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COMMENTARY

Robotic Percutaneous Coronary Intervention in Coronary Heart Disease: Applications and Recent Advances

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Abstract

Traditional percutaneous coronary intervention (T-PCI) has long been an effective method for treating coronary heart disease (CHD), but the radiation hazards and orthopedic injuries among T-PCI operators are concerning. These problems have been mitigated with the emergence of robotic percutaneous coronary intervention (R-PCI), which is expected to increase intervention accuracy and safety. In this review, we first summarize the current status of PCI development, including robot systems, and PCI application and evaluation. Second, we compare T-PCI and R-PCI to identify the benefits for patients and physicians. In addition, we describe a new R-PCI system, R-PCI WSER-CD01, which incorporates multi-instrument collaborative delivery and provides full-process assistance in minimally invasive vascular intervention. This system introduces three key innovations that address safety concerns, and improve the accuracy, wire compatibility, and remote operation capabilities of existing of vascular intervention robot systems. Finally, we discuss prospects for the development of R-PCI. As an emerging technology, R-PCI aligns well with the trends of precision medicine and telemedicine, and therefore warrants continued innovation.

Keywords: Coronary heart disease; Percutaneous coronary intervention; Robotic percutaneous coronary intervention; Innovation

Introduction

Coronary heart disease (CHD) is the main cause of death in both developed and developing countries. On the basis of data from the National Health and Nutrition Examination Survey 2017–2020, an estimated 20.5 million adults older than 20 years in the United States have CHD, and the total prevalence rate is 7.1% [1]. In 1977, Gruntzig first used percutaneous coronary intervention (PCI) to treat angina in stable CHD [2]. Over the next 40 years, PCI developed into one of the most effective methods for treating CHD. In 2018, an estimated 482,000 PCIs, were performed in inpatients in the United States [1]. According to the statistics of the National Center for Cardiovascular Disease Quality Control, the number of patients who

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received PCI in China increased to 1,325,993 in 2021 [3].

With the widespread application of PCI, experts have discovered its shortcomings, primarily radiation exposure and orthopedic injuries among operators. Vano et al. have suggested that interventional cardiologist operators have a much greater risk of posterior subcapsular opacities than unexposed controls [4]. Cumulative professional radiation exposure is also associated with a clear lifetime attributable risk of cancer [5]. Furthermore, in an experiment involving 2407 clinical physicians, cardiologists had the highest frequency of absenteeism due to back or neck pain, and received more nonsteroidal anti-inflammatory drugs and mechanical support devices than other physician groups [6].

Given the shortcomings of traditional PCI (T-PCI), robotic PCI (R-PCI) research and development has been aimed at addressing these disadvantages. After the advent of the first R-PCI robot system, Niobe, new robot systems, such as CorPath®200, CorPath GRX, R-One, and Sensei® X, were launched. R-PCI is currently undergoing small-scale clinical trials to verify its safety and effectiveness through case reports. Therefore, this potential value of R-PCI and how this method might be promoted on a large scale require further exploration.

In this review, we provide a comprehensive overview of R-PCI, covering the research advances in both the basic robot system and its clinical applications. We summarize the key comparisons between R-PCI and T-PCI to highlight the advantages and disadvantages of R-PCI. In addition, we describe a new robot system, R-PCI WSER-CD01. Finally, we present future perspectives on the development of R-PCI.

Research Advances in R-PCI

R-PCI Systems

Stereoaxis, in the United States, developed the Niobe magnetic navigation robot system in 2002, on the basis of the earliest research on vascular intervention robots. This system uses active catheter technology driven by magnetic navigation, which can decrease the difficulty of catheter passage through tortuous regions of blood vessels and shorten the time required for catheter placement in bifurcated blood vessels [7–9]. In 2019, Stereoaxis developed the Genesis RMN magnetic navigation cardiac ablation robot system based on the Niobe system. The Genesis RMN system integrates a Vdrive magnetic navigation delivery system, which can achieve operations such as catheter delivery, rotation, and deflection [10].

