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Design and Evaluation of a Bio-inspired Robotic Hand for Percutaneous Coronary Intervention

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Abstract— **The percutaneous coronary interventions (PCI) require complex operating skills of the interventional devices and make the surgeons being exposed to heavy X-ray radiation. Accurate delivery of the interventional devices and avoiding the radiation are especially important for the surgeons. This paper presents a novel dedicated dual-finger robotic hand (DRH) and a console to assist the surgeons to deliver the interventional devices in PCIs. The system is designed in the master-slave way which helps the surgeons to reduce the exposure to radiation. The mechanism of the DRH is bio-inspired and motions are decoupled in kinematics. In PCI procedures, the accuracy of the guidewire delivery and the catheter tip placement have significant effects on the surgical results. The performances of the DRH in delivering the guidewire and the balloon/stent catheter were evaluated by three surgical manipulations. The results show that the DRH has the ability to deliver the guidewire and the balloon/stent catheter precisely.**

I. INTRODUCTION

Cardiovascular disease is the leading cause of death globally. More than 17.3 million people died of cardiovascular disease in 2008, which represented 30% of all deaths [1]. Among these deaths, an estimated of 7.3 million were caused by the coronary heart disease [2]. Currently, coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI) are two main treatments for the coronary heart disease. CABG belongs to open surgery, which brings large trauma to the patients and needs long recovery time. While PCI is performed in a minimally invasive way and has become the most prevalent treatment for the coronary heart disease.

In the conventional PCI procedures, X-ray imaging is used to guide the interventional devices (the guidewire and catheters) in the human blood vessels. Therefore, the interventional radiologists have been worked in the ionized catheterization laboratory for several decades. To reduce the radiation to the surgeon, heavy lead aprons are worn during the operation. However, the radiation to the surgeon's head and hands is still unavoidable. Thus, longtime working in catheterization laboratory results in the cumulative effect of radiation is significant. Long hours of working by wearing lead aprons also leads to orthopedic injuries. These disadvantages of PCI bring poor performance and loss of workdays to the interventional radiologists [3].

To address these problems, researchers have developed a variety of robotic systems to assist the surgeon in delivering the interventional devices [4]. Friction wheels or belts are used for delivering the interventional devices. Beyar *et al.* proposed a remote navigation system (RNS) [5]. The system consists of a bedside unit and an operator control unit. The guidewire and balloon/stent are separately delivered. The RNS is then commercialized by the Corindus Inc. and named CorPath 200. The CorPath 200 robotic system has performed clinical studies and obtained FDA approval [6], [7]. The Magellan robotic system developed by Hansen Medical is a specialized robotic catheter system designed for vascular interventional surgery [8]. Tanimoto *et al.* developed a telesurgery system for intravascular neurosurgery [9]. Thakur *et al.* developed a remote catheter navigation system that includes a catheter sensor and a catheter manipulator [15].

Another kind of catheter robotic systems use translational platforms and graspers to deliver the interventional devices. Arai *et al.* presented a linear stepping mechanism (LSM) for intravascular neurosurgery [10]. Cercenelli *et al.* developed a telerobotic system for delivering the electrophysiology catheter into human body during the cardiac interventional procedures [11]. Kesner *et al.* proposed a robotic catheter system to perform structural repairs within the beating heart [12]. Guo *et al.* developed a robotic catheter manipulating system for the endovascular intervention [13], [14]. Payne *et al.* presented a robotic system for catheter manipulation and evaluated the effectiveness of force feedback during the catheter insertion [16]. Srimathveeravalli *et al.* developed a system for endovascular teleoperated access and analyzed the human motions [17].

Magnetically steered robotic systems have also been proposed in the last few years. The Niobe magnetic navigation system (Stereotaxis, MO, USA) uses a magnetic field created by two permanent magnets to steer a specialized catheter with magnets at the tip [18]–[21]. Another magnetically steered robotic catheter system is the Catheter Guidance Control and Imaging (CGCI) system (Magnetecs Inc., CA, USA), which uses reshaping of magnetic fields created by eight electromagnets mounted around the patient to steer a magnetized electrophysiology catheters [22].

