THE THESIS OF DOCTOR OF PHILOSOPHY

Study on a Guidewire and Catheter Collaborative Operating System

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Abstract

The challenge of vascular interventional surgery is that doctors require to be exposed to the X-ray radiation for a long time, operating guidewires and catheters to perform the treatment. To reduce the fatigue of doctors, it is of great significance to develop a tactile sensing robot-assisted system for vascular interventional surgery (VIS). The tactile sensing robot-assisted system for VIS is an emerging surgical technique, which can improve the comfort, precision, and stability of the surgery, eliminate the physiological tremor, and reduce the X-ray radiation of the doctors compared with the traditional manual operation.

By summarizing the current researches, most of robot-assisted systems lack the functions of haptic force feedback and collaborative operating of guidewires and catheters, which cannot guarantee the safety, the external disturbance forces easily affect the accuracy of the haptic force feedback and the judgment of doctors, and the blood vessel is easy to be punctured due to the doctor's misoperation and the medical accident.

In general, the purpose of this thesis is to solve the challenge of how to guarantee the safety of the robot-assist system during the operation. And the approaches of this thesis are developing a tactile sensing robot-assisted system with the function of haptic force feedback, analyzing the total force and eliminating the disturbance force between the catheter and the blood vessel, and proposing active enhancing safety methods to avoid the danger caused by the doctor's misoperation and the medical accident. The main topics of this thesis include (1) Development and evaluation of the novel robot-assisted system with haptic force feedback for VIS. (2) Total force analysis and safety enhancing for operating both guidewire and catheter in endovascular surgery. (3) Study on the active enhancing safety method of the robot-assisted system in endovascular surgery.

To verify the developed tactile sensing robot-assisted system, a series of experiments in "Vitro" were carried out. Experimental results obtained in Chapter 3 indicated that the developed robot-assisted system has good tracking performance, the maximum error of the rotation motion was less than 2 degrees, and the maximum error of the linear motion was less than 2 mm. Besides, under the guidance of the collaborative operation and the haptic force feedback, the safety performance of the operation with haptic force feedback was significantly higher than that of without haptic force feedback. The safety increased by 4.32% on average after five participants completed the experiment. And experimental results obtained in Chapter **6** indicated the accuracy of the haptic force feedback can be enhanced by eliminating the disturbance force, and the collision force at the tip of the catheter can be confirmed by using the self-developed force sensor, which is helpful for the doctors to make the accurate judgment and improve the safety of the robot-assisted system. The proposed active enhancing safety methods can reduce the risk in time. The collision force at the tip of the catheter was reduced by 0.104 N, and the average and the maximum total force between the catheter and the blood vessel was reduced by 0.1 N and 0.054 N, respectively, under the condition of the active enhancing safety

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method. Besides, the strong sense of the tactile presence of the doctor was generated by the developed master manipulator when the total force from the slave side was reaches the level B listed in Table 5-1 (The classification of the force levels during the operation).

The contributions of this thesis can be briefly summarized as: A novel tactile sensing robot-assisted system was proposed to assist the doctors to perform the operation. The developed slave manipulator can operate the guidewire and the catheter, it can navigate the target point accurately and smoothly, just like the doctor's hand. A master manipulator based on the magnetorheological fluids was used to achieve the haptic force feedback by generating the haptic force acting on doctors' hand, it can guarantee the safety performance of the robot-assisted system. The forces on the guide wire and the catheter were analyzed, the disturbance force was eliminated the contact force was used as the reference force to realize the haptic force feedback of the robot-assisted system, and the accuracy of the haptic force feedback was improved. A force sensor based on pressure sensitive rubbers was used to confirm and detected the collision force between the tip of the catheter and the blood vessel. A preliminary method was proposed to assist the deflection of the catheter tip to pass through the curved blood vessel with a relatively small collision force. An active enhancing safety method was proposed to avoid the danger caused by the doctor's misoperation and the medical accident during the operation. Finally, a series of experiments in "Vitro" were carried out, and experimental results were analyzed, and discussed.

The significance of this thesis is that the tactile sensing robot-assisted system can guarantee the safety of the operation, prevent the doctor from being exposed to x-ray radiation, and reduce the burden on the doctor.

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I sincerely wish my relatives, teachers, classmates, and friends can be healthy and happy.

Declaration

I hereby declare that this submission is my own work, and to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for the award of any other degree or diploma of a university or other institute of higher learning, except where due acknowledgment has been made in the text.

