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# Remote robotic-assisted interventions in endovascular therapy

Ph.D. Thesis

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**List of Abbreviations**

ALARA – as low as reasonably achievable

AVM – arteriovenous malformation

CAS – carotid artery stenting

DSA – digital subtraction angiography

EVAR – endovascular aneurysm repair

FEVAR – fenestrated endovascular aneurysm repair

FORS - Fiber Optic RealShape

HITS – high-intensity transient signal

HMH – Houston Methodist Hospital

LAN – local area network

MITIE - The Houston Methodist Institute for Technology, Innovation & Education

PCI – percutaneous coronary interventions

PPE – personal protective equipment

PVD – peripheral vascular disease

PVI – peripheral vascular interventions

RoR - rotate on retract

SFA – superficial femoral artery

TCD – transcranial doppler ultrasound

TASC – Trans-Atlantic Inter-Society Consensus Document

TEVAR – throracal endovascular aneurysm repair

TP – telepresence system

## 1. Introduction

Minimally invasive interventions and surgeries are rapidly evolving and significantly improve outcomes of invasive patient care. These techniques are associated with reduced morbidity and mortality rates, shorter in-hospital stays, fewer transfusions, and intensive-care unit services, therefore they have become the preferred treatment modality in surgical fields (1). Percutaneous endovascular interventions now replace several types of coronary, peripheral vascular, and neurovascular open procedures. Hence, operators spend more time in the interventional suite, exposed to ionizing radiation. Despite protective measures to prevent the harmful effects of radiation exposure, interventionalists are still at risk of developing radiation-related complications.

Endovascular robotic systems allow the operator to remotely control the catheter system from an utterly radiation-shielded workspace or from outside the radiation field (2). Catheter robotics was first introduced in 2008 (3). This is an important technical advancement because it provides enhanced radiation protection and may allows us to perform endovascular procedures remotely even from long geographical distances.

With robotic-assisted endovascular surgery, our knowledge is limited in patient outcomes with different interventions, procedural characteristics, patient and physician benefits, and learning curves for the physician and the bedside technician. As a novel interventional modality, robotic-assisted endovascular surgery needs to be thoroughly studied. Furthermore, the idea of performing remote interventions as a routine practice is still theoretical. Therefore, we have only a little experience with it.

Before performing robotic-assisted remote interventions in human patients, several questions need to be addressed. On one hand, we have to understand the effect of network quality on the operator's performance and need to specify the threshold of acceptable network speed. Besides that, sufficient protocols for communication and procedural steps should be defined. This current work aims to explore the criteria and characteristics of remotely performed robotic-assisted endovascular interventions in preclinical models.

## *1.1. Place of robotic assistance in surgery*

### 1.1.1. Occupational hazards in the interventional suite

In the last decades, endovascular techniques have shown substantial improvements. Novel minimally invasive procedures and treatment methods gained space due to the rapidly expanding technical armamentarium, increasingly sophisticated imaging techniques, and image guidance systems. This improvement allowed interventional physicians to use endovascular treatment methods for patients whose lesions would only have been suitable for open reconstruction. In the US population, endovascular procedures for peripheral arterial disease showed a 25% increase, while open surgery volume decreased by 20% between 2011 and 2016 (4). This change in patient care leads to a higher volume of fluoroscopy-guided interventions and a rise in cumulative radiation dose for interventional physicians, which raises concerns about consequent occupational hazards affecting the endovascular team (5,6).

Radiation-related complications, such as cataracts (7) and left-sided neck and brain tumors (8,9), are more prevalent among interventionalists. Therefore, all operators working with radiation should follow the ALARA (as low as reasonably achievable) principles (10) and pursue the limitation of radiation exposure for themselves, the patient, and the interventional team (11).

Currently, the complications mentioned above are mainly described in cardiologists, but with the growing number and the increasing complexity of peripheral, aortic, and neurovascular interventions, vascular surgeons, neurovascular interventionalists, and interventional radiologists are predicted to be also be affected.

Personal protective equipment (PPE) is one cornerstone of limiting radiation exposure. It includes lead aprons, protective neck collars, lead caps, and leaded glasses. Unfortunately, however, the increasing time while wearing lead equipment contributes to a growing incidence of musculoskeletal complications, such as chronic neck and spine injuries. A survey-based study highlighted, that spine problems occur in 42% among cardiovascular interventional specialists (70% lumbosacral, 30% cervical), while hip, knee, or ankle complications occur in 28% of operators. The findings also correlated with annual procedural case load, and years of practice (12,13).

On the patient side, radiation exposure carries the increased risk of radiation-induced skin injuries, connective tissue disorders, lupus, scleroderma; however, the incidence of such radiation induced injuries related to interventional procedures remains low. Obesity is a risk factor of radiation-related injuries, since obese patients require higher radiation doses to penetrate their body, and to acquire accurate images. Factors, which might increase skin entrance doses are incorrect patient positioning, use of image magnification, incresed duration of fluoroscopy, use of high-intensity mode, use of C-arm angulation (7,11).

There are attempts to achieve radiation-free navigation; Electromagnetic tracking and Fiber Optic RealShape (FORS) technology may offer zero, or significantly reduced X-ray use while enable visualization of the devices in the 3D space (14,15). The main limitation of these techniques are the limited number of compatible catheter shapes and lengths. Therefore, our experience with these devices are still limited to preclinical studies, and case series.

### 1.1.2. Advantages of robotic-assisted laparoscopic and endovascular surgery

Robotic-assisted laparoscopic surgery was first introduced in the early 2000s, which helped to eliminate some difficulties of conventional laparoscopic surgery. The operating surgeon performed surgeries on a personalized workstation, which allowed ergonomic posture, three-dimensional visualization, precise movements, and excellent eye-hand coordination. Due to these advantages, the learning curves of laparoscopic procedures are shortened with robotic assistance (16). Since laparoscopic techniques are mainly used in general surgery, urology and gynecology, these were the disciplines where surgeons gained extensive knowledge and experience with robotic-assisted laparoscopic surgery. However, it also became accessible for vascular surgeons for certain procedures. For example, some centers reported successful reconstructions of renal artery aneurysms (17), uni- and bilateral iliac artery aneurysm (18), or nutcracker syndrome (19). These procedures are performed by a multidisciplinary team consisting of a vascular and general surgeon. However, vascular surgeons need to be trained in robotic-assisted laparoscopic techniques, since with the growing availibility of laparoscopic robotic systems, the number of vascular complications will probably grow, and inclusion of vascular surgeons will often be necessary in high-volume centers.

While robotic-assisted laparoscopy has never become widespread in routine vascular surgical care, the need for a new robotic approach formed. With the rapid development of endovascular surgery, radiation protection has become a crucial issue in preventing radiation-related complications. Robotic systems for endovascular use provide an alternative form of radiation protection. These systems allow the operator to perform operations from outside the radiation field or with the use of a radiation-shielded workstation, so the operator receives only a fraction of the intraoperative radiation dose. Moreover, the workstation's design eliminates the need for wearing personal protective equipment, which contributes to the prevention of orthopedic complications (20). During these procedures, the bedside technician and the interventional staff can keep more distance from the radiation source than usual and transparent lead walls can also be utilized since, instead of the bedside technician, the robot keeps the endovascular tools stable during navigation and device exchange.

Besides radiation protection, device stability and precise endovascular navigation are also important aspects of endovascular interventions. The navigation's precision can translate to a lower incidence of iatrogenic vessel injury and decreased embolization risk. This is especially impportant in procedures, where endovascular navigation in the aortic arch is performed, such as structural heart interventions, thoracic endovascular aneurysm repair (TEVAR) or carotid artery stenting (CAS) (21-23).

## 1.2. Endovascular robotic systems

The presented robotic systems are summarized in Table 1. The first robot designed for peripheral and aortic endovascular interventions was the Magellan Robotic Catheter System (Hansen Medical, Mountain View, California)(Fig. 1). The main components of the Magellan robot consist of a remote wire and catheter manipulator. The catheters are steerable, which means that the operator or actuators (i.e., automatically) can change the catheter tip angulation. The robotic steerable catheter systems are available in two sizes; The low profile (6 Fr) system includes two bending sections and is used for navigation in smaller arteries. The larger system consists of a 6 Fr inner leader catheter capable of 180-degree multidirectional articulation and a 9 Fr outer sheath with an additional 90-degree multidirectional articulation.

***Table 1.*** *Endovascular robotic systems, which were or currently commercially available. Detailed specifications*

| Robotic system | Developer | Compatible wires | Compatible catheters | Therapeutic device delivery | Navigation | Remote capability |
|---|---|---|---|---|---|---|
| Magellan | Hansen Medical (Mountain View, California) | 0.014<br>0.018<br>0.035 | 6 Fr or 9 Fr Magellan Robotic catheter system | Robotically stabilized manual delivery | Wire and catheter advancement-retraction; 6Fr catheter 180° multidirectional angulation; 9Fr catheter 90° multidirectional angulation | No |
| CorPath 200 | Corindus Vascular Robotics (Waltham, MA, USA) | 0.014 | Any commercially available 5–7 Fr catheter | Robotic Rx device delivery | Rx-device advancement, retraction; Wire advancement, retraction, rotation | Yes |
| CorPath GRX | Corindus, a Siemens Healthineers Company (Waltham, MA, USA) | 0.014 | Any commercially available 5–7 Fr catheter | Robotic Rx device delivery | Rx-device advancement, retraction; Wire advancement retraction, rotation; Guide-catheter advancement retraction, rotation | Yes |

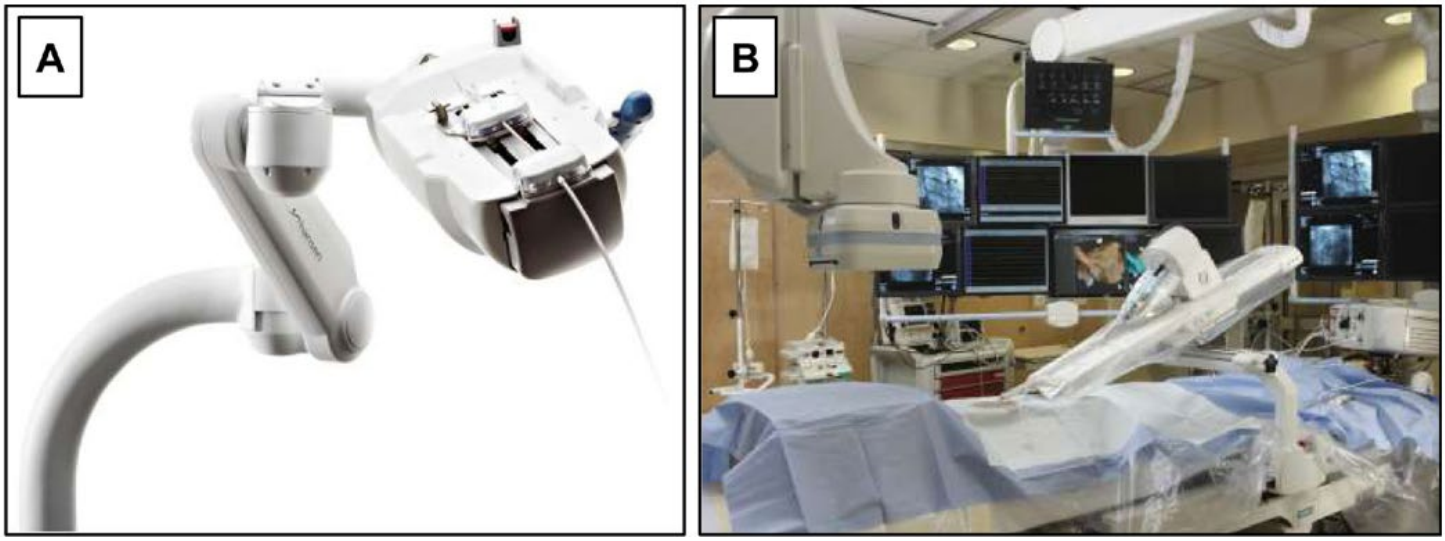


***Figure 1.*** *Hansen Medical's Magellan Robotic System. A, The robotic arm in frontal view; B, Robotic arm prepared and draped in the operating suite.*(24)

The multidirectional articulation is driven by remotely controllable pull wires integrated into the catheters (25). Catheter advancement, retraction rotation, and bending of the catheter system are coordinated by the patient-side robotic manipulator, which is mounted on the operating table. The robotic workstation, which is placed outside the

radiation source, consists of the robotic console and monitors, displaying the fluoroscopic images and the real-time catheter orientation. Vascular targets are approached with robotic manipulation. However, the therapeutic devices must be delivered manually through the robotic catheters after reaching the target.

