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Evaluation of a Clamping Mechanism for Vascular Interventional Surgery Robotic System

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***Abstract* - At present, the vascular interventional surgery has attracted more attention. Because it has the advantages of smaller trauma, lower pain, and quicker recovery after the operation. As for the design of the clamping mechanism, fast and lossless clamping of the catheter has always been a hot and difficult point in the current research. In this paper, a novel slave manipulator is introduced (contains coordinate system). It simulates the twisting of human fingers for the catheter during the actual vascular interventional surgery. Moreover, we evaluated its clamping form. Simulation results show that: From the angle of total deformation, strain, and stress, it is analyzed that there is no damage to the catheter; From the point of view of the clamping force analysis, it is obtained that the clamping force is enough to guarantee the forward and backward of the catheter; From the perspective of conflict protection, the size of the clamping force can be changed by adjusting the clamping depth. In this way, the tip of the catheter can be avoided puncturing the vessel wall, thus increasing the actual clinical safety performance.**

Index Terms – Vascular interventional surgery , Clamping mechanism , Slave manipulator , Catheter

I. INTRODUCTION

The cardiovascular system oxygenates the entire human body through the complex fluid network. This provides opportunities for doctors and scientists to implement and study minimally invasive surgery. Taking advantage of this opportunity, the use of catheterization techniques [1]-[3] routinely completed the diagnosis and treatment of obvious abnormalities and diseases, such as strokes, vascular tumors, arteriovenous malformations, vascular sclerosis, and aneurysms. Vascular interventional surgery is one of the typical representatives of these techniques. Because it has many advantages in this field, such as smaller trauma, lower pain, and quicker recovery after the operation.

In the traditional interventional surgery, in order to avoid long-term X-ray radiation, doctors need to wear a lead suit weighing 20 kilograms. However, the doctor's hands, face, and eyes are still exposed. Doctors wearing a heavy suit for a long time can cause neck and back pain and injury [4]. Doctors who are exposed to X-ray radiation for a long time to manipulate catheters and guidewires are prone to eye disease and cancerous tumors. [5]-[7]. Therefore, it is necessary to study a novel vascular interventional surgery robotic system to overcome these shortcomings.

In recent years, professor Guo has led three research teams. In Kagawa University, the research team realized the system's tactile force feedback based on the characteristics of the MR (magnetorheological) fluid in the master manipulator [8]-[10]. This reduces the cognitive workload and improves the transparency of the doctor's remote operation. Moreover, a novel method based on the characteristics of the MR fluid was proposed by Lingling Zheng to reduce the tremor when the surgeon operating the handle during vascular interventional surgery [11]. In the slave manipulator: Linshuai Zhang et al [12]-[14] developed a slave robot system with a collision protection mechanism based on electromagnetic braking to protect the vascular tissue; Xiaoliang Jin et al [15] developed a slave manipulator based on remote cooperation of the catheter and the guidewire, as well as research on the sensor installed on the tip of a catheter to detect the contact force. In Beijing Institute of Technology, Xianqiang Bao et al [16]-[22] developed a remote-controlled robotic system with coordinated operation of the guidewire and the catheter to improve the accuracy and stability of the operation, thereby reducing the risk of doctors being exposed to X-ray radiation. It completed the evaluation experiment in the human body in 2018. Results show that it has a good performance that can be used in clinical surgeries. In Tianjin University of Technology, Jian Guo et al [23] developed a monitoring system that combines Force-Visual feedback to improve the safety of the robotic system. When the surgeon operates the master manipulator, the visual feedback interface will show the force and movement information of the catheter, and feedback the current operating status (safe or dangerous).

Moreover, other research teams made some achievements. In Imperial College London, Guangzhou Yang, et, al [24] was to design and evaluate a novel vascular interventional robotic platform includes MR-safe slave robot, master device, navigation system, and control work station. It is should be noted that the medical images can show visual and haptic feedback for operator guidance. The robotic system is well received in terms of technical design and clinical usability, but the robotic platform does not allow the simultaneous operation of the catheter and the guidewire. In Shanghai Jiao Tong University, a vascular intervention robot with four manipulators (with 12 DOFs in total) was designed by K. Wang, et al [25]. It has better force feedback accuracy and lower time delay [26]. The design of its four manipulators can replicate the hands of doctors and their assistants. Intervention devices and stents can be manipulated by this robot. Three stents were successfully deployed in pigs, which proved that the robot has high flexibility, precision, and efficiency, and can meet the requirements of endovascular interventional surgery. In University of Hong Kong, K.H. Lee et al [27] proposed a MR Safe robotic manipulator to realize robot-assisted intracardiac catheterization in magnetic resonance imaging (MRI) environment. It only concludes non-magnetic, non-metallic, non-conductive materials, which meets the MR Safe standard (ASTM F2503-13).