Hansen Medical, in the United States, developed the Sensei® X vascular intervention robot system in 2006. This robot system uses a primary-secondary structure comprising an operator's console at the primary end and a robot body at the secondary end. The robot's design uses an active catheter driving method. The robot can also measure the distal contact force of the catheter and provide feedback to the operator [11–14]. Hansen Medical later developed the Magellan™ vascular intervention robot system based on Sensei® X, in which new types of active catheters were added to meet the requirements of various situations during interventions [15].

Corindus Vascular Robotics in the United States developed the CorPath®200 vascular intervention robot system in 2012. Like the Sensei® X, this robot uses a primary-secondary structure; however, this robot uses a passive catheter and friction wheel drive to achieve wire delivery and rotation operations, thus making it the first vascular intervention robot to achieve friction wheel drive [16, 17]. In 2018, the second-generation vascular intervention robot CorPath GRX, developed on the basis of CorPath®200, was approved for peripheral vascular intervention therapy. The CorPath GRX vascular intervention robot system added automatic control of the guide catheter, thus providing greater support for the guidewire delivery process. However, this robot does not have a fully controllable catheter [18]. This issue has not been resolved in current generations of robot systems.

Beyond the representative robots introduced above, R-One [19], CGCI [20], and Amigo [21] have been developed (companies and dates listed in Table 1).

Application and Evaluation of R-PCI

Currently, R-PCI is advancing from animal experiments, to human experiments, to clinical

Table 1 Summary of Robot Systems.

Companies	Names of R-PCI	Date
Stereotaxis	Niobe	2002
Stereotaxis	Genesis RMN	2019
Corindus Vascular Robotics	CorPath® 200	2012
Corindus Vascular Robotics	CorPath GRX	2018
Robocath	R-One	2021
Hansen Medical	Sensei® X	2006
Hansen Medical	Magellan™	2013
Magnetecs Inc.	CGCI	2011
Catheter Robotics Inc.	Amigo	2008

applications. The following clinical studies have provided insights into R-PCI application and evaluation.

The PRECISE study, the first large multicenter study of a remote-controlled intervention robotic system, further validated the security and feasibility of the CorPath 200 system in 2013. Of 164 patients included at nine study sites, 162 (98.8%) achieved device technical success, and 160 (97.6%) achieved clinical intervention success [17]. However, the studies presented above focused on the treatment of simple lesions and did not include control groups to validate the results.

The CORA-PCI study was conducted in a group of patients with complex coronary artery anatomy and severe comorbidities in 2017 [22]. No significant difference was observed in clinical success (99.1% with R-PCI vs. 99.1% with T-PCI; P = 1.00), stent use (stents per procedure 1.59 ± 0.79 with R-PCI vs.1.54 ± 0.75 with T-PCI; P = 0.73), and fluoroscopy time (18.2 ± 10.4 min with R-PCI vs. 19.2 ± 11.4 min with T-PCI; P = 0.39) among 334 PCI attempts in 315 patients. The clinical results achieved with R-PCI were comparable to those of T-PCI. In addition, some case reports with complex coronary lesions treated with R-PCI provided further support for this conclusion [20, 21]. A recent meta-analysis including 1535 patients (552 receiving R-PCI and 983 receiving T-PCI) has shown comparable clinical success between R-PCI and T-PCI, and has indicated that R-PCI requires less contrast use than T-PCI [23].

The above trials have indicated that R-PCI exhibits the expected efficacy for simple or complex coronary artery lesions. In addition, although cardiovascular experts are increasingly considering the safety and effectiveness of R-PCI, large-sample, multicenter, randomized controlled trials remain lacking.

T-PCI and R-PCI: Which is Better?

As R-PCI gradually gained popularity, increasing data became available comparing T-PCI and R-PCI. This section discusses the patient and operator perspectives separately.