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Chapter 1 Introduction

1.1 Background

In recent years, cardiovascular disease has become a typical disease that seriously endanger human health, it usually affecting the heart and blood vessels, leading to heart attacks and strokes and accounting for one third of all deaths worldwide each year [1]. With the development of medical technologies, vascular interventional surgery (VIS) has saved more and more patients with cardiovascular diseases. At present, there are two ways to treat cardiovascular diseases, one is the manual operation, and other is the emerging robot-assisted minimally invasive surgery [2][3]. As shown in Figure 1-1, it is the procedure of the manual operation, the doctor needs to operate guidewires and catheters in the operating room for a long time to perform the treatment, but the long operation time is easy to fatigue the doctors and increase the risk of surgery. In addition, the health of doctors can hardly be ensured because of the X-ray radiation. Some publications [6]-[8] have reported that doctors exposed to X-ray radiations for a long time are prone to cancerous tumors, eye diseases (lens opacity), and bone diseases (cervical and lumbar injuries). Compared with traditional manual operation, the robot-assisted minimally invasive surgery has outstanding

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advantageous, which can improve the comfort, precision, stability of the operation, eliminate the physiological tremor and reduce X-ray radiations of doctors. The robot-assisted minimally invasive surgery for VIS can help doctors perform the operation safely and accurately.

1.2 Current Research Status

To protect the doctors from X-ray radiations and reduce the burden of the doctors during the operation, the tactile sensing robot-assisted system mostly adopts the "Master-Slave" structure [9]-[26]. As shown in Figure 1-2, the doctor performs the surgery by operating the master device at the master side (also the proximal side) to control the slave manipulator at the slave side (also called the distal side).

The surgical tools were delivered by the robot-assisted system, so, good information interaction between the robot-assisted system and the doctor is required. The novel master manipulator with the function of haptic force feedback was developed to provide the doctors with tactile presence and guaranteed the safety of the operation. The realization of the haptic force feedback is very novel, for instance, the method inspired by the damping characteristics of magnetorheological (MR) fluids [27]-[32], as shown in Figure 1-3 (a), and the method inspired by the torque characteristics of the linear motor [33]-[35], as shown in Figure 1-3 (b). In addition to the haptic force feedback, the safety can be enhanced by avoiding the tremor during the operation [36][37], and by combining the image guidance [38]-[42].

To monitor and detect the force between the surgical tool and the blood vessel, the modeling estimation based on the noninvasive techniques was proposed in [43], and the direct detection method based on the optical fiber pressure sensor was proposed in [44]-[46], as shown in Figure 1-4.

The control of the robot-assisted system is another important metric for evaluating its performance. To improve the accuracy of the robot-assisted system, the control algorithms were designed, including reducing the error of the master-slave tracking motion [47]-[50], as shown in Figure 1-5, and generating the ideal motion trajectory of the catheter and shortening the time-varying of the response [51].

Robot-assisted systems are gradually developing towards the direction of intelligence. For instance, to analyze the natural behaviors of the doctor and recognize the motion patterns of the guidewire, the classification and analysis framework was designed in [52]-[55], as shown in Figure 1-6. To lessen the fatigue of repetitive tasks, and shorten the operation time, the supervised semi-autonomous control was proposed in [56][57].

The application of the magnetic fields in the robot-assisted system has also obtained the good results, the current magnetic manipulation systems were proposed to achieve the actuation of the surgical devices, which has the characteristics of large working space, high precise [58]-[62], and low damage [63], as shown in Figure 1-7.

Currently, most of the catheter and the guidewire often cannot advance into small diameter blood vessels due to their large diameters and lack of sharp steering capacity, a hydraulically steerable guidewire with 400 μ m

diameter was developed in [64], which can access 1 mm diameter vessels whose branching angle was larger than 90 degrees, the schematic diagram is shown in Figure 1-8. In addition, the transmission characteristics of the steerable ablation catheter was studied in [65], the linear displacement of the proximal handle was translated to the bending of the distal shaft.

It is worthy to emphasize that the design and development of the tactile sensing robot-assisted system is very fast, some of robot-assisted systems have completed the evaluation in animal [66][67], and in human [68].

