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Design of a non-destructive gripper based on flexible materials

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***Abstract* - Vascular interventional surgery is an effective method for the treatment of cardiovascular and cerebrovascular diseases, and compared with traditional surgery, vascular interventional surgery is a minimally invasive surgery, causing less damage to patients and faster postoperative recovery. Catheters and guide wires are important medical devices for interventional procedures, because they need to travel a long distance in the body, and the operation time may last for several hours. During the operation, changing the equipment will reduce the efficiency of the operation and increase the insecurity of the operation. Therefore, the non-destructive clamping of the catheter guide wire is very important. We proposed a soft clamping method, and redesigned the clamping module of the end effector for this clamping method, and carried out the force analysis and structural force analysis of the module. The results show that the module has good clamping effect and protection effect on the catheter and guide wire, and the structure is relatively stable.**

Index Terms - Clamping method, non-destructive clamping, surgical safety, vascular intervention.

I. INTRODUCTION

The "China Cardiovascular Disease Report 2018" compiled by the National Cardiovascular Disease Center of China summarizes that: The current number of cardiovascular disease patients in China is about 290 million, and the death rate of cardiovascular disease is still the first, accounting for more than 40% of the residents' disease deaths [1]. The frequent occurrence and high hazard of cardiovascular disease have brought great distress to residents and society, and it has become a major public health problem that needs to be solved. As a type of minimally invasive surgery, vascular interventional surgery (VIS) has many advantages that traditional interventional surgery does not have. Patients suffer less surgical trauma, recover faster after surgery, reduce possible postoperative complications, and greatly reduce the amount of radiation the doctor is exposed to [2]–[5]. Because of these advantages, a large number of interventional surgical devices have emerged all over the world [6]–[8].

A. *VIS robot system*

The VIS robot system mainly includes a master controller and a slave manipulator. The master controller detects the surgeon's operation information, transmits the operation information to the slave side, and the slave manipulator reproduces the doctor's operation, the principle is shown in Fig. 1 [9]. In some cases, a vascular access procedure may take several hours, and prolonged clamping may damage the catheter and guidewire. Because the replacement of the equipment requires aseptic operation and the disassembly is complicated, if the equipment is damaged and needs to be replaced, the operation time will be prolonged, the operation efficiency will be reduced, and the safety of the operation will be affected [10]. Therefore, the non-destructive clamping of medical devices is very important.

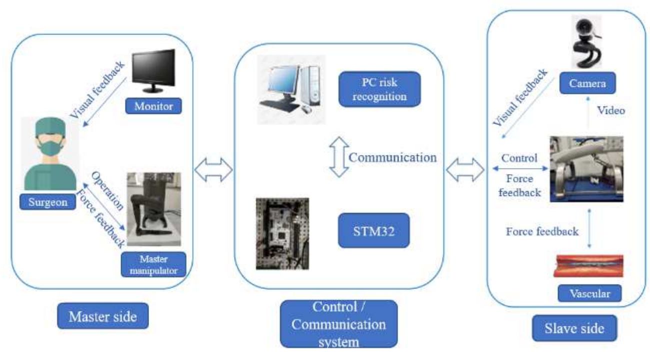


Fig. 1. Working principle of the VI robot system.

B. *Current Research Status*

At present, the common clamping methods mainly include clamping claw and driving wheel. Zhao et al. developed a clamping jaw with an inclined surface that is squeezed to clamp the guidewire catheter when the tightening device is tightened [11]. Jueun Choi et al. proposed a roller module for clamping and driving, this module consists of a motor/gearbox and cartridge frame with four rollers. The catheter and guide wire are pushed by rolling two roller modules, and twisting is performed in a staggered up and down motion [12]. Jin et al. used a spring and a trapezoidal module to design a clamping device, which clamped the catheter by the elastic force of the spring, and released the catheter when the trapezoidal module was pushed inward [13]. However, the above studies mainly discuss and address the efficiency of catheter and guide wire advancement and rotation, and the protection of catheter and guide wire is rarely discussed.

In this paper, a new way of clamping catheters and guide wires is proposed, and a soft-body clamp is designed. The gripper based on soft material design has little damage to the catheter guide wire, and the current control of the motor can minimize equipment damage. In addition, we conducted a simulation analysis of this clamping method, and the results show that the force on the catheter can be controlled within a safe range, and the catheter and guide wire will not be in danger of damage.

The remainder of this article is organized as follows. Section II presents the system description of our master-slave vascular interventional robot system. In the section III, the simulation analysis of the soft clamping mechanism is carried out. Section IV discusses the safety and security strategies of the soft gripping mechanism. The discussion is analyzed in Section V. Finally, Section VI concludes this article.

II. Platform and Grip Design

This section introduces the master-slave equipment we use, and combines the advantages of soft materials to design a new safe clamping method for catheters and guidewires.