Compared with T-PCI, R-PCI can decrease the incidence of longitudinal geographic miss (LGM) and can more accurately select the stent length. The term of geographic miss was first proposed to describe the failure of intravascular radiation therapy to fully cover injured or diseased arterial segments [24, 25]. LGM is a type of geographic miss involving a failure to fully cover the diseased coronary artery segment during PCI. Bezerra et al., in a comparison of data from the STLLR trial and the PRECISE trial, found a significantly lower incidence of LGM in the R-PCI group than the T-PCI group in a smaller matched subset of patients (10.3% vs 64.1%; $P < 0.0001$) after propensity score matching [26]. In addition, the variability of visual estimation is reflected not only in LGM but also in stent length selection [27]. A clinical trial involving 60 patients has compared the accuracy of stent length selection by cardiologists versus the CorPath 200® Robotic PCI System. In 8.3% of cases, one stent was less in R-PCI group, because the lesion measurement was shorter with R-PCI than T-PCI [28]. R-PCI can also measure lesion length more accurately (accuracy of 0.1 mm) than T-PCI, thereby decreasing insufficient or excessive stent implantation.

Occupational hazards are the main concern for interventional operators and cardiac catheterization laboratory staff [29]. The common occupational hazards are operator radiation exposure and orthopedic injury risk [22, 30]. Many studies have demonstrated that long-term radiation exposure in operators may be associated with posterior subcapsular cataracts, brain cancer, breast cancer, and early atherosclerosis [31–34]. Wearing lead aprons to avoid exposure can lead to issues such as cervical spondylosis and back pain. Table 2 presents several related studies demonstrating the universality of occupational hazards among interventional operators.

Table 2 Summary of Occupational Hazards to Interventional Staff.

Author	Number of interventional staff	Occupational hazards	Outcomes in interventional staff
Ross et al. [6]	385	Occupational pain	A total of 52.7% of respondents required treatment for back or neck pain.
Ciraj-Bjelac et al. [31]	56	Radiation-induced cataracts	The prevalence of radiation-associated posterior lens opacities was 52% (95%CI: 35–73) among interventional cardiologists.
Klein et al. [29]	314	Orthopedic injury	A total of 49.4% operators reported at least one orthopedic injury: 24.7% cervical spine disease, 34.4% lumbar spine problems, and 19.6% hip, knee, or ankle joint problems.
		Skin, hematologic, and cancerous diseases	Reported outcomes: skin 4.8%, cataracts 5.5%, and hematologic and cancerous diseases 4.8%.
Andreassi et al. [35]	466	Skin, cataracts, and hematologic and cancerous diseases	Reported outcomes: skin lesion 8.6%, orthopedic illness 30.2%, cataract, thyroid disease 7.5%, anxiety/depression 12.4%, hypertension 12.9%, hypercholesterolemia 12.0%.

Notably, R-PCI can substantially address the risk of radiation hazards. Most R-PCI system designs use a primary-secondary structure, wherein operators behind a leaded shield, use remote control technology to manipulate the guidewire, thus fundamentally solving the problem of radiation hazards. Among 336 procedures performed over 30 weeks, Madder et al. have observed a median head-level exposure in R-PCI of 0.1 [0.2] μSv, a value 99.3% less than that in T-PCI performed with traditional lead shielding [36]. Because operators' radiation exposure is avoided, heavy lead aprons are no longer needed. Consequently, the main symptoms of heavy lead apron use in intervention physicians (such as spinal problems, harm to the hip, and pain in the knees, ankles, and back), as well as operational errors due to physician fatigue, can be avoided [6, 37, 38]. Finally, the use of R-PCI can decrease contact between operators and patients, thus effectively minimizing the risk of infection of medical staff during infectious disease epidemics, such as the COVID-19 pandemic [39].

However, the separation between the operator and patient, arising from the primary-secondary design, results in a lack of tactile feedback—a major drawback of R-PCI [40]. Studies have demonstrated the importance of tactile feedback in the accuracy of remote robot operations [41]. The lack of tactile feedback also increases the risk of accidental damage to blood vessels during the intervention [42]. This issue has not been well addressed in most R-PCI systems. In addition, the design of R-PCI has a drawback of poor compatibility with guidewires and conduits. Some R-PCI systems that use a single-size guidewire have difficulty in meeting the needs of common interventions. Moreover, several experiments have indicated that the procedure time of R-PCI is significantly longer than that of T-PCI (R-PCI vs. T-PCI: 42:59 ± 26:14 min vs 34:01 ± 17:14 min, P = 0.007) [22]. Similar results have been reported in a study by Tripathi et al. [23], in which the procedure time of R-PCI was significantly longer than that of T-PCI, with a risk ratio of 5.52 (95% CI:1.85–9.91, P = 0.003).