In addition. Some of the more mature robot-assisted systems have been applied in clinical practices, and the results of surgical reports have been published. (1) the Magellan Medical Vascular Catheter Control System (VCCS) [69][70]. (2) the Sensei XTM Robotic Navigation System (RNS) [71]. (3) the CorPath GRX Robotic-assisted System [72]. (4) the AmigoTM System [73]. And (5) the Niobe Magnetic Navigation System [74].

1.3 Objectives

1.3.1 Research Purposes

- To develop a tactile sensing robot-assisted system with haptic force feedback for VIS.
- 2) To improve the safety performance of the developed tactile sensing robot-assisted system for VIS.
- To prevent the puncture of the blood vessel due to the fatigue of the doctors and the medical accidents.

1.3.2 Research Approaches

- Develop a tactile sensing robot-assisted system with the function of haptic force feedback to guarantee the safety of the system.
- 2) Analyze the total force and eliminate the disturbance force between the catheter and the blood vessel.
- Propose active enhancing safety methods to avoid the danger caused by the doctor's misoperation and the medical accident.

1.4 Thesis Overview

The remained of this thesis is organized as follows, and the structure of this thesis is shown in Figure 1-11.

In **Chapter 2**, a new type of tactile sensing robot-assisted system with the function of the collaborative operating the catheter and the guidewire and the haptic force feedback of doctors is developed based on the actual operating requirement. The structure design of the master manipulator and the slave manipulator is introduced in detail.

In **Chapter 3**, to evaluate the developed tactile sensing robot-assisted system, a series of experiments in "Vitro" are conducted, and experimental results indicated that the safety of the developed robot-assisted system can be guaranteed under the condition of there is the haptic force feedback in the robot-assisted system.

In **Chapter 4**, the forces on the guidewire and the catheter are analyzed, and the disturbance force are eliminated in the procedure of the operation.

Besides, a self-developed force sensor based on pressure sensitive rubbers is developed to confirm the collision force between the tip of the catheter and the blood vessel wall.

In **Chapter 5**, a preliminary method is proposed to assist the deflection of the tip of the catheter to pass through the curved blood vessels with the relatively small collision force, and the active enhancing safety method is proposed to avoid the danger caused by the doctor's misoperation and the medical accident.

In **Chapter 6**, to evaluate the methods proposed in **Chapters 4 and 5** can improve the safety of the developed system, a series of experiments in "Vitro" are completed. Experimental results indicated that the accuracy of the haptic force feedback can be improved by eliminating the external disturbance force in the procedure of the operation, and the collision force between the tip of the catheter and the blood vessel wall can be confirmed and detected by using the self-developed force sensor based on pressure sensitive rubbers. Besides, the danger caused by the doctor's misoperation and the medical accident can be avoided.

In **Chapter 7**, the research results and the contribution of this thesis is summarized, and the future work of this thesis is given.

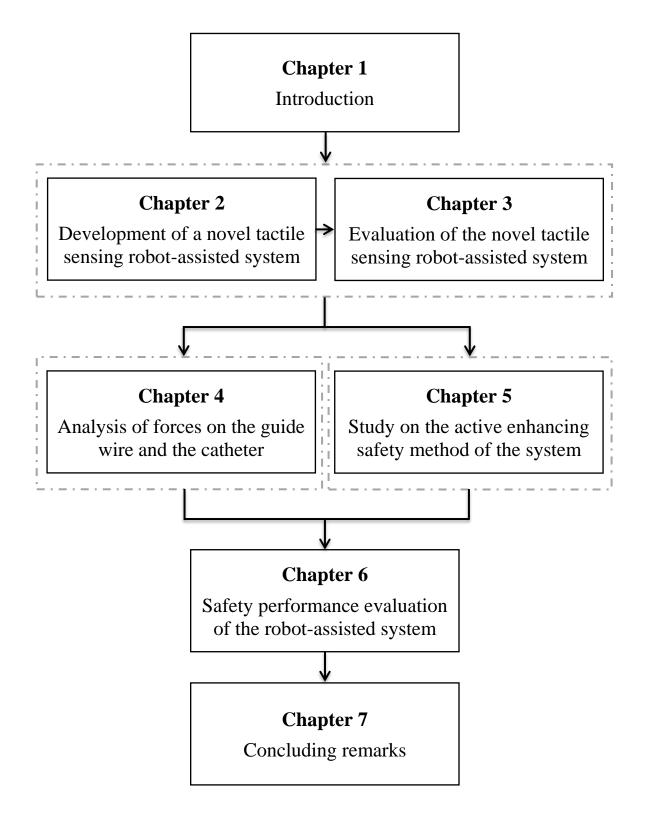


Figure 1-11 The structure of this thesis

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Chapter 2 Development of a Novel Tactile Sensing Robot-Assisted System