However, some problems still exist in the current endovascular robotic systems. In [5]–[7], two sets of rollers are used for the axial and radial movement of the guidewire, but the motions of the two sets of rollers would hinder each other when translating and rotating the guidewire simultaneously. [8] uses belts structure and special active catheter, the diameter of the active catheter is large and can not enter the coronary artery. The problem of the belts structure is the torsion of the guidewire. Besides, it cannot deliver the

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balloon/stent catheter after the guidewire delivering. [9]–[17] use graspers to deliver the catheters. The problem of grasper structure is not convenient for the loading and unloading of the interventional devices in real surgery. In addition, the grasper structure can only deliver a single catheter and can not handle other devices in the PCI procedures. The magnetically steered robotic systems in [18]–[22] use special magnetic devices and not suitable to the patients with implanted devices.

To address these problems, we developed a novel robotic hand (DRH) to help the surgeons to manipulate the interventional devices in the PCI procedures [23]. Compared with the previous work, the DRH has a novel structure and realizes the delivering of the guidewire and balloon/stent catheter in a more dexterous way. The DRH is designed to imitate the surgeon's finger operation by two bionic rollers. It can deliver different kind of devices in the PCI. The loading and unloading of the devices are very convenient because of the open structure of the DRH. An intuitive console was designed for the DRH, so the surgeons can control the DRH via the console outside the catheterization laboratory. Because the accuracy and precision of delivering the guidewire and the catheter are especially important in PCI procedures, the purpose of this paper is to evaluate the performances of the DRH. The results of the performance evaluation provides the basis for animal and clinical trials.

The remainder of this paper is organized as follows. Section II provides the architecture of the DRH and the console. In Section III, experiments are carried out to evaluate the performance of the DRH. Finally, we conclude in Section IV with the discussion of results and directions for the future work.

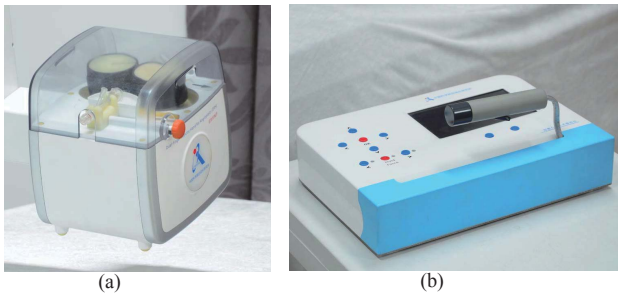
II. System Architecture

A. Dual-finger Robotic Hand

The PCI robotic system developed by our lab contains two main sections: the Dual-finger Robotic Hand (DRH) and the console (Fig.1). The function of the DRH is to deliver the interventional devices such as the guidewire and the balloon/stent catheter. The operator uses the console to control the DRH.

The human vascular system has numerous branches and bifurcations. To reach the stenotic vessel, the advancement and rotation manipulation of the devices are performed by the surgeon's right thumb and right forefinger. Specifically, when the surgeon clamps the device with the right thumb and the right forefinger, then moves the whole right hand from the right side to the left side, the device will be advanced along its axial direction; when the surgeon moves the two fingers in the opposite directions that perpendicular to the device's axis, the device will be rotated around its axis. Inspired by the motions of the surgeon's two fingers, the DRH imitates the function of the surgeon's two fingers by using two rollers.

Since the mechanism of the DRH is bio-inspired, the two rollers are named bionic thumb and bionic forefinger. The bionic thumb is the driver roller and has two degrees of freedom (DOF); the bionic forefinger is the passive roller



(a) (b)

Fig. 1. The master-slave vascular intervention robotic system. The slave side is the DRH (a), which delivers the guidewire and the balloon/stent catheters. The console (b) is the master side and operated by the surgeon to control the DRH.

and has three DOFs. The first DOF of the bionic thumb and the bionic forefinger is rotating about their axes. By rotating about the axes, the DRH advances or retracts the interventional devices. The second DOF of these two bionic fingers is translating up or down along their axes. To hold the height of the devices unchanged, the translational directions of those two bionic fingers are always opposite.

