Force Analysis of Catheter Tip Influenced by Multiple Factors in Interventional Surgery Robot

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Abstract - The mortality rate of cardiovascular and cerebrovascular diseases is very high, which poses a great threat to human life and health. It has long plagued the middle-aged and elderly people. There are also many young people who suffer from cardiovascular and cerebrovascular diseases. Vascular interventional surgery is an effective means to treat cardiovascular and cerebrovascular diseases, compared with traditional surgery, vascular interventional surgery causes less damage to patients. But interventional surgery will also bring some new problems, for example, the catheter used for surgery needs to pass through long and narrow blood vessels, and lack of real force feedback. In order to avoid or reduce iatrogenic injury, we decided to explore the possible impact of different factors in the surgical process. Firstly, based on real blood vessel size, we designed three simulated blood vessels in vitro. Secondly, through multiple sets of controlled experiments, we successfully explored the impact of robot push speed, blood vessel depth, and blood vessel width on the risk of robot operation. Finally, through the ATI Force/torque sensor to record the data of the tip force of the catheter, through comparative analysis and control variables, we had obtained the influence of different factors on the tip force of the catheter.

Index Terms - Vascular intervention. Extracorporeal vessel design. Remote force measurement. Risk of surgery.

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. Cardiovascular disease has always been a major disease affecting human health, and has always been widely concerned by the community. At present, vascular interventional surgery is a good way to treat endovascular diseases. Vascular interventional surgery has many unique advantages in the treatment of cardiovascular and cerebrovascular diseases, such as minimally invasive, less blood loss, fast recovery, it also allows clinicians to get rid of diseases that may be caused by radiation [1],[2]. It is precisely because of these advantages that interventional surgery receives widespread attention in recent years, and more and more interventional operations have been implemented in clinical practice.[3],[4] Many interventional surgery devices have also appeared in China and abroad [5],[6]. These devices are designed to reduce doctors' pressure.

The interventional robot imitates the surgeon's operation and inserts the catheter from the patient's femoral artery or radial artery to the lesion [7]. Because the incision is far away from the target location, the catheter needs to pass through long blood vessel in the patient's body, and it will inevitably collide with blood vessels, and if the doctor is not skilled enough, or some other factors will cause iatrogenic injuries [8]. These injuries may cause major problems in the clinical process, or there may be no major problems during the operation, but in the patient's recovery and later life, may cause great distress to the patient [9]. When an experienced doctor operates, the frequency of collisions between the tip of the catheter and the vessel wall will be significantly reduced. In addition to the surgeon's efforts, researchers who study interventional surgery are also working on reduce iatrogenic injury [10].

Digital subtraction angiography (DSA) plays an important role in surgical navigation [11]. With this technology, the vascular structure can be observed. Surgeons can have a view of the structure of the blood vessel where the catheter is currently located, and then can actively avoid the collision between the tip of the catheter and the blood vessel wall [12], this makes the doctor's operation no longer blind. However, this image-based surgical strategy has some obvious shortcomings. For example, the surgeon has actually caused injuries to the patient after seeing the catheter bend, and the delay of the image may have a greater potential risk. And has a certain impact on the patient's kidneys [13]. In addition to this method to assist the doctor in the operation, methods such as CNN can also be used to improve operational capabilities [14],[15].

Interventional surgery currently relies on surgical robots for operation, but because of the lack of force feedback, it is easy to cause damage to the patient. Therefore, it is necessary to explore the factors that affect the risk of robot operation.

A. Current Research Status

For example, to obtain a more accurate force on the tip of the catheter, Yu Song of Kagawa university uses an optical fiber sensor to measure the force on the tip of the catheter [16], and Jian Guo of Tianjin University of Technology adds more force sensors to the tip of the catheter on the basis of the optical fiber force sensor [17]. Some scholars have studied non-contact surgeon operations [18].

Whether the operation is dangerous is ignored to a certain extent, or it is subjectively determined by the doctor. In order to reduce the damage caused by the surgical operation to the patient and provide a basis for doctors to judge the danger. We decided to conduct experiments in vitro, to explore the influence of different factors on the risk of surgery. Because the catheter tip force measured in vivo will have a large deviation from the true value, this paper designs three simple in vitro blood vessels with reasonable size based on the EVE model [19], and uses the ATI Force/Torque sensor (ATI, FT17123) to directly measure the catheter tip force. The bending of the catheter during the experiment was recorded by a camera.