2.1 Challenges

A developed robot-assisted system for VIS should satisfy the operating requirements of the doctors. Through analysis, there are some important points. 1) The master manipulator of the developed robot-assisted system should respect the doctor's operating habits, so that the doctor can make full use of rich experiences and dexterous skills. 2) The slave manipulator of the system should realize the collaborative operating between the guide wire and the catheter, which has the advantage of fast navigation to target position. And 3) The novel developed robot-assisted system should have the ability of haptic force feedback, which has the advantage of enhancing the safety of the operation.

At present, some of systems have realized the collaborative operating between the guidewire and the catheter, improved the navigation ability of the robot-assisted system, but lack the haptic force feedback. And some of systems have realized the haptic force feedback, guaranteed the safety of the system, but lack the collaborative operating between the guidewire and the catheter. In addition, the guidewire plays the role of guiding and supporting the catheter during the operation. For the system that lacks the collaborative operating, the catheter is easily buckled.

In view of the above-mentioned challenges, this **Chapter** developed a novel slave manipulator has the ability of collaborative operating between the guidewire and the catheter, the robot-assisted system can navigate the target position accurately, just like the doctor's hand. In addition, a master manipulator based on the MR fluids was used to achieve the haptic force feedback by generating the haptic force acting on the doctor's hand, which can guarantee the safety of the robot-assisted system.

Chapter 3 Evaluation of the Novel Tactile Sensing Robot-Assisted System

In **Chapter 2**, the structure, the working principle, and the analysis of the developed robot-assisted system have been introduced. Therefore, in this **Chapter**, the developed robot-assisted system will be evaluated by the experiments in "Vitro", including the tracking performance evaluation of the novel slave manipulator, and the collaborative operation evaluation in the cardiovascular. Each experiment consists of experimental setup and experimental results, Experimental results indicated that the robot-assisted system has good collaborative operation performance and high safety.

3.1 Summary

In this **Chapter**, a novel tactile sensing robot-assisted system for VIS was evaluated by experiments in "Vitro". Experimental results indicated that the proposed robot-assisted system has good performance in tracking motion, the maximum error of the linear motion was less than 2 mm, and the maximum error of the rotation motion was less than 2 degrees. Under the guidance of the collaborative operation and haptic force feedback, the guidewire and the catheter were delivered to the target point smoothly, the

safety of the operation with haptic force feedback was significantly higher than that of without haptic force feedback. After five participants repeated the experiment, the safety performance of the robot-assisted system was increased by 4.32% on average. So, we consider that the developed tactile sensing robot-assisted system is effective.

Chapter 4 Analysis of Forces on the Guide wire and the Catheter

4.1 Challenges

Currently, the most of robot-assisted systems needs to be improved, the total force on the guidewire and the catheter during the operation needs to be analyzed and determined. Among them, the disturbance force needs to be eliminated, because the disturbance force is easy to reduce the accuracy of the haptic force feedback of the robot-assisted system and increase the difficulty of the operation.

Based on the above challenges, the forces on the catheter and the guide wire and the catheter was analyzed by modeling, the disturbance force was eliminated, and a force sensor based on the pressure sensitive rubbers was developed to confirm the collision between the tip of the catheter and the blood vessels.

4.2 Summary

In this **Chapter**, to improve the accuracy of the haptic force feedback and reduce the difficulty of the doctor's judgment, the total force on the guidewire and the catheter during the operation was analyzed in detail by modeling, the disturbance force was eliminated, and a force sensor based on the pressure sensitive rubbers was developed to confirm the collision force between the tip of the catheter and the blood vessel. The safety of the robot-assisted system can be improved by combining the haptic force feedback with the collision detection of the self-developed force sensor based on the pressure sensitive rubbers.

Chapter 5 Study on the Active Enhancing Safety Method of the System

5.1 Challenges

The safety performance has always been an important part in the study of the robot-assisted system for VIS. The active enhancing safety method should be studied and integrated into the robot-assisted system, compared with the passive method, it can actively reduce the dangerous behaviors in time during the operation. However, lack of the active enhancing safety method may cause the puncture of the blood vessels due to the fatigue of the doctor. So, aiming to the above challenges, an active enhancing safety method was proposed to avoid the danger caused by the medical accident and the doctor's misoperation during the operation.