In the DRH, the first and second DOF of the bionic fingers are completely decoupled. Therefore, the translation and rotation of the interventional devices are completely independent. So, no mutual resistance exists between the axial and the radial movement of the devices. As mentioned above, when passing through bifurcations, the devices should be advanced and rotated simultaneously. The decoupled structure benefits the DRH to manipulate the devices as dexterous as human's fingers, especially passing through the bifurcations.

The bionic forefinger has one more DOF. The additional DOF is translation away from the bionic thumb. This DOF enables the DRH to clamp the devices like human's fingers. A motor is used to control the clamping force. Besides, the gap between the two bionic fingers in the DRH is implemented in an open structure. This structure is convenient for the loading and unloading of the devices.

B. Console for the DRH

To reduce the radiation to the surgeons, a console is designed to control the DRH remotely. As shown in Fig. 1(b), the console of the DRH is composed of a handle and a control panel. The handle consists of an enable button and a rotation tip. Since the master-slave structure is adopted, the linear displacement of the handle makes the DRH deliver the guidewire or catheter in the axial direction; the rotation tip makes the DRH rotate the guidewire in the radial direction. The control panel contains some functional buttons and a LCD screen. To reduce the lag time, we implemented the control algorithms on a 32-bit ARM microcontroller (STM32F4, STMicroelectronics, USA). The axial and translation movements of the rollers are driven by two stepper motors.

In DRH, the displacement of the guidewire/catheter can

be calculated by the following formula:

$$s = \frac{\pi n_p \theta_s R_{roller}}{180 i_s i_r} \tag{1}$$

where n_p is the number of pulses generated by the controller, θ_s is the step angle of the stepper motor, i_s is the subdivision number of the motor driver, i_r is the reduction ratio of the gearbox, R_{roller} is the radius of the driver roller.

The rotation angle of the guidewire/catheter is calculated by

$$\theta = \frac{n_p \theta_s i_g i_l}{\pi i_s i_r D} \tag{2}$$

where i_g is the gear ratio of the rotation motor, i_l is the lead of screw, D is the diameter of the guidewire/catheter.

III. Experiments and Results

A. Experimental Design and Setup

To evaluate the effectiveness and performance of the DRH, two experiments were designed according to the sequence of the PCI procedures. The first experiment was delivering the guidewire. The manipulation of delivering the guidewire can be divided into axial translation and radial rotation. In our experiment, the axial translation and radial rotation of the guidewire was conducted respectively. It is worth mentioning that the surgeons sometimes advance and rotate the guidewire simultaneously in real surgery. The purpose of the second experiment was to validate the delivering of the balloon/stent catheter after the guidewire delivering. Thus, the balloon/stent catheter was delivered along the guidewire in the second experiment.

To measure the position and orientation of the interventional devices directly, an electromagnetic (EM) tracking system (Aurora, Northern Digital Inc., Canada) was used in our experiments. The system is resistant to medical metals, so the precision of the measurements can be guaranteed. An experimental guidewire was made by attaching a six DOFs sensor (Aurora Mini 6DOF sensor, NDI) to the tip of a medical guidewire (Reflex steerable guidewire, Cordis Corp., USA). In order to measure the rotation angle of the guidewire exactly, the sensor and the guidewire were connected by a piece of guiding catheter to ensure they were coaxial to each other. Because the balloon and stent catheters are delivered along the guidewire, only position data are needed. Therefore, five DOFs sensors (Aurora 5 DOFs sensor, NDI) were installed on the tip of a medical balloon catheter (Emerge dilatation catheter, Boston Scientific Corp., USA) and a stent catheter (Promus Premier, Boston Scientific Corp., USA) (see Fig.2 (a)). The dimensions of the guidewire, catheter, and sensors used in our experiments are detailed in Table I.