Finally, beyond R-PCI's technical issues and interventional procedures, the substantial economic burden posed by the introduction and maintenance of equipment has hindered the promotion and use of R-PCI. The time and resources required to develop operator skill are also a major challenge.

In summary, R-PCI can decrease the probability of LGM and target vessel revascularization (TVR), provide more accurate stent selection, and avoid radiation exposure during the intervention in patients. In addition, R-PCI protects operators from radiation hazards and orthopedic injuries, and also diminishes the probability of iatrogenic infection. However, R-PCI still faces issues such as a lack of

a force feedback system, poor wire compatibility, potentially prolonged operation time, and high cost.

R-PCI WSER-CD01: A New Interventional Robot with Full-Process Assistance

R-PCI WSER-CD01 is a minimally invasive vascular interventional robot system that enables multi-instrument collaborative delivery. R-PCI WSER-CD01 uses a primary-secondary design, with the primary console collecting physicians' operation instructions and the secondary actuator executing the corresponding operations to complete the intervention (Figure 1). The secondary actuator section is divided into two parts: the secondary robot body (Figure 2) and the instrument operation box (Figure 3).

On the basis of previous research on R-PCI and clinical practice, this new system is making innovative breakthroughs in safety indicators, the guidewire

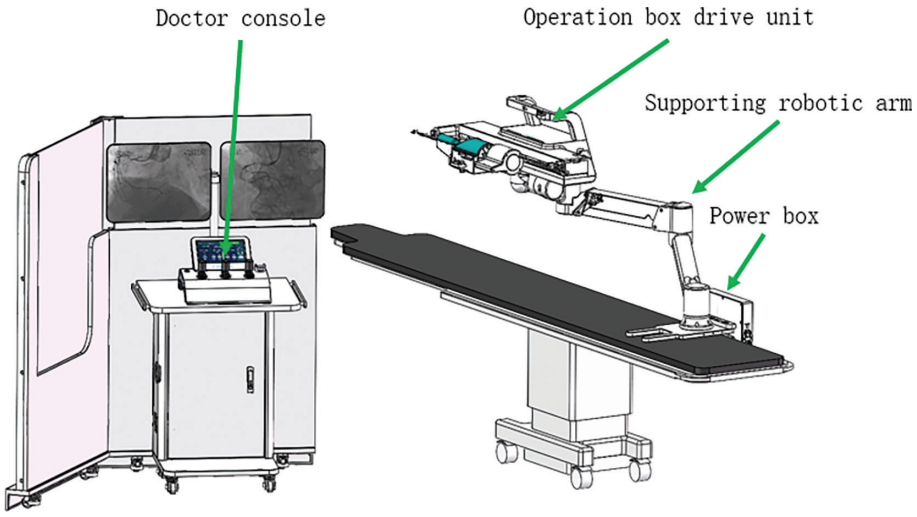

Figure 1 Primary-Secondary Design of R-PCI WSER-CD01.