A. *Master-slave control system*

The master-slave control system used in this article was developed by our team [14]. As shown in Fig. 2, the surgeon controls the master manipulator to perform surgical operations. The operation information collected by the manipulator is transmitted to the slave end effector, which reproduces the operation of the surgeon. In order to better collect the operation information of doctors, we adopted a commercial haptic device (Geomagic® Touch™ X, 3D Systems, Inc., USA) as the master controller) [15]. The controller can obtain the speed, displacement, acceleration, and angle of the doctor's operation. And different force feedback strategies can be adopted according to the force feedback information from the slave end. Achieve different types of force feedback effects for surgeons (such as viscous force, elasticity, etc.).

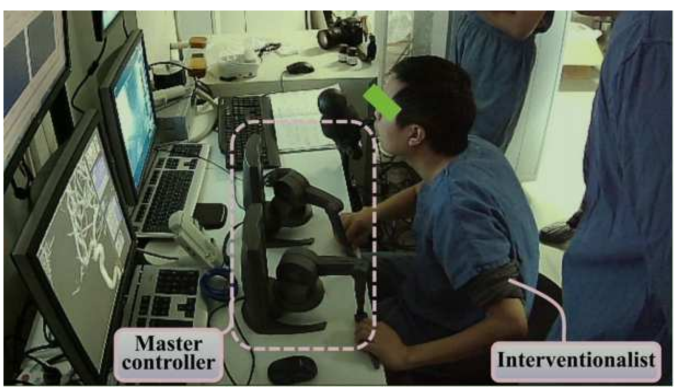


Fig. 2. The surgeon is operating the master controller.

B. *Soft gripper*

Interventional procedures generally involve the delivery of surgical instruments from a puncture site (usually the groin or arm) to the site of the lesion, which travels large distances within the body[16]. Our synergistic device travel is 200mm, so we use a loose and re-advance approach, the principle is shown in Fig. 3 [17]. Inspired by soft robotics, we redesigned gripper and redesigned gripping equipment with soft materials. The

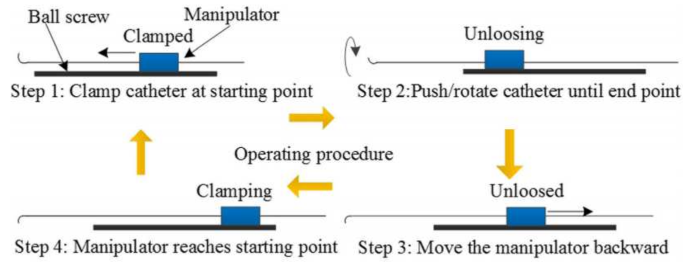


Fig. 3. The surgeon is operating the master controller.

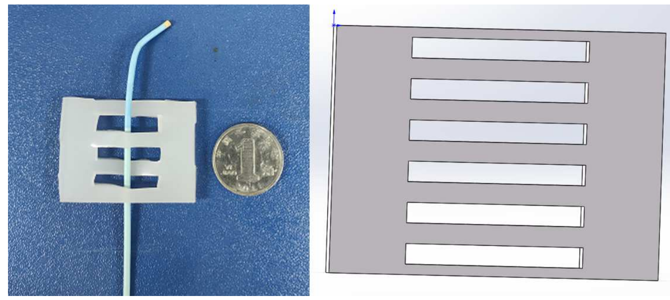


Fig. 4. Soft clamping device.

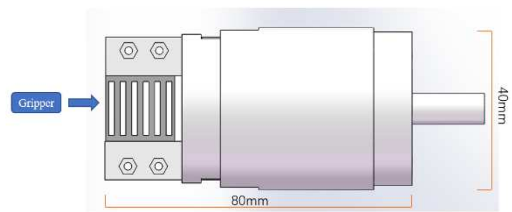


Fig. 5. Clamping module.

simulation map and physical map are shown in Fig. 4.

As the sides are pushed toward the middle, the flexible material expands and the catheter passes through the middle. When the two sides are taut, the flexible material clamps the catheter. We use a silicone material with a hardness of 30. Due to the nature of the flexible material, it is not toxic to humans. And due to the surface friction of the silicone material, the catheter and guide wire can be prevented from sliding during the pushing and rotating process.

In view of this clamping method, we designed a new clamping device to realize the clamping and pushing of the catheter and guidewire, as shown in Fig. 5. The more complex the design of the module, the larger the volume will be, and the accuracy and speed of the movement will be difficult to guarantee. Therefore, we adopted a very simple design method to compress the volume and mass of the module. We convert the rotary motion of the motor into horizontal motion through gears, and then use a wedge-shaped structure to convert the horizontal motion into the motion of clamping and loosening, and the motor controls the clamping state. The movement principle is shown in Fig. 6.

