of catheter/guidewire accurately.

In addition, to permit easy disengagement of the catheter/guidewire, we design the upper gear and grasper as a disposable module. The catheter/guidewire mounted on the grasper and the disposable module can be disassembled easily. Therefore, this novel sensing principle can also allow for a simple and reliable assembly/disassembly of catheter/guidewire from the RVIR.

2.3 Prototype

As shown in Fig. 5, the sensing unit consists of a ball spline, gear, linear slide, sensor, bracket and grasper. The grasper clamping the catheter/guidewire can be quickly assembled and disassembled from the bracket.

The proposed sensorized RVIR is composed of a linear motion platform, catheter manipulator (CM), guidewire manipulator (GM), catheter guiding sleeve and guidewire guiding sleeve (Fig. 6a). Two sensing units are set inside the CM and GM, respectively (Fig. 6b, c). The CM can perform rotary motion and capture the force of the catheter; the GM is designed to perform rotary motion and capture the force of the guidewire. The force signals of catheter and guidewire will be sent to the master controller and the master controller will reconstruct force feedback (Fig. 2). Owing to different characteristics of catheters and guidewires, the grasper in the disposable module for CM is different from that for GM. The disposable modules for CM and GM are shown in Fig. 6b and c.

3 Experiment

To validate the performance of the new prototype, three types of experiments were carried out. Experiment I is used to verify that the proposed sensing unit can accurately detect resistance force. Experiment II is used to test

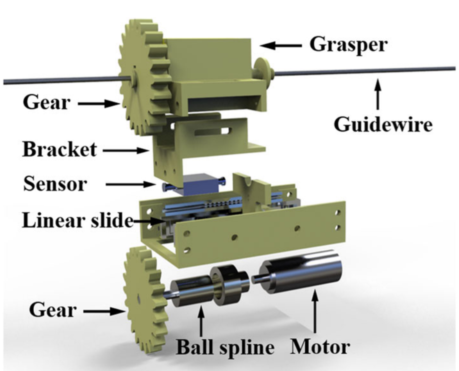

Fig. 5 Mechanical implementation of the sensing unit for the proposed sensorized RVIR

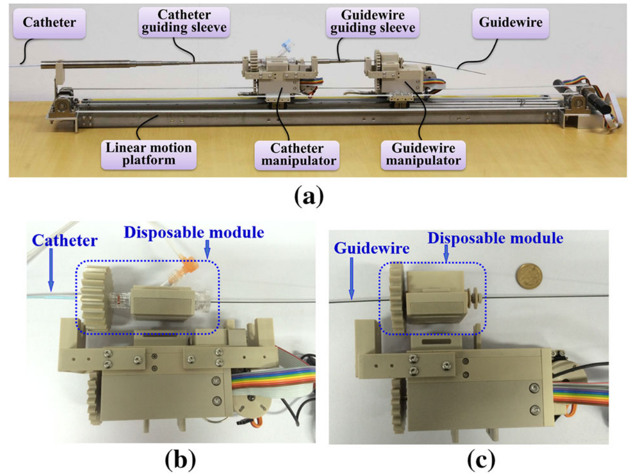

Fig. 6 Physical prototype of the proposed sensorized RVIR: **a** overall structure diagram; **b** CM; **c** GM

whether the proposed sensorized RVIR can complete a surgery and capture subtle change of resistance force. Operation efficiency experiments were conducted to test whether the proposed sensorized RVIR can perform a surgery more efficiently compared with our previous RVIR in Experiment III.

3.1 Verification of the sensing unit

To verify that the proposed sensing unit can accurately detect the resistance force, static force experiment and time-varying force experiment were performed.

The experimental set-up for static and time-varying force measurement is shown in Fig. 7. In the static force experiment, the CM was positioned vertically to keep the axis of the grasper oriented in the vertical direction, and a standard weight was placed on the end of the grasper. We added different loads (20–400 g) to the sensing unit, and ten cycles of repetition were carried out for each load. In the time-varying force measurement, we applied a time-varying dynamic force to the stent of the force sensor. During this process, the force sensor measured the time-varying force and the sensing unit acquired simultaneous force signals in real-time.