The experimental setup is shown in Fig.2 (b). To simulate the delivery of devices in the vessel, the guidewire and catheter were delivered in a acrylic tube. The tube was mounted on an acrylic table, under which was the magnetic field generator of the EM tracking system. The position of the sensor can be easily converted to the displacement of the interventional devices. The position and orientation data from the EM tracking system were sampled at 40 Hz. Because of the limited measurement volume of the tracking system and the flexibility of the guidewire/catheter, we constrained the displacement of the guidewire and catheter within a distance of 200 mm. The data acquisition program runs on a quad-core Intel Core i7-2600 PC. The number of pulses from the robotic system is sampled at 200 Hz. The parameters in Eq. 1 and Eq. 2 are listed in Table II.

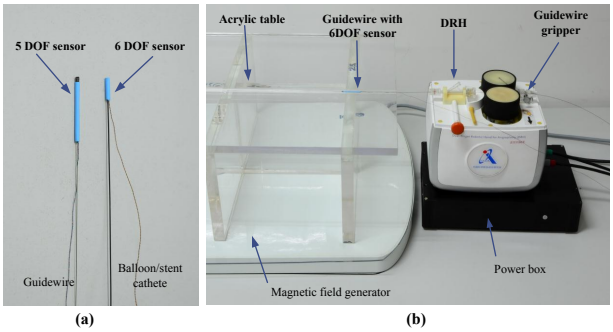


Fig. 2. (a) The guidewire and the balloon/stent catheter used in the experiment, the tips of the guidewire and the catheters are with 6 or 5 DOF sensors. (b) The experimental setup. A electromagnetic tracking system is used to obtain the displacement and the rotation angle of the interventional devices.

TABLE I
Dimensions of the Interventional Devices and Sensors

Interventional devices	Diameter(mm)	Sensors	Size(mm)
Guidewire	0.36	Five DOF sensor	0.8 x 11
Balloon catheter	0.7	Six DOF sensor	1.8 x 9
Stent catheter	0.7		

B. Experiment I: Guidewire Delivery

1) Guidewire Translation: In order to evaluate the translational performance, the guidewire was advanced at a speed of 10 mm/s for 5 trials. The number of pulses from the robot controller and the position of the sensor from the EM tracking system were simultaneously sampled by the data acquisition program. The number of pulses from the robot controller was used to calculate the expected trajectory; the position data from the EM tracking system were used to calculate the actual trajectories. The ith position data set from the EM tracking system was denoted as $P_i = \{p_{i1}, p_{i2}, p_{i3}, ..., p_{iN}\}$, where p_{i1} was the initial position of the guidewire, p_{iN} was the final position of the guidewire, N was the number of data in each set. The desired displacement data set calculated by Eq. 1 was $Q = \{q_1, q_2, q_3, ..., q_N\}$, where $q_1 = 0$, q_N was the desired final position of the guidewire. The RMS error of the jth position was calculated by Eq.3, where $M = 5$.

$$RMS_{tj} = \sqrt{\frac{1}{M}\sum_{i=1}^{M}(p_{ij} - q_j)^2} \tag{3}$$

Performances of the guidewire translation at different speeds were evaluated. In operating room, the surgeon inserts the guidewire at different speeds. Specifically, when the

TABLE II

THE VALUE OF DRH PARAMETERS

Parameter	Value	Parameter	Value	Parameter	Value
θ_s	7.5 °	i_r	25	i_s	8
R_{roller}	30.60 mm	i_l	1 mm	i_g	2

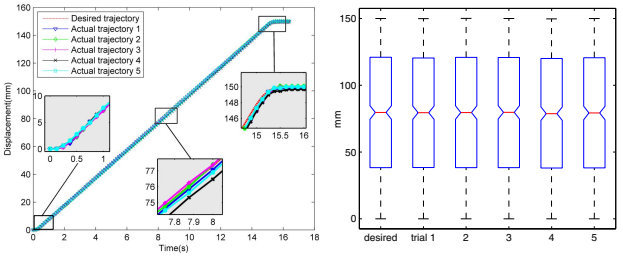


Fig. 3. *(Left)* The dynamic tracking trajectories of the DRH in the guidewire translation under v = 10 mm/s. *(Right)* The statistical boxplot of the desired and actual trajectories. No statistical significance between the desired and actual trajectories ($p > 0.05$).