Since the guide wire and the catheter need to pass through the push rod, the thickness of the common guide wire does not

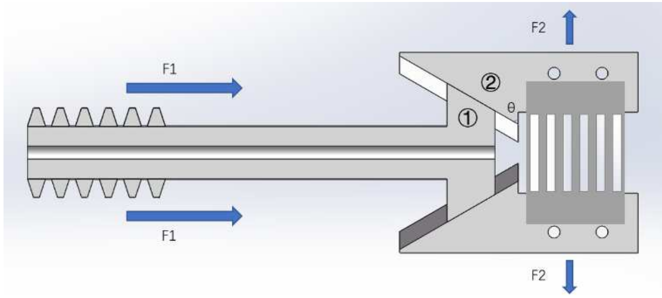


Fig. 6. Clamping transmission principle.

exceed 0.85mm, and the thickness of the catheter does not exceed 1.67mm, so we reserve a 3mm through hole.

C. Force analysis

The component holding the soft material is a passive drive component, and its mass is very light, 4.23 grams on one side. In addition, when we make the entity, the material we choose is transparent photosensitive resin, and the surface is very smooth. If the gravity effect of the component is ignored and the surface friction is ignored, the force result of F_2 is:

$$F_2 = \frac{F_1}{\tan\left(90^\circ - \theta\right)} \quad (1.)$$

where F_1 is the horizontal pushing force given by the motor, and F_2 is the force on the component holding the soft material, that is, the pulling force on the soft material. The angle θ has been marked in Fig. 6, we designed the θ angle to be 60°. The study by Guo et al. showed that a tip force of 0.12N may pierce a blood vessel [18]. Considering the viscous force of blood and the frictional force of blood vessels on the catheter, it may be necessary to have at least 1N pushing force on the catheter to ensure the smooth operation of the operation. What we need is the pushing force of the material on the conduit, that is, the static friction force. The formula for calculating static friction is as follows.

$$F_f = \mu F_N \quad (2.)$$

where F_f is the push force we need, F_N is the pressure of the material on the conduit, and μ is the friction coefficient between clamping device and catheter.

Since the friction coefficient is difficult to measure, we assume that F_2 is 2N, and F_1 can be calculated as 1.15N by formula 1.

D. Push force

In order to measure the thrust of the clamping module in the actual situation, we produced the clamping module by 3D printing technology, and the material used is a transparent resin. The silica gel sheet having a hardness of 30 is used as a clamping material, and the thickness is 2 mm. The upper limit of the push force of the soft material is the maximum static friction that it can provide, which affects the maximum static friction force, including the contact area, material type, and pressure. Because these factors are dynamically changed when we actually use, it is difficult to measure and calculate. Therefore, we measure the most static friction by physical measurement.

We use spring dynamometer (LTZ-3, China Changshu City) to measure the actual maximum static friction, measurement process and method as shown in Fig.7. The catheter maintains clamped, with the spring dynamometer to pull the catheter, record the force of the force to be slidable. While the catheter remains clamped, pull the catheter with the spring dynamometer. Record the forces that will slide. The experiment was measured to be 3N of the maximum static friction. When the tension exceeds this value, the catheter and clamping materials will relatively slow slid.

III. Simulation analysis

In the previous section, we introduced the master-slave equipment used in the experiment, designed a new non-destructive clamping method, and performed a simple force analysis. In this section, we will analyze the force and displacement of the clamping module we designed, and study the force of the soft clamping material to prevent the catheter and guide wire from being overstressed.

A. Force simulation

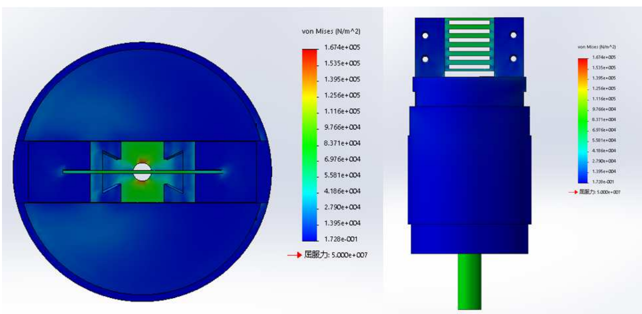
In the previous section, we designed a new clamping method and clamping principle for the non-destructive clamping theory of catheters and guidewires, and performed a simple force analysis. In order to verify possible forces and deformations, we performed simulation analysis using SOLIDWORKS 2016 x64 Edition in this section. The computer used for the simulation is i7-4790 CPU, the GPU is AMD Radeon R5 235, and the operating system is win10 professional edition.

Set the cylindrical bucket as a fixed surface. In practical applications, we will place large bearings on both sides to keep the cylindrical and the base remain relatively relatively static. And the cylindrical barrel can drive the clamping device to perform rotation operation. Set contact mode is free of friction. In practice, it may cause lack of clamping force due to friction. So we set the push rod thrust as 3.5N, rather than the previous calculated theoretical thrust 1.15N, and the number of divided grid nodes was 97180. The material used for the clamping device has an elongation of 3%, a tensile strength of 50 MPa, and a Poisson's ratio of 0.41.

