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Design and Performance Evaluation of a Novel Vascular Robotic System for Complex Percutaneous Coronary Interventions

Han-Lin Zhao[1,2], Shi-Qi Liu[2], Xiao-Hu Zhou[2], Xiao-Liang Xie[*,1,2], Zeng-Guang Hou[1,2,3], Yan-Jie Zhou[1,2], Lin-Sen Zhang[1], Mei-Jiang Gui[1,2], and Jin-Li Wang[4]

Abstract— **The robotic-assisted percutaneous coronary intervention is an emerging technology with great potential to solve the shortcomings of existing treatments. However, the current robotic systems can not manipulate two guidewires or ballons/stents simultaneously for coronary bifurcation lesions. This paper presents VasCure, a novel bio-inspired vascular robotic system, to deliver two guidewires and stents into the main branch and side branch of bifurcation lesions in sequence. The system is designed in master-slave architecture to reduce occupational hazards of radiation exposure and orthopedic injury to interventional surgeons. The slave delivery device has one active roller and two passive rollers to manipulate two interventional devices. The performance of the VasCure was verified by *in vitro* and *in vivo* animal experiments. *In vitro* results showed the robotic system has good accuracy to deliver guidewires and the maximum error is 0.38mm. In an animal experiment, the interventional surgeon delivered two guidewires and balloons to the left circumflex branch and the left anterior descending branch of the pig, which confirmed the feasibility of the vascular robotic system.**

I. Introduction

Benefit from minimally invasive, short recovery time, and low risk, percutaneous coronary intervention (PCI) has become the standard strategy for cardiovascular disease (CVD). However, accumulated radiation exposure for interventional surgeon increases the risk for cancers and cataracts [1]. Heavy lead apron and long hours of standing also cause orthopedic problems [2]. Vascular robotic systems are developed to overcome these problems. Vascular robotic systems mainly adopt the master-slave architecture, which makes surgeons get rid of lead aprons. Clinical evidence has shown robotic-assisted PCI can decrease radiation exposure by over 97% compared to traditional PCI [3]. Besides, the vascular robotic systems can improve control accuracy and measure lesion length precisely.

One type of vascular robotic systems adopts friction wheels to deliver the guidewire, such as Corpath GRX robotic system [4], R-One robot [5]. Thakur *et al.* designed a remote catheter navigation system and the catheter is held by the drive wheel and a series of spring rollers. A motor actuates the catheter in the axial direction by the drive wheel [6]. The other type of system uses translational platform to achieve linear motion of guidewires [7]–[10]. Wang *et al.* designed a unique mechanism that has multi-manipulators to realize the translation and rotation of catheter [11].

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[1]State Key Laboratory of Management and Control for Complex Systems, Institute of Automation, Chinese Academy of Sciences, Beijing 100190, China;(*corresponding author to email:xiaoliang.xie@ia.ac.cn)

[2]School of Artificial Intelligence, University of Chinese Academy of Sciences, Beijing 100049, China; Email:zhaohanlin2019@ia.ac.cn

[3]CAS Center for Excellence in Brain Science and Intelligence Technology, Beijing 100190, China.

[4]China University of Mining and Technology, Beijing 100083, China.

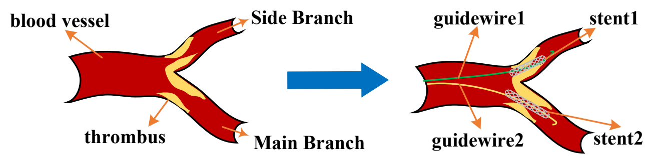


Fig. 1. Two-stent technique for bifurcation lesion

Interventional surgeons often encounter complex lesions of the coronary arteries, especially bifurcation lesions, which account for 1520% of all PCI [12]. As shown in Fig. 1, the two-stent technique is an approach to treat complex bifurcation lesions. However, the existing vascular robotic systems are unable to manipulate multiple interventional devices simultaneously so that many complex lesion cases still need manual assistance [13].

To address the limitation that the vascular robotic systems only control a single interventional device, we present VasCure, based on the vascular robotic system [14] to achieve manipulating two guidewires, balloons/stents during the vascular intervention. Besides, the mechanical structure of the system is convenient for loading and unloading interventional devices. The performance of the vascular robotic system was verified by *in vitro* and *in vivo* animal experiments.