The CorPath 200 (Corindus, A Siemens Healthineers Company, Waltham, MA, USA) was established primarily for percutaneous coronary interventions (PCI). This system allows the navigation of guidewires, catheters and the delivery of rapid exchange devices. Compatible devices include the commercially available 5 to 7 Fr guide catheters, 0.014-inch guidewires, and standard rapid exchange balloon and stent delivery systems. Without the support of higher profile systems, it was not widely spread in the peripheral arterial field. Several additional features were added to the second-generation CorPath robot, the CorPath GRX (Fig. 2). The most important advancements are active guide catheter control, which is enabled by a third joystick in the workstation, and the „rotate on retract" (RoR) function. While the CorPath 200 system did not allow the guide catheter control, this is enabled in the new system up to a 20 cm distance. The guide catheter can also be rotated. The RoR means that the wire automatically rotates approximately 270 degrees every time the wire is retracted after advancement. This mimics the operator's torquing movement of the guidewire, however, in a controlled way. This automated function may play a role in lesion crossing and vessel branch catheterization. Vessel length measurements may also be performed with the robot, which facilitates the selection of the ideal stent length. This is done by passing the balloon through the lesion, reset the length measurement tool to zero, and robotically pull the balloon back to the proximal end of the lesion.


***Figure 2.*** *A schematic figure to demonstrate the parts and setup of the CorPath robotic system. The interventional cockpit is radiation shielded. The operator sits throughout the robotic interventional part and coordinates the robot with the control console. The bedside component is attached to the operating table. Endovascular devices are loaded in the robotic system.*(26)

The CorPath system allows the operator to drive the guide catheter, guidewires, and rapid exchange balloons and stents from a separated interventional cockpit. However, the origin of the target vessel has to be reached manually with the guide catheter. When positioning balloons or stents, the touchscreen can be used to advance or retract the devices by 1 mm increments instead of using the joysticks (27).

The Magellan and the CorPath systems are compatible with any commercial interventional suites. The Magellan system received a CE mark in 2011 and FDA clearance in 2012. Although the preclinical and clinical studies described reliable and

precise navigation, the Magellan robot was not widely adopted and is no longer commercially available (28,29). The CorPath GRX has received FDA approval, and CE mark for PCI and peripheral vascular interventions (PVI), and a CE mark for neurovascular interventions.

## 1.3. Scientific evidence with endovascular robotics

### 1.3.1. Magellan system

Scientific data with the Magellan robotic system mainly consist of preclinical studies, case reports, and clinical studies with small subject numbers. This evidence emphasizes the navigational advantages of the Magellan robot. Clinical trials investigated renal and visceral target vessel catheterization during fenestrated endovascular aneurysm repair (FEVAR) using the Magellan system (30). An 81% success rate with a median cannulation time of 263 seconds was shown. In addition, Bismuth and colleagues demonstrated the successful application of the Magellan system for chronic iliofemoral and femoropopliteal lesions with crossover technique (31). The study highlighted that with the assistance of the robotic system, even complex tasks could be performed by operators less experienced in PVI.

Cheung et al. described that contralateral gate cannulations with robotic assistance during endovascular aortic repair (EVAR) were associated with increased movement economy and shorter path lengths (pathway of the endovascular tool-tip, while navigating to the target) when compared with manual navigation (32). Another preclinical study by the same group demonstrated reduced contact forces exerted on the vessel wall when cannulating supra-aortic branches (23), which might reduce cerebral embolization risk. As a continuation of this work, a clinical study was conducted. HITS (high-intensity transient signals), as the sign of cerebral embolization, were detected by TCD (transcranial doppler ultrasound) during robotic and manual catheter placement into the aortic arch. Results showed that robotic assistance significantly reduced cerebral embolization (22), which might result from reduced vessel wall contact.

Advanced 3 dimensional imaging capabilities and electromagnetic motion tracking systems may allow us to perform endovascular navigation without the use of radiation. A preclinical study combined the steerable catheter of the Magellan robot with the

electromagnetic tracking system and achieved automation in endovascular navigation in an aortic aneurysm phantom. The function of „assisted-navigation" oriented the catheter tip toward the predefined target vessel. Next, the operator only had to advance the guidewire to cannulate the vessel. „Assisted-navigation" compared to conventional fluoroscopy guided manual cannulation significantly reduced cannulation time (8:12 min vs 3:09 min), while fluoroscopy time was reduced almost to zero (2 seconds). (33,34)

### 1.3.2. CorPath system

As the CorPath 200 robotic system was primarily designed for coronary arterial interventions, the first studies focused on percutaneous coronary interventions. A proof-of-concept study included eight patients with coronary artery disease undergoing PCI. A procedural success of 97.9% was reported, and a 97% decrease in radiation dose was achieved for the operator (19). The PRECISE trial, a large multicenter study, evaluated the effectiveness of robotic-assisted PCI with the inclusion of 164 patients. The clinical success rate was high (97.6%), and no major complications occurred throughout the study. In addition, radiation exposure for the operating physician was reduced by 95.6% (35). A single-center trial (36) of 71 consecutive rPCI patients reported similar results; despite including more patients with a majority (88.4%) of complex coronary lesions (B2/C)(33), the robotic PCI success rate was 94.2, due to the need of manual conversion in 5.8% of the cases.

The first prospective clinical trial to evaluate the use of the CorPath system for PVI was the RAPID trial (37). A total number of 20 patients with 29 superficial femoral and popliteal arterial lesions were enrolled in this study. Robotic-assisted balloon angioplasty was performed in 65.5% of the cases, while 34.5% of the lesions required stent implantation. Investigators concluded that robotic-assisted peripheral transluminal angioplasty and stenting is feasible with 100% technical, safety, and clinical success. The mean total procedural time (39.1±15.8 min) and the mean fluoroscopy time (7.1±3.2 min) were comparable with the reports of treating leasions with similar characteristics. No significant adverse events occurred. The RAPID II clinical trial (38) evaluated the effect of robotic assistance on radiation exposure for the operator in patients undergoing peripheral drug-coated balloon angioplasty. The clinical success rate was 100%, no adverse events occurred, and a radiation reduction of 96.9% was demonstrated. Case

reports and case series report the successful use of the CorPath system for below-the-knee intervention (39,40) and renal arterial revascularization (41,42).

Another peripheral application of the CorPath system is carotid artery stenting (CAS). A preclinical study conducted by our research team demonstrated that robotic-assisted CAS is associated with smoother endovascular tool movements compared to manual CAS (43). The difference between manual and robotic navigational properties may be associated with a lower cerebral embolization risk. Therefore, clinical studies with robotic-assisted CAS are warranted to evaluate this concept. Although larger clinical trials with robotic-assisted CAS have not been published yet, several case series are available with promising results of this treatment modality (44-46).

Technical modifications were applied to the CorPath GRX system, so it became able to facilitate neuro-endovascular interventions (47). Preclinical studies demonstrated the capability to navigate in external carotid arterial branches (48) and arteriovenous malformation (AVM) embolization (49) in porcine and flow model. The first case report of the in-human neurovascular use of the CorPath GRX system was presented by Pereira et al (50). They managed to perform stent-assisted coiling of a basilar artery aneurysm. A recent publication reports a case series of 6 patients treated with intracranial aneurysms with robotic assistance (51). Patients were treated with neck-bridging or flow-diverting stents with an excellent 100% procedural success rate without the need for manual conversion.

## 1.4. Remote interventions

The fact that endovascular robotic systems can be driven from outside the operating room, and there is no need for the operator to stay in the immediate proximity of the interventional suite opens the possibility of remotely performed interventions, even from long geographical distances (52). After introducing software developments of the CorPath robotic systems and with advancements in telecommunicational systems, the robot became capable of remote interventions.

The rapid technical evolution of endovascular interventions and the introduction of novel procedures and devices is leading toward a highly specialized medical service in this field. Medical specialists with extensive experience with specific procedures are usually available in higher-level specialty care centers. Remote interventions could play a role in distributing care to remote, underserved areas. This could be particularly useful in acute cases, such as acute stroke (53), acute myocardial infarction, active bleeding, or acute peripheral arterial occlusion. Obviously, limitations exist; besides the operator, the interventional staff on the patient side require training on the robot and the procedure in question. Moreover, these cases often require care postoperatively in the cardiovascular intensive care unit, which is also an important condition to fulfill in these centers.

The quality of telecommunication and reliable network stability are key factors during these procedures and are needed for both endovascular navigation and audiovisual communication. To establish a high-speed network connection and sufficient vocal and visual communication, a local area network (LAN) should be used. Monitors are needed at both local and remote sites to enhance communication between teams.

During remote interventions, the operator navigates the endovascular tools with joysticks. Movements of the joysticks translate to robotic-driven movements of the endovascular tools. After that, the movement information of the endovascular tool appears in the fluoroscopic image so that the operator can see the operational field. The time between manipulating the joystick and the actual movement of the robot is defined as network latency. It is mandatory to keep the network latency low throughout the procedure to reach real-time manipulation by the operator. To achieve good patient safety and robotic navigation, we need to mark the threshold of network latency, which is acceptable for the interventionalist.

Such procedures have been demonstrated previously with the DaVinci (Intuitive Surgical, Inc, Sunnyvale, Calif) robotic system. Cases of transatlantic robot-assisted telesurgery were presented in 2001 (54). Since then the support for even more reliable, and faster connections allowed surgeons to perform radical nephrectomies with 5G connection over great geographical distances (1775 km) (55).

Madder et al published a study on regional and transcontinental endovascular robotic interventions, where Boston to New York (206 miles), and Boston to San Francisco (3085 miles) long-distance robotic coronary navigation was performed with 5G connection (56). They achieved the cannulation of 20/20 navigational targets in the regional model, and 16/16 navigational targets in the transcontintenal model. The transcontinental network latency was significantly higher compared tot he regional latency (162.5 ± 1.1 ms vs. 86.6 ± 0.6 ms), however it was found to „imperceptible" by the operator.

The first in-human case series of long-distance tele-stenting done by the CorPath 200 system was published by Patel et al. (57). Their group described five cases of percutaneous coronary interventions (PCI) from a distance of 20 miles in patients with single, type A coronary lesions. The procedural success was 100% without the need of manual conversion, and no major adverse events occured.

Although a few studies have already reported remotely performed endovascular procedures, our knowledge still needs to be improved in terms of the optimal network quality and personal and technical requirements for effective telecommunication between the interventional (remote and patient-side) teams. In addition, previous works only covered remote robotic-PCIs, and have not studied peripheral vascular interventions which differ in multiple procedural aspects.

