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Development of Collaborative Clamping Devices for a Vascular Interventional Catheter Operation

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***Abstract* - Increasingly high incidence of cardiovascular and cerebrovascular diseases, which has become one of the three major causes of human disease death, because of its high incidence, disability, and mortality, it brings tremendous mental stress and heavy weight to individuals, families and society economic burden. Vascular interventional technique is a newly developed treatment for prevention and treatment of cardiovascular and cerebrovascular diseases. Under the guidance of medical imaging, the doctor enters the lumen of the blood vessel through the catheter directly to the blood vessel of the lesion in the body, and then uses the catheter to transport the therapeutic agent or surgical instrument. Minimally invasive diagnosis and treatment of distant lesions in the body. Therefore, it is critical to accurately and stably deliver the catheter to the designated location. This paper proposes a reciprocating towed slave robot, which mainly includes four degrees of freedom: linear motion, torsional motion, catheter front clamping release, and catheter end clamping release. The catheter motion operation is achieved by the four degrees of freedom of the end robot. And the linkage is released by the clamping of the front of the catheter to achieve the operation of transporting the catheter to a further destination. This method was demonstrated to meet clinical operational requirements by experiments in a simulated vascular model.**

Index Terms –Vascular interventional surgery, Catheter and guide wire clamping, Robot collaboration, Reciprocating tow surgery.

I. INTRODUCTION

Coronary atherosclerotic heart disease, referred to as coronary heart disease, is a common cardiovascular disease caused by stenosis or occlusion of coronary artery. In order to solve the blood flow caused by narrowing of blood vessels, in the 1970s Gruentzig, a well-known interventional cardiologist, pioneered the introduction of balloon dilatation catheterization into coronary heart disease treatment, successfully eliminating the stenotic lesions in the proximal left anterior descending coronary artery of the patient [1]. After more than 30 balloon dilatation years of development, from the initial simple balloon expansion to a series of minimally invasive vascular interventions including balloon expansion and stent placement. Because minimally invasive vascular intervention has the characteristics of clear effect, small trauma and rapid recovery. It has become the main means of treating coronary heart disease. Although minimally invasive vascular interventional surgery has emerged in the development of interventional devices, the way in which interventional devices are used by physicians has not changed in the past three decades, because interventional surgery have always used physics. The method of contact is to operate an interventional instrument such as a guide wire and a catheter. Therefore, the doctor directly manipulates the guide wire and catheter in the X-ray environment of the catheterization chamber to deliver it from the patient's femoral artery to the stenotic coronary lesion after percutaneous puncture. The biggest problem for the doctor to directly operate the interventional device is the long-term work. In X-ray environment, in order to reduce radiation, doctors need to wear heavy lead clothing. However, lead clothing cannot completely avoid X-ray radiation damage, long-term cumulative radiation and heavy lead clothing burden will cause serious illness [2-5].

