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Design and Evaluation of a Novel Guidewire Navigation Robot

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***Abstract*—Robotically controlled steerable guidewire navigation systems has been paid much attention to, because it can allow the surgeons to be released from radiation and heavy radiation protection garments, reduce radiation exposure, increase precision and stability of motion, and add operator comfort. The aim of the study was to improve the precision of axial motion， rotational motion and force measurement, as well as installation convenience. A novel guidewire navigation robot, composed of a master side and a slave side was developed, which can reach the high precision, measure the force/torque of guidewire, and realize the force/torque feedback to the surgeon. To evaluate feasibility of the novel guidewire navigation robot, a system evaluation was developed. The experimental results show that: axial error was no more than 0.5mm, the rotational error was no more than 1 degree, and force error was no more than 0.031N. The novel guidewire navigation robot, potentially increasing guidewire motion precision and accuracy, is feasible for minimally invasive surgery.**

***Index Terms*—Minimally invasive surgery, Guidewire navigation robot, Force feedback**

I. Introduction

Minimally invasive surgery is widely used in surgery because it can reduce pain of patients and allow for quick recovery. However, the minimally invasive surgery causes several difficult problems for surgeons: the partial protection for the radiation [1], heavy radiation protection garments, chronic neck, and back pain [2], due to the specific surgical procedure and small work space. Therefore, development of the surgical support devices with the application of robot technology is in demand [3]. Robotically controlled steerable catheter navigation systems, allowing the surgeons to be released from radiation and heavy radiation protection garments, have seen a growing interest in the field of endovascular surgery. Also, the catheter navigation system can reduce radiation exposure, increase precision and stability of motion, and add operator comfort [4].

At present, the main commercial interventional robots mainly include: Sensei (Hansen Medical) [5], Niobe (Stereotaxis Inc.) [6], Corpath (Corindus Vascular Robotics) [7], and Amigo (Catheter Robotics Inc.) [8]. The Sensei system has been successfully used in different clinical applications, such as endovascular aneurysm repair and cardiac ablation, because of the validation of its efficacy in reducing radiation exposure and fluoroscopy time. Meanwhile, the shortage of the Sensei system is obvious, including large size, high cost, and longer setup times. The Sensei system can provide 2-DOF in catheter manipulation, as well as the Niobe system and the Amigo system. Meanwhile, the Corpath system allows for only 2-DOF to control catheters in vascular applications.

In the meantime, several research groups have been devoted to the study of remote robotic catheter navigation system. A remote-controlled interventional robot was developed in [9], which has 2-DOF and force feedback. In [10], an endovascular tele-operated system including haptic feedback was presented, which can manipulate both catheter and guidewire. The endovascular tele-operated system can provide 2-DOF in catheter manipulation. In [11]-[12], another master–slave robot system allowing for 3-DOF was designed, which allow the surgeons to operate with a joystick or a graphical user interface. In [13]-[17], a tele-operated system, proving 2-DOF in the slave side, can measure the force precisely and realize the force feedback in the master side.

Based on the analysis of the above researches, some problems, having a greater impact on the operation precision, entire utilization of surgeon's existing dexterity, and convenient of installation of guidewire/catheter, exist. These problems are listed as follows: Firstly, the robot operates the guidewire/catheter in continuous promotion instead of reciprocating promotion, which cannot imitate the surgeon operation absolutely, and do not take good advantage of the surgeon's existing dexterity. Secondly, the guidewire/ catheter is operated by the rollers using the friction between the guidewire/ catheter and rollers, whose movement and rotation is not precise because of the possible slippage between the guidewire/catheter and the gripper. Thirdly, it is inconvenient for the assembly, such as guidewire/catheter installation before surgery and guidewire/catheter replacement during surgery. Finally, inaccurate force feedback makes surgeons' operation more error-prone, because of the existence of great axial friction existence in moving components.