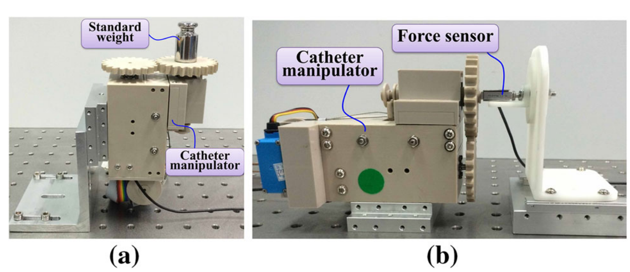

Fig. 7 **a** Experiment set-up for static force measurement; **b** experiment set-up for time-varying force measurement

The results of the static and time-varying force measurement for the sensing unit are shown in Fig. 8. In the static force experiment, the maximum relative error between the measured and the referenced forces is 3.21%. In the time-varying force experiment, the maximum relative error and the average relative error between the force signals for the sensing unit are 11.05% and 8.14%, respectively.

3.2 Verification of the sensorized RVIR

To test whether the proposed sensorized RVIR can complete a surgery and capture subtle change of resistance force, an experiment was conducted using the proposed sensorized RVIR to propel a catheter and guidewire to a target position. A catheter (VER135°, Cordis Corporation, USA) and guidewire (451-514HO, Cordis Corporation, USA) were propelled by the proposed sensorized RVIR from the starting position to the target position in a human body model (General Angiography Type C, FAIN-Biomedical, Inc. JP) (Fig. 9). The starting position was located in the aortic arch (position B), and the target position was located in the left subclavian artery (position C) (shown in Fig. 9). Ten operators were enrolled in this experiment and the operation was performed ten trials per operator.

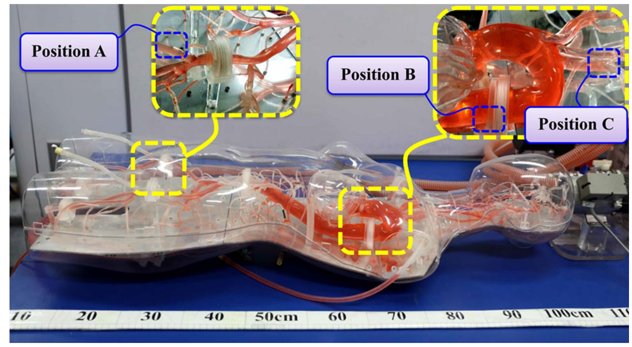

Fig. 9 Human body model, and the starting and target positions

The catheter and guidewire reached the target position successfully in all experiments performed by the ten operators. One of the experiments was selected and the results are presented in Fig. 10. In this figure, the blue, black, and red line represent the linear motions, rotary motions, and forces, respectively. Figure 10a shows the motions and forces of the catheter; Fig. 10b shows the motions and forces of the guidewire.

As shown in Fig. 10a, the force of the catheter increased drastically and immediately at approximately 38–40 s because the catheter collided with the vessel wall of the aortic arch and began to rotate. At approximately 39 s and 42 s, the direction of linear/rotary movement of the

