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学 位 論 文 題 目	Study on a Guidewire and Catheter Collaborative Operating System
論 文 審 査 委 員	（主査）郭　書祥 （副査）平田　英之 （副査）鈴木　桂輔

論文内容の要旨

1.Research Background

In recent years, some diseases are caused by people's unhealthy lifestyle. Among them, vascular disease is a typical disease that seriously endanger human health, usually affecting the heart and the blood vessels, and leading to heart attacks and strokes. With the development of the medical technology, VIS (Vascular Interventional Surgery) has saved more and more patients with cardiovascular disease. There are two ways to treat the cardiovascular disease, including the traditional manual operation and the emerging robot-assisted minimally invasive surgery. In the process of the manual operation, the doctor needs to operate guidewires and catheters in the operating room for long time to complete the treatment. However, the long operation time is easy to fatigue the doctors and increase the risk of the operation. In addition, the health of the doctors can hardly be guaranteed because of the X-ray radiation. In contrast, the robot-assisted minimally invasive surgery is particularly advantageous, it can improve the comfort, precision, and stability, eliminate the physiological tremor, and reduce the doctor's exposure to X-ray radiation.

2.Challenges

1)Most of robot-assisted systems lack force feedback, and the safety of system is low.

2)The existence of disturbance force easily affects the accuracy of the force feedback.

3)Lack of the active enhancing safety method may cause the puncture of blood vessels due to the fatigue of the doctor and the sudden accidents.

3.Research Purposes

1)To develop a novel robot-assisted system with haptic force feedback for VIS.

2)To eliminate the disturbance force during the operation and improve the accuracy of the haptic force feedback.

3)To prevent the puncture of the blood vessels due to the fatigue of the surgeons and the sudden accidents.

4.Research Approaches

1)Develop a robot-assisted system with haptic force feedback to enhance the safety.

2)Analyze the total force and eliminate the disturbance force between the catheter and the blood vessel.

3)Propose the active enhancing safety method to avoid the danger of the misoperation.

5.Research Topics

I.Development and evaluation of a novel robot-assisted system with force feedback for endovascular surgery.

II.Total force analysis and safety enhancing for operating both guidewire and catheter in endovascular surgery.

III.Study on the active enhancing safety method of the robot-assisted system in VIS.

6.Conclusions and Future Work

1)A novel tactile sensing robot-assisted system for VIS was developed. This system can accurately deliver the guidewire and the catheter to the target point and detect the force information between the surgical instruments and the blood vessel in real time. In addition, a master manipulator based on the MR fluid was used to generate the haptic force acting on the doctor's hand to achieve the haptic force feedback. The 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 collaborative operation and the haptic force feedback, the safety performance of the operation with haptic force feedback was obviously higher than that of without haptic force feedback. After five participants completed the experiment, the safety increased by 4.32% on average.

2)The total force on the guidewire and the catheter during the operation was analyzed in detail by modeling. In addition, a force sensor based on pressure sensitive rubbers was designed to confirm the collision between the tip of the catheter and the blood vessel. The accuracy of the force feedback can be enhanced by using the proposed analysis method, and the collision force can be detected by the self-developed force sensor, which is helpful for surgeons to make accurate judgments and improve the safety performance of the system.

3)The active enhancing safety method was proposed for the developed robot-assisted system, mainly including the reduction of the collision force at the catheter tip, the

enhanced haptic force feedback that occurs at the master side, and the identification and reduction of dangerous behaviors that occurs at the slave side. Compared with the passive enhancing safety methods, it can reduce the risk in time. The collision force at the catheter tip was reduced by 0.104 N when there was a misoperation in the procedure under the active enhancing safety method. And the strong sense of the tactile presence for the doctor was generated by the developed master manipulator when the total force from the slave side was greater than 1.0 N.

4)In the future, the tactile sensing robot-assisted system will be verified through the experiments in “Vivo”.

審査結果の要旨

The defense committee examined the Ph.D. thesis “Study on a Guidewire and Catheter Collaborative Operating System”, submitted by the above applicant for a doctoral degree. The aim of this thesis is to develop a novel tactile sensing robot-assisted system for vascular interventional surgery and solve the challenge of how to guarantee the safety of the robot-assist system.

The thesis consists of 7 chapters, as follows.

Chapter 1: Introduction

With the development of medical technologies, vascular interventional surgery has saved more and more patients. And there are two ways to treat cardiovascular disease, one is the manual operation, and other is the emerging robot-assisted minimally invasive surgery. The challenges of the current research are as follow: 1) Most of robot-assisted systems lack haptic force feedback, and the safety cannot be guaranteed. 2) The existence of the disturbance force easily affects the accuracy of haptic force feedback. 3) Lack of the active enhancing safety methods may cause the puncture of blood vessels due to the doctor’s misoperation. The purpose of this thesis is to solve the challenge of how to guarantee the safety of the robot-assist system. The approaches of this thesis are developing a novel robot-assisted system with the haptic force feedback, analyzing the total force, 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.

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

According to the operating requirements of the doctors, a novel tactile sensing robot-assisted system for vascular interventional surgery was developed. The slave manipulator can accurately deliver the catheter and the guidewire to the target position

and detect the total force between the surgical tools and the blood vessel environment in real time. The master manipulator based on MR fluids was used to generate the haptic force acting on doctors' hand to achieve the haptic force feedback. Besides, the principles of the haptic force feedback, the grasper device, and the force detection mechanism were introduced, and the robot kinematics was analyzed.

