Universal Journal of Computational Analysis **9 (2021), 18-24**
www.papersciences.com **EU Academy of Sciences (EUAS) e-Symposium**

Robotics in Percutaneous Cardiovascular Interventions

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Abstract
Medical robotic technologies are currently used in various disciplines including surgery, orthopedics, pulmonology, and most recently interventional cardiology and radiology. In this review, the evolution of coronary and vascular robotics over the last two decades is described. The primary objectives for robotics in this disciple are twofold: to protect physicians from the hostile radiation environment next to the patient bed, and to allow for precise control of the devices. Following development of the pilot system that showed proof of concept in a small patient cohort, the first- and second-generation CorPath™ robotic systems, used today in clinical practice, are now applied to a variety of complex coronary lesions and can facilitate performance of almost the entire spectrum of coronary interventions. The system's use has expanded into the peripheral arteries and is currently been evaluated for brain interventions. The validation of remote procedures both *in vitro* and in patient studies will provide expansion of treatment to remote locations, with particular application to stroke interventions, where the lack of experts is clearly felt. The future of robotics will involve smart movements, artificial intelligence, and deep learning algorithms to increase safety and efficiency of the procedure by autonomous image based functions.

Key Word and Phrases
Percutaneous Interventions, Remote Control, Robotics, Vascular Navigation, 5G, Automation.

1. Introduction

Robotic surgery was developed in response to a variety of needs, including the United States (US) army's need for tele-surgery in remote locations [1],[2] and is extensively used today in a wide spectrum of procedures. The Da-Vinci Robot [3] is by far the most advanced system today for surgical procedures, but other systems are in various stages of development [4]. Specific robotic solutions for orthopedic interventions, bronchoscopy based pulmonary interventions, and other applications are also gaining access to the clinical arena.

Vascular based robotic systems have been developed in parallel. Some of the early robotic systems were in the field of electrophysiology, where the intended use was for catheter navigation within the heart chambers for ablation [5],[6].

This paper describes the development of robotic coronary and vascular interventions and discusses the future applications of this novel technology.

2. Clinical Challenges and Needs in the Catheterization Laboratory

Interventional cardiology started with the first balloon angioplasty performed by Andreas Gruenzig in 1987 [7]. The procedure was performed by inserting a guiding catheter into the aortic orifice of the coronary artery, and through that guiding a wire and a balloon across the occlusion followed by balloon dilatation by inflation. During the procedure, the operator typically stands at the side of the operating table, exposed to the harming effects of the x-ray system. Various methods to protect the operator from the X-ray effects have been employed; however, despite them, accumulation of radiation over the years has translated into long term harmful effects to the operator [8]–[11]. With the huge growth of interventional procedures worldwide, a large number of interventional cardiologists are being exposed to this harmful environment. In addition, wearing heavy lead aprons for many hours on a daily basis results in extensive back problems that lead to loss of time worked and disability. In addition, long periods of standing under less than optimal conditions does not contribute to a precision- friendly environment for the duration of a procedure.

Despite these known effects, most procedures in the catheterization laboratory are performed today in the same manner as was done 40 years ago.

Hence, the advent of modern technology has clearly identified the need to develop a novel robotic tool to facilitate performance of these procedures by the operator from a remote location. Such a tool would eliminate the radiation hazard and enable achieving safe and precise results in a comfortable environment for a wide variety of coronary interventional procedures.

3. Early Feasibility Period

While guide wire navigation for coronary interventions has been previously attempted using magnetic navigation [12], it could not be applied to the entire procedure, including balloon dilatation and stent implantation. Therefore, in order to allow for robust remote control of percutaneous interventions, a system to navigate the wires and balloons was developed (Fig. 1).