To reduce the radiation damage to X-rays from doctors during minimally invasive vascular interventions, the researchers combined robotic techniques with minimally invasive vascular interventions. They designed the specialized surgical robot system to assist the doctor to complete the delivery of the guide wire and catheter. The current vascular interventional robots can be divided into friction-driven and sliding platform types [6]. In the case of friction-driven vascular interventional robots, Tanimot et al., Nagoya University, Japan, earlier proposed a surgical robot for cerebrovascular intervention. The slave robot is driven by two rollers in the forward and reverse directions of the catheter, and the rotation of the catheter is realized by the clamping and integral rotation of the roller mechanism [7]. Israel's Haifa Hospital developed the Remote Navigation System (RNS) in 2006, a surgical robot for cardiovascular intervention, which uses multiple sets of friction wheels to deliver guidewire and balloon/stent catheters, respectively. The first clinical trial was carried out [8]. On the basis of RNS, Corindus developed the CorPath 200 vascular interventional robot system. CorPath 200 obtained the FDA (Food and Drug Administration) approval after conducting a number of human clinical trials [9-10]. Hansen Medical Company of the United States developed a Magellan vascular interventional robotic system based on friction, which cooperates with Hansen's dedicated active catheter to achieve interventional treatment of peripheral blood vessels [11]. Thakur et al., University of Western Ontario, Canada developed a remote catheter delivery system that included a catheter sensor and catheter manipulation device. The master of system detects the movement of the catheter, the slave part passes the friction wheel to drive the catheter forward or retract [12-13]. In the sliding platform type vascular interventional robot, Arai, Nagoya University, Japan developed a linear stepping mechanism for cerebrovascular intervention, realizes the delivery of the interventional catheter by clamping and the sliding platform [14]. Guo and others at Kagawa University in Japan developed a master-slave robotic system for endovascular interventional surgery. The slave using a sliding platform to achieve delivery of the catheter through the reciprocating motion of the sliding platform [15]. The vascular interventional robot developed by Payne et al. can assist the doctor in delivering the catheter and study the effectiveness of the robotic force feedback [16]. The SETA system developed by Srimathveeravalli et al. combines the friction wheel drive and sliding platform structure. The friction wheel is used to drive the axial movement of the guide wire, and the sliding platform is used for the axial movement of the catheter [17]. In addition, Jayender et al. of Canada studied the impedance control method of the active conduit based on shape memory alloy in the forward feeding process, using the industrial robot arm as the catheter delivery device, and detecting the resistance of the end through the force sensor of the arm of the arm [18-20]. U.S. Harvard University's Yuen and Kesner et al. developed a vascular interventional robot for delivery catheters, and studied the position control and force control method of the robot in the beating heart. The robot is mainly for electrophysiological treatment because the delivery device has only a single degree of freedom [21]. In recent years, Guo Laboratory at the School of Life Sciences, Beijing Institute of Technology, developed an interventional robot for cardiovascular and cerebrovascular, and they have carried out related research on mechanism design and navigation control methods, which achieved fruitful results and great breakthroughs [22-24].

Although the current vascular interventional surgery robot can assist the doctor in performing surgery, there are still some problems in the delivery of the catheter guidewire by the robot [25-27]. For example, although the catheter guide wire can travel in the blood vessel according to the route under the operation of the interventional surgeon, the length of the catheter guide wire limits the maximum distance that the doctor can operate, and the excessive length of the catheter guide wire also increases the difficulty of the operation of the slave robot, which leads to deformation of the catheter guide wire and hinders the operation of the robot [28-30]. Therefore, it is necessary to design a method capable of transporting the catheter to any given position without affecting the accuracy of the movement of the catheter guidewire.

This paper proposes an operation mode in which the front magnet clamping and the vascular surgery are coordinated with the end clamp on the end robot. By controlling the guide wire movement of the catheter, the front clamping and the end clamping are clamped and released. This operation ensures that the catheter guide wire reaches the destination of the specified distance without changing the catheter. The second section explains the operation method of the front clamping and the end clamping linkage. In the third section, the frictional force of the front clamping and the end clamping is evaluated and the results are discussed. The fourth section summarizes the research work and points out the future work.

II. Design of Catheter Guide Wire Clamping

During the vascular interventional procedure, the doctor's hand movements are shown in Fig. 1. The doctor performs a reciprocating towed operation by holding the end of the extravascular sheath. The doctor uses the right hand to grasp the catheter, and through the rotation of the wrist and the rotation between the fingers, the axial pushing and circumferential torsional movement of the catheter is completed. When the wrist reaches the turning limit, the right hand finger releases the catheter, the left hand fixes the catheter, and the right hand wrist rotates in the opposite direction to the proper position, then the right hand finger re-holds the catheter, and continues the rotation of the wrist and the rotation between the fingers to complete the catheter. Axial push-pull and circumferential torsional motion, in this reciprocating cycle, achieve long-distance delivery of the catheter.