Some commercial companies developed some vascular interventional surgery robot system. Such as Amigo TM (Catheter Robotics, Inc., Mount Olive, NJ, USA) remote catheter system (RCS) [28], Sensei X robotic catheter system (Hansen Medical, Inc., Mountain View, CA, USA) [29], [30] and CorPath GRX Robotic System (Corindus, A Siemens Healthineers Company, Waltham, MA, USA) [31]. These vascular interventional surgery robot systems have been used in clinical surgeries.

However, at present, in the clamping mechanism design of clamping the catheter/guidewire, it is difficult to assemble and disassemble the catheter and the guidewire quickly. Its channels are closed. For example, Beijing Institute of Technology [16], [17], [32], [33] uses the clamping method of catheter/guidewire with gear extrusion, Kagawa university [13] [15], Tianjin University of Technology [34], [35], Yanshan University [36], etc. In the process of clamping the catheter or the guidewire, the device needs to be threaded through a closed channel. This greatly increases the time it takes the doctor to actually install and remove the catheter or the guidewire, adding to the additional burden on the surgeon. Therefore, it is necessary to study a kind of fast clamping mechanism, which can not only realize the rapid clamping of the catheter to avoid perforation, but also provide sufficient clamping force. In this paper, a novel slave manipulator is proposed. It simulates the twisting of human fingers for the catheter during the actual vascular interventional surgery. Moreover, we evaluated its clamping form.

The structure of the paper is as follows. The robotic system is introduced in Sec. II. The Clamping Mechanism of novel slave manipulator is shown in Sec. III. Moreover, Sec. IV presents the evaluation of the clamping form using the finite element analysis software. Finally, Sec. V shows the conclusions and future work.

II. Robotic System

A. *Introduction of the Robotic System*

The robotic system has two main parts: the master side and the slave side. The schematic diagram of the master-slave robotic system is shown in Fig.1. The surgeon operates the remote slave manipulator by operating the master manipulator with tactile force feedback at the master side. The master manipulator will record the doctor's movement information and send the information to the slave side through the master controller, when the surgeon operates the master manipulator. The slave manipulator replicates the effective behavior of the surgeon, operating the catheter or the guidewire to the desired location in the patient's body. The slave controller at the slave side will transfer the force of the catheter and the guidewire to the master side during operation. The master manipulator will generate the haptic force to the surgeon's hand at the same time. Under the guidance of the IP camera, the surgeon can operate the master manipulator smoothly to control the movement of the catheter/guidewire.

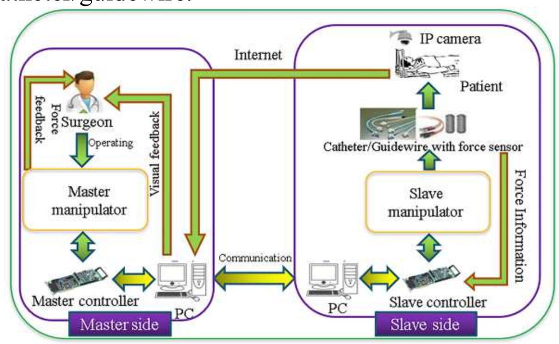


Fig. 1 Schematic diagram of the master-slave robotic system.

B. *Master Manipulator*

Fig.2 shows the master manipulator was designed and fabricated by our research team [8]-[10]. It mainly includes a calibration unit, a catheter control unit, and so on. The surgeon can operate it to remotely control the movement of the catheter/guidewire with haptic feedback.