## 1.5. Endovascular simulators

Endovascular simulators are capable of modelling human vascular anatomy, and they allow us to complete endovascular interventional cases in a virtual environment. The user can access multiple modules based on their specialty. The main application of these simulators is endovascular training and evaluation of technical skills. Studies show that endovascular simulator based training plays a role in shortening the learning curves of procedures (58,59). Moreover, it helps to achieve decreased fluoroscopy times in real-life cases, when operators train with the simulator before. Residents, who participated in

simulator training for EVAR performed significantly better in terms of procedural time, fluoroscopy tim, and contrast media dose compared to those, who did not receive training (60).

Besides training, simulators are becoming a tool for device testing purposes (Fig. 3). Nogueria and collegues, who were amongst the first ones to describe in human robotic-assisted carotid artery stenting used the Simbionix AngioMentor simulator to train for robotic assisted carotid artery stenting with the CorPath GRX system (46).

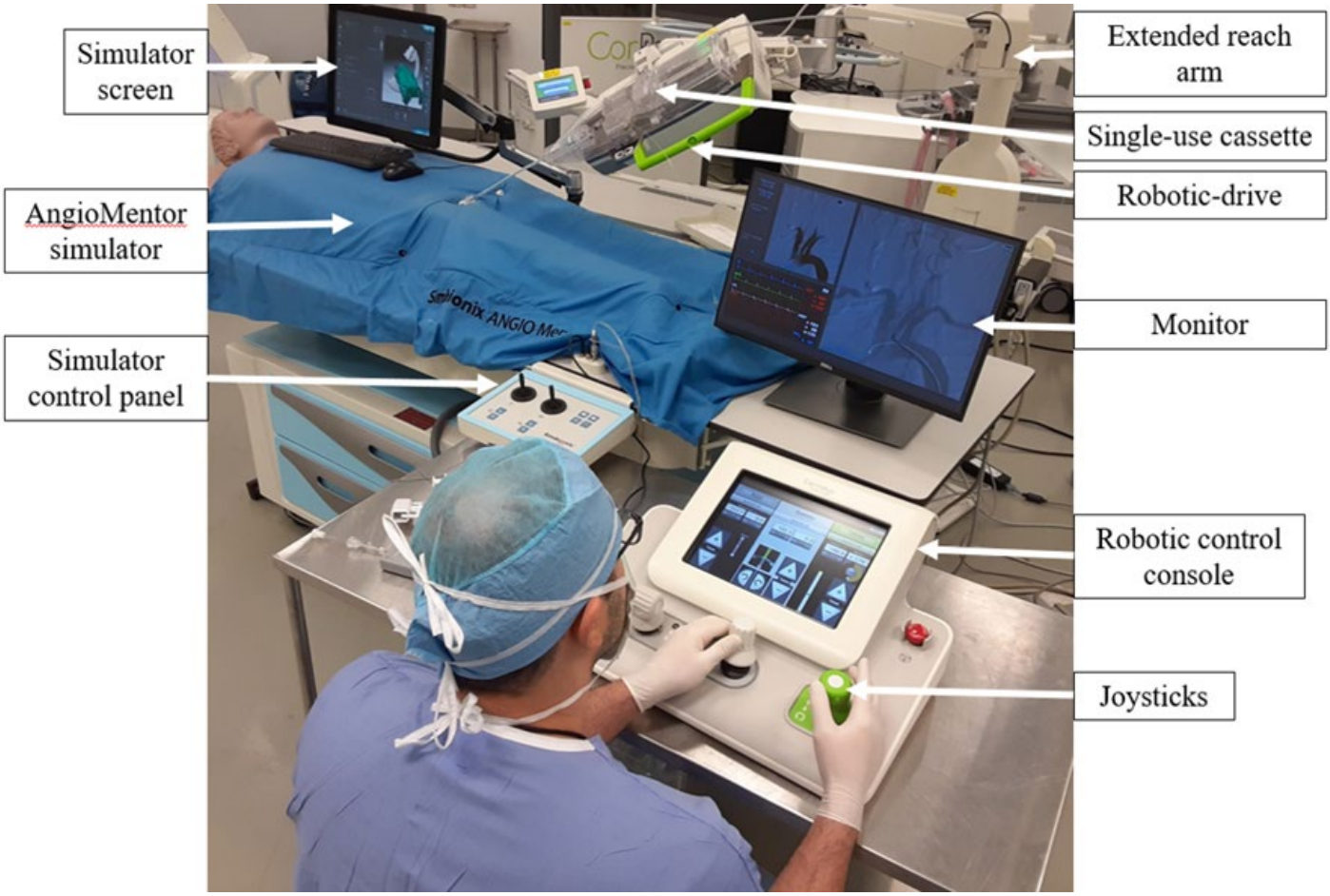


***Figure 3.*** *Using the Simbionix AngioMentor simulator system with the CorPath GRX robot. The robotic work station is set up next to the simulator. (43)*

## 2. Objectives

The current work aims to understand the requirements, characteristics, and limitations of remote robotic-assisted endovascular interventions. Our objectives are the following:

1. to perform successful robotic-assisted navigation to anatomical targets with the remote prototype CorPath GRX system in peripheral, carotid, and coronary arteries

2. to evaluate the effect of network latency on robotic-assisted endovascular navigation and to determine the amount of tolerable latency in coronary, lower extremity, and extracranial arteries using an in vivo experimental model.

    - Hypothesis 1: increased network latency time is associated with increased guidewire navigation time
    - Hypothesis 2: increasing network latency time affects the operator's perceived latency, and impacts the completion of the procedure

3. to evaluate the feasibility of tele-PVI, and to assess the procedural workflow and the possible obstacles in telecommunication during telerobotic peripheral vascular interventions
    - Hypothesis 3: After completing a first set of cases, procedural time and the quality of communication improves in the second set of cases

## 3. Methods

The summary of the study plan is illustrated in Figure 4.

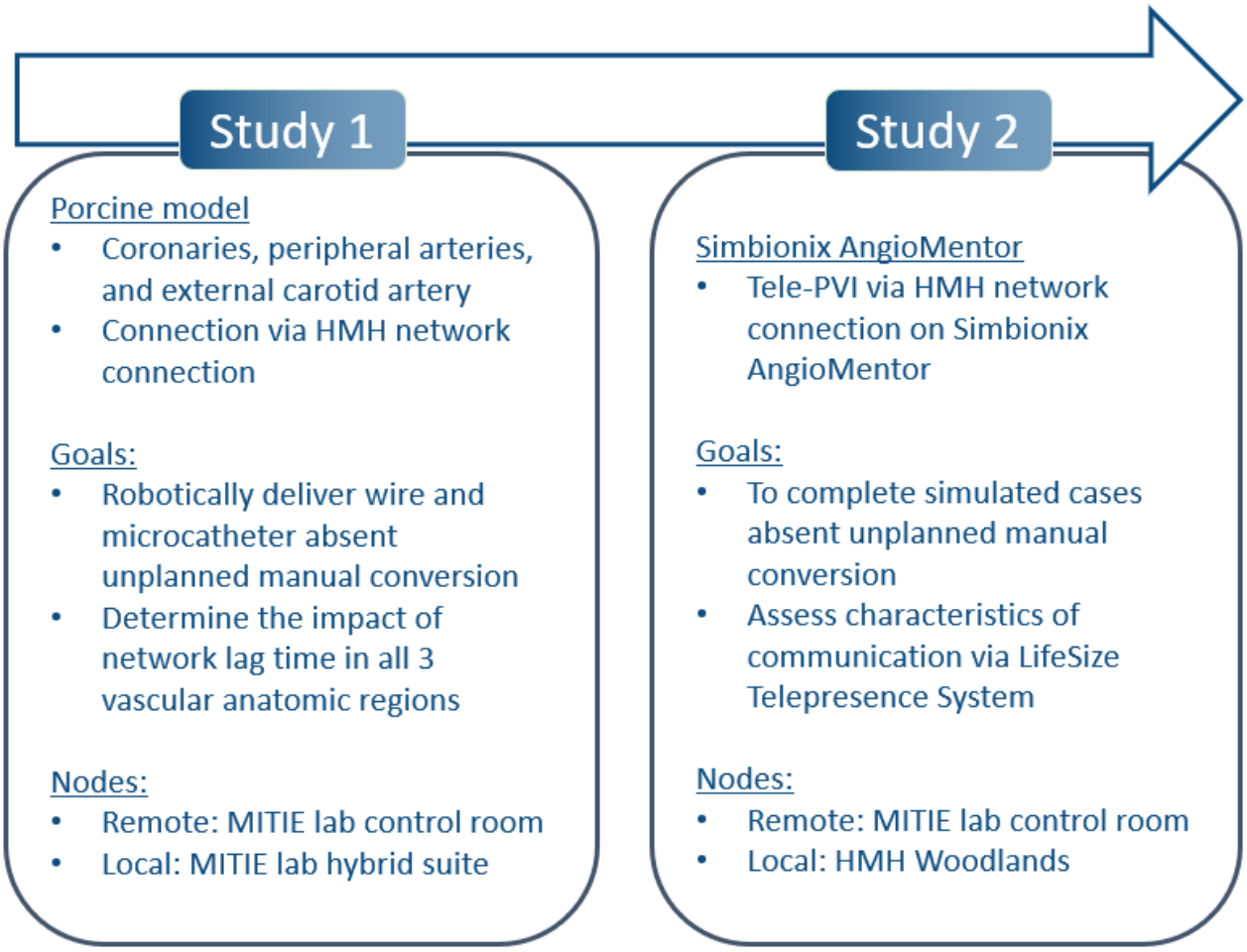


***Figure 4.*** *Illustration of the study plan. The first study was performed in a porcine model and assessed the effect of network latency for endovascular robotic navigation. The second study utilized an endovascular simulator to evaluate the procedural characteristics of remote interventions. HMH: Houston Methodist Hospital, MITIE: the Houston Methodist Institute for Technology, Innovation & Education, PVI: peripheral vascular intervention*

## 3.1. The CorPath GRX system

The CorPath GRX system (Corindus, A Siemens Healthineers Company, Waltham, MA, USA) and its prototype modification were used in the studies. The system includes three main components; an interventional cockpit, a robotic arm, and a robotic drive.

The operator drives the robot from the interventional cockpit, a workstation. It consists of an X-ray foot pedal, a touchscreen control console (Fig. 5), three joysticks for the navigation of the different endovascular tools, and monitors displaying the patient's vital parameters, real-time fluoroscopy, and angiographic images. It can be located either in the operating room with a radiation shield or outside the operating room.

In the currently discussed studies, the workstation was complemented by a telepresence system (LifeSize, Austin, TX) to ensure audiovisual communication between the operator and the interventional team.