A. Hardware Devices

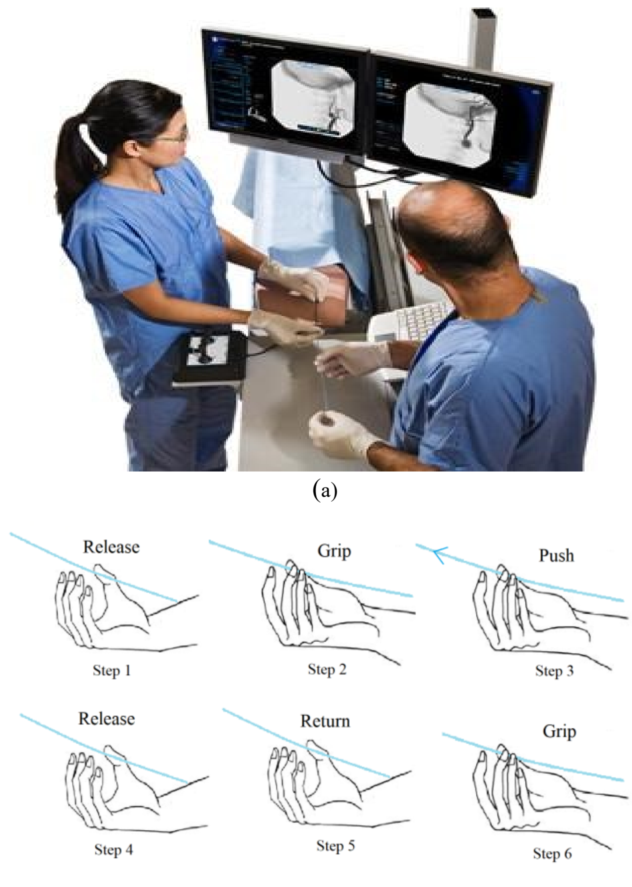

Fig. 1. Doctor catheter operation diagram. (a) Clinical operation. (b)Decomposition action.

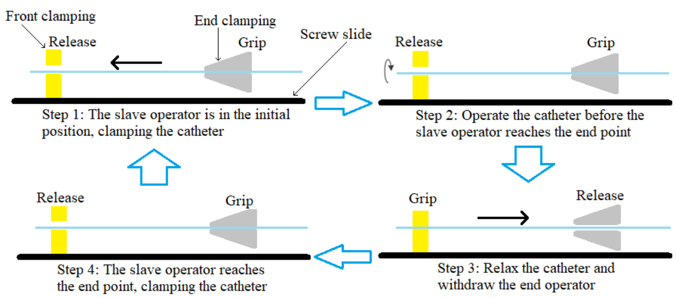

Fig. 2. Schematic diagram of the reciprocating drag operation from the end operator.

According to the above analysis of the doctor's hand movement, this paper proposes a linkage method based on the front clamping and the end clamping under the general framework of the existing slave robot, respectively, by clamping the front section of the catheter and clamping the end of the catheter respectively or The release operation is performed to maintain the catheter without further displacement when the end robot or the end restriction position is operated from the end robot control catheter, and the operation of the catheter is further moved or retracted by using the mutual linkage of the two devices to achieve the purpose of operating the same catheter to reach its destination. The operation process of the slave robot is shown in Fig. 2.