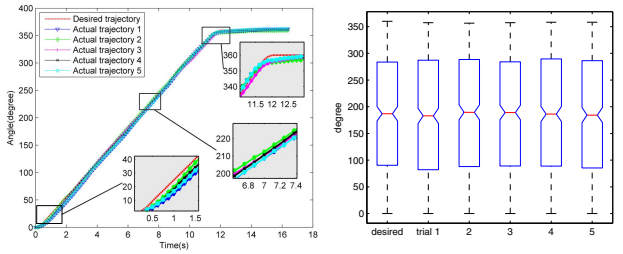


Fig. 4. *(Left)* The tracking trajectories of the DRH in the guidewire rotation under w = 30°/s. *(Right)* The boxplot of the desired and actual trajectories showed no statistical significance ($p > 0.05$).

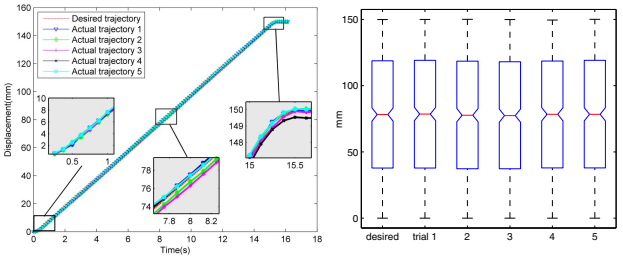


Fig. 5. *(Left)* The dynamic tracking trajectories of the DRH in the balloon/stent catheter translation, the translational speed v = 10 mm/s. *(Right)* The boxplot of the desired and actual trajectories showed no statistical significance ($p > 0.05$).

distal of the guidewire is in the guide catheter, a high speed is needed for reducing surgical time; when the distal of the guidewire is in the coronary artery, especially passing through a bifurcation or a stenotic vascular, a very low speed is needed for precise manipulation. In this experiment, different speeds from 0.5 mm/s to 60 mm/s were chosen and the tracking performance under these speeds were evaluated. To assess the tracking performance under varying speed, the speed of the guidewire was set to increase at constant acceleration or decrease at a constant deceleration.

2) Guidewire Rotation: The rotation manipulation of the guidewire is much difficult than the translation manipulation

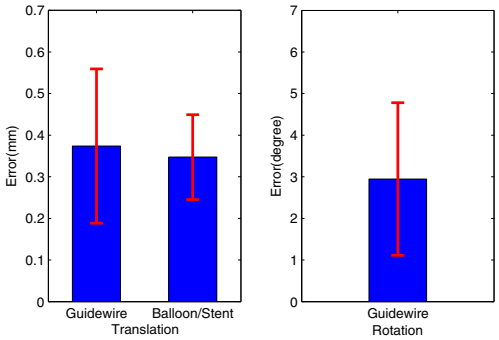


Fig. 6. The mean and standard deviation of the RMS error in the translation of the guidewire, balloon/stent catheter *(Left)*, and the rotation of the guidewire *(Right)*.

since the dimension of the guidewire. As shown in Table II, the diameter of the guidewire is extremely small (0.35 mm), thus the perimeter of the guidewire is also very small (1.08 mm).