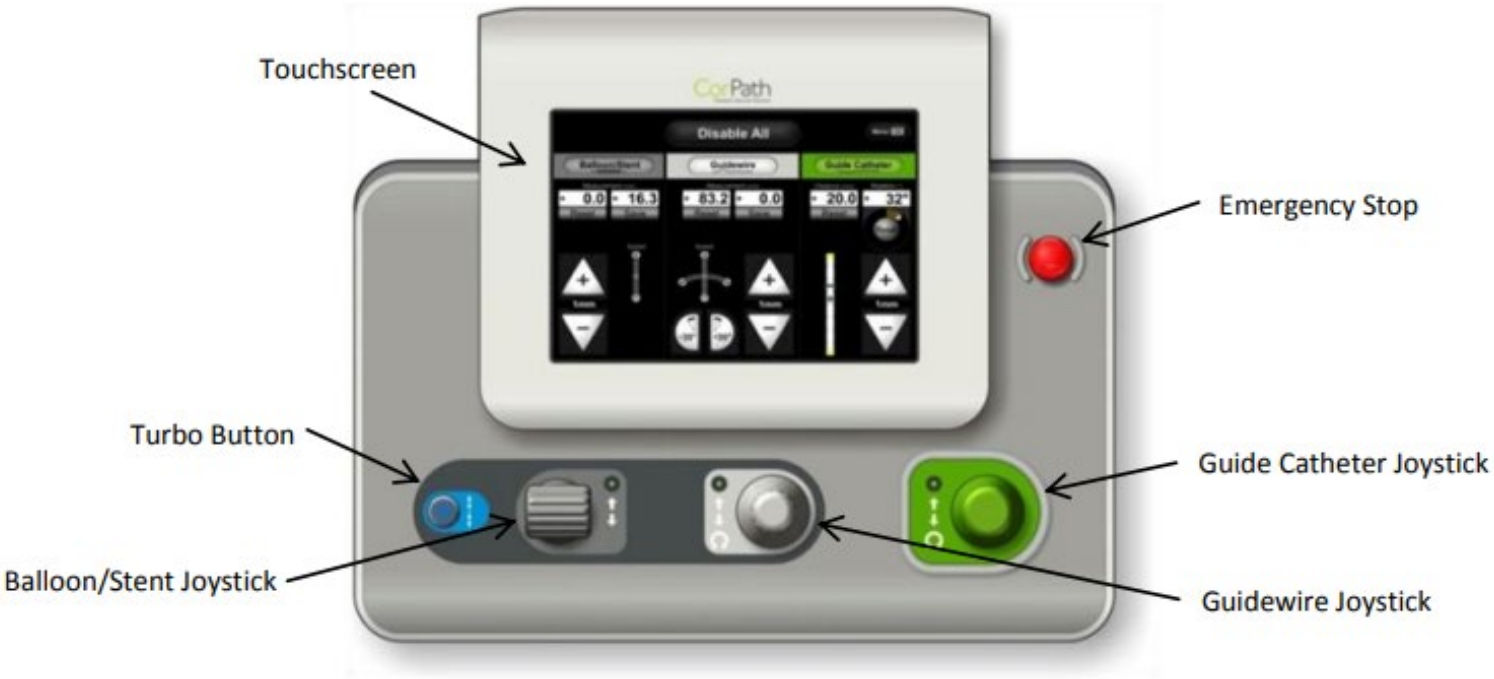


***Figure 5.*** *CorPath GRX Workstation for robotic control. The touchscreen displays the device coordinates and allows stepwise precision control of the endovascular tools. Three joysticks serve for guide catheter, guidewire navigation, and balloon/stent positioning. The turbo button accelerates device exchanges. (27)*

The bedside component (Fig. 6) includes a flexible robotic arm, a robotic drive, and a single-use sterile cassette. The flexible robotic arm is mounted on the operating table's rail, supporting the robotic drive. The robotic drive accomplishes mechanical operations received from the control console. The forward and backward movements of the robotic drive actuate the movements of the guide catheter. The single-use sterile cassette is attached to the robotic drive, enabling the guidewire, catheter movements (advance, retract, rotate), and rapid-exchange device movements (advance, retract).

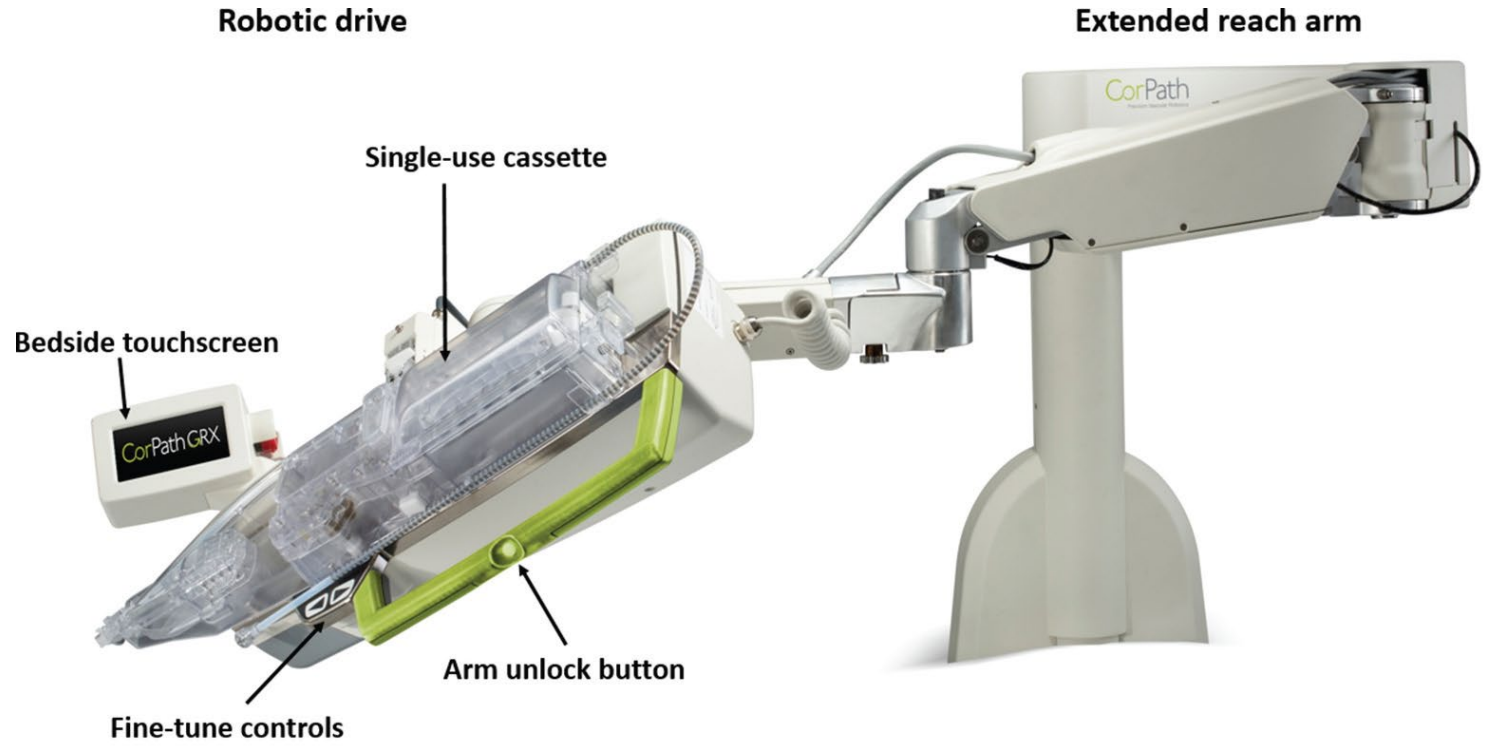




***Figure 6.*** *The bedside component of the CorPath GRX system. The robotic drive can be positioned with the extended reach arm, which is unlocked only when the arm unlock button is pressed. Fine-tune controls are used to adjust the robotic drive to the access site. The single-use sterile cassette is replaced for each procedure. Endovascular devices are placed in the cassette manually, so the gears of the cassette can navigate them. Commands for device exchange, cassette exchange, or procedure termination are given on the bedside touchscreen. (27)*

## 3.2. Network and communication

A remote prototype modification of the CorPath GRX system was utilized for the study. This modification allowed us to physically separate the remote and patient side (local) nodes. The institutional network was used to connect the nodes. The robotic control unit and the robotic drive were connected to a target computer (Mobile RT, Speedgoat, Inc., Natick, MA) that each utilized a grandmaster clock and global positioning system antenna for synchronization of the control unit with the robotic drive. The operator's input was transmitted from the control console joysticks into the target computer on the control side. The institutional network provided network access (wide area network) on both sides. However, all communication between the target computers on the control side and patient side is routed through a virtual private network, which also serves as a firewall (FortiGate; Fortinet). The commands were received by the patient-side target computer and transmitted to the robotic drive to actuate the desired devices. The robotic drive actuated the devices in the patient simulator, the simulated fluoroscopy video was updated according to device movement, and the fluoroscopy video was transmitted back to the control side operator via the same target computers (61).

To simulate network latency, an engineer programmed the system to delay robotic commands. Simulated latency times ranged between 0 and 1000 ms (0-150-250-600-1000 ms), and these values were added to the low – but not zero – native latency of the institutional network.

Communication between the remote and patient side teams was achieved by a telepresence system (LifeSize, Austin, TX). By integrating multiple cameras, and microphones, this system provided live audiovisual stream of the interventional suite, operational field, and remote workstation. In addition, the telepresence system allowed the operator and the patient side team to communicate without interruption verbally.

## 3.3. Study I – The effect of network latency on performance

### 3.3.1. Study design and data collection

Three interventional specialists participated in the study. Operators had extensive endovascular experience and have performed over 20 endovascular, robotic-assisted procedures in preclinical and clinical settings. Peripheral arterial (femoral artery), neurovascular (external carotid artery), and coronary arterial navigation (Fig. 7) was performed by a vascular surgeon, neurosurgeon, and an interventional cardiologist, respectively. Specialists performed navigation only in their field of expertise. It is important to note that intracranial endovascular navigation cannot be performed in a pig model since an anatomical structure called rete mirabile. Therefore external carotid artery branches were used to simulate the intracranial navigation best.

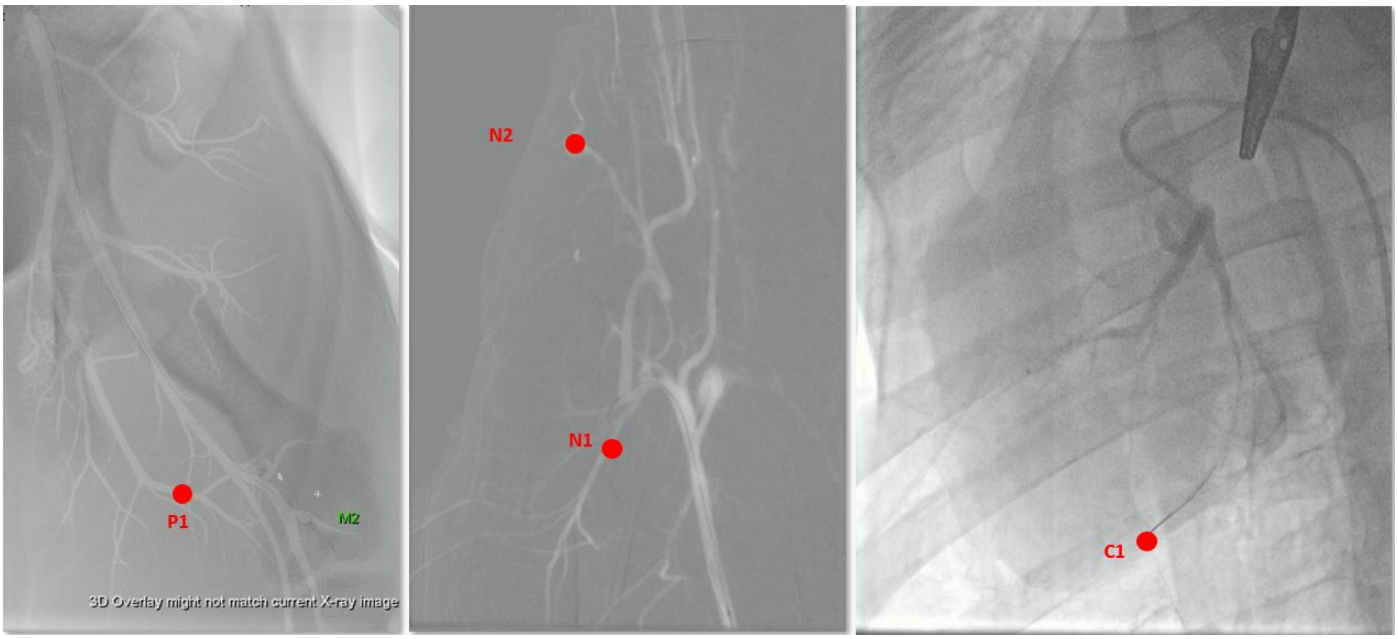


***Figure 7.*** *Mask images from the porcine model. The navigational target vessels are marked. Operators navigated to the following vascular targets: distal branch of the deep femoral artery (P1), branch of the popliteal artery (P2), a branch of the lingual artery (N1), a branch of the facial artery (N2), and the diagonal branch of the the left anterior descending coronary artery (62)*

Each operator performed robotic-assisted navigation. Their task was to drive the guidewire tip to the preselected vascular target marked on their monitor. First, four practice navigational runs were completed. After that, robotic command latencies (delays) ranging from 0 to 1000 ms (0, 150, 250, 400, 600, 1000 ms) were randomly added to the system. Operators were blinded to latency times. It is essential to add that the local area network connection has an intrinsic command and image latency. Although it was incremental to the artificially added latency times, it was negligible.