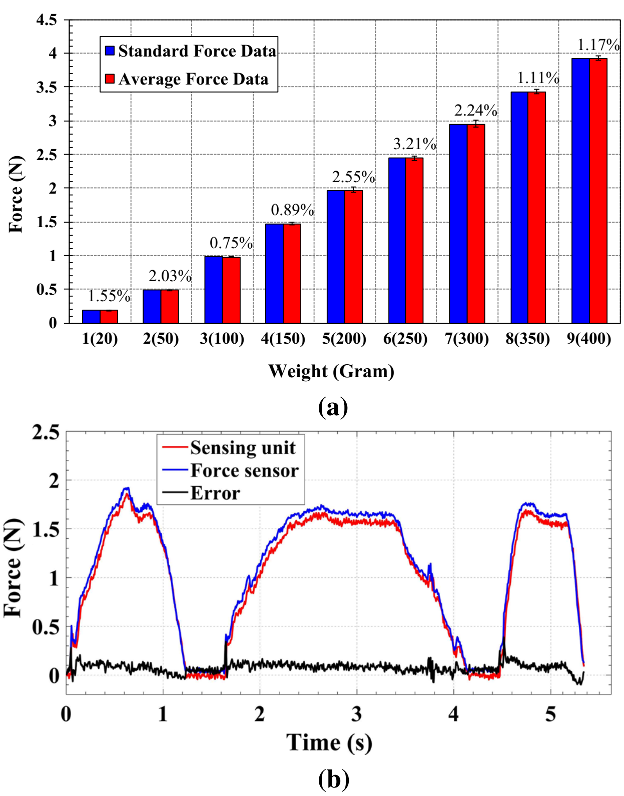

Fig. 8 **a** Results of the static force measurement; **b** results of the time-varying force measurement

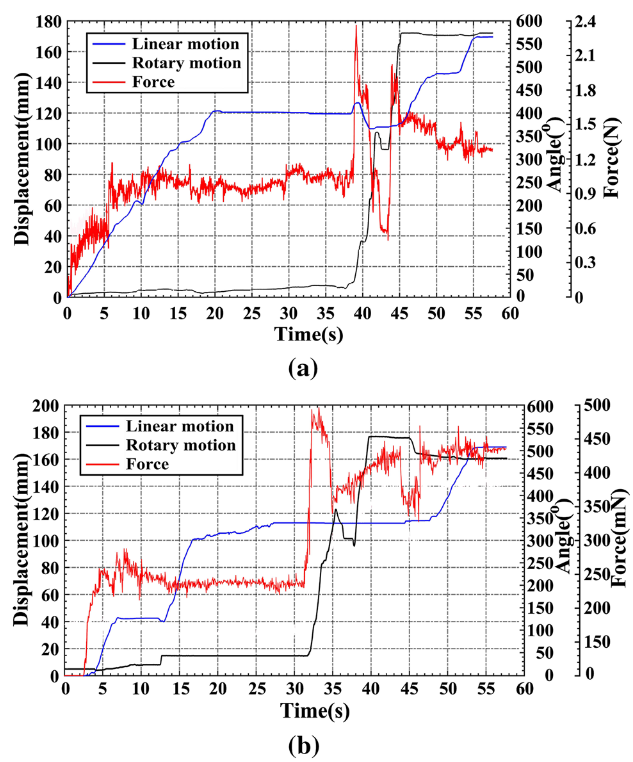

Fig. 10 **a** The linear motions, rotary motions, and forces of the catheter, **b** the linear motions, rotary motions, and forces of the guidewire

catheter changed, and force of the catheter changed immediately. Similarly, the force of the guidewire increased drastically and immediately at approximately 31–33 s (as shown in Fig. 10b). The force values of the guidewire at approximately 35–57 s (the guidewire located in the aortic arch) were much larger than at 0–32 s (guidewire located in the left subclavian artery). We believe that this can be attributed to the fact that the guidewire generated larger frictional force when it was located in the left subclavian artery. The guidewire had larger bend angle when it passed through the narrow vessel branch and entered the left subclavian artery.

3.3 Operation efficiency of the sensorized RVIR

To test the operation efficiency, a catheter (VER135°, Cordis Corporation, USA) and guidewire (451-514HO, Cordis Corporation, USA) were also operated by the proposed sensorized RVIR from a starting position to a target position in a human body model (General Angiography Type C, FAIN-Biomedical, Inc. JP) (Fig. 9). The starting position was located in the femoral artery (position A), and the target position was located in the left subclavian artery (position C) (shown in Fig. 9). The operation was performed by an interventionalist with > 1 year of experience in catheterization. The interventionalist firstly performed this operation by using the proposed sensorized RVIR, and the surgery operation time was recorded. Then the same operation was performed by using our previous RVIR. The previous RVIR lacks sensing unit and cannot provide force feedback. Ten interventionalists participated in the experiment, and each operation was performed ten trials per operator.