The second section introduces the design process of the simulate blood vessels in vitro and introduce the master-slave control system we use in this paper, this system was previously developed in our laboratory [19],[20]. The third section uses this system and three simulated blood vessels to conduct experiments, change different influencing factors to obtain the relationship between the tip force and these factors, process and analyze the experimental results. The fourth section is conclusion.

II. SYSTEM INTRODUCTION

This section mainly introduces the master-slave equipment used in the experiment, design and realization of in vitro simulated blood vessels. The master-slave equipment including three parts: master control PC, slave manipulator and controller. The simulated blood vessels can realize multi-variables control and use the ATI Force/Torque sensor to measure the real force of the catheter tip in real time.

A. Experimental Platform

As shown in Fig.1, this is the equipment used in the experiment [21]. The overall structure is master-slave, the operator operates on the master manipulator, and the slave robot reproduces the actions of the master manipulator. In this article, the master control PC only needs to give forward, backward, and rotate instructions. Master-slave operating system is our team's previous design. The master computer sends out motion instructions, and the single-chip microcomputer controls the two motors to move forward, backward, and rotate on the slave side.

And the clamping device drives the rotation and axial movement of the catheter. Clamp the catheter to advance, retreat and rotate. The maximum pushing distance of the slide rail is about 200mm, this article only needs to push the distance up to 70mm, therefore, the catheter does not need to be loosened in this experiment.

B. In Vitro Blood Vessel Phantom

The structure of the simulated vessel is inspired by real human blood vessels, according to the real blood vessel size, we decide to design a total of three simulation devices. In vitro vessels, we consider setting the top as a flat structure, because the upper and lower sides of the vessel are symmetrical about the horizontal plane, and the flat structure makes it easier to record dynamic images of the catheter from the top with a camera. And to be able to get the true value of the force on the tip of the catheter, we left a catheter protruding hole at the tip of the simulated blood vessel, to install the ATI sensor on the front end of the hole during the experiment [22].



Fig. 1 Overall experimental equipment.



Fig.2 Imitation of vascular vessels in vitro. A, B, C are simulated blood vessels with inner cavity radius of 15, 10, and 5 mm respectively.



Fig.3 Push plate for controlling blood vessel depth. A, B, C are push plates with radius of 15, 10, and 5mm respectively.

We use 3D printing technology to complete the production of simulated blood vessels, as shown in Fig.2. A total of 3 devices are used for catheter force measurement. There are three sizes of inner cavity radius of 15mm, 10mm and 5mm, which can imitate different vascular environments, such as Aortic arch, Jugular vein angle, et al,

The matching push plates are designed, and as shown in Fig.3. There are also three different push plates, the push plate matches the size of the inner diameter of the imitation of vascular vessels in vitro. The entry position and angle of the catheter have a restrictive effect on the catheter, and can realize the restriction on the length of the catheter.

Although the device has a simple structure, but it can achieve multi-factor control variables, such as: blood vessel width, height, depth of branch vessel, insertion angle, what this paper needs to use are blood vessel width and depth. And install a camera above the equipment to record the different shape information of the catheter in real time, the force measurement device is shown in Fig.4, the robot pushes the catheter, and the ATI sensor records the force data. The force analysis is shown in Fig.5, this experiment focuses on the tip force. The tip force is mathematically given by:

$$F_t = F_p - F_d \tag{1}$$

where (1), F_t is tip force measured by ATI sensor, F_p is pushing force of the slave robot, F_d is force of catheter deformation. The mathematical formula for the error of the tip force measured by the sensor is as follows:

$$F_e = F_{ty} + F_f \tag{2}$$

where (2), F_e is the error of the tip force measured by the sensor, F_{ty} is the y-axis component of the tip force, F_f is the friction force that the catheter receives in the blood vessel phantom.

In this article, the vessel wall is idealized as a straight-tube structure, change different factors to measure the force of the catheter in vitro. In order to prevent the catheter from sliding, we installed a clamping device on ATI sensor, and the position of the fixing device and the ATI remain unchanged. Masterslave robot operating system can prevent inconsistent deformation of the catheter caused by manual operation.