To evaluate the performance of the rotation, the guidewire was set to rotate 360 degrees at the speed of 30 degree/s. The rotation experiment was also conducted for 5 trials. The ith orientation data set from EM tracking system was denoted as $W_i = \{w_{i1}, w_{i2}, w_{i3}, ..., w_{iN}\}$, where w_1 is the initial angle of the guidewire, w_{iN} is the final angle after rotation. The desired rotation data set calculated by Eq. 2 was denoted as $V = \{v_1, v_2, v_3, ..., v_N\}$, where $v_1 = 0$, v_N is the desired final angle. The RMS error of the jth angle was calculated by Eq.4, where $M = 5$.

$$RMS_{rj} = \sqrt{\frac{1}{M}\sum_{i=1}^{M}(w_{ij} - v_j)^2} \tag{4}$$

C. Experiment II: The Balloon/Stent Catheter Translation

In PCI surgery, after delivering the guidewire to the target vascular, the balloon catheter and the stent catheter are then delivered along the guidewire in sequence. Because the diameter of the balloon and stent catheter are much larger than that of the guidewire(0.35 mm vs. 0.7 mm), the DRH only delivered the balloon or stent catheter when the two bionic fingers clamped the guidewire and the catheter at the same time. To evaluate the performance of delivering the balloon and stent catheter along the guidewire, we put both the guidewire and the balloon catheter between the two bionic fingers; the guidewire was also clamped by the guidewire gripper.

D. Results

As shown in Fig. 3 (*Left*), the actual trajectories of the guidewire tracked the desired trajectory during the guidewire advancement under the speed of 10 mm/s. Three stages were magnified, the first stage was the acceleration process and a = 20 mm/s^2. In this stage, the translational speed of the guidewire was accelerated from 0 to 10 mm/s within 0.5s. In the second stage, the guidewire was set to advance at a constant speed of 10 mm/s, the measured data showed the actual displacement of the guidewire was very close to the desired

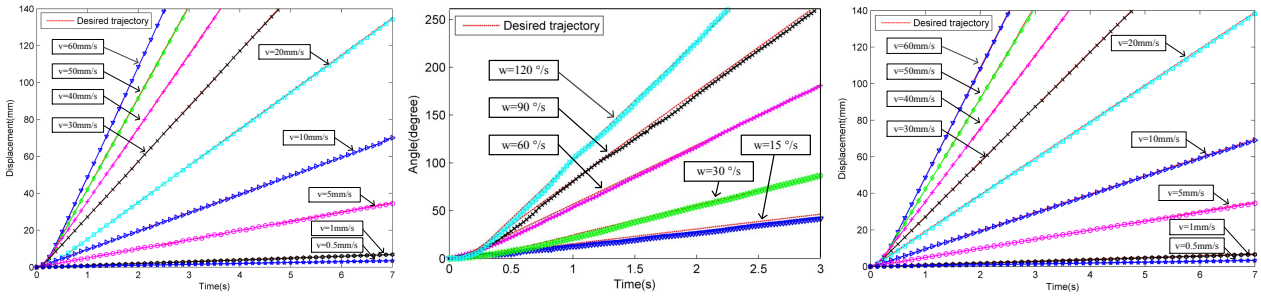


Fig. 7. The trajectories of the guidewire translation *(Left)*, guidewire rotation *(Middle)*, and the balloon/stent catheter translation *(Right)* under different speeds. The translation speed ranged from 0.5 mm/s to 60 mm/s, the rotation speed ranged from 15 °/s to 120 °/s.

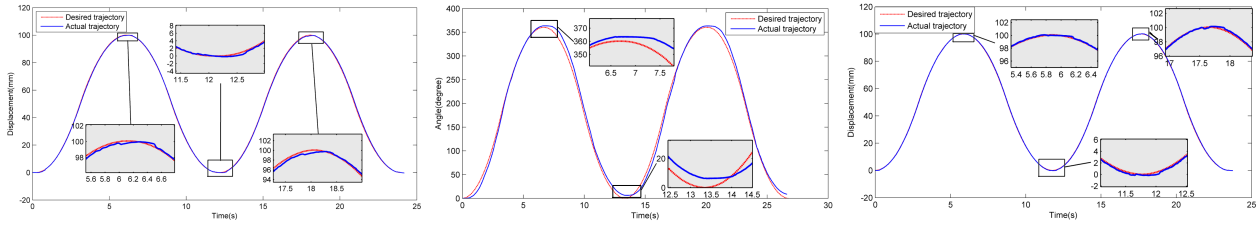


Fig. 8. The trajectories of the guidewire translation *(Left)*, guidewire rotation *(Middle)*, and the balloon/stent catheter translation *(Right)*. The acceleration of the guidewire and balloon/stent catheter translation was ± 12 mm/s^2, the acceleration of the guidewire rotation was ± 33.17 °/s^2.