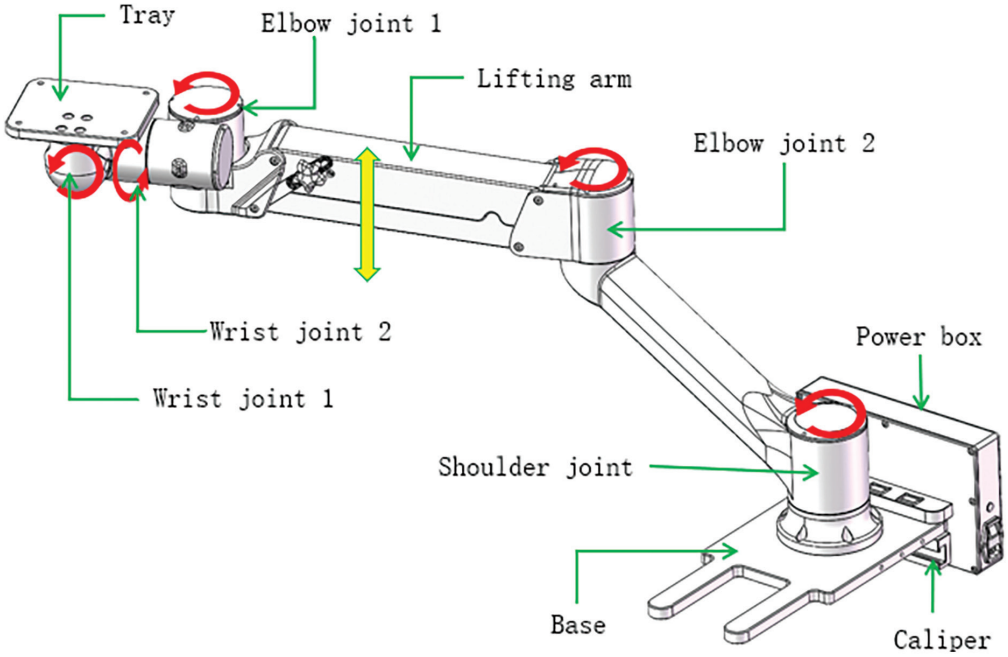

Figure 2 Mechanical Transmission Device.

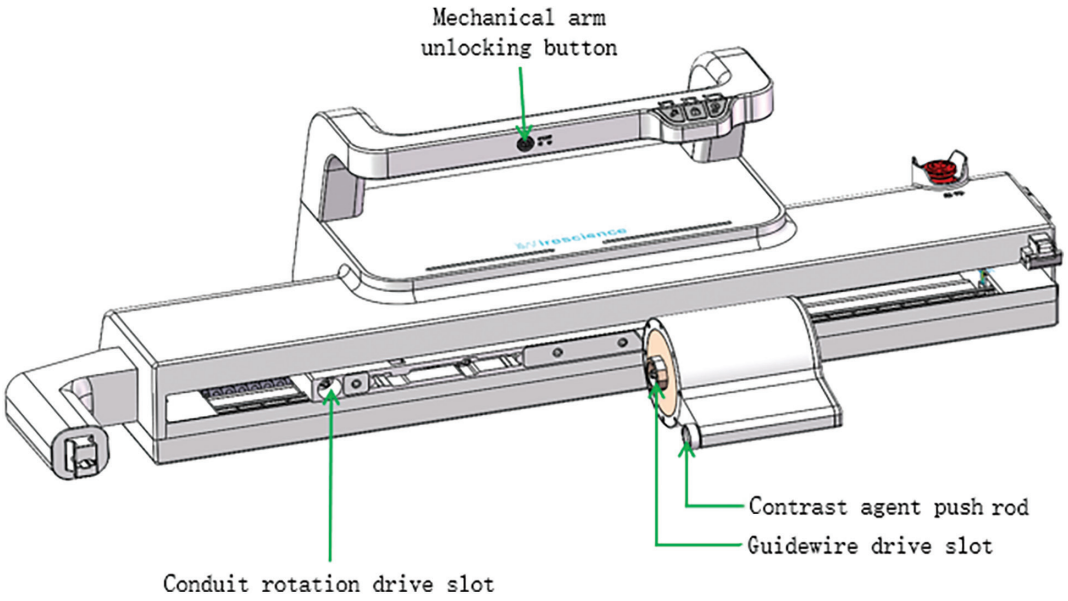

Figure 3 Operation Box Drive Unit.

drive mechanism, and the multi-joint collaborative control algorithm and remote-control algorithm.

Safety Indicators of Vascular Interventional Robots

In R-PCI, the risk of vascular wall damage, particularly to small arteries, should be monitored. During the procedure, the tip of the guidewire may contact the vascular wall. Owing to the complexity of the vascular pathway or the possibility of excessive pressure on the vascular wall, the patient's blood vessels may be damaged, and the injury may be life-threatening. For R-PCI WSER-CD01, theoretical modeling has been conducted on the basis of blood vessel wall deformation, and the following safety indicators have been explored (Table 3).