II. System Architecture

The VasCure consists of a master console and a slave delivery device. During the vascular intervention, the surgeon operates the master console in a radiation-free room. The master console acquires the surgeon's push, pull and twist motion. Then, the slave delivery device advances and rotates guidewires following the motion information from the master console. The communication between the master console and the slave delivery device is based on TCP/IP protocol. The 5G commercial network provides low-latency connections, which makes it possible for the surgeon to control coronary devices over hundreds of kilometers. The schematic diagram of the VasCure is shown in Fig. 2.

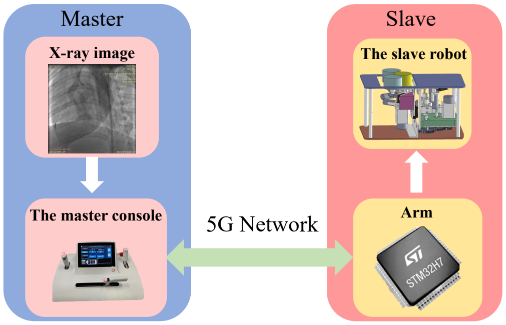


Fig. 2. The schematic diagram of the VasCure

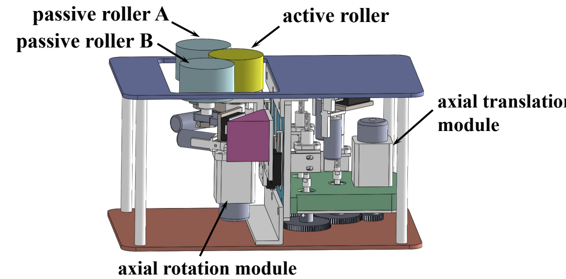


Fig. 4. The structure of the delivery device

A. The Master Console

As shown in Fig. 3, the master console consists of a guidewire handle, two joysticks, and a graphical user interface (GUI). The translation movement of guidewires is controlled by pushing and pulling the handle, the rotation of guidewires is controlled by rotating the knob on the handle in clockwise or counterclockwise directions. The surgeon can push the handle while rubbing the knob to control the longitudinal and rotational movements of the guidewires. The left joystick advance and retract the catheter, the right joystick advance and retract the balloon.

The GUI can display real-time information of the guidewire, catheter, and balloon during the delivery process, including delivery distance, delivery speed, and rotation angle. The surgeon can touch the button on the screen to adjust the interval between the active roller and passive rollers to select the working channel.

B. The Slave Delivery Device

The structure of the delivery device, as shown in Fig. 4 , is inspired by the motion of the surgeon's thumb and forefinger in vascular intervention. The delivery device consists of an active roller and two passive rollers. Two passive rollers are mirror-symmetrical for the axis of the active roller. Two guidewires can be placed between the active roller and two passive rollers separately, so the slave delivery device has two channels to deliver guidewires. Each passive roller has a motor to adjust the interval from the active roller. When the active roller and passive roller clamp a guidewire, the guidewire can be advanced or retracted through the active roller rotate about its axis. The active roller and passive roller could translate up or down along their axes to imitate the surgeon's thumb and forefinger to rotate guidewire. The slave delivery device could insert and rotate guidewire simultaneously, which is similar to surgeons' natural gestures and makes it easier to pass the lesions. When the surgeon uses the VasCure to operate the two-stent technique to treat bifurcation lesions, the active roller and the two passive rollers clamp guidewires to deliver them to the main branch and the side branch in sequence. Two graspers behind the active roller are used to clamping guidewires to avoid sliding when the active roller and the passive rollers release guidewires. As shown in Fig. 5, the following sequence of operation is applied:

(1) The surgeon loads the first guidewire in channel A. The guidewire is clamped by the active roller and the passive roller A to achieve both linear and rotary motion (Fig. 5(a)).

2) After the first guidewire is placed at the target location, grasper A grips the guidewire to prevent it from moving. Then, passive roller A moves away from the active roller, and the surgeon puts the second guidewire between the active roller and passive roller B. The active roller and the passive roller B clamp the second guidewire to advance or rotate (Fig. 5(b)).