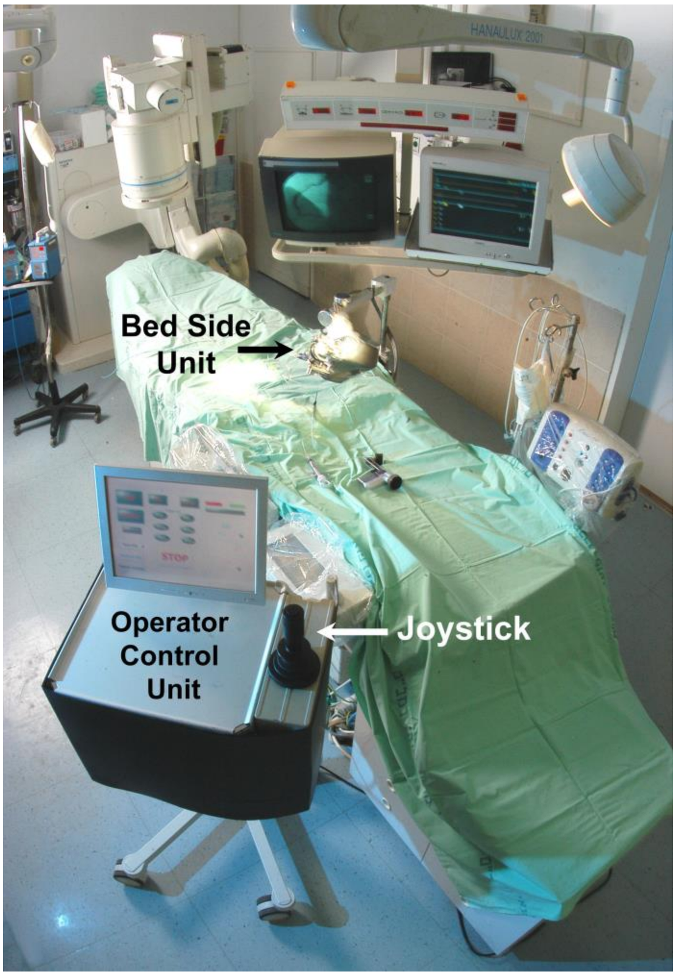

Fig. 1 The System Used for the First Percutaneous Interventions in Patients.
The system was designed to operate the wire (advance – retract - rotate) and the balloon/stent (advance – retract). Discrete movements and rotations were programmed as well.

The system was designed for the following tasks:

Guide Wire: Advance retract and rotate the guide wire including options for rotation at discrete 45% steps.

Device manipulation (balloons, stents, etc.): The system was designed for advancement and retraction of devices, without the need for rotation. Discrete 1 mm steps were programmed for precise positioning. By measuring precise motion distances for both the wire and the device, precise lengths can be determined by tracking either the balloon and/or the wire markers.

An important feature of the system was that after the wire is placed across the lesion in its final position, it is locked in this position while device advancement is under way.

The system was initially tested both *in vitro* and in the animal laboratory [13]. In a series of dogs, the wire was successfully guided to any location within the coronary tree followed by successful stent implantation. No damage to the arterial tree was observed and the safety of the device was accepted as a prerequisite for the human pilot clinical trial.

Following animal experiments, the first in man studies were performed in two hospitals, as summarized by Beyar et al. [14]. The PCI with stent implantation procedure was conducted robotically, following femoral approach placement of the guiding catheter. Initial clinical studies were done with the device operators at the bedside. Overall, 18 patients were treated with successful robotic implantation in 17 of the cases. One case experienced a technical system failure that was immediately handled by switching to standard manual operation and successful completion of the procedure. The results were published and showed the feasibility of remote procedures for the first time.

This initial study set the stage for further development into a commercial system that could be used in a pivot multicenter trial.

4. The Road to FDA Approval

The next phase after the initial feasibility trial was to design and test a remote control robotic system that could be used for a US-based pilot study for testing the safety and effectiveness of this system for US Food and Drug Administration (FDA) regulatory approval. The CorPath 200™ (Corindus, Natick MA) system was the first clinical prototype, designed to repeat the same procedures as did the previous pilot system. The remote control unit was designed in a lead glass protected cockpit, where the operator could run the equipment comfortably while sitting next to the control monitor. The bedside unit was designed with a computerized motor and a disposable cassette that operated the selected procedural devices. An overview of the system within the catheterization laboratory is shown in Fig. 2.

Fig. 2 The CorPath 200 System Within the Catheterization Laboratory. The control system is placed within a lead glass shielded cockpit and the bedside unit is firmly mounted on the bedside.