The structure of the slave robot is shown in Fig. 3, which mainly includes the robot arm, the end shell, the bottom plate, the duct, the catheter sheath, the front clamping mechanism, the end clamping mechanism, the electromagnet A, the outer casing, and the motor A (Maxon EC-max). 16, the highest speed 12000rpm, equipped with gearbox GP 16C, reduction ratio 84:1, drive ESCON 50/5), herringbone gear pair, ball screw, slider, motor B (Yaskawa SGMJV-01ADE6S, maximum speed 3000rpm, Rated torque 0.318N·m), electromagnet B, and towline. The front clamping mechanism is driven by the electromagnet A; the herringbone gear pair is driven by the motor A to realize the torsional movement of the catheter; the end holding mechanism is driven by the electromagnet B, and cooperates with the catheter torsion unit to realize the clamping end release of the catheter; the catheter torsion unit the end holding mechanism is fixed by the slider of the shell and the ball screw (THK SKR/KR26, stroke 240mm), and the ball screw is driven by the motor B to realize the axial motion control of the slider, thereby driving the catheter to realize the axial movement.

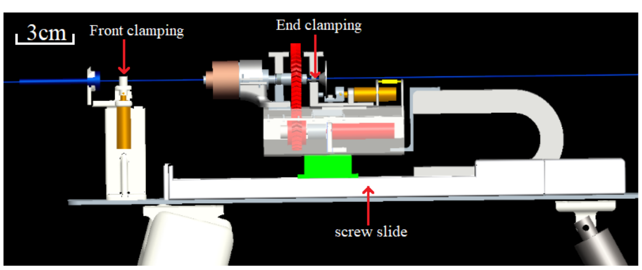

Fig. 3. The overall framework of the slave robot.

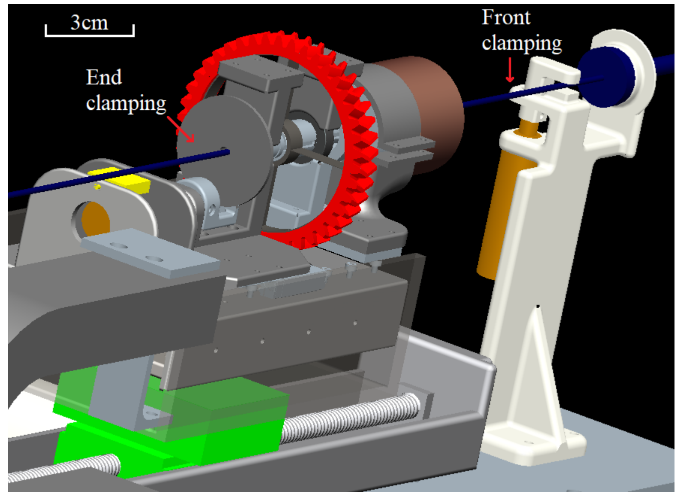

Fig. 4. Conceptual diagram of front clamping and end clamping.

One side of the device fixes the electromagnet by drilling, and the head of the electromagnet is bonded and pressed. The non-slip material is adhered to the lower portion of the tablet and the upper portion of the device. When the electromagnet is charged, the control tablet is pressed down, the front clamping is in the clamping state, and the catheter guide wire is fixed; when the electromagnet is powered off, the pressing piece is bounced, and the front clamping is in a released state. The catheter can be operated for the corresponding operation. The conceptual diagram of the three directions of front clamping is shown in Fig. 4.

As for the end clamping, the wire clamping device is based on a medical grade wire guide rotator first. The guide wire clamping device includes a pair of screws and a clamping member. The screw pair can be self-locking after the wire is clamped. A portion of the pair of screws provides a tapered surface for the clamping portion; another portion of the screw serves as a schematic illustration of the restraining sleeve. The wire clamping member is shown in Fig. 5. The clamping portion and the tapered surface are coaxial.