III. EXPERIMENT AND MEASUREMENT

In the previous section, we introduced design and implementation of in vitro simulated blood vessels, as well as some equipment and master-slave operating systems. The whole experiment is dynamic and multiple variables. The variables of vessel width and depth are inspired by the EVE model, which is a high-precision model that completely imitates the human body. Therefore, we selected the experimental variables one-to-one according real blood vessel. Each experiment is the result of different factors. In addition, we analyze the results of each experiment and draw the corresponding graphs.

A. Experimental Design

There are three kinds of inner cavity radius devices to simulate different kinds of blood vessels. The designed push plate can change the depth of blood vessels. The depth of all them three devices is in the dynamic range of 0-80mm, but after measuring the EVE model, we find that the depths of several blood vessel branches commonly used in interventional surgery are close to 4.3mm and 7mm, so we decide to conduct experimental explorations on these two blood vessel depths. Push plates with different diameters have different access designs, and select different access points can simulate different access angles, but this experiment only enter from the top hole.

There are many influencing factors that can be considered for dynamic measurement. The factors considered in this experiment are: pushing distance, pushing speed and blood vessel width (here we use different vessels to achieve this goal).

In order to prevent the instability and non-repeatability of manual operation, the power source of the pushing device used in this experiment are two motors. Motor 1 (Maxon, EC-max16) controls the rotary motion of the catheter, and motor 2 (Yaskawa, SGMJV-01ADE6S) controls the linear motion of

TABLET					
CHANGE FACTORS					
	Factors	Parameter			
1	Three simulate blood vessel radius (mm)	5 & 10 & 15			
2	Two simulate blood vessel depths (mm)	4.3 & 7			
3	Robot pushing speed v1 (cm/s)	0.428			
1	Robot pushing speed v3 (cm/s)	1.283			
5	Robot pushing speed v5 (cm/s)	2.132			



Fig.4 The force measurement device.



Fig.5 The force analysis.

the catheter.

We use the controlled variable method to conduct experiment, the factors we change in this experiment are as shown in Table1. Change one variable each time, and then conduct comparative analysis to conclude that the changing factors are depth, width, and speed. Please refer to section B for details of the experiment.

B. Result Analysis and Graphing

When surgeons operate the catheter, because of insufficient force feedback, doctors can only avoid injury subjectively, and lack of objective indicators to reduce injury.

We use the method of controlled variables to compare and analyze the experimental results to obtain the influence of univariate on the force of the catheter tip. Analyzing the influence of different factors on the force of the catheter tip is of great significance and can provide a basis for doctors to operate safely.

During the experiment, we clamp the tip of the catheter with a holding device on the ATI sensor, and use the slave robot to clamp the catheter forward and backward the same distance each time. Because the force generated by the vascular surgery is very small, the ATI sensor will have certain fluctuations and errors, so some experimental results have obvious abnormal data. We remove some data sets with too large deviations, and add the third comparative experiment when big errors occurred.

The first thing we change is the width of the blood vessel, which is achieved by changing different device. The width of the blood vessel is designed based on the aortic arch and other human vasculature. There are three widths with inner cavity radius of 5mm, 10mm and 15mm.

The depth design is also based on the depth set by the blood vessels in the human body, inspired by the thick blood vessels entering the thin blood vessels in the human body. The depth is set according to the depth of the capillaries, which is divided into two depths, 4.3mm and 7mm.

The values recorded are too dense (about 16 values per second), so we use the Origin drawing tool (Origin 2019b 64bit) to fit the force values to obtain a more intuitive comparison effect. The actual measured value of velocity v1 is 0.428cm/s, velocity v3 is 1.283cm/s, and velocity v5 is 2.132cm/s. The following table lists the factors that changed in the experiment.

We have performed many experiments and matched the forces recorded by the ATI sensor to get the following figures. The experimental results must be sufficiently verified, so we set a verification experiment each time. But even in this case, because the force fluctuation of the is obvious, the conclusions drawn may be inconsistent. We will add a third verification when abnormal data sets appear.

The data set obtained by changing the width at speed v3 is shown in Fig.6. According to the experimental data, we compare the maximum value of the catheter tip force, the time when the maximum value appears under different experimental conditions and impulse generated by greater than 0.4N (15mm vessel change peed is beyond 0.2N) in Table II. According to the data set corresponding to Fig.6, because the speed of pushing the catheter is the same, the slope of the force rise remains the same. When other conditions are the same, a vessel with a radius of 10 mm wide seems to produce the greatest tip force, but the time for the greatest tip force to appear is also the latest. A vessel with a radius of 15mm width produces the smallest tip force, and the time to the maximum appears later than that of a vessel with a radius of 5mm, the conclusion drawn from the momentum is consistent with the maximum force.