The pivot "Precise" study [15], enrolled 164 patients with single de-novo lesion of less than 24 mm. The results showed a 98.8% success rate and a dramatic 95.2% decline in radiation exposure to the operator. Following the pilot study and FDA approval in 2012, real world began, leading to more realistic experience in various complex lesions [16]. Based on early experience, it became clear that guide catheter control is extremely important if the system is to be used to treat all types of lesions. Advancing and rotating of the guide catheter during a procedure is often necessary to allow better support and alignment of the guide catheter within the vessel [17].

5. Real Clinical World Experience

In 2017, the FDA approved the new CorPath GRX™ system [18],[19], which introduced a robust system that could control all three major elements in every PCI: the wire, the device, and the guide catheter.

Large experience was accumulated in treating complex lesions including bifurcation lesions [16], left main procedures [20], total occlusion [21],[22], and the use of auxiliary devices such as intravascular ultrasound as well as laser angioplasty [23]. High risk angioplasty using Impella, together with robotic procedures was also applied [24]. Yet one of the major limitations of the system is that it cannot control over-the wire systems.

6. Breaking Into Other Vascular Territories

With the experience gained in coronary interventions, the CorPath™ system has been tested in additional vascular territories. The system showed excellent results in peripheral artery diseases [25] as well as in carotid stenting [26]. Understanding the major need in intracranial vascular procedures, the coronary system was also applied to aneurism closure; in parallel, a major effort to develop uses for stroke thrombectomy is under way [27]. Pereira et al [28] described the first successful robotic aneurism closure, using the coronary system and robotically driving coils into the aneurism. Closure of arteriovenous malformation in the brain was also evaluated in an animal model with the coronary system [29]. Modifications of the coronary system are currently being tested to improve its utility for the more delicate and tortuous neurovascular environment. This will set the stage for development of a neurovascular-specific robot [30].

7. The Role of Medical Robotics in Digital Medicine

Interventional robotics is opening new opportunities for remote interventions over the internet. This expands the possibilities for patient care using professional expertise, not necessarily associated with a geographic location. This was one of the original ideas leading to development of the Da-Vinci Robot for surgical procedures [1] and has already been applied to transatlantic surgery [2],[31]. However, it has never gained wide experience due to technological, financial, and regulatory barriers.

Remote robotic PCI is now being tested. One of the first studies was assessment of remote PCI feasibility in an animal study conducted within the Mayo Clinic [32]. The first demonstration in patients was published by Madder et al [33], where the control system was placed in different room within the catheterization laboratory complex, and was wired to the bedside unit. The next challenge was to prove that a PCI procedure could be completed over a standard Internet connection and over great geographic distances. Following an *ex vivo* over the internet study [33],[34], the first in man study was conducted in India by Patel et al [35], where the entire procedure was performed over the internet, with the catheterization laboratory 30 km distant from the control station. During this session, five patients were successfully treated with stents via full robotic intervention. With this in mind, and with extensive exploration of the latency limit allowed during such interventions [36], the option of 5G rapid connection and transcontinental communications opens a new horizon for fast wide band connection allowing the necessary video and remote control transmission requirements [37],[38].

This opens up the possibility of remotely treating patients in regions with limited access to experts. Such access is particularly important for stroke interventions, where the availability of an experienced operator may be limited.

8. Automation and Future Directions

Robotic interventions open up a new world of potential for automated procedures. The first attempts were to program semiautomatic wire movements, which were typically done by expert and experienced physicians. Such movements include rotation, screw like motions, wiggling, and dottering effect, and were partially described by Nooryani et al. [39]. Frequency, speed of advancement, and rotation can be programmed for maximum efficiency in crossing the lesions with the wire. Exact stent positioning can also be programmed accordingly. The potential to close the feedback loop between image-based analytic guidance and robotic movements can now progress.

The future catheterization laboratory will include semi-autonomic portions of the catheterization procedure supervised by the physician [40]. These can be achieved through artificial intelligence and deep learning algorithms [41]. Similar to the automobile industry, where autonomic driving is under intense development, the expectation is that gaining similar autonomy will be part of the future trends in this rapidly moving field of transvascular interventions.

9. Conclusions

The development of robotics and remote operations for PCI offer new opportunities for our patients and caregivers; radiation safety for the operators, precision for the patients, and remote operations, which may expand patient reach. Such systems have been extended to neurovascular and peripheral interventions. They open new horizons for possible semiautomatic movements by machine learning for improving precision and enhancing the physician's skill set.

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