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

A novel tactile sensing robot-assisted system was evaluated by experiments in "Vitro". Experimental results indicated that the system has good performance in tracking performance, 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 the haptic force feedback, the guide wire and the catheter were delivered to the target position 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 increased by 4.32% on average.

Chapter 4: Analysis of Forces on the Guidewire and the Catheter

To improve the accuracy of the haptic force feedback and reduce the difficulty of doctors' judgment the total force on the guidewire and the catheter was analyzed in detail by modeling, the disturbance force was eliminated, and a force sensor based on pressure sensitive rubbers was designed to confirm the collision force between the tip of the catheter and the blood vessel. The safety performance of the tactile sensing 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

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 robot-assisted system, which can actively avoid the dangerous behaviors in time.

Chapter 6: Safety Performance Evaluation of the Robot-Assisted System

A series of experiments in "Vitro" were carried out to verify the safety of the robot-assisted system was improved by the methods proposed in Chapters 4 and 5. Experimental results indicated that the accuracy of the haptic force feedback can be enhanced by eliminating the disturbance force during the procedure, the collision force

at the tip of the catheter can be detected by using the developed force sensor, which is helpful for the doctor to make the accurate judgment during the operation. The active enhancing safety method can reduce the risk in time. The collision force at the tip of the catheter was reduced by 0.104N and the average and the maximum total force between the catheter and the blood vessels was reduced by 0.1N and 0.054N, respectively, under the active enhancing safety method.

Chapter 7: Concluding Remarks

This thesis carries out in-depth research on a novel tactile sensing robot-assisted system for vascular interventional surgery. And three new points of this thesis can be summarized as follow, 1) 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 vessel environment has been analyzed and eliminated, and the safety has been improved. And 3) The active enhancing safety method has been proposed to avoid the dangers of the operation caused by the doctor's misoperation and the medical accident. If possible, the developed tactile sensing robot-assisted system for vascular interventional surgery will be verified through the experiments in “Vivo” in the future.

The main papers published during the doctoral period are as follows, including two journal papers as the first author, one journal paper as the co-first author.

1.Xiaoliang Jin, Shuxiang Guo, Jian Guo, Peng Shi, Takashi Tamiya, et al, “Development of a Tactile Sensing Robot-Assisted System for Vascular Interventional Surgery”, IEEE Sensors Journal, Vol.21, No.10, pp.12284-12294, 2021. (IF:3.301)

2.Xiaoliang Jin, Shuxiang Guo, Jian Guo, Peng Shi, Takashi Tamiya, Masahiko Kawanishi, and Hideyuki Hirata, “Total Force Analysis and Safety Enhancing for Operating Both Guidewire and Catheter in Endovascular Surgery”, IEEE Sensors Journal, Vol.21, No.20, pp.22499-22509 2021. (IF:3.301)

3.Jian Guo, Xiaoliang Jin, Shuxiang Guo, Qiang Fu, “A Vascular Interventional Surgical Robotic System Based on Force-Visual Feedback”, IEEE Sensors Journal, Vol.19, No.23, pp.11081-11089, 2019. (IF:3.301)

最終試験結果の要旨

令和 4 年 2 月 3 日に公聴会ならびに最終試験を実施した。公聴会では、申請者が学位論文の内容に関する発表を行った（約 40 分間)。その後、口述試験として学位論文の内容にかかわる審査委員の質疑に的確に答えることを求め、更に学位論文に関連した分野の専門知識を確認することで最終試験とした（約 40 分間)。
最終試験における学位論文に対する質疑応答の概要は以下のとおりであり、審査申請者はすべて的確に回答した。

●提案したロボティックカテーテル操作システムの新規性は何か。
（回答）従来のマスターシステムでは、ハンドルやジョイスティックを用いていたが、提案した新しい方法は、実際の手術用カテーテルを用いて測定するため、機械に慣れてない医師でもすぐに扱うことができる新規性がある。新型触覚特性を持つマスターオペレーティング･システムを開発、先端とサイドの両方の力情報をモニターリング可能にした。カテーテルインターベンション力モデルを作成、触覚フィードバックと視覚的な情報フィードバックの効果を検証、開発されたシステムが操作性と安全性を高めることを実証した。
●カテーテル操作支援システムの安全性をどのように保証されるか。
（回答）現段階では、先端とサイドの両方の力情報を力センサーで測定し、それをもとに、安全操作の最大値を超えないように、フィードバックを制御することにより、安全性の確保を目指す。
●カテーテルインターベンション力モデルにおいて、衝突力はどのように対処されるか。
（回答）カテーテルインターベンション力モデルにおいて、疑似衝突（Pseudo Collision）力と真実衝突(Real Collision) 力を同時にハプティックフィードバックに用いている。その情報を医者側に提示し、危険域などを判別し、事故を防ぐ操作方法を実現した。
●開発したカテーテル操作支援システムについて、ガイドワイヤとカテーテルの協調操作制御は重要であるが、今後どう展開されるか
（回答）ガイドワイヤとカテーテルの協調操作は熟練医者の操作スキルである。それを抽出して、データベースを構築し、熟練医者の操作スキルを含めたデータベースに基づいて初心者を訓練する。さらに、患者の血管 CT と MRI データを開発した VR システムに導入して、患者の血管モデルを再構築する。実際の手術をする前に医者が訓練できるため、手術の安全性を高めて医療事故を減少できる。

本審査委員会における審査は、学位論文の内容、研究方法論を確認しようとするものである。
本審査委員会は、提出された博士学位請求論文が博士（工学）の学位に値するものであり、かつ審査申請者は専門領域に関する十分な学識と研究能力を有するものと判断した。
以上より、本最終試験の評価を合格とする。