displacement. The third stage was the deceleration process and a = 20 mm/s^2. In this stage the speed was decelerated to 0 within 0.5 s. The acceleration and deceleration process were essential for achieving a high accuracy, because the phenomenon of losing steps of the stepper motors should be eliminated. The main factor for the error between the desired and actual trajectories was the roundness error of the thumb finger.

Fig.4 (*Left*) shows the dynamic performances of the five rotation trials of the guidewire. In the beginning stage, the error between the desired trajectory and the actual trajectory were large because the actual rotation speed was less than desired rotation speed. The error became smaller in the second stage. In the third stage, the speed of rotation decreased to zero. The translational tracking trajectories of the balloon/stent catheter under the speed of 10 mm/s are shown in Fig.5. Acceleration and deceleration stages were also designed.

For each of the manipulations repeated in five trials, statistical significance was assessed with the Kruskal-Wallis test. The statistical distributions of the desired and actual trajectories were shown in Fig.3*(Right)*, Fig.4*(Right)* and Fig.5*(Right)*. Fig.7 shows the performances of the guidewire translation *(Left)*, guidewire rotation *(Middle)*, and balloon/stent catheter tanslation *(Right)* under different speeds. The guidewire tracked the desired translational speed from 0.5 mm/s to 60 mm/s and the desired rotational speed from 15 °/s to 120 °/s. The balloon/stent catheter also tracked the desired translational speed from 0.5 mm/s to 60 mm/s. The tracking error showed no significant difference between different speeds.

Fig. 8 shows the tracking trajectories of varying speeds. The tracking performance of the guidewire under varying speed was shown in Fig.8 *(Left)*, the translation speed of the guidewire and balloon/stent catheter varied at a constant acceleration of $a = \pm 12$ mm/s^2. The acceleration of the guidewire rotation was ± 33.17 °/s^2. The guidewire rotation had a larger error when the speed changing direction because the deformation effect of the rubber sheath.

IV. Discussion and Conclusion

In this paper, a robot for assisting the interventional radiologists in percutaneous coronary interventions (PCI) is presented. The system is designed in a master-slave way to assist the surgeons in delivering the guidewire and the balloon/stent catheter during the PCI. The bio-inspired DRH has a very compact driving mechanism and a decoupled structure in kinematics, which benefits the dexterity of the manipulation. The performances of the DRH were evaluated by three surgical manipulations: translating the guidewire, rotating the guidewire, and translating the balloon/stent catheter. The results show the DRH has the ability to manipulate the guidewire and the catheters precisely.

The main factor that affected the accuracy of the translation manipulation was the roundness error of the thumb finger. Since the translation displacement was the arc length of the thumb roller, a minor error of radius was amplified by 2π. Factors that caused error in guidewire rotation manipulation were the elastic deformation of the rubber sheath and the parallelism of the two rollers. The deformation effect of the rubber sheath caused a delay in the rotation manipulation. These limitations will be solved by improving the machining process and using less deformative materials. Also, methods on compensating the roundness and parallelism error of the rollers will be investigated to improve the delivering precision of the DRH.

In our next step, the time lag and accuracy of the robotic system including both the DRH and the console of the DRH will be evaluated. A torque sensor will be installed into the DRH to measure the resisting force during the delivery of the interventional devices and feedback this force to the console for the surgeon. Future work will also include the animal and clinical trials to validate the safety, effectiveness, and robustness of the robotic system.

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