In this study we addressed these limitations and developed a

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novel guidewire navigation robot that allows 2-DOF in manipulation of conventional steerable guidewire. Specifically, it can allow for various diameters guidewires, through the replacement of guidewire grippers with different diameters. The operation mode of the novel guidewire navigation robot imitates surgeon's manipulation of a conventional guidewire completely. Thus, the guidewire navigation robot can continue to take advantage of the surgeon’s existing dexterity. Also, the slippage between guidewire and guidewire gripper is eliminated, using a novel guidewire gripper, which fixes the guidewire with static connection instead of dynamic connection. It can improve the pushing and rotation precision of the guidewire. Another improvement in the presented robot is that it allows for simple and rapid assembly of guidewire installation before surgery and simple and rapid guidewire replacement during surgery. Furthermore, the proposed robot is easy to sterilize by replacing the rubber hose located in the slave side for supporting and isolating the guidewire from other components. Finally, the proposed robot can measure the axial force more accurately through the decrease of axial friction.

II. System Description

The novel guidewire navigation robot was designed as a telerobotic system, which is composed of master side and slave side. These two components work together to provide 2-DOF in guidewire navigation. Fig. 1 is a schematic diagram describing the interactions of system components. The surgeon manipulates the master side: pulls, pushes, and rotates the handle of the master side, with the help of image guidance (such as fluoroscopic imaging). The master side that takes advantage of surgeon existing dexterity skills, obtains the control signal imparted by the surgeon on the master unit, and control the movement of slave side after the real-time signal processing in the control unit. The slave side manipulate the guidewire with 2-DOF using the control signal transfered by the master side.

A. Master side

To collect the movement information of the surgeon operation, and reconstruct the movement of the guidewire, a master side performs two functions at least: collecting 2-DOF movement information, reconstructing the position and force/torque of the guidewire. In view of these requirements, a haptic device (Desktop-e, Phantom®device,Geomagic, US) is used.

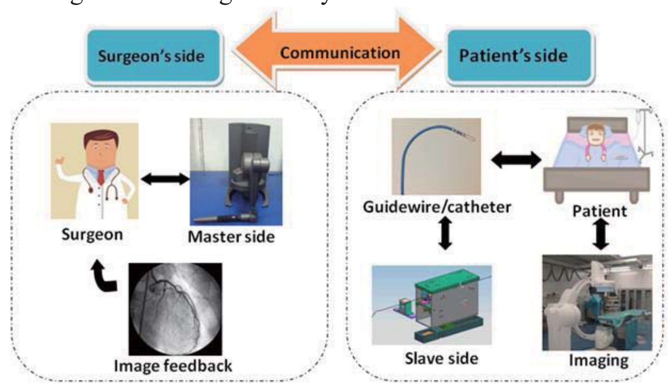
B. Slave side

The slave side, shown schematically in Fig. 2, is composed of a mobile platform, a shell, a gripping unit, and a driving unit.

(1)Mobile platform

The mobile platform was designed to manipulate the shell, which mount a driving unit, and a gripping unit. The mobile platform making use of motor and silk pole, allows for axial manipulation of the guidewire. When the surgeons operate (pull or push) the master side, the mobile platform move forward or backward by executing the command of control signal imparted by the master side. Meanwhile, the gripping unit and the driving unit, as well as the guidewire, will have the same movement with the mobile platform, because they are mounted on the shell.

The slave side operates the guidewire in reciprocating promotion instead of continuous promotion, which can imitate the surgeon operation absolutely, and take good advantage of the surgeon’s existing dexterity.



(a) Master side. (b) Slave side.

Fig. 1 Schematic diagram of the system, displaying the workflows and interactions of different components.

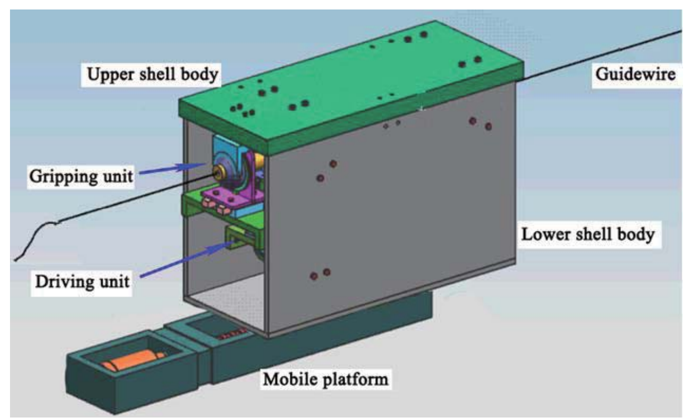


Fig. 2 Structure diagram of the slave side.