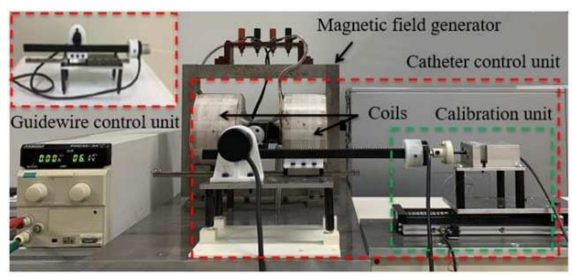


Fig. 2 The master manipulator [15].

C. *Slave Manipulator*

Fig.3 shows the novel slave manipulator was designed by us. Its design principle comes from Fig.4. It simulates the twisting of human fingers for the catheter during the actual vascular interventional surgery. It is noted that robotic accuracy should be taken into account, so we introduce the coordinate system into the slave manipulator. The slave manipulator's main structure uses two mobile platforms. The bottom mobile platform simulates the human wrist and realizes the forward and backward of the catheter. The top platform's screw adopts positive and negative threads, which can realize unified clamping and releasing of the catheter, which is beneficial to realize the coaxial positioning of the catheter. When installing the catheter, the catheter should be located in the center of the entire coordinate system. There are gear and rack structures on both sides of the clamping mechanism, and the rotation of the catheter can be realized by rotating the gears of the respective stepper motors.

As a slave manipulator, it mainly consists of the insertion/retraction driving mechanism, and clamping mechanism. So the clamping mechanism is very important for the design of the slave manipulator. Firstly, it must not damage the surface of the catheter/guidewire. Secondly, it can clamp the catheter/guidewire effectively. Thirdly, in the clinical process, it is also necessary to install and exchange easily. Based on these, we propose a novel slave manipulator.

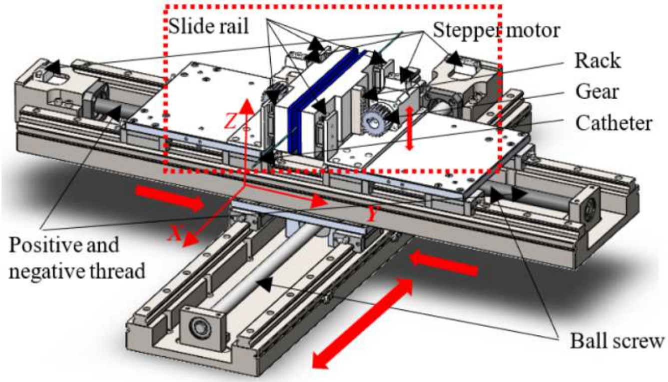


Fig. 3 The proposed novel slave manipulator.

III. The Clamping Mechanism of Novel Slave Manipulator

A. *The Principle Analysis of the Clamping Mechanism*

Inspired by the Fig.4, the clamping of the catheter is in the form of face-to-face clamping. The material in contact with the catheter is silica gel. Silicone gel simulates the flesh of fingers. Medical-grade silica gel is colorless, non-toxic, and has a certain degree of flexibility. The clamping and releasing principles of the catheter are shown in Fig.5 and Fig.6, respectively. The rotating principle of the catheter is shown in Fig.7.

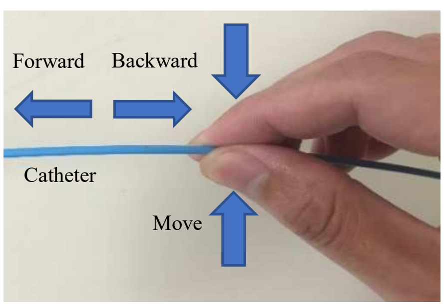


Fig. 4 The surgeon moves the thumb and the forefinger to clamp the catheter

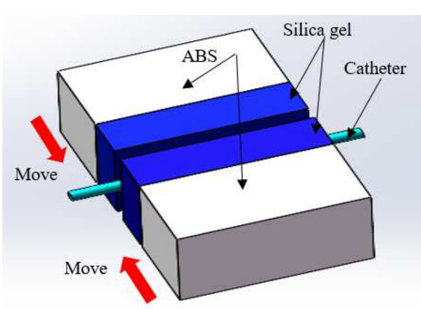


Fig. 5 The clamping principle of the catheter.