The determination of speed indicators can ensure that the contact pressure between the guidewire and the vascular wall is controlled to within a safe range. When implementing robot assisted vascular intervention, operators usually first place a guidewire into the coronary artery, then advance a wire across the lesion. The safe speed of wire delivery from the end effector is below 1.96 cm/s, and the delivery speed of the guidewire from the end effector of this robot is set to 1 cm/s.

The error of the secondary actuator is limited in this R-PCI system to ensure accuracy. In R-PCI WSER-CD01, the maximum error between repeated positioning of the guidewire and catheter delivered from the end effector does not exceed ±1 mm/±30°, and the maximum positioning error of delivering the balloon/stent from the end effector does not exceed ±1 mm. Furthermore, this vascular intervention robot uses a primary-secondary design, and the maximum error between the theoretical and actual positions of the primary console and the secondary actuator does not exceed ±2 mm.

In addition, determining the maximum safety delay can decrease the network environment fluctuation that may cause delays during remote robot-assisted vascular intervention. The speed of the vascular intervention robot's delivery of the

Table 3 Safety Indicators for Vascular Interventional Robots.

Indicators	Numerical values
Speed indicator	1 cm/s
Precision indicator	
Maximum error of repeated positioning (delivery)	±1 mm
Maximum error of repeated positioning (rotation)	±30°
Maximum error of delivery stents/balloons positioning	±1 mm
Maximum error of dynamic tracking positioning	±2 mm
Maximum safety delay	261.19 ms

guidewire from the end effector is set to v = 1 cm/s. The total displacement of the secondary actuator during the human average reaction time and network delay should not exceed the safe displacement of the guidewire in the small artery, thus enabling calculation of the maximum allowable safe delay for remote robot-assisted vascular intervention. The maximum allowable safety delay time for remote robot-assisted vascular intervention is 261.19 ms.

Because of the limits of the critical values of the above safety indicators, even if the end face of the guidewire directly contacts the arterial wall, the R-PCI WSER-CD01 system can ensure the safety of the blood vessel and avoid damage to the vascular wall to the greatest extent possible.

A New Type of Guidewire Drive Mechanism

The main body of the secondary robot is composed of a power unit and a mechanical transmission device, and the primary console and secondary actuator are installed. Unlike traditional friction wheels and clamping mechanisms, or recently developed magnetic navigation methods, this structure consists of a guidewire disc, a guidewire roller, and a guidewire delivery and rotation drive device.

The guidewire disc adopts a belt pulley designed guidewire pressing device, which tightly presses the guidewire onto the guidewire reel, thus ensuring that the displacement of the guidewire reel is consistent with the displacement of the guidewire reel. Precise control of the guidewire delivery operation is achieved by using a motor to control the rotation speed of the guidewire disc. Simultaneously, the guidewire is pressed onto the side wall of the reserved channel on the guidewire reel through a fixed pressure plate with a spring connection. This new type of wire guide fixing mechanism allows the wire guide disc to be compatible with various sizes of wires, thus meeting the requirements of different interventional procedures.

The guidewire roller is a device that combines the guidewire disc with the guidewire delivery and rotating machinery, thereby simplifying the installation process and shortening the preparation time for interventions. In addition, the guidewire rotation function is achieved by rotating the guidewire drum around the shaft, thereby driving guidewire rotation. Compared with the traditional friction wheel-driven guidewire rotation scheme, this design greatly increases the force arm of the guidewire rotation driving force, decreases the difficulty in precisely controlling the driving force, and achieves controllability and positioning accuracy of the guidewire in a humid environment.

Implementation of Multi-Joint Collaborative Control and Remote Control

Implementation of Multi-Joint Collaborative Control

To achieve collaborative operation of catheter guidewires, collaborative control between multiple joints is a key design point. Below, we describe the electrical system design and algorithm design of the R-PCI WSER-CD01 system.