5.2 Summary

In this **Chapter**, to avoid the dangerous behaviors caused by doctor's misoperation and the medical accident during the operation, a preliminary method was proposed to assist the deflection of the tip of the catheter to pass through the curved blood vessels with the relatively small collision

force, and active enhancing safety methods occurring on the master side and the slave side were proposed to improve the safety of the developed robot-assisted system, which can actively avoid the dangerous behaviors in time during the operation compared with the passive method.

Chapter 6 Safety Performance Evaluation of the Robot-Assisted System

To verify the methods proposed in **Chapters 4** and **5**, the experiments in "Vitro" were completed in this **Chapter**, including "Determination of the Force between the Catheter and the Catheter Sheath", "Determination of the Force between the Guidewire and the Catheter", "Safety Evaluation of the System in Two Tasks", "Evaluation of the Method to Reduce the Collision Force Occurs at the Tip of the Catheter", and the "Evaluation of Active Enhancing Safety Methods". The first three experiments are used to verify the method proposed in **Chapter 4**, and the last two experiments are used to verify the method proposed in **Chapter 5**. Each part includes experimental setup and experimental results.

6.1 Summary

In this **Chapter**, a series of experiments in "Vitro" were carried out to verify the safety performance of the robot-assisted system was improved by the methods proposed in **Chapters 4** and **5**. And experimental results indicated that the accuracy of the haptic force feedback can be enhanced by eliminating the disturbance force in the procedure, the collision force

at the tip of the catheter can be detected by using the self-developed force sensor, which is helpful for doctors to make the accurate judgment during the operation, the active enhancing safety methods can reduce the risk in time. The collision force at the tip of the catheter was reduced by 0.104 N and the average and the maximum total force between the catheter and the blood vessels was reduced by 0.1 N and 0.054 N, respectively, under the condition of the active enhancing safety method. The strong sense of the tactile presence of doctors was generated by the master manipulator when the total force of the slave side was greater than 1.0 N.

Chapter 7 Concluding Remarks

Nowadays, cardiovascular disease is very harmful to human beings, if left untreated, it may cause myocardial infarction or stroke. Therefore, the development of the VIS has brought good news to patients. VIS has been widely concerned due to its advantages of reducing the patient's pain. The treatment of cardiovascular disease usually includes the manual operation and the emerging robot-assisted minimally invasive surgery, its purpose is to operate the guidewire and the catheter and place them into blood vessel branches and targets for diagnosis and therapy. In manual operation, it is impossible to completely protect doctors from X-ray radiation, although they can wear protective clothing. Besides, the physiological tremor, and the long-time operation, easy to fatigue the doctors and bring the dangers of the operation. Compared with the manual operation, the robot-assisted minimally invasive surgery has the characteristics of high accuracy and good stability, which can reduce the burden on the doctors, and avoid the damage of X-ray radiation to their own health.

7.1 Objectives

The objective of this thesis is to address three challenges of the current research. (1) Some of robot-assisted systems have realized the function of

collaborative operating between the guidewire and the catheter, improve the navigation ability of the robot-assisted system, but lack the haptic force feedback. And some of robot-assisted systems have realized the function of haptic force feedback, guarantee the safety of the system, but lack the collaborative operating between the guidewire and the catheter. (2) Total force on the guide guidewire and the catheter during the operation needs to be analyzed and determined. Among them, the disturbance force needs to be eliminated, the disturbance force is easy to affect the accuracy of the haptic force feedback of the robot-assisted system, increase the difficulty of the operation. (3) The active enhancing safety method should be studied and integrated into the robot-assisted system, compared with the passive method, it can actively reduce the dangerous behaviors in time during the operation. But lack of the active enhancing safety method may cause the puncture of the blood vessels due to the fatigue of the doctors.

Based on the above challenges, the purpose of this thesis is to solve the scientific problem of how to guarantee and enhance the safety performance of the novel tactile sensing robot-assist system during the operation. And the approaches of this thesis are listed below,

- Develop a tactile sensing robot-assisted system with the function of haptic force feedback to guarantee the safety of the system.
- 2) Analyze the total force and eliminate the disturbance force between the catheter and the blood vessel.
- Propose active enhancing safety methods to avoid the danger caused by the doctor's misoperation and the medical accident.