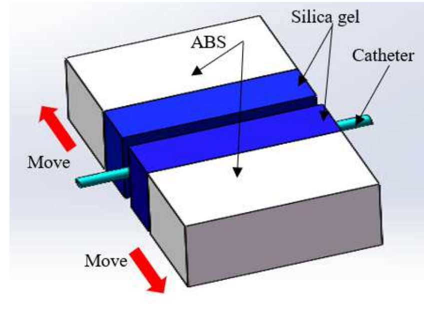


Fig. 6 The releasing principle of the catheter.

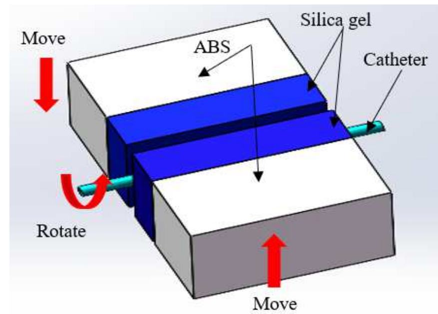


Fig. 7 The rotating principle of the catheter.

B. *The Model of Clamping Mechanism*

The red flame in Fig.3 shows the clamping mechanism.

IV. Simulation Analysis of The Clamping Mechanism

To prove the safety of the clamping mechanism, the ANSYS finite element analysis software is used to conduct the simulation analysis of the clamping process of clamping the catheter. Firstly, the 3D software is used to draw the clamping mechanism, and it is imported into ANSYS software. The size of the catheter is based on the commercial 5F catheter. Secondly, in ANSYS finite element software, the catheter's material is set to nylon. Other material settings are shown in Fig.7. Thirdly, setting up the movement conditions. According to Newton's third law of motion, to simplify the simulation, we set the left part of the clamping mechanism is fixed. So we use the clamping model to replace the clamping mechanism, as shown in Fig.8. The right part of the clamping model moves to the left of the outer diameter length of the catheter. Under the above conditions, the results are shown in the figures below.

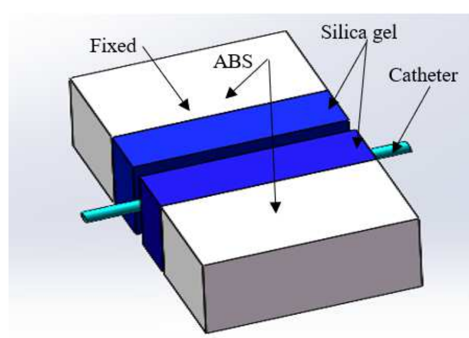
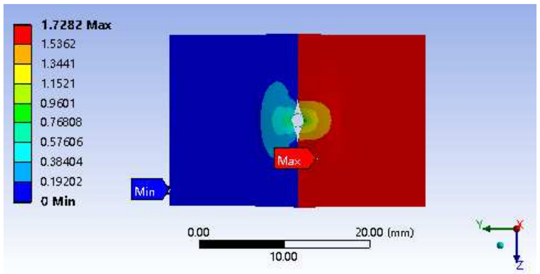
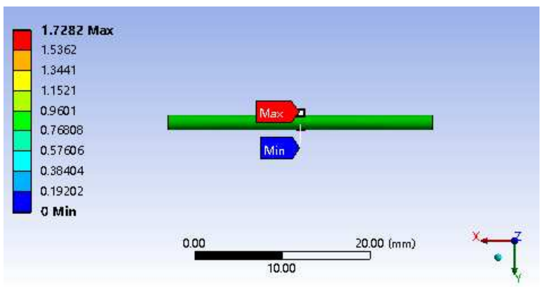


Fig. 8 The simulation model.

As shown in Fig.9(a), we can see that the silica gel in contact with the catheter has undergone obvious deformation. However, the deformation of the catheter is small, as shown in Fig.9(b). As shown in Fig.10, the deformation size parameter of the clamped catheter is within a acceptable range (less than 10%).



(a) The total deformation of the clamping model.



(b) The total deformation of the catheter.

Fig.9 The total deformation of the clamping model and the catheter.