(2)Shell

To enable axial positioning of the guidewire with respect to the patient’s vein, and to allow for support of a driving unit and a gripping unit, a shell was developed. The shell is composed of a lower shell body and an upper shell body. The lower shell body mounted on the slipway of the mobile platform, connect to the upper shell body using hinges. The upper shell body is composed of a cone platen, a linear bearing platen, and an electromagnetic brake platen. The cone, the linear bearing, and the electromagnetic brake are fixed respectively in rotational direction, by closing the upper shell body and pressing the surface of the cone, the linear bearing, and the electromagnetic brake with the cone platen, the linear bearing platen, and the electromagnetic brake platen.

The surgeon can easily fixate and release the guidewire gripper quickly through opening and closure of the upper shell body, when the guidewire need to be installed before surgery or replaced during surgery.

(3)Gripping unit

The gripping unit, illustrated in Fig. 3, composed of measurement part and mechanical control part, can accurately measure the axial force and allow for manipulation of the guidewire. To measure the axial force of the guidewire accurately, a measurement part was developed, including force sensor, sliding bearing, thrust bearing, force platform, and cone. The force sensor mounted on the stent, is connected to the force platform, which is mounted on the sliding bearing. The guidewire gripper mounted on the stent with the linear bearing, transfer the force of guidewire to the force sensor through the force platform. Because of the assembly of guidewire installation before surgery and guidewire replacement during surgery, an axial clearance exists continuously, which takes a significant impact on the measurement of force. To eliminate axial clearance, a cone was designed, which is closed to the thrust bearing and can transfer the force of guidewire. The axial clearance can be eliminated quickly through compression of the cone platen when upper shell body is shut down by the surgeon. Also, the linear bearing and electromagnetic brake are fixed respectively by the compression of the linear bearing platen and electromagnetic brake platen, when upper shell body is closed.

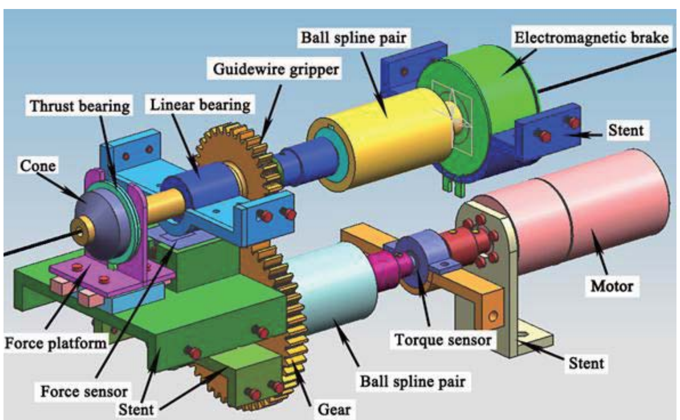
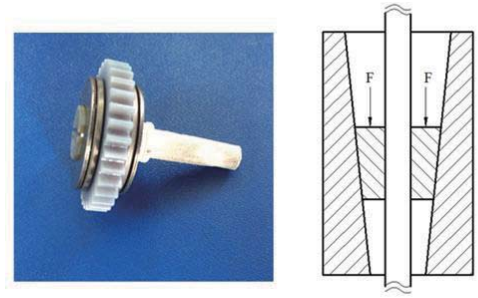


Fig. 3 Structure diagram of gripping unit and driving unit: the upper side is the gripping unit, and the lower side is the driving unit.

Besides, the shell of the ball spline pair is attached to the guidewire gripper by a coupling, and the electromagnetic brake mounted on a stent, connect to the ball spline pair using another coupling. The ball spline pair can transmit the torque of electromagnetic brake without axial friction, so all the components connected with the guidewire can move in the axial direction freely. In view of this, the force sensor measure axial force of the guidewire more accurately.