7.2 Contributions

The contributions of this thesis are listed below,

A novel tactile sensing robot-assisted system for VIS was developed to assist doctors to complete the operation. The developed slave manipulator can operate the guidewire and the catheter, it can navigate the target point accurately, just like a doctor's hand. Besides, a master manipulator based on MR fluids was used to realize the haptic force feedback by generating the haptic force acting on doctors' hand, which can guarantee the safety of the robot-assisted system.

The forces on the guidewire and the catheter during the operation was analyzed, the disturbance force was eliminated, the contact force was used as the reference force to realize the haptic force feedback, the accuracy of the haptic force feedback was improved, and a force sensor based on the pressure sensitive rubber was used to confirm the collision force between the tip of the catheter and the blood vessel.

A preliminary method was proposed to assist the deflection of the tip of the catheter to pass through the curved blood vessels with a relatively small collision force, and an active enhancing safety method was proposed to avoid the danger caused by the doctor's misoperation and the medical accidents during the operation.

A series of experiments in "Vitro" were carried out to verify the tactile sensing robot-assisted system, including (1) Tracking performance of the system, (2) Collaborative operation evaluation, (3) Determination of the force between the catheter and the catheter sheath, (4) Determination of the force between the guidewire and the catheter, (5) Safety evaluation of the robot-assisted system in two tasks, (6) Performance evaluation of the method to reduce the collision force occurs at the tip of the catheter, and (7) Performance evaluation of active enhancing safety methods.

Experimental results indicated that the developed slave manipulator has good tracking performance, the maximum error of the linear motion was less than 2 mm, the maximum error of the rotation motion was less than 2 degrees. Under the guidance of the collaborative operation and the haptic force feedback, the safety of the operation with haptic force feedback was significantly higher than that of without haptic force feedback. The safety performance increased by 4.32% on average after 5 participants performed the experiment. The accuracy of the haptic force feedback can be enhanced by using the proposed analysis method, the collision force can be detected by using the self-developed force sensor, which was helpful for doctors to make the accurate judgment and improve the safety of the robot-assisted system. The proposed active enhancing safety methods can reduce the risk in time. The collision force at the tip of the catheter was reduced by 0.104 N and the average and the maximum total force between the catheter and the blood vessels was reduced by 0.1 N and 0.054 N, respectively, under the condition of the active enhancing safety method. The strong sense of the tactile presence of the doctor was generated by the master manipulator when the total force from the slave side was reaches the level B listed in Table 5-1 (The classification of the force levels during the operation).

7.3 New Points

Corresponding to the three research topics mentioned in the abstract of this thesis, this thesis carries out in-depth research on the tactile sensing robot-assisted system for VIS. And three new points of this thesis can be summarized as follow,

- A novel tactile sensing robot-assisted system with the haptic force feedback was developed, and it can realize the accurate positioning of the guidewire and the catheter in the blood vessel.
- 2) The total force and the disturbance force between the catheter and the blood vessels has been analyzed and eliminated, and the safety has been improved.
- The active enhancing safety method has been proposed to avoid the danger of the operation caused by the doctor's misoperation and the medical accident.

7.4 Future Works

In this thesis, a novel tactile sensing robot-assisted system for vascular interventional surgery has been developed and verified through a series of experiments in "Vitro". However, there are differences between the vitro environment and the vivo environment. So, in the future, if possible, the proposed tactile sensing robot-assisted system for vascular interventional surgery will be verified through the experiments in "Vivo".

Publication List

International Journal Papers

- <u>X. Jin</u>, S. Guo, J. Guo, P. Shi, et al, "Total Force Analysis and Safety Enhancing for Operating Both Guidewire and Catheter in Endovascular Surgery," *IEEE Sensors J.*, vol.21, no.20, pp.22499-22509, 2021.
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Biographic Sketch



Xiaoliang Jin was born in Liaoning, China, in 1993. He received the B.S. degree in Electronic and Information Engineering from University of Science and Technology Liaoning (USTL), Liaoning, China, in 2016 and the M.S. degree in Control Engineering from Tianjin University of Technology (TJUT), Tianjin, China, in 2019. He is currently pursuing the Ph.D. degree in Intelligent Mechanical Systems Engineering at Kagawa University (KU), Takamatsu, Japan.

He has published seven refereed journal and conference papers in recent years. His current research interests are on haptics, robot-assisted system for VIS, and medical robots.