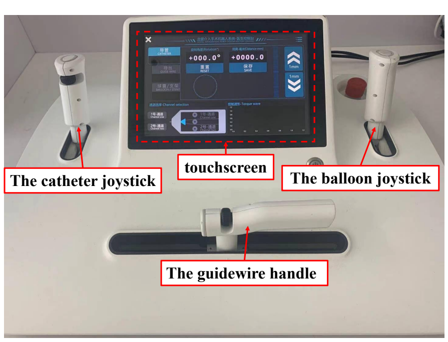


Fig. 3. The master console

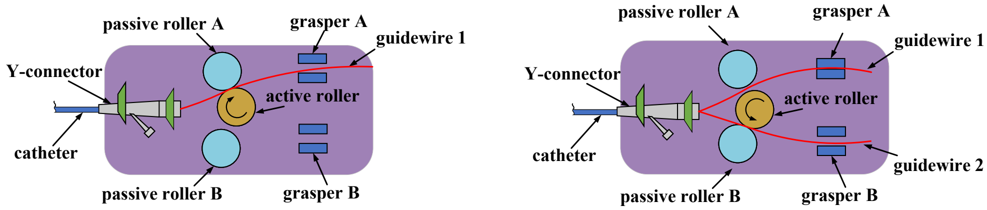
III. Experiments And Results

A. Guidewire Delivery Experiment

A comparative experiment is designed at different speeds to evaluate the accuracy of the vascular robotic system. The actual displacement of guidewires is measured by an electromagnetic (EM) tracking system (Aurora, Northern Digital Inc. Canda). A 5DOF sensor is attached to the tip of the guidewire coaxially. Therefore, the sensor displacement is equal to that of the guidewire. The guidewire is delivered in an acrylic tube to simulate the delivery of guidewire in the blood vessel. The EM tracking system sampled the position data at 40Hz.

In this experiment, speed varies from 7.2 mm/s to 25.2 mm/s (increased by 3.6 mm/s between two adjacent ones) and the displacement of guidewire is set to 150mm. the guidewire is advanced and retracted in channel A and channel B separately at different speeds for ten trials each.

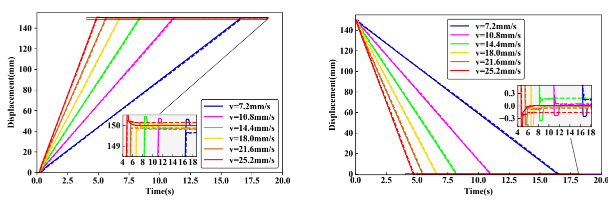
The trajectory of advancement and retraction motion of guidewire in both channels under different speeds are shown in Fig. 6 and Fig. 7. The measured data shows the actual



(a) (b)

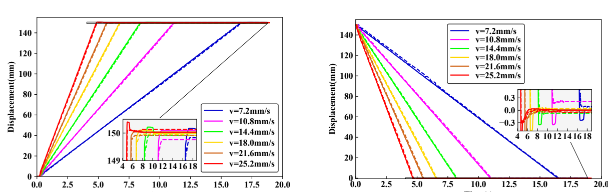
Fig. 5. The actuation principles of two guidewires. (a) guidewire A is delivered in channel A. (b) guidewire B is delivered in channel B and guidewire A is clamped by grasper A to prevent it from moving.

displacement of the guidewire is very close to the desired trajectory. Fig. 8 shows that the actual trajectory is lower than the desired trajectory when the guidewire is delivered at low speed (7.2 mm/s, 10.8mm/s), while the actual trajectory is higher than the desired trajectory when the guidewire is advanced at high velocity (21.6 mm/s, 25.2 mm/s). The motor has an overshoot phenomenon at high speed, which causes the guidewire to move beyond the set value. According to table I and II, the maximum advancement error is 0.25mm and the maximum retracement error is 0.38mm.



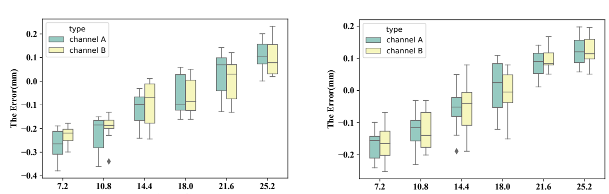
(a) (b)

Fig. 6. The trajectory of the advancement and retraction motion of the guidewire in channel A at different speeds. The dotted lines are actual trajectories, and the solid are desired ones. (a) The advancement motion. (b) The retraction motion.



(a) (b)

Fig. 7. The trajectory of the advancement and retraction motion of the guidewire in channel B at different speeds. The dotted lines are actual trajectories, and the solid are desired ones. (a) The advancement motion. (b) The retraction motion.



(a) (b)

Fig. 8. The error of the advancement and retraction motion of the guidewire in both channels. (a) the error of the advancement motion of the guidewire in both channels. (b) the error of the retraction motion of the guidewire in both channels.