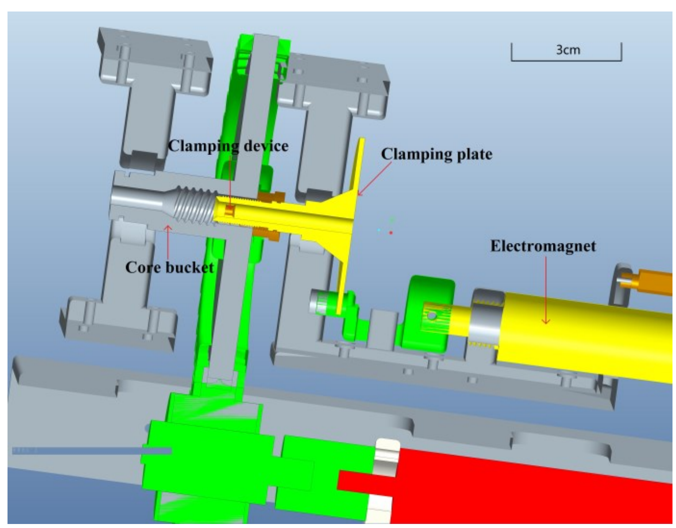

Fig. 5. Partial cross-sectional view of the catheter clamping mechanism in the clamped state.

B. The Method of Operation

The linkage between the two is mainly reflected in the axial linear motion of the catheter: the overall division is forward operation and backward operation:

1) The Forward Operation: If the robot is located at the rear limit position, confirm whether the front clamp device of the duct (hereinafter referred to as the front clamp) is in a released state, and whether the end clamp device (hereinafter referred to as the end clamp) For the clamping state, if it is not adjusted to the above two states; if the robot is not in the rear limit position, the front clamping is adjusted to the clamping state, and the rear clamping is adjusted to the released state, because the conduit is from the slave robot. At the same time, the catheter and the slave robot are separated, and the relative motion can be realized. The movement moves from the end robot to the rear limit position, the front clamp is changed from the clamp state to the released state, and the rear clamp is changed from the released state to the released state. In the clamped state, the catheter is tightened by the robot at this time, and the two are relatively stationary, and the catheter can be operated.

At this time, the catheter can be operated for axial advancement and circumferential torsion operation. When the catheter moves to the front limit position and cannot continue to advance, the control front clamp changes from the released state to the clamped state, and the end clamps. From the clamped state to the released state, the conduit is separated from the slave robot again, and the two can move relative to each other, and the front robot is retracted to the appropriate position, and the front clamp is changed from the clamped state to the released state. The clamping changes from the released state to the clamped state, and the catheter is tightened by the robot, and the axial forward and circumferential twisting operations can be continued. If the previous limit is reached again, repeat the above procedure.

2) The Back Operation: It is similar to the preparation stage of the forward operation, except that the starting position is changed to the front limit position, ensuring that the slave robot starts to withdraw from the previous limit position, and the remaining operations and forward operations: when moving from the end robot to the rear limit When the position cannot be retracted, the front grip is released and becomes the grip, the end grip is changed from the grip to the loose, and the front is moved forward to the appropriate position, the front grip is changed from the grip to the loose, and the end grip is held. From release to clamping, continue to retreat.

It is also similar to the forward operation, when the post-restriction position is reached, that is, when the robot is required to be separated from the catheter, the front grip is released and becomes the grip, and the end grip is changed from the grip to the released; when it is necessary to operate the catheter movement, the front end clamp is changed from the clamp to the loose, and the end clamp is changed from the relaxed to the grip.

III. Experiments and Results

As can be seen from the overall structure of the front, since the duct is passed through the inside of the slave robot, friction is generated when the duct and the slave robot are relatively displaced. The slave robot is formed by the nesting combination of the small layer devices, so there is a rugged joint at the joint; the clamping of the catheter by the end clamp may cause the deformation of the catheter, and there is a rugged condition; the catheter is in the blood vessel. It also curves, which also causes the catheter to bend. These kinds of situations will suddenly increase the friction between the originally smooth catheter and the slave robot, and become a factor that cannot be ignored.