This system uses EtherNet Control Automation Technology (EtherCAT) as the communication method and CANopen on EtherCAT (CoE) as the application layer protocol for the EtherCAT bus [43]. Five rotating motors and one linear push rod motor compatible with the EtherCAT communication protocol are connected as power sources. Human-machine interaction is achieved through three joystick controls on the console. In addition, Simple Open EtherCAT Primary (SOEM) is the EtherCAT primary station software package, a proportional-integral-derivative (PID) is used as the control algorithm for the servo motor, and the conduit guidewire collaborative delivery algorithm is used to achieve multi-joint collaborative control [44].

The R-PCI WSER-CD01 system uses EtherCAT communication technology with distributed clocks, which improve the fault tolerance of the communication system jitter and control the communication system jitter to below 1 μs [45]. The drive system, sensors, and human-machine interaction development board are all compatible with the EtherCAT communication protocol, thus achieving unity of multi-joint communication systems. SOEM has good compatibility with systems including Linux and Windows. PID combines three control algorithms, which eliminate the effects of steady-state errors and improve the accuracy of the control system, according to actual situations. PID improves the independence of the three joints while maintaining the synchronous delivery function of multiple

interventional devices. With the design of electrical systems and control algorithms, this system can achieve multi-joint collaborative control with high accuracy and stability.

Implementation of Remote Control

The remote interventional function is important for the clinical application of R-PCI robots. In terms of hardware device selection, customized peer-to-peer network services provided by domestic broadband operators are used. Transmission Control Protocol serves as the internet communication protocol for this system.

In the implementation of remote vascular intervention, delay and fluctuation caused by the network environment may cause the delivery distance between the catheter and the guidewire to exceed the maximum safe travel that can be withstood by the patient's artery wall, thus causing artery wall damage and endangering the patient's life. The hardware devices and communication protocols selected for the R-PCI WSER-CD01 system effectively avoid the occurrence of the aforementioned issues. Peer-to-peer network services can be customized, and the main console on the physician's side and the secondary actuators on the patient's side must achieve low-latency real-time data transmission. Transmission Control Protocol has the advantages of flow control and acknowledgment mechanisms, which can address packet loss, retransmission, and sequence issues. In addition, the remote-control algorithm of this system can achieve real-time communication between the primary and secondary ends.

Concluding Remarks and Future Perspectives

With increasing awareness regarding operator protection and precision intervention, R-PCI is expected to be a major future trend in PCI. This review summarized the robot systems of R-PCI commonly used worldwide and provided a brief introduction, followed by a summary of the current application status of R-PCI and the evaluation findings from clinical trials. Subsequently, R-PCI and T-PCI were compared from the perspectives of patients and operators, thus demonstrating the advantages and disadvantages of R-PCI. The above summary and evaluation of the current state of the art may help researchers review and further explore R-PCI technology.

Furthermore, this review describes the new R-PCI WSER-CD01 system, which introduces three major innovations: safety indicators for vascular interventional robots, a new type of guidewire drive mechanism, and multi-joint collaborative control and remote control. With modern mechanical technology and 5G communication, the above innovations are expected to have growing influence on the R-PCI field. The lack of computer vision-assisted navigation systems and force feedback systems, a longstanding challenge in R-PCI, has not yet been fully resolved in R-PCI WSER-CD01. In future research, work will be to address these challenges.

R-PCI is a major innovation that not only demonstrates the advantages of protecting operators and achieving precision intervention, but also continues to contribute to the development of "telerobotics" and robot-assisted intervention. In areas lacking sufficient skilled operators or professional equipment, patients' door-to-balloon time is inevitably prolonged, thus providing an opportunity for the introduction and development of R-PCI. The ability to perform remote intervention is expected to aid in achieving timely and widespread application of advanced interventional techniques. The REMOTE-PCI study [46] and Anvari et al. [47] have demonstrated the potential of this method.

To fully unleash the potential of R-PCI, new robot systems must address the technological limitations of previous generation systems. Improving the compatibility of R-PCI, expanding the applicable interventional range, and increasing the accuracy of operators through computer vision-assisted navigation systems and force feedback systems will be key research and development directions in the future.

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Conflict of Interest Disclosures

No potential conflicts of interest relevant to this article are reported.

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