B. In Vivo Animal Experiment

The remote vascular intervention animal experiment was carried out in the Shanghai Huadong Hospital. The experimental procedures were approved by the Institutional Animal Care and Ethics Committee. The interventional surgeon operated the master console to controlled the slave delivery device, 10Km away from the surgeon, to advanced guidewires and balloon catheters. The operation signal and video were transmitted in real-time via the 5G network. The experimental pig was anesthetized and fixed on the operating bed and a 6-French introducer sheath was introduced into the artery. The slave delivery device was attached to a robot arm so that it is consistent with the sheath by adjusting the angle of the robot arm. The assistant in the lab loaded a guide catheter and a guidewire to the system. The whole slave system was placed near the operating bed. (Fig. 9).

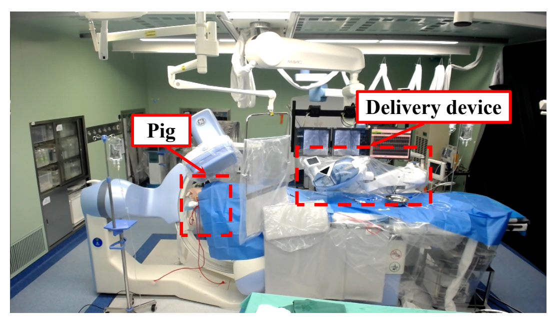


Fig. 9. Animal experiment site.

Firstly, the assistant advanced the guide catheter manually to the coronary ostium. Then the surgeon controlled the guidewire handle to deliver the guidewire to the left circumflex artery (Fig. 10(a)). After the guidewire was placed at the target position, grasper A clamped the guidewire to keep the guidewire position unchanged. Secondly, the assistant loaded another guidewire to the slave device and the surgeon switched the working channel to advance the second guidewire to the left anterior descending coronary (Fig. 10(b)). Finally, the surgeon advanced the balloon catheters along both guidewires in sequence (Fig. 10(c), 10(d)).

IV. Conclusions And Future Work

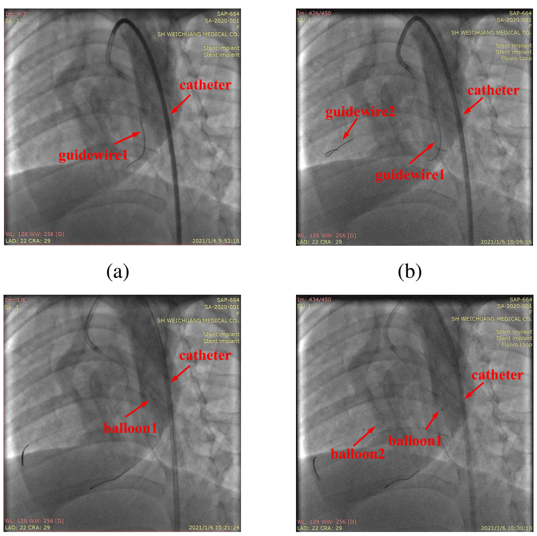
In this paper, a novel vascular robotic system with the ability to manipulate multiple devices is presented, which

TABLE I
THE ERROR OF ADVANCING THE GUIDEWIRE AT DIFFERENT SPEEDS.

	channel A						channel B					
Speed(mm/s)	7.2	10.8	14.4	18.0	21.6	25.2	7.2	10.8	14.4	18.0	21.6	25.2
Min error(mm)	0.10	0.03	0.02	0.01	0.01	**0.06**	0.07	0.03	0.01	0.02	0.05	**0.05**
Max error(mm)	**0.24**	0.23	0.19	0.12	0.14	0.20	**0.25**	0.20	0.19	0.15	0.17	0.20
Mean error(mm)	**0.17**	0.12	0.07	0.070	0.08	0.12	**0.16**	0.12	0.08	0.06	0.10	0.12

TABLE II
THE ERROR OF RETRACTING THE GUIDEWIRE AT DIFFERENT SPEEDS.

	channel A						channel B					
Speed(mm/s)	7.2	10.8	14.4	18.0	21.6	25.2	7.2	10.8	14.4	18.0	21.6	25.2
Min error(mm)	**0.19**	0.15	0.03	0.02	0.02	0.01	**0.18**	0.13	0.01	0.020	0.03	0.02
Max error(mm)	**0.38**	0.36	0.24	0.16	0.14	0.20	0.30	**0.34**	0.24	0.16	0.13	0.23
Mean error(mm)	**0.27**	0.22	0.12	0.09	0.09	0.11	**0.23**	0.20	0.10	0.09	0.08	0.10