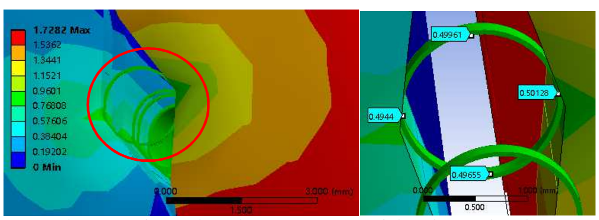
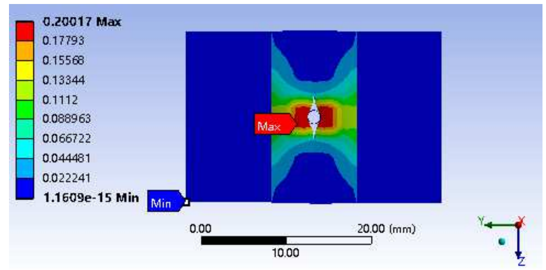


Fig.10 Deformation size parameters of the clamped catheter.

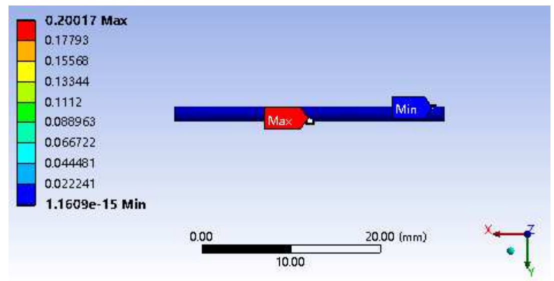
Therefore, it can be seen from Fig.9 that the silica gel material is very good at protecting the catheter from deformation when it is held by the clamping model. In the process of actual vascular interventional surgery, the possibility of thrombosis can be avoided and the risk of clinical operation can be decreased.

As shown in Fig.11(a), the silica gel in contact with the catheter has the biggest strain. This has much to do with the characteristics of silica gel materials. However, the strain value of the catheter is so small that it is also negligible, as shown in Fig.11(b). Therefore, from the point of strain, the clamping model and the use of silica gel material are effective. It does not cause damage to the catheter's surface.

As shown in Fig.12(a), there is almost no stress on the clamping model. As shown in Fig.12(b), there is some stress on the catheter where it is in contact with the silicone gel. From the point of view of friction, this situation helps increase the friction between the silicone gel and the catheter. Thus, the clamping function of the clamping model is improved. The clamping process of the ultimate distance clamping model is analyzed above, and it is proved that the clamping process is not damaged to the catheter.

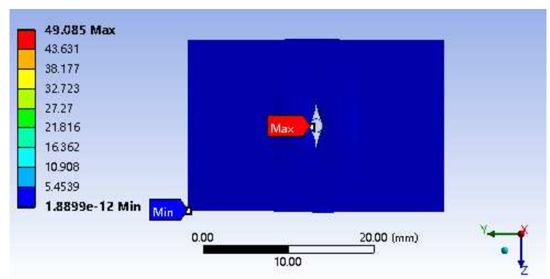


(a) The strain of the clamping model.

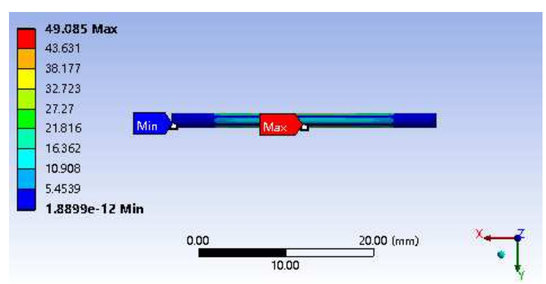


(b) The strain of the catheter.

Fig. 11 The strain of the clamping model and the catheter.



(a) The stress of the clamping model.



(b) The stress of the catheter.

Fig. 12 The stress of the clamping model and the catheter.