The mechanical control part can effectively realize the clamping/relaxation and rotation of the guidewire. The rotation of the ball spline pair can be restrained when electromagnetic brake is in the process of loss of power, as well as the right end of the guidewire gripper. A guidewire gripper, shown in Fig. 4(a), was developed to clamp and relax the guidewire, using the cone clamping theory. When right end of the guidewire gripper is fixed and left end is pushed inward by the rotation of the gear, the pawl clearance of guidewire gripper become smaller, so the guidewire is gripped by the guidewire gripper (Fig. 4(b)). Similarly, the guidewire can be relaxed with the assistance of outward pushing of left end of the guidewire gripper by inversion of the gear.

When the rotation of the guidewire is needed, the guidewire gripper grip and then rotate the guidewire, with the help of the rotation of the motor and gear, and no circumferential restriction of the ball spline pair because of loss of power of electromagnetic brake. When the axial movement guidewire is needed, the guidewire gripper grip the guidewire and then move forward or backward, with the assistance of shell movement drove by the mobile platform.



(a) (b)

Fig. 4 The guidewire gripper: (a) structure diagram of guidewire gripper, (b) schematic diagram of the cone clamping theory on the guidewire gripper.

(4) Driving unit

A driving unit, shown in Fig. 3, is designed to control the motion of guidewire gripper and the rotation of guidewire, and measure the torque of the guidewire. The driving unit is composed of motor, coupling, torque sensor, ball spline pair, linear bearing, gear, and stents. The motor, torque sensor, and linear bearing mount to the shell with stents. The motor can drive the gear effectively with the help of the ball spline pair, which transmit the torque of guidewire and can realize the axial moving without axial friction. The torque sensor, whose inner axis and outer axis mounted on the shaft of ball spline pair and motor shaft respectively, can easily measure the torque of the guidewire. The ball spline pair can move in axial direction freely with the help of linear bearing, which support the shell of the ball spline pair. The gear mounted on the shell of the ball spline pair, mesh the upper gear of the gripping unit, which can transmit the torque of guidewire and move in axial direction with no friction.

C. *Control method*

Under the instruction of control information from the master side, the salve side accomplishes the mission successfully, including clamping/relaxation, pushing/pulling and rotation of the guidewire, as well as the force/torque measurement, with the assistance of coordination of motor, gears, guidewire gripper, electromagnetic brake, and so on.

In slave side, the power source comes from two motors and electromagnetic brake, while the motion is diversiform, including clamping, relaxation, pushing, pulling, and rotation. So, the control method of the guidewire navigation robot is complex.

When the surgeon need to pull/push the guidewire, the model of guidewire is Advance/Retreat. In this state, the guidewire gripper should grip the guidewire firmly and no slippage between the guidewire and the gripper exists. So the state of the guidewire gripper must be turned into On. Also, the state of the guidewire gripper does not change until the slave side moves to the end of the mobile platform and need to move continuously and the gripped position of the guidewire need to be changed. The rotation of the ball spline pair and the right end of the guidewire gripper can't be restrained (can rotate freely), so electromagnetic brake is in the process of loss of power (in other words, the state of electromagnetic brake is Off). The guidewire realizes advance or retreat with the help of movement of the mobile platform through the corotation or inversion of the mobile platform's motor. In the process of advancing or retreating, the state of motor (in the shell) should be kept in Corotation or Inversion, if the guidewire need to realize corotation or inversion.

When the surgeon need to rotate the guidewire merely and no axial movement exists, the state of electromagnetic brake and guidewire gripper are similar to those description above. Meanwhile, the state of motor (in the shell) is Rotation and the motor rotates directionally under the command of control signal imparted by the master side.