(c) (d)

Fig. 10. Position of guidewires and balloons in blood vessel. (a) The distal end of the catheter is located at the coronary ostium and the first guidewire was advanced to left circumflex artery. (b) the second guidewire was inserted to left anterior descending coronary. (c) The balloon is delivered to the target location along the first guidewire. (d) The balloon is delivered to the target location along the second guidewire.

makes it possible for the robotic system to be used in complex lesions. The *in vitro* experiment demonstrates that the vascular robotic system can deliver guidewires precisely at different speeds. The max error of the actual and desired axial movement is less than 0.4mm, which is acceptable for vascular intervention. With the low-latency signal of 5G, the surgeon completed remote intervention surgery through the system. This study illustrated the potential of the vascular robotic system to overcome barriers to access care for patients in rural regions. In the future, a torque sensor will be used to measure the resistance during the intervention, and the haptic force feedback will be provided for surgeons to enhance the safety of the system.

REFERENCES

[1] A. Karatasakis, H. Brilakis, B. Danek, *et al.*, "Radiation-associated lens changes in the cardiac catheterization laboratory: Results from the ic-cataract (cataracts attributed to radiation in the cath lab) study," *Catheterization and Cardiovascular Interventions*, vol. 91, no. 4, pp. 647–654, 2018.

[2] N. Smilowitz, S. Balter, and G. Weisz, "Occupational hazards of interventional cardiology," *Cardiovascular Revascularization Medicine*, vol. 14, no. 4, pp. 223–228, 2013.

[3] N. Smilowitz, J. Moses, F. Sosa, *et al.*, "Robotic-enhanced pci compared to the traditional manual approach," *J Invasive Cardiol*, vol. 26, no. 7, pp. 318–321, 2014.

[4] D. Walters, J. Omran, M. Patel, *et al.*, "Robotic-assisted percutaneous intervention coronary," *Updates in Percutaneous Coronary Intervention, An Issue of Interventional Cardiology Clinics, Ebook*, vol. 8, no. 2, pp. 149–159, 2019.

[5] Robocath successfully carries out europes first remote robotic-assisted coronary angioplasty. [Online]. Available: https://www.robocath.com/robocath-successfully-carries-out-europes-first-remote-robotic-assisted-coronary-angioplasty/

[6] Y. Thakur, J. Bax, D. Holdsworth, *et al.*, "Design and performance evaluation of a remote catheter navigation system," *IEEE Transactions on biomedical engineering*, vol. 56, no. 7, pp. 1901–1908, 2009.

[7] O. Omisore, S. Han, L. Ren, *et al.*, "Towards characterization and adaptive compensation of backlash in a novel robotic catheter system for cardiovascular interventions," *IEEE transactions on biomedical circuits and systems*, vol. 12, no. 4, pp. 824–838, 2018.

[8] J. Woo, H. Song, H. Cha, *et al.*, "Advantage of steerable catheter and haptic feedback for a 5-dof vascular intervention robot system," *Applied Sciences*, vol. 9, no. 20, p. 4305, 2019.

[9] S. Guo, Y. Song, X. Yin, *et al.*, "A novel robot-assisted endovascular catheterization system with haptic force feedback," *IEEE Transactions on Robotics*, vol. 35, no. 3, pp. 685–696, 2019.

[10] J. Zhou, Z. Mei, J. Miao, *et al.*, "A remote-controlled robotic system with safety protection strategy based on force-sensing and bending feedback for transcatheter arterial chemoembolization," *Micromachines*, vol. 11, no. 9, p. 805, 2020.

[11] K. Wang, B. Chen, Q. Lu, *et al.*, "Design and performance evaluation of real-time endovascular interventional surgical robotic system with high accuracy," *The International Journal of Medical Robotics and Computer Assisted Surgery*, vol. 14, no. 5, p. e1915, 2018.

[12] H. Gwon, "Understanding the coronary bifurcation stenting," *Korean circulation journal*, vol. 48, no. 6, p. 481, 2018.

[13] J. Chakravartti and S. Rao, "Robotic assisted percutaneous coronary intervention: hype or hope?" *Journal of the American Heart Association*, vol. 8, no. 13, p. e012743, 2019.

[14] Z. Feng, G. Bian, X. Xie, *et al.*, "Design and evaluation of a bio-inspired robotic hand for percutaneous coronary intervention," in *2015 IEEE International Conference on Robotics and Automation (ICRA)*, 2015.