The picture drawn according to the verification data set is shown in Fig.7. The peak with a radius of 10mm is still the largest, and the radius of 5mm reaches the peak first. We add a set of verification experiments. And draw Fig.8 based on the experimental data. In this experiment, the force with a radius of 10mm is still the largest, but the time to reach the maximum is later than the 15mm vessel.

Then we decided to carry out two variable experiments of depth according to the depth of real blood vessel bifurcation. The depths are 4.3mm and 7mm respectively. After the experiment, we draw a figure as Fig.9 according to the dataset, and carry out a verification experiment, and we draw a figure base on the verification shown as Fig.10.

TABLE II EXPERIMENTAL DATA STATISTICS

	Factors	Max Force (Absolut e value)	When max force appears (s)	Impulse (Absolute value)
Change	5mm-7cm-v1	0.825	1.992	2.800
width	10mm-7cm-v1	0.772	5.742	4.034
at v1	15mm-7cm-v1	0.831	3.867	4.240
Change	5mm-7cm-v3	0.762	0.523	1.378
width	10mm-7cm-v3	0.831	1.511	2.738
at v3	15mm-7cm-v3	0.450	2.150	0.100
Change width	10mm-7cm-v5	0.884	1.170	2.114
at v5	15mm-7cm-v5	0.481	0.937	0.154
10mm vessel	10mm-4.3cm- v1	0.666	3.776	1.761
change depth at v1	10mm-7cm-v1	0.772	5.782	4.067
15mm vessel	15mm-4.3cm- v1	0.709	5.957	3.438
change depth at v1	15mm-7cm-v1	0.831	3.893	4.268
10mm vessel	10mm-7cm-v1	0.771	5.782	4.067
change	10mm-7cm-v3	0.831	1.534	2.779
speed	10mm-7cm-v5	0.884	1.180	2.130
15mm vessel	15mm-7cm-v3	0.444	1.341	0.797
change speed	15mm-7cm-v5	0.481	0.933	0.705



The force value graph obtained from the two experiments both show that the catheter has a greater force at the deeper tip of the vessel, and the same is true for the maximum value shown by the dataset in table II. Then we keep other conditions unchanged and only change the robot push speed. The experimental group of Fig.11 is shown below. In addition to the experimental group, we also conduct a verification group experiment, as shown in Fig.12. According to the data of the experimental group, when the speed is higher, the peak force will be greater, and the peak force will appear earlier.



Fig.9 10mm vessel change depth at speed v1.



Fig.12 15mm vessel at different speeds.

IV. CONCLUSIONS

We design in vitro simulated blood vessels, and conducted experiments to verify three different risk factors, and obtain a more scientific verification result. According to table II and combined with the intuitive phenomenon of force value, we can make the conclusion, when the catheter is advanced in a thin blood vessel, the risk is more likely to occur, because the force generated by the tip may be greater, but it is not that the thinner blood vessel is more dangerous.

Because the wall of the 15mm vessel does not restrain the catheter strongly, part of the pushing force may cause the catheter to bend rather than just increase the tip force. Therefore, in this case, the harm may not be so serious. However, what is the situation with the finer blood vessels still needs to be explored by more rigorous experiments. In addition, when the catheter travels deep, if there is a collision, the tip force will increase quickly, and the peak value is also very large. The faster the catheter is pushed, the faster the tip force will increase when a collision occurs, and the peak will be larger.

To sum up, when the catheter enters the thin blood vessel from the thick blood vessel, or as the catheter is deep in the blood vessel, or in these cases, when the speed of travel is still very fast, we need to adopt some strategies to prevent harm. In view of the delay of X-ray images and the delay of human response, the right to take active strategies may also need to be given to surgical robots.

During the experiment, we found that when we use the computer operating system to perform actions, because people need time to react, there may be time inconsistencies. And we did not take into account the torque generated by rotating the catheter, torque may be taken into consideration in the future work. And we will take the form of full computer automatic instructions to conduct experiments, rather than people sending instructions through the computer.

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