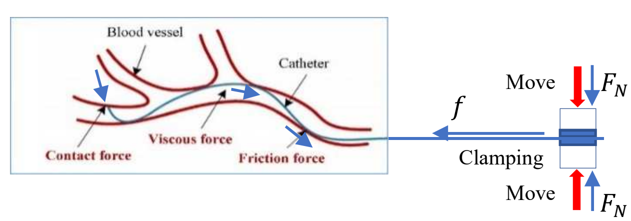
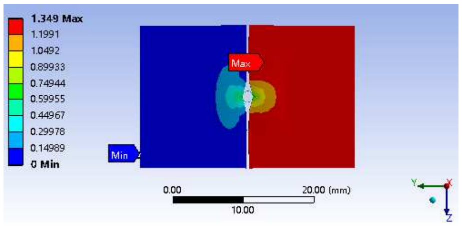
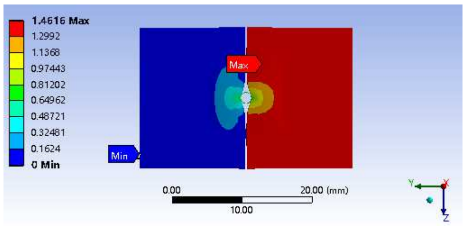


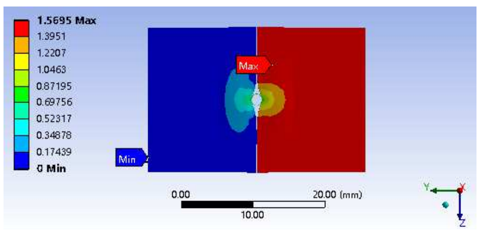
Fig. 13 Diagram of the force of a catheter in blood vessel.



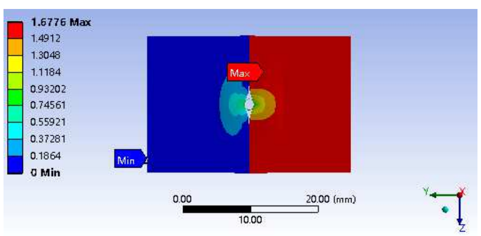
(a) The clamping force of 1.1N.



(b) The clamping force of 1.2N.



(c) The clamping force of 1.3N.



(d) The clamping force of 1.4N.

Fig. 14 The total deformation of the clamping model under different clamping conditions.

As shown in Fig.13, when the catheter enters the patient's blood vessel, there are three forces between the catheter and the vessel wall: contact force, viscous force, friction force. Among these three forces, the contact force is the largest, and it is most likely to affect the safety of patients. To determine whether the size of the specific clamping force is sufficient to ensure the clamping of the catheter forward and backward in the process of clamping the catheter by comparing the Fig.4 and the Fig.13. Therefore, it is necessary to analyze and determine the actual size of the clamping force.

$$f = \mu * F_N. \quad (1)$$

Where μ is the friction coefficient, f is the friction force, F_N is the clamping force.

From the (1), the friction force between the catheter and the silica gel can be changed by changing the amount of clamping force. Using ANSYS finite element analysis, we can know the friction force between the catheter and silica gel under different clamping conditions, as shown in the figures below.

As shown in Fig.14, when the clamping deformation changes, its F_N also changes along with it. When μ =0.51 and F_N is substituted into (1), it can be concluded that the friction force between the catheter and the silica gel is 0.561 N, 0.612 N, 0.663 N, and 0.714 N, respectively. Therefore, from the practical clinical point of view, it is sufficient to meet the requirements of clamping the catheter forward and backward [18].According to the clamping force analysis, when the contact force between the catheter and the vessel wall is greater than the friction force, the catheter will slip between the silica gel material. From the perspective of conflict protection [12], the size of the clamping force can be changed by adjusting the clamping depth. In this way, the tip of the catheter can be avoided puncturing the vessel wall, thus increasing the actual clinical safety performance.

V. Conclusions and Future Work

At present, the procedure of vascular interventional surgery is still very complicated. The safety of the operation has always been important. In this paper, a novel slave manipulator is introduced (contains coordinate system). It simulates the twisting of human fingers for the catheter during the actual vascular interventional surgery. Moreover, we evaluated its clamping form. Simulation results show that: From the angle of total deformation, strain, and stress, it is analyzed that there is no damage to the catheter. From the point of view of the clamping force analysis, it is obtained that the clamping force is enough to guarantee the forward and backward of the catheter. From the perspective of conflict protection, the size of the clamping force can be changed by adjusting the clamping depth. In this way, the tip of the catheter can be avoided puncturing the vessel wall, thus increasing the actual clinical safety performance.

In future work, we will evaluate its performance about rotating the catheter. Moreover, we will add the force detection mechanism and integrate it into the novel slave manipulator.

Acknowledgment

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