Therefore, when the relative movement of the catheter and the robot is required, if the frictional force formed by the front clamping on the catheter clamping is smaller than the friction between the robot and the catheter. This will lead to the movement of the catheter when the catheter is fixed for the operation of the slave robot or the retraction operation, which will seriously damage the surgical effect of the vascular interventional operation and even bring danger to the patient. We define three variables: friction of the catheter in the clamped state of the front clamping device (hereinafter referred to as F1). In the loose state of the end gripping device, the frictional force of the catheter in the case of the forward and reverse movements of the slave operator (hereinafter referred to as F2, F3, respectively). Then the requirements for F1, F2 and F3 are that F1 is much larger than F2 and F3.

In the measurement preparation phase, the dynamometer is first fixed on a plane parallel to the catheter, and the catheter clamping device is fixed on the dynamometer to measure the friction of the catheter. The field diagram of the connection between the force measuring device and the robot is shown in Fig. 6.

When measuring F1, clamp the front clamp and move the dynamometer at a constant speed to obtain the maximum static friction. As shown in Fig. 7. When measuring F2 and F3, the dynamometer is kept stationary, the front clamping and the end clamping are released, and the operation is moved back and forth from the end operator to obtain the frictional force of the catheter, which is shown in Fig. 8.

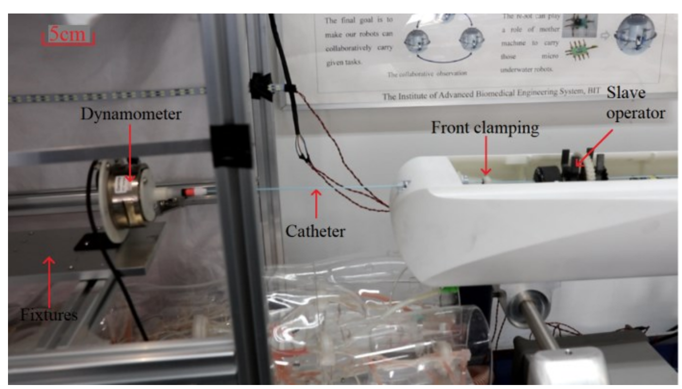

Fig. 6. Actual diagram of the force measuring device.

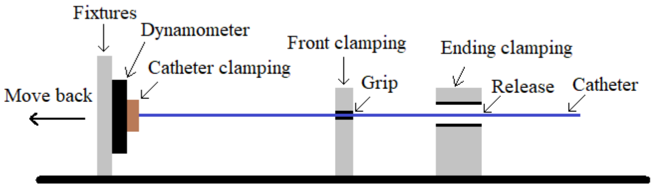

Fig. 7. The friction of the catheter under the clamping condition of the front clamp.

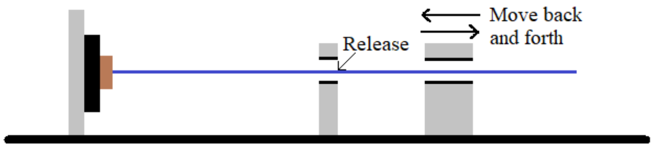

Fig. 8. Friction of the catheter due to movement from the end effector when the end clamp is released.

Before the force measurement is carried out, the clamping success rate is tested to ensure that the force measuring device is not damaged in the force measurement experiment, and the test is carried out accurately. Three sets of experiments were performed on the front clamping and the end clamping, and each set of tests was carried out 5 times on the clamping success rate. Compare the number of successes with the number of failures, summarizing the front side and the end clamping respectively, which can obtain Fig. 9 and Fig. 10; it can be seen from the two Figures that the clamping success rate is 100%.

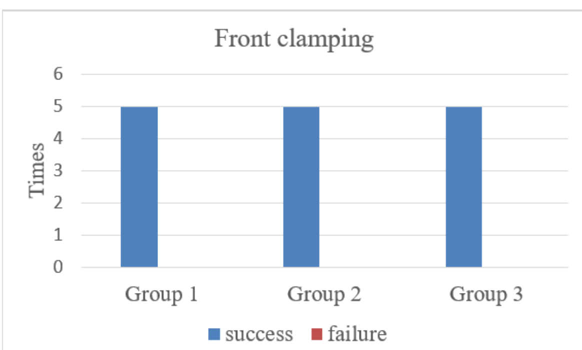

Fig. 9. Comparison of the number of successful front clamping.