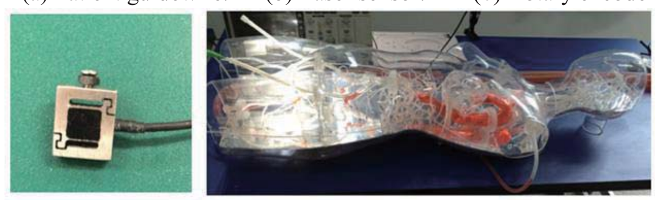
When the slave side moves to the end of the mobile platform and needs to move continuously (in other words, the gripped position of the guidewire should be changed), the model of guidewire is Switch. In this model, the state of electromagnetic brake is On, so the rotation of the ball spline pair is restrained, as well as the right end of the guidewire gripper. Meanwhile, the state of motor (in the shell) is turned into Corotation, and the state of the guidewire is turned into Off (the guidewire is relaxed) with the assistance of outward pushing of left end of the guidewire gripper by corotation of the gear (drove by the motor in the shell). Then, the state of the mobile platform is turned into Corotation or Inversion, in order to achieve the purpose of changing the gripped position of the guidewire. After that, the state of motor (in the shell) is turned into Inversion, and the state of the guidewire is turned into On (the guidewire is grasped) with the assistance of inward pushing of left end of the guidewire gripper by inversion of the gear (drove by the motor in the shell). Finally, the state of electromagnetic brake is turned into On, and the model of guidewire will be turned into another model, which can realize the advance, retreat, and rotation of the guidewire.

With the assistance of cooperation of the mobile platform, motor (in the shell), electromagnetic brake, and anther components, the model of guidewire can be turned into different models easily, and the slave side can realize the advance/retreat and rotation simply.

III. System Evaluation

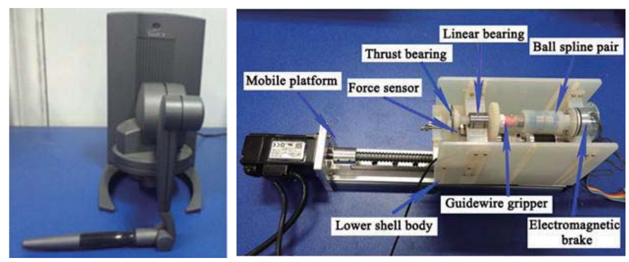
To evaluate feasibility of the novel guidewire navigation robot, a system evaluation is developed, including the verification of axial motion, rotational motion and axial force measurement. For these experiments, the patient guidewire was confined to a 0.014 inch (0.36mm) diameter (Shinobi, Cordis, JP) (Fig. 5(a)) and an EVE model (General Aniography Type C, FAIN-Biomedical, Inc. JP)(Fig. 5(e))was used. A laser sensor (LI-100, KEYENCE, JP)(Fig. 5(b)), a rotary encoder (HK50, Shenzhen HZJ Co., Ltd, CN) (Fig. 5 (c)), and a force sensor (LA-S2,BBLTC, CN) (Fig. 5(d)) were used for measuring the axial motion, rotational motion, and axial force separately. The complete developed system is shown in Fig. 6.

(a) Patient guidewire. (b) Laser sensor. (c) Rotary encoder.



(d) Force sensor. (e) EVE model.

Fig. 5 Experimental components.



(a) Master side (a haptic device) (b) Slave side.

Fig. 6 The guidewire navigation robot.

A. *Axial motion*

Axial motion precision has a great impact on the motion of the guidewire, which can allow the guidewire to pierce the vein easily because of the inaccuracy of the axial motion. To ensure security of the surgery, a high standard is developed: axial error is no more than 0.5mm. A laser sensor (LI-100, KEYENCE, JP) is used to measure the axial motion of the guidewire. The laser sensor, mounted on test-bed, is located on the front of the slave side. A piece of paper, mounted on the guidewire, is used for reflecting laser launched by the laser sensor. The position of the guidewire is confirmed by using the paper, which is used as a reference. The experimental devices are shown in Fig. 7. To evaluate the axial motion reliability of slave side, the axial motion of the guidewire and that of the mobile platform are compared. The axial motion of the guidewire is measured by the laser sensor, and the axial motion of the mobile platform is got from its own motor control unit. In order to obtain the axial error, the measurements are repeated 10 times.

B. *Rotational motion*

To measure the accuracy of rotational motion, a rotary encoder (HK50, Shenzhen HZJ Co., Ltd, CN) was used, whose inner ring is mounted on the guidewire. The mounted position is located at 5mm lateral side of the slave side on the guidewire. We enact the accuracy of rotational motion at a high standard: no slippage between the guidewire and the gripper exists. In order to evaluate the rotational motion reliability of slave side, the rotational motion of the guidewire and that of the motor (in the shell) are compared. The rotational motion of the guidewire is measured by the rotary encoder, and the rotational motion of the motor (in the shell) is got from its own rotary encoder. Also, the measurements are repeated 10 times, in order to obtain the rotational error.