A navigational run was defined as the wire advancement from the tip of the sheath until the wire tip reaches the preselected vascular target. A study team member recorded the procedural time of each navigational run. After each run, the operator was asked to score the perceived latency and how the latency impacted the procedure.

The scoring system used for the perceived latency:

1= imperceptible

2 = noticeable but minor

3 = noticeable

4 = noticeable and major

5 = too long

The scoring system used for the procedural impact:

1 = no impact

2 = minor impact (acceptable performance)

3 = noticeable impact (loss in efficiency, successful outcome)

4 = significant degradation (can complete, but not desired)

5 = unacceptable to complete

### 3.3.2. Animal model and procedural details

A domestic cross, female swine (49 kg) was utilized. The procedure was conducted under a protocol approved by the Institutional Animal Care and Use Committee. A clinical veterinarian did the anesthesia and the monitorization of the animal. The in vivo model and the bedside technician were located in the hybrid interventional suite. Operators were driving the robot from the control room, separated by a wall, and facing away from the hybrid suite (Fig. 8).

After introducing standard general anesthesia, the right femoral access site was prepared and draped, and femoral arterial access was gained. Under fluoroscopy guidance (Zeego; Siemens Healthineers, Malvern, PA) a 6 French sheath (Destination; Terumo Interventional Systems, Somerset, NJ) was introduced in the contralateral common femoral artery manually. Then robotic-assisted lower extremity arterial navigation was performed by a 0.014 inch (BMW; Abbott Vascular, Santa Clara, CA) and a 0.018 inch (V18; Boston Scientific, Marlborough, MA) guidewire and a 0.027″ microcatheter (Renegade; Boston Scientific, Marlborough, MA). Next, the sheath was exchanged to a 7 French, 90 cm system (Codman, Raynham, MA), and the external carotid artery was cannulated manually. Robotic-assisted navigation was performed by a 0.014-inch guidewire (Synchro2, Stryker Neurovascular, Fremont, CA) and a Renegade Hi-Flo microcatheter (0.027″ ID, 135 cm). After completing the external carotid artery navigation, we prepared for the coronary arterial navigation. Manually, a Q3.5 guide catheter (Boston Scientific, Marlborough, MA) was placed in the left coronary artery ostium. Robotic-assisted navigation was performed with a 0.014-inch guidewire.

Whenever the observed arterial bed was accessed, angiography was performed from the sheath. The navigational target vessels were marked based on the angiographic image. These endovascular targets were one of the distal branches of the deep femoral artery, the lingual artery, a branch of the facial artery, and the diagonal branch of the left anterior descending coronary artery. After completing the endovascular navigational tasks, devices were removed, the access site was closed, and the animal was euthanized.

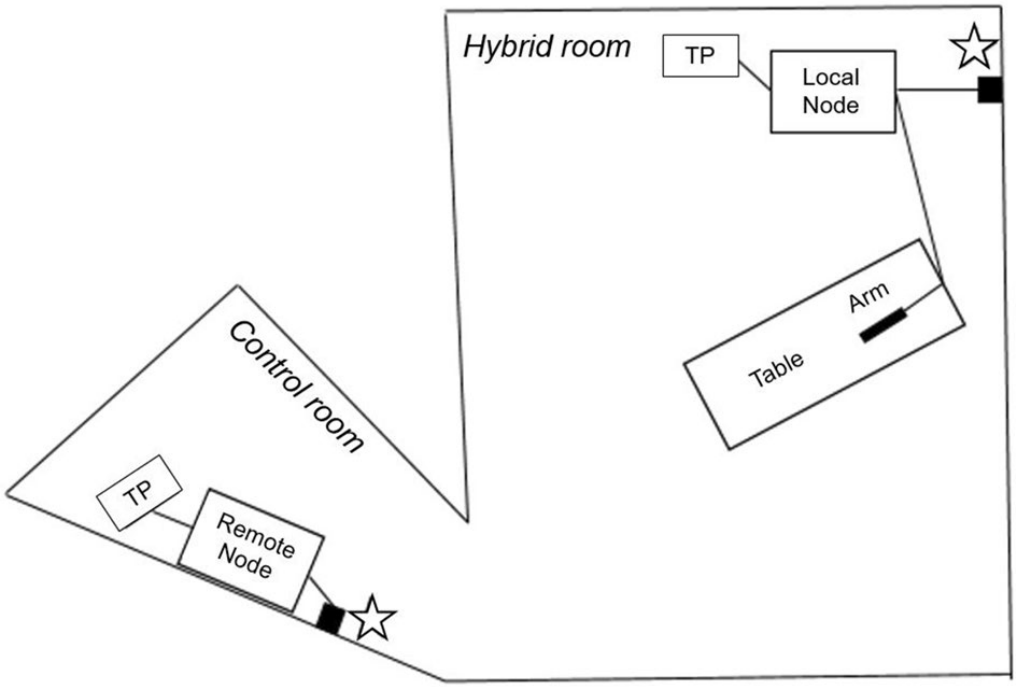


***Figure 8.*** *The layout of the interventional hybrid suite and the control room, which was set up to assess the effect of network latency. The operator was in the control room, facing away from the hybrid room. The hospital network connection was used for the study (stars). Between the two rooms, communication was achieved by telepresence system (TP). The operating table and robotic arm is marked in the figure. (62)*

## 3.4. Study II - Remote interventions for peripheral vascular disease

Before performing remote robotic-assisted endovascular procedures in human subjects, it is necessary to gain knowledge of the personal communicational features and audiovisual telecommunicational conditions and to understand the possible hardships of this novel procedural modality. As a second part of our study, remote peripheral vascular interventions were simulated from a long geographic distance.

### 3.4.1. Study design and data collection

The study included two locations. The remote operator was a vascular surgeon with an extensive experience in peripheral endovascular procedures and has performed over 20 robotic-assisted in vivo and ex vivo cases. He was navigating the robot from the robotic workstation (Houston Methodist Hospital Medical Center – "remote"), while the

robotic arm was located 70.8 km away (Houston Methodist Hospital Woodlands – "patient side") (Fig. 9).

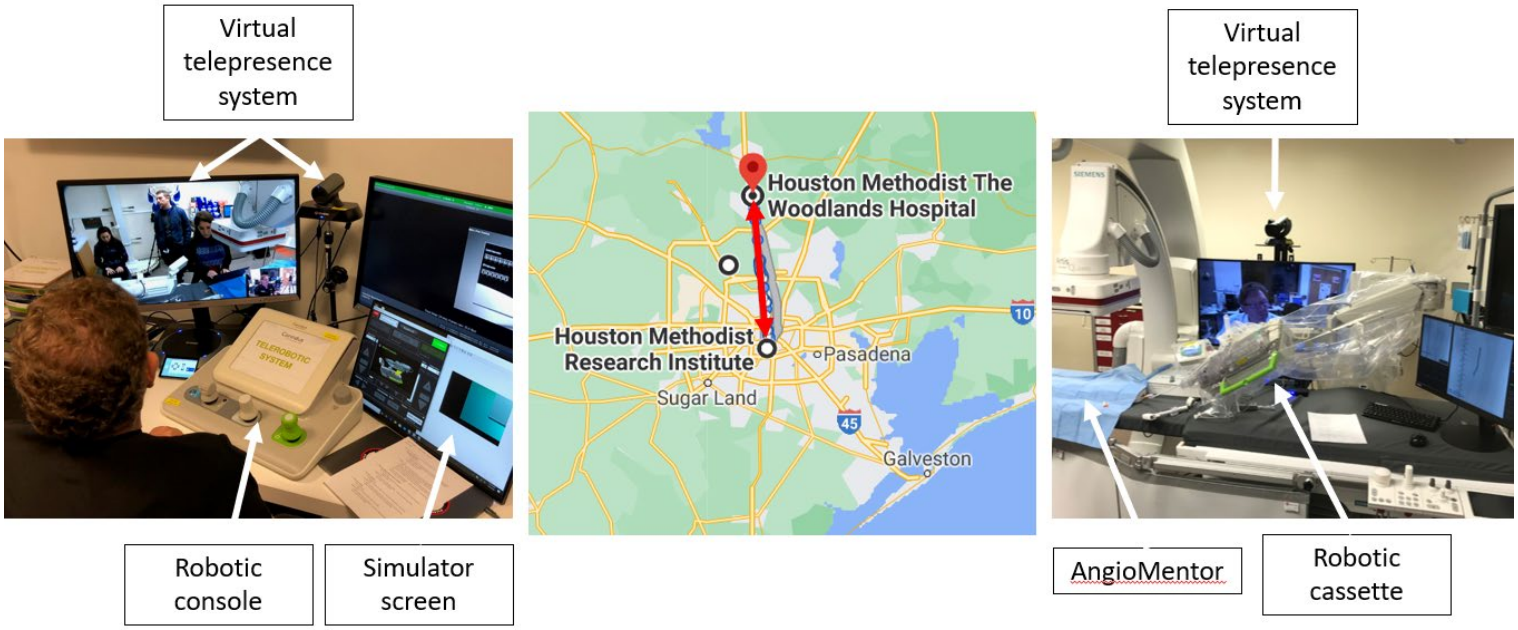


***Figure 9.*** *Left: remote site for long-distance PVI simulation. The workstation included the remote prototype control console, a virtual telepresence system, and the simulator screen to facilitate device selection and to see the fluoroscopic image. Middle: geographical positions of the two sites. The distance between HMH and HMH Woodlands was 40 miles. Right: layout of the patient-side interventional room. The AngioMentor endovascular simulator was used. The robotic system was prepared and draped. The virtual telepresence system provided audiovisual telecommunication. (61)*

An endovascular simulator was used to simulate five superficial femoral arterial cases, which were suitable for endovascular interventions. Arterial lesions were selected based on the TASC II (Trans-Atlantic Inter-Society Consensus Document II) classification system and had to fall into A and B classes. Lesion lengths varied between 12.9 and 121.15 mm (Fig. 10). Cases were completed randomly by the operator in two procedural blocks. The two blocks were completed with 3 hours difference. In each procedural block, a planned "emergency" occurred when manual conversion was required, for which the remote operator was blinded. One case occurred during balloon positioning, while the other occurred during stent placement.