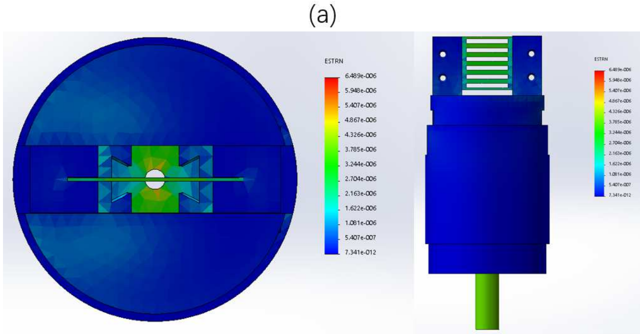
B. Results and analysis

After simulation calculation, we obtained the simulation results of stress and strain. As shown in Fig.8. Since the gripping force of the soft gripping material is provided entirely by the push rod, the push rod experiences the greatest stress, which occurs at the center of the push rod. The overall force of the soft clamping material is uniform, and the simulation results show that there will be no damage to the catheter due to uneven force. In addition, under this stress condition, the simulation

Fig. 7. Measure the maximum push force.



(a)



(b)

Fig.8 Stress and strain simulation results, including front and top views: (a) Clamping module stress conditions. (b) Clamping module strain condition.

results show that the structure is stable without fracture or severe deformation.

IV. Security Strategy

In the previous section, we carried out a simulation force analysis on the designed module, and the results show that the structure is stable under the expected force. This section proposes some security policies for the designed modules.

A. Prevention strategy

Blood vessels can be damaged by excessive force at the tip of the catheter, resulting in problems such as complications for the patient [19]. Based on the previous studies of our group, we explored the influence of three factors, which are the effects of push speed, vascular depth and vascular width [1]. When the push speed is fast, the blood vessels are deep or wide, the tip force is easy to be excessive. Therefore, when the catheter is pushed to these positions, the operator needs to slow down and take a more cautious operation under the guide of visual feedback. We're also working on integrating multiple sources of information to give surgeons status feedback and force feedback [20]. Our goal is to determine the current surgical status based on visual feedback. Our goal is to determine the current surgical status based on visual feedback. When a dangerous position reached, a scaling factor is applied to the speed of movement to limit the pushing speed.

B. Safety strategy for non-destructive clamping

When there is uncertainty about whether a dangerous situation has occurred, routine retraction maneuvers may reduce surgical efficiency. Our clamping modules can loosen the catheter, and due to the properties of the soft material, the release of the force will be very fast, thus avoiding too much impulse to the vessel.

In addition, the gripping force of the soft material on the catheter is a static frictional force. The maximum static friction force can be limited by changing the thickness and degree of deformation of the material, thereby limiting the max catheter tip force and thus avoiding damage to the patient's blood vessels. These will be calibrated and set up by subsequent experiments. During surgery, the maximum static friction force can be set by the surgeon. Sliding occurs when the resistance to the catheter exceeds the maximum static friction provided by the soft material, so there is no excessive penetration force.

V. Discussion

To enhance the safety of interventional surgery. This paper introduces a novel non-destructive clamping method for guide wires and catheters. In the process of clamping and rotating, the soft material used in the module will not damage the equipment due to excessive force. To facilitate the replacement of equipment during interventional surgery. The materials used in this clamping module are inexpensive and small, and can be easily implemented and replaced.

Furthermore, we used SolidWorks software to analyze the force of the module. According to the simulation results of stress and strain, it can be seen that the force of the soft clamping material is uniform, and the clamping force to the catheter is also relatively uniform. The deformation of the module after being thrust is small, there is no extreme stress point, and there is no risk of structural fracture.

However, we also found some problems. Soft materials do have significant advantages in protecting the device, but when the force is large, the sliding of the catheter may occur, this may lead to insufficient push force. In addition, when we carry out force and simulation analysis, the calculation was carried out in a frictionless way. There are difficulties in installing catheters and guide wires, so the structure of this soft material still needs to be improved.

VI. Conclusion

To improve the safety of interventional surgery, this paper presents a flexible material for clamping guide wire and catheter. The corresponding clamping module is designed for this new clamping device. In order to verify the mechanical stability, we carry out the corresponding force and simulation analysis. Experimental results show that the flexible non-destructive gripper is effective in protecting interventional equipment.

In order to ensure the accuracy of the experiment, we will conduct more calibration experiments on the equipment in the future. Due to the lack of time, we only carried out simulation and force analysis, and in the future, we will carry out physical operation experiments to further verify and improve.

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