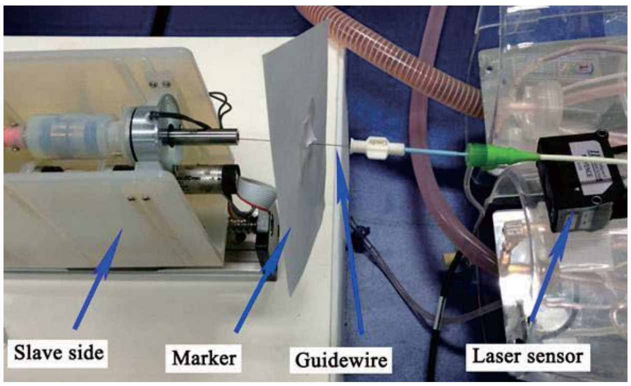


Fig. 7 The experimental devices for axial motion evaluation.

C. Force measurement

When the surgeon operates the master side, the surgeon can perceive the force feedback, which is similar to operating the end of guidewire by hand. The force feedback reappears by measuring the force of the end of guidewire with slave side's force sensor. So, the slave side's force sensor is the key component, and it should precisely measure the force of the end of guidewire. In order to evaluate the accuracy of the force measurement on the slave side, we compare the force of the tip of guidewire with that of the end of guidewire. The force of the end of guidewire is measured by the slave side's force sensor (LA-S2,BBLTC, CN). The force of the tip of guidewire is measured by the other force sensor (LA-S2,BBLTC, CN), which is located on the front of the slave side (the force sensor is contact with the tip of guidewire). The experimental devices are illustrated in Fig. 8. The measurements are repeated 10 times.

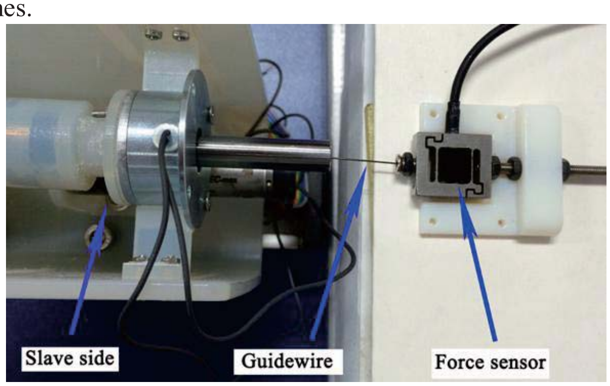


Fig. 8 The experimental devices for force measurement evaluation.

IV. Results and Discussions

A. Evaluation in axial motion

To evaluate the axial motion reliability of slave side, axial motion of the guidewire and that of the mobile platform were measured separately. These motion date were compared, and a representative set of comparison date were shown in the Fig. 9. Fig. 9 shows the excellent agreement between the axial motion of guidewire and that of the mobile platform. The maximum axial error between the axial motion of the guidewire and that of the mobile platform was 0.5mm.

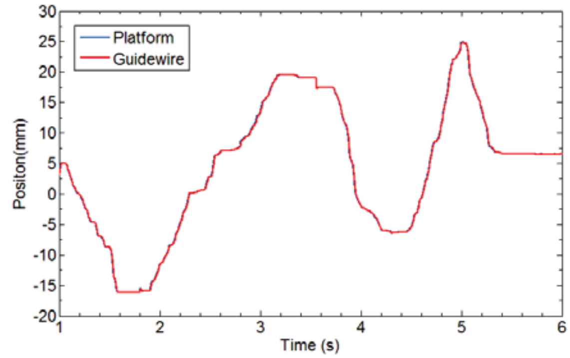


Fig.9 Axial motion of the guidewire and the mobile platform.

The axial motion error exists because of measurement error and the deformation of guidewire. Also, the deformation of guidewire plays the lead role in the axial motion error. The axial motion error is inevitable but acceptable. So the slave side can realize the required accuracy in axial motion.