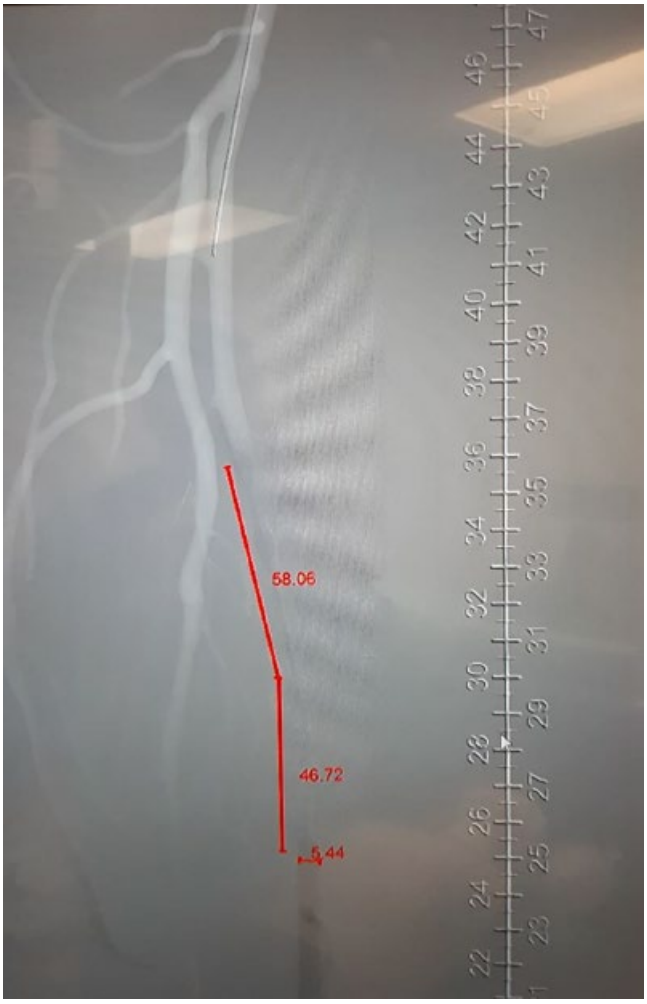


***Figure 10.*** *DSA image of case no. 5. A superficial femoral artery stenosis is shown in the image. Lesion length and diameter was measured in the simulator screen, to choose the correct stent and balloon size. DSA: Digital subtraction angiography (61)*

The procedure was considered successful when the robotic-assisted treatment of the lesion was achieved without any unplanned manual conversion and with 30% or less residual stenosis in the final angiogram. Technical success was defined as completing the procedure without communication break or any device-related difficulties. Network latency was calculated at every 50 ms throughout the entire study. It was defined as the time which elapsed from the joystick command until the endovascular device movement was seen in the remote-side fluoroscopy image by the operator. It was noted if the latency of the network exceeded 1000 ms at any point during the study. The simulator software registered the fluoroscopy time, the amount of contrast media used, and the residual

stenosis. These data were listed after the completion of each procedure. The remote operating physician and the bedside technician were interviewed after each pocedure and rated the quality of the communication on a 1 to 5 scale:

1 = unacceptable—cannot hear or see the other person

2 = poor—can hear and see, but not sufficient to complete the case

3 = sufficient to complete the case

4 = good—connection does not affect case completion, miscommunication occurred

5 = ideal—as effective as in-person communication

### 3.4.2. Endovascular simulator and procedural details

The AngioMentor endovascular simulator (3D Systems, Israel) is a highly realistic system used for training and device testing purposes. An industry representative trained the participants with the endovascular simulator and the robotic system (CorPath GRX). The entire team underwent training on the remote procedure workflow and learned communication techniques through the telepresence system. To achieve optimal results, and avoid the failure of communication between team members, standardized commands and feedback were used to coordinate best the procedural tasks (e.g., 'inject contrast,' 'injecting'; 'fluoro off,' 'fluoro is off').

Every procedure began with the patient-side vascular surgeon manually gaining contralateral common femoral arterial access. After that, a 0.035-inch guidewire and a 6 French guide catheter were manually placed in the ipsilateral common femoral artery. The bedside technician connected the guide catheter to the robot, and the endovascular tools (guidewire, catheter/balloon/stent) were placed in the robotic cassette. From this point, the remote operator continued the intervention from the remote robotic cockpit by performing robotic-assisted crossing of the stenosis, predilation, stent positioning, stent deployment, and postdilation. Balloon and stent selection was left to the operator's decision based on the measurements made in the angiographic images. The bedside technician was responsible for the contrast media injections, balloon inflations, and device exchanges. These tasks were performed based on the remote operator's voice commands.

### 3.5. Statistical analysis

Categorical data are presented as count (n) and percentage (%), and continuous variables are demonstrated as mean and standard deviation (SD), or median and range. Shapiro–Wilk test of normality was used to assess normal distribution. To analyze the effect of network latency during the endovascular navigation in the porcine model, two groups were constructed as peripheral – including femoral and external carotid –, and coronary arterial. The Kruskal–Wallis test was used to determine if wire navigation times, perceived latency scores, and procedural impact scores were different among the artificially induced latencies. P for trend was obtained from a Wilcoxon-type test for trend to evaluate the tendency in perceived latency and procedural impact scores by the increased latency times. Post-hoc tests for comparing added latency of 0 ms with added latencies up to 1000 ms were performed with the Man-Whitney test. To evaluate the results of remotely performed endovascular procedures between the procedural blocks, a two-sample t-test, Wilcoxon rank-sum test, and Fisher's exact test were used when appropriate. A p-value below 0.05 was considered significant. STATA statistical software (StataCorp LP, College Station, TX, USA), and SPSS (IBM, Armonk, New York, USA) was used for statistical analysis.

# 4. Results

## 4.1. Study I – The effect of network latency on interventional performance

### 4.1.1. Procedural success and guidewire navigation time

A total of 65 robotic-assisted guidewire navigation attempts were included in the study. Added network latencies varied from 0 to 1000 ms. The procedural success was 100%, which means that every guidewire navigation attempt ended in reaching the preselected vascular target with the guidewire's tip.

Femoral arterial navigation to the P1 target was completed in 9 cases (13.8%) with a mean guidewire navigation time of 131 ± 84.25 seconds. External carotid arterial navigation included 38 cases (58.5%). The mean navigation time to N1 (n=19) and N2 (n=19) vascular targets were 26.26 ± 29.66 and 104.9 ± 84.25 seconds, respectively. Coronary arterial navigation to the C1 target was performed in 18 cases (27.7%). The mean navigation time for coronary arterial navigation was 70.22 ± 65.18 seconds. No significant difference or trend was registered between added latency times and the guidewire latency times across the vascular regions (Fig. 11).

### 4.1.2. Procedural impact and perceived latency scores

By increasing the network latency, a significant trend of higher scores were observed in procedural impact and perceived latency scores in the three anatomic regions ($p = 0.006$ and $p = 0.002$, respectively) (Fig. 12). In addition, the distribution of procedural impact scores ($p=0.048$) and perceived latency scores ($p=0.038$) showed significant differences when comparing them across the different added latencies. When peripheral arterial (deep femoral, external carotid), and coronary arterial navigation were separately analyzed, no significant difference was seen in the scores. However, a non-significant tendency of higher scores with longer latencies could be observed. (Fig. 13).

Post-hoc analysis of the procedural impact and perceived latency scores was performed by multiple comparisons. No significant difference was seen between the baseline latency (0 ms) and latencies of 150 and 250 ms. However, when comparing the

baseline latency to latencies of 400 ms and above, both procedural impact and perceived latency scores have significantly increased (Tables 2 and 3).

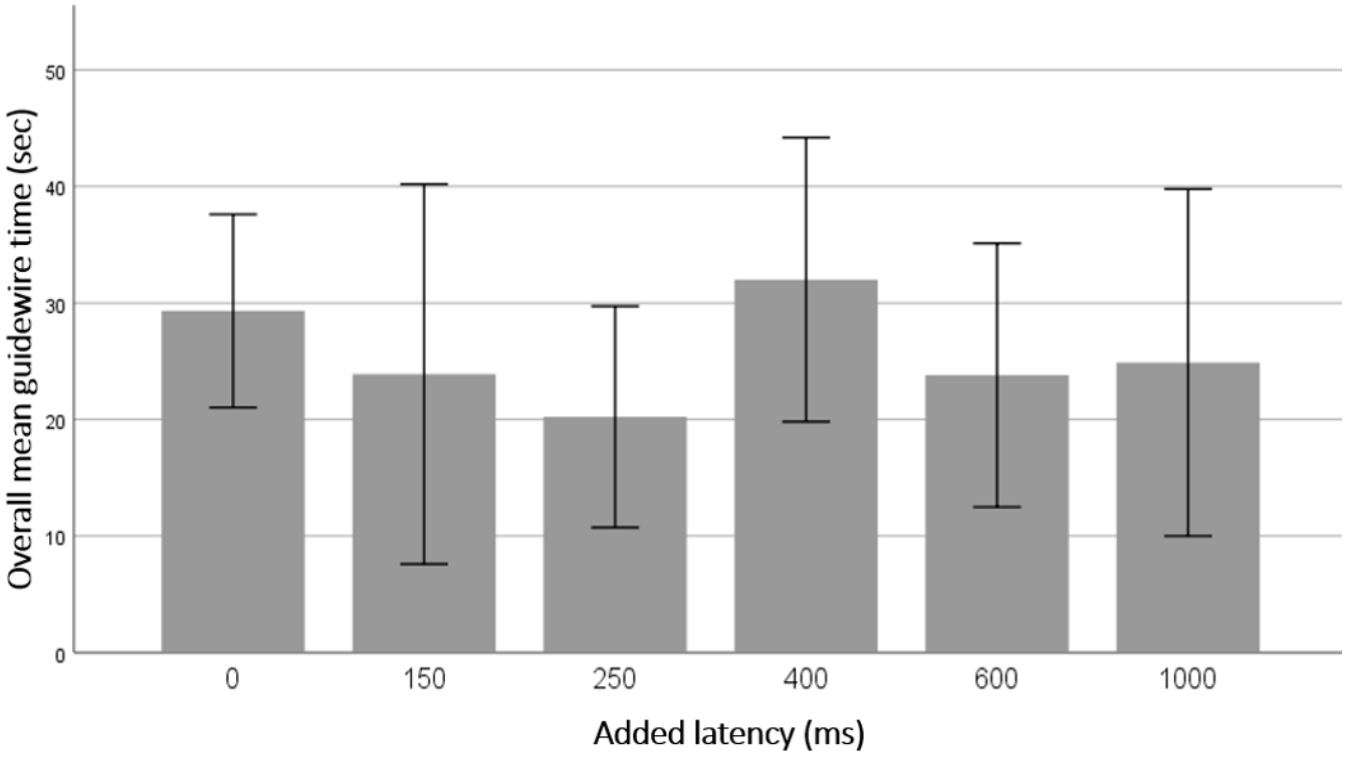


***Figure 11.*** *Line graph illustrating the overall guidewire navigation times across the different anatomic regions. Added latencies from 0 to 1000 milliseconds (ms) are presented in the x-axis, while overall mean guidewire navigation time is presented in the y-axis. No significant difference was seen when comparing guidewire navigation times with different added latencies. (62)*

***Table 2.*** *Procedural impact scores with different added latencies. Procedural impact scores (mean±SD) with different added command latencies (ms). Scores with added latencies were compared to scores with 0 ms added latency. The P-value was considered significant <0.05*

| Added latency (ms) | Procedural impact (mean±SD) | p-value |
|---|---|---|
| **0** | 1 | N/A |
| **150** | 1.07±0.7 | 0.55 |
| **250** | 1.11±0.33 | 0.55 |
| **400** | 1.55±0.93 | **0.03** |
| **600** | 1.8±1.23 | **0.01** |
| **1000** | 1.67±1 | **0.02** |