The surgery operation time for the proposed sensorized RVIR and that for the previous RVIR are compared and shown in Fig. 11. The compared results include the average measured time and the standard deviation of the measured time data. The maximum surgery operation time difference between them is 32 s, and the average surgery operation time difference between them is 13.4 s.

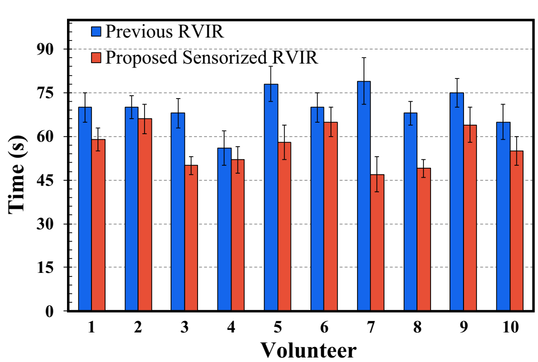

Fig. 11 Comparison results of surgery operation time

4 Discussion

In the time-varying force experiment, the relative error between the force signals was higher with larger force. The sensing unit will deform when it is used to measure the force. The deformation will offset part of the force applied to the sensing unit and it results in that the measured force is smaller than the real force. Moreover, when we periodically apply the force to the sensing unit, the sensing unit deforms periodically and the relative error will change periodically. Previous research shows that the perceptual resolution in force discrimination, as measured by the just noticeable difference (JND), is 7–10% over a range of 0.5–200 N (Jones 2000). Considering the results of experiment I, we may argue that the proposed sensorized RVIR is sensitive enough to accurately detect small changes in force.

In experiment II, we have preliminarily verified that the proposed sensorized RVIR can propel a catheter and guidewire to a target position through a narrow vessel branch, even though operating a catheter and guidewire from the aortic arch to the left subclavian artery in a human body model is not an extremely complex operation. Hence, the proposed sensorized RVIR can complete complex surgeries because it can direct a catheter and a guidewire simultaneously to pass through a narrow vessel branch by utilizing cooperation of catheters and guidewires. In addition, experiment results also show that the proposed sensorized RVIR can detect subtle force changes caused by changes of movement direction in surgeries.

In experiment III, when the interventionalist operated the proposed sensorized RVIR to perform surgical procedures in a human body model, it averagely cost less time compared with using the previous RVIR. We think it is mainly due to that the proposed sensorized RVIR can provide more operation information for the interventionalist. When the interventionalist performed a surgery, the proposed sensorized RVIR detected the force of catheter/guidewire and reconstructed force feedback. The force feedback will help the interventionalist to take advantage of the existing experience of themselves. In addition, with the help of the force feedback, the surgery can be performed more safely.

5 Conclusion

In this paper, a novel sensing principle was proposed and a sensorized RVIR was fabricated. The performance was validated through three types of experiments. The results show that the proposed sensorized RVIR can detect the resistance force accurately, reconstruct effective force feedback, and have higher operation efficiency than the previous prototype.

However, several limitations exist in this research. First, a special master controller is needed to collect actual surgical motions from a surgeon and to reconstruct the force feedback of the catheter and guidewire. In this paper, two commercial haptic devices are used as the master controller, and it will be difficult to take full advantage of the existing experience of a surgeon because the operating handle of the commercial haptic device is different from the catheter/guidewire. Second, the torque of the catheter and guidewire should be measured by the slave manipulator and reconstructed by the master controller. The torque of the catheter/guidewire is another important factor for the discrimination of collision in actual surgical operations. Third, the efficiency for assembly and disassembly of catheter/guidewire should be tested. The assembly and disassembly of catheter/guidewire are indispensable during surgeries and they will affect the whole operation process. Finally, the performance of proposed RVIR should be evaluated in actual clinical operation. In the future, we will improve the proposed RVIR to overcome the limitations mentioned above and validate it through in-human experiments.

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