B. Evaluation in rotational motion

We supposed that there is no transmission error exists between rotational motion of the guidewire gripper and that of the motor (in the shell), because of rigid transmission of the gear. The result shows that the diversification of the rotational motion of the guidewire was consistent with that of guidewire gripper. We could get a conclusion that the slippage between guidewire and guidewire gripper did not exist, even if the errors appear: the maximum rotational error between the rotational motion of the guidewire and that of the guidewire gripper was 0.8 degree, because the measurement error and the deformation of guidewire are inevitable.

C. Evaluation in force measurement

The force of the end of guidewire was measured by the slave side's force, and the force of the tip of guidewire was measured by the other force sensor (Fig. 8, Force sensor). These motion dates were compared, and a representative set of comparison date were shown in Fig. 10. The maximum error between the force of the end and that of the tip was 0.031N.

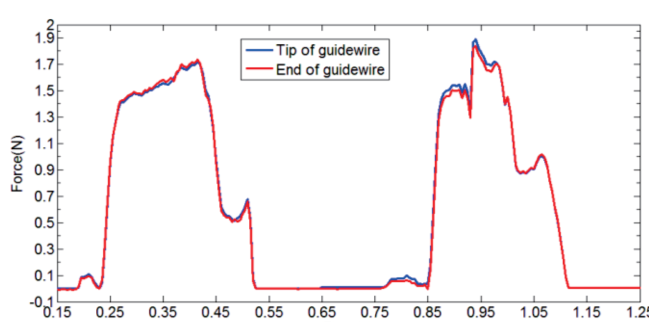


Fig.10 Comparison the force: the end of guidewire and the tip of guidewire.

In Fig. 10, the trend of the end of guidewire' force was agreeable with that of the tip of guidewire's force. The force error exists because of measurement error, deformation of guidewire, and friction. Also, the friction, existing in the connection of different components, can't be eliminated. In order to improve the operation accuracy of slave side, the only practical measure is decrease of friction, which exists in the connection of different components in slave side. Fig. 10 shows that the friction is decreased in the range of acceptable situation, and the slave side can measure the force correctly enough.

Actually, when the surgeons operate the guidewire in traditional way (without the help of robot), the surgeons operate the end of guidewire directly with their hands, and the axial motion, rotational motion, and force of the guidewire that they perceived all come from the end of guidewire. In this case, these errors did not have serious impact on the axial motion control, rotational motion control and force feedback. So, these results proved the feasibility of the novel guidewire navigation robot, and the proposed robot can potentially increase guidewire motion precision and accuracy.

V. Conclusions

A novel guidewire navigation robot was developed to manipulate the guidewire, that allow for 2-DOF and take advantage of the surgeon's existing dexterity. Also, we fix the guidewire with static connection instead of dynamic connection, thus the slippage between guidewire and the gripper of robot is eliminated. Meanwhile, the slave side of the presented robot can easily fixate and release the guidewire gripper quickly by open and closure of the upper shell body of slave side. A system evaluation including axial motion, rotational motion, and force measurement were given to evaluate the feasibility of the novel guidewire navigation robot. We got the results of the experiment using the novel guidewire navigation robot to operate the guidewire. The results proved feasibility of the novel guidewire navigation robot by referring to the system evaluation.

Meanwhile, some disadvantages will likely to appear with the usage of the novel robot. Firstly, the guidewire is grasped by the guidewire gripper by passing through the cone, thrust bearing, linear bearing, guidewire gripper, ball spline pair, and electromagnetic brake one by one. The route of passing through these components is so long that it is difficult for disinfection. Secondly, the slave side of the presented robot can easily fixate and release the guidewire gripper quickly through the open and closure of the upper shell body of slave side. So, the operation accuracy of robot depends on the assembly accuracy of slave side. But the assembly of slave side is completed by the surgeons during the minimally invasive surgery. In this case, the operation accuracy of robot is fairly random because of the tension and lack of mechanical knowledge of the surgeons during the surgery. In the future work, we should pay great attention to those factors, which can take a significant impact of operation precision and installation convenience.

VI. Acknowledgment

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