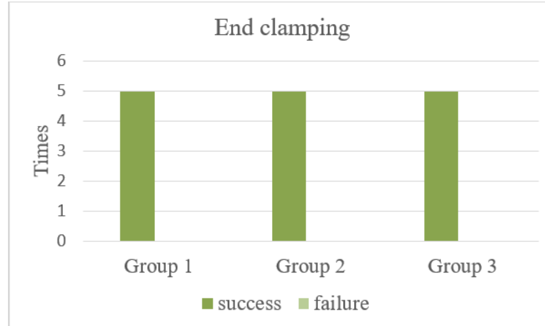

Fig. 10. Comparison of the number of successful front clamping.

Ten sets of data were measured for each of F1, F2 and F3. For F1, what needs to be obtained is the maximum value of F1. During the measurement process, continuous data is obtained, and the useful data is the maximum value of F1 and the average value of its adjacent range. Therefore, take 10 sets of data of F1 to collect the above two kinds of data. For F2 and F3, consistent with the processing method for F1, take the maximum value of each group of data in 10 sets of data of F2 and F3 and the average value of the nearby range, and summarize the three data to obtain the Table 1.

By comparing the maximum values of F1, F2 and F3 and their average values, and plotting the maximum values of F1, F2 and F3 as scatter plots, Fig. 11 is obtained. It is concluded that F1 is much larger than F2 and F3. It can be ensured that the two grippers work together without causing the wrong movement of the catheter and avoiding the error.

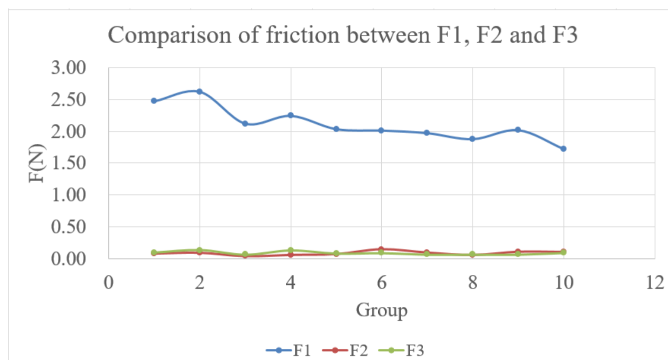

Fig. 11. Comparison of friction between F1, F2 and F3.

TABLE I
MAXIMUM AND AVERAGE VALUES OF F1, F2 AND F3(N).

Friction	Types	Group1	Group2	Group3	Group4	Group5	Group6	Group7	Group8	Group9	Group10
F1	Maximum	2.47	2.62	2.12	2.24	2.03	2.01	1.97	1.88	2.02	1.72
	Average	2.01	2.29	1.99	1.96	1.97	1.91	1.86	1.83	1.75	1.68
F2	Maximum	0.081	0.094	0.044	0.063	0.075	0.147	0.097	0.063	0.109	0.106
	Average	0.058	0.051	0.063	0.049	0.054	0.051	0.077	0.053	0.093	0.084
F3	Maximum	0.100	0.138	0.069	0.131	0.084	0.091	0.069	0.069	0.069	0.094
	Average	0.075	0.106	0.059	0.128	0.056	0.074	0.059	0.056	0.056	0.075

IV. CONCLUSIONS

In this paper we proposes a method based on the front clamping and end clamping association of the vascular surgery robot. Make sure that the error caused by the movement of the catheter from the end effector is avoided when the catheter is not being operated. Then, by measuring the three frictional forces received by the conduits respectively, it is found that the minimum friction of the front clamp is 11.7 times the maximum friction of the end clamp, which proves that the design of the front clamp is feasible.

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