Remote robotic-assisted interventions in endovascular therapy

Ph.D. Thesis

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1. Introduction

Minimally invasive interventions 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. 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. This provides enhanced radiation protection and 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.

Before performing robotic-assisted remote interventions in human patients 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.

2. Objectives

The current work aims to understand the requirements, characteristics, and limitations of remote robotic-assisted endovascular interventions (Fig.1). 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

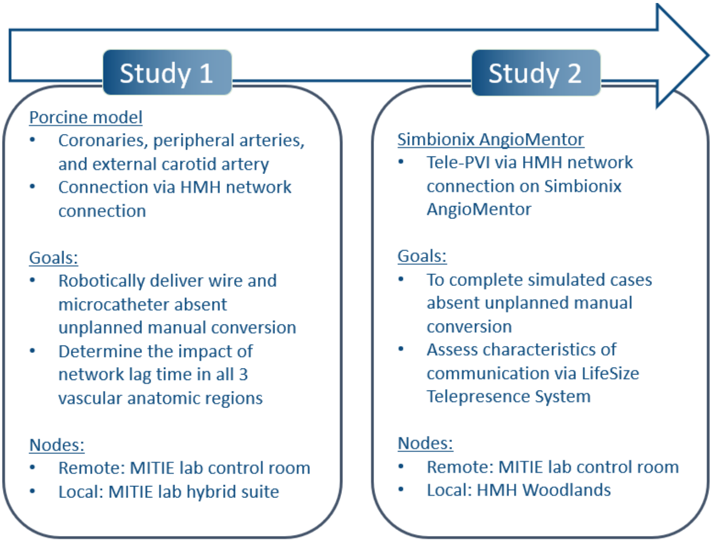

Figure 1. *Illustration of the study plan. The first study was performed in a porcine model and assessed the effect of network latency for endovascular robotic navigation. The second study utilized an endovascular simulator to evaluate the procedural characteristics of remote interventions. HMH: Houston Methodist Hospital, MITIE: the Houston Methodist Institute for Technology, Innovation & Education, PVI: peripheral vascular intervention*

3. Methods

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 (Fig. 2). In the currently discussed studies, the workstation was complemented by a telepresence system to ensure audiovisual communication between the operator and the interventional team. 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).