***Table 3.*** *Perceived latency scores with different added latencies. Perceived latency scores (mean±SD) with different added command latencies (ms). The scores with added latencies were compared to scores with 0 ms added latency. The P-value was considered significant <0.05*

| Added latency (ms) | Perceived latency | p-value |
|---|---|---|
| **0** | 1 | N/A |
| **150** | 1.14±0.1 | 0.32 |
| **250** | 1.33±0.5 | 0.13 |
| **400** | 1.91±1.04 | **<0.01** |
| **600** | 1.9±1.45 | **0.03** |
| **1000** | 2±1.41 | **0.02** |

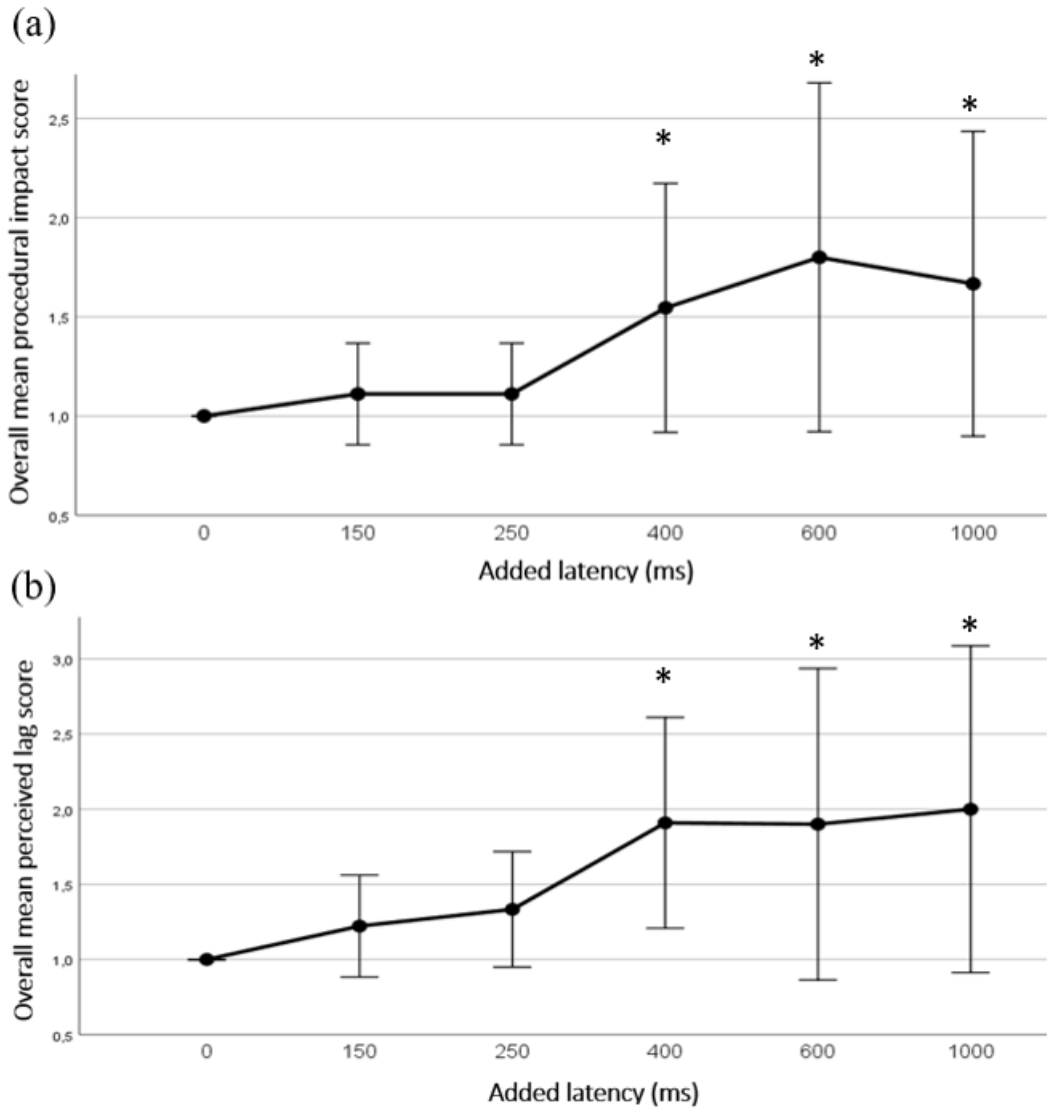


***Figure 12.*** *Line graphs of procedural impact and perceived latency scores (a) Overall procedural impact score (mean±SD) with different added command latencies (ms), (b) Overall perceived latency score (mean±SD) with different added command latencies (ms). Statistically significant values are marked with asterix (*) (62)*

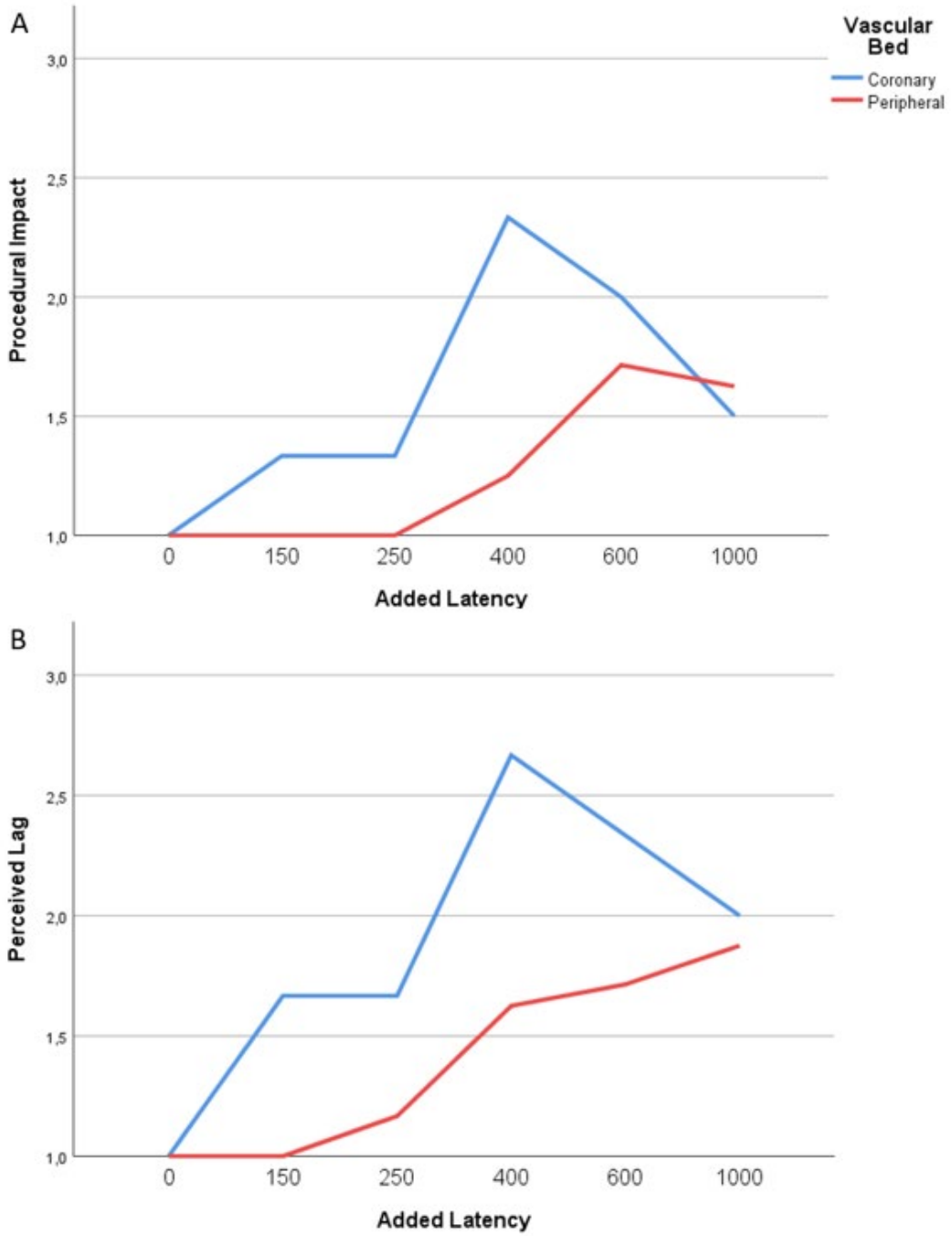


***Figure 13.*** *(a) Procedural impact score (mean ± SD) with command latencies ranging between 0-1000 ms, (b) Perceived latency score (mean ± SD) with command latencies ranging between 0-1000 ms. Blue line: coronary arterial navigation; Red line: peripheral arterial navigation (62)*

## 4.2. Study II - Remote interventions for peripheral vascular disease

A total number of ten superficial femoral interventions were performed from a long geographical distance with a procedural success rate of 100%. The technical success rate was 80%. In two cases, minor robotic system failures had to be corrected. In one case, a catheter prolapse occurred within the robotic support track. Therefore a manual catheter exchange was required. In the other case, the guidewire got stuck in the robotic cassette; hence the guidewire and the cassette needed to be exchanged during the procedure. After the successful device exchanges, the team continued the procedures and successfully completed the interventions. As discussed above, two planned emergencies were simulated, where manual conversions had to be performed. These were finished with no significant adverse events.

The mean residual stenosis, mean fluoroscopy time, and the mean contrast media use across the 10 cases were 1.7 ± 5.25%, 6.5 ± 1.8 min, and 58.8 ± 14.8 ml, respectively. By comparing the two times 5 cases in the two procedural blocks, no statistically significant change in the fluoroscopy time (6.8 ± 2 and 6.2 ± 1.85 min; $p = 0.53$) and in the contrast media use (61 ± 19.3 and 56.6 ± 10.4 ml; $p = 0.33$) (Table 4) was shown. The overall mean network latency throughout the ten cases was 38.9 ± 3.5 ms. The connection was stable during the cases (range: 34-44 ms), and no connection drops were detected between the remote and patient-side locations.

Audiovisual communication feeds were found to be stable during the cases, and no interruptions or lags were experienced. After the completion of each procedure, the remote operator and the bedside technician scored the audiovisual quality of communication; these scores varied between 4 and 5, with a mean value of 4.5. No

significant differences were registered between the two procedural blocks (remote operator, p=0.08; bedside technician, p=0.16).

***Table 4.*** *Outcome measurements in total and for each blocks. The outcomes were compared between block#1 and block#2. There was no significant difference between the procedural blocks. The significance level is $p<0.05$*

| | Mean±SD (total) | Mean±SD (block#1) | Mean±SD (block#2) | p-value |
|---|---|---|---|---|
| Fluoroscopy time (min) | 6.52±1.8 | 6.8±2 | 6.2±1.85 | 0.53 |
| Residual stenosis (%) | 1.7±5.25 | 3±7.35 | 0.38±1.06 | 0.49 |
| Contrast use (ml) | 58.8±14.8 | 61±19.3 | 56.6±10.4 | 0.33 |
| Mean total delay (ms) | 38.9±3.5 | 38.4±3.64 | 39.4±3.7 | 0.68 |

## 5. Discussion

Robotic assistance in endovascular surgical procedures allows the interventionalist to perform interventions from a physically separate location from the patient, even from long geographical distances. However, high-speed and stable network connection requirements and good visual and vocal communication must be fulfilled to perform these procedures efficiently.

The two preclinical, experimental studies presented in this thesis aimed to evaluate the procedural characteristics of remote, robotic-assisted endovascular interventions. Our first study determined the threshold of acceptable network latency during robotic navigation in peripheral vessels, external carotid arteries, and coronary arteries. The second study was designed to demonstrate the feasibility of remote peripheral vascular interventions and to outline the telecommunicational requirements of this interventional novelty.

Results showed that network latency between 0 and 250 ms does not influence navigation time to a vascular target and is acceptable for the operator. Above 250 ms, operators perceived the latency as noticeable, and operators felt that the amount of latency could have a minor impact on their performance. The second study demonstrated the feasibility of successful remote robotic-assisted peripheral vascular interventions in an endovascular simulator model. An excellent procedural success rate (100%) and an 80% technical success rate were seen. The study outlined that a clear verbal communicational protocol and stable network connection are essential to achieve the desired procedural result and an outcome comparable with conventional peripheral vascular interventions.

Robotic-assisted endovascular interventions have been reported in the field of interventional cardiology, peripheral vascular, and neuroendovascular surgery (34,41,50). However, our knowledge is limited to remotely performed robotic-assisted interventions. So far, remote robotic-assisted laparoscopic procedures, including laparoscopic cholecystectomy and nephrectomy have been performed from a long geographic distance. As for endovascular procedures, remote percutaneous coronary interventions have been investigated through a case series by Patel et al (57). This study evaluated five cases where tele-PCI was performed with excellent procedural outcomes, without any adverse events or need for manual conversion. However, remote

interventions have not been studied in the peripheral vascular or neurovascular space before.

Real-time navigation is a critical factor for the interventional team since any flaws or delays in the image transmission can disturb the interventionalist in completing a task, which may decrease procedural success. Therefore, network stability and high network speed are essential requirements for remote interventions. Telerobotic studies of laparoscopic cholecystectomy and nephrectomy suggested that a delay of 330 ms should be the acceptable limit of network latency (52). Madder and colleagues determined that 400 ms or longer network latency during coronary interventions is perceptible for the operating physician (63).

In our preclinical study, operators performed femoral, external carotid arterial, and coronary arterial endovascular navigation with the robot. We intended to select target arteries, which require complex wire and catheter manipulation to reach. No interventional procedures were involved in this current investigation. Therefore the effect of network latency could not be assessed in other endovascular maneuvers, such as stent positioning or deployment. The navigation success to preselected vascular targets reached 100%, which is promising for the precision of endovascular robotic navigation. No difference was seen when analyzing navigation times with the different added latencies, which might be due to the operator's capability to compensate the delay of up to 1000 ms. Besides measuring navigation time to reach the targets, we applied a subjective scale for the operator. The perceived latency score describes how the operator detects the presence of latency throughout the navigational task. The procedural impact score represents the operator's subjective feeling of how the latency affected the task completion. The results show, that there was a tendency of higher scores given by the operators as increasing the latency times to 400 ms and above. Although an increase in scores could be seen the means of the scores remained below and at 2 for both parameters, which means that operators noticed the latency and had only a minor impact on their performance. Since no data was collected on latency times above 1000 ms, we cannot assess the effect of that. However, we could expect the tendency of higher scores would continue outside the tested latency range. Even only noticeable but minor impact on one's performance can affect the successful outcome of a procedure. Therefore, this increase in the scores should

already be considered as a cutoff when determining the threshold of acceptable latency time.

There are limitations to this work. The number of guidewire navigational runs was too low to reach a high enough statistical power to get significant results for the separate vascular regions. This could have been increased by utilizing further porcine models. However, the tendency of higher scores was already demonstrated throughout this study. The only objective measurement was guidewire navigation time. Besides that, only subjective scores were given by the interventionalists. Future studies should include more complex endovascular tasks for the operators to assess other variables, such as fluoroscopy time, radiation time, and procedural success.

The second study we are discussing is a preclinical study, where characteristics of long-distance robotic-assisted PVI have been tested in a high-fidelity endovascular simulator model. Ten cases of PVI were performed from a distance of 44 miles. Lesion crossing, balloon angioplasty, and stent deployment were performed with 100% procedural success from a distance of 44 miles. The network connection was stable, with a mean network latency of 38.9 ± 3.5 ms. The latency ranged between 34-44 ms, and no connection drops occurred. Audiovisual communication between the operating physician and the bedside technician was found to be effective, with scores varying between 4 and 5 (out of 5). Planned manual conversions were also successfully executed.

So far, studies have yet to be conducted to assess PVI from a great geographical distance. A previous proof-of-concept study by Madder et al. (56,64) evaluated the feasibility of remote PCI in a simulator model. Successful balloon and stent delivery and deployment were demonstrated in coronary arteries. However, our work was the first study reporting the utilization of the CorPath GRX system for tele-PVI from a long-geographical distance in a preclinical model.

Vascular surgery is a rapidly evolving field. The newly introduced techniques require highly expertized vascular specialists. Remote interventions might play a role in distributing these advanced endovascular skills to hospitals where no endovascular specialists are available. Moreover, tools we have used in this study to communicate (telepresence systems) can be utilized for remote proctoring, which method might be available widely in medical practice sooner than endovascular robotics. Remote proctoring can assist in procedural support or training. It gained popularity during the

COVID-19 pandemic when restrictions did not allow proctors to be personally present at the hospitals (65).

Using high-fidelity simulator models for device testing, workflow assessment, or training is not a novel solution (66-68). It is a validated tool that allows us to perform procedures through standardized cases in a fixed environment without compromising patient safety and the burden of radiation exposure. Moreover, the standardized cases enable us to evaluate intraprocedural characteristics objectively. In our study, we aimed to select non-complex infrainguinal PAD cases to evaluate the feasibility of tele-PVI appropriately. Cases included SFA lesions, and they were required to use the robotic system's navigational capabilities, such as active guide control, guidewire rotation, or vessel length measurement.

As discussed above, a stable network connection is essential for remote interventions. In the current study network connection was stable, with a mean network latency of 38.9 ± 3.5 ms. Based on the previous findings, this amount of latency is considered a lot below the acceptable latency threshold and imperceptible. The results are consistent with the paper published by Patel et al (57). In their study of tele-PCI the network latency was 53 ± 11 ms. Our study was conducted during regular business hours. Although the network traffic or connection type could influence the network performance, the assessment of this variable was not the purpose of the current study.

Besides fulfilling the technical requirements for seamless audiovisual telecommunication, we established a uniform communication protocol to increase the effectiveness of vocal communication between the two locations. This protocol was found to be successful. Neither of the participants reported communication issues. The operator and the bedside technician rated the quality of the communication 4 (= 'good') or 5 (= 'ideal') after each case.

The mean fluoroscopy time was 6.5 ± 1.8 min, while the mean contrast media dose was 58.8 ± 14.8 ml. The results are comparable to previous robotic studies. In the RAPID trial (37), where simple femoropopliteal arterial lesions were treated with robotic assistance a mean fluoroscopy time of 6.8 ± 3.4 min was demonstrated. Conventional endovascular treatment of lesions with similar characteristics is reported to be associated with a mean fluoroscopy time varying between 7.4 and 16.4 min (69-71). The study did not measure total procedural time. Procedural time could be longer when performing

robotic-assisted endovascular procedures. There is an excess time required to set the system up for intervention. For a trained nurse, the preparation and draping of the system take about 3 to 5 minutes. A non-significantly shorter fluoroscopy time was seen in the second procedural block. The better verbal communication may explain the improvement.

Any unexpected or emergency events with the robotic system and the patient need to be recognized immediately. The patient-side team has to detect these events and communicate them to the operating physician. Preplanned protocols should exist for these cases to rapidly resolve the issue. In addition, the patient-side team needs to understand the limits of the robotic system, and to recognize complications with the patient or the robot. There were two planned manual conversions during the cases. The operator was blinded for these cases. The aim was to assess the team's capability to overcome an emergency event based on the remote operator's instructions. The team has successfully completed both manual conversions.

Limitations of this study exist. They include the low number of observed cases per procedural block, the simple SFA lesions, the single operator, and the use of the endovascular simulator instead of an in vivo model or a clinical case. It is also important to discuss the limitations of the CorPath GRX robotic system. The axial movement range of the catheter is limited – about 20 cm. Current systems are only compatible with 0.014 and 0.018-inch guidewires. However, future-generation devices will be compatible with 0.035-inch guidewires as well. This will be an important step toward usability for PVI. The cost of the robotic system, and the accessories should also be considered. The price CorPath GRX device is ranging between 480 000-650 000 USD, with an additional 400-750 USD cost per procedure. With the currently available generation of the robot these interventions could best be adopted for routine, easily reproducable procedures, such as PCIs, carotid artery stenting, simplex infrainguinal leisons. Available endovascular robotic studies only observed the use of the robot in non-complex lesions, and experience with complex lesions, and complex procedures are needed. Our experience shows that an interventionalist with extensive endovascular knowledge and skills can quickly become familiar with robotic navigation.

## 6. Conclusions

Thesis 1: Guidewire navigation times to preselected targets are not significantly affected between the tested latency range (0–1000 ms).

Robotic-assisted femoral, external carotid, and coronary navigation are feasible with the remote prototype CorPath GRX system in animal model. Guidewire navigation times were not affected by the added latencies.

Thesis 2: Latency of 250 ms is non-perceptible, and latency at 400 ms and above is perceptible but acceptable for the operators.

Interventionalists reported a "minor impact" on their performance with network latencies of 400 ms or above. These results suggest that remote robotic-assisted femoral, carotid or coronary arterial interventions should be performed with network latency below 400 ms to achieve sufficient and safe remote endovascular tool control.

Thesis 3: The first and second procedural blocks of remote robotic-assisted peripheral arterial interventions were completed with equally high procedural success. No significant differences were seen between the two blocks.

Remote robotic-assisted peripheral arterial intervention from a long geographical distance is feasible in a high-fidelity endovascular simulator with high procedural success. Stable network connection, workflow planning, and communication are crucial for the success of remote procedures.

## 7. Summary

These two studies are important in outlining the requirements of robotic-assisted remote interventions and significant first steps towards this interventional modality becoming a reality.

Network connection speed and stability are vital factors for remote interventions. Good audiovisual communication is also crucial since the operator is not present in the angiography suite, and the interventional steps are based on their decision.

Our first study aimed to assess the threshold of acceptable network latency. A porcine model was utilized to perform coronary arterial, femoral arterial, and external carotid arterial navigation with robotic assistance. Network latencies from 0-1000 ms were artificially added to the intrinsic (minimal) network lag. Guidewire navigation times, perceived latency, and procedural impact scores were registered. Results highlighted that network latency should be kept below 400 ms during remote robotic-assisted endovascular procedures to be imperceptible for the operator.

In the second study, long-distance tele-PVI was performed. The operator navigated the robot from a distance of 40 miles and completed ten successful robotic-assisted superficial femoral arterial interventions. The network connection was found to be stable throughout the study, with a network latency imperceptible for the operator. A communication protocol was established before the study. Communication between the interventionalist and the bedside technician was rated on a 1 to 5 scale after each intervention, and results varied between 4 and 5 ("good", "ideal").

Currently, endovascular robotic surgery is not widely spread, and the advancement of the technology is expected in the future. Modern telepresence systems, high-speed wireless networks, and more sophisticated robotic systems will serve this interventional modality to become a reality in the everyday clinical routine in the future.

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## 9. Bibliography of the candidate's publications

### 9.1. Publications with relevance to the current work

**Legeza P**, Britz GW, Shah A, et al. Impact of network performance on remote robotic-assisted endovascular interventions in porcine model. J Robot Surg. 2022;16(1):29-35. doi:10.1007/s11701-021-01196-6

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### 9.2. Publications not related to the current work

**Legeza PT**, Lettenberger AB, Murali B, et al. Evaluation of Robotic-Assisted Carotid Artery Stenting in a Virtual Model Using Motion-Based Performance Metrics [published online ahead of print, 2022 Sep 22]. J Endovasc Ther. 2022;15266028221125592. doi:10.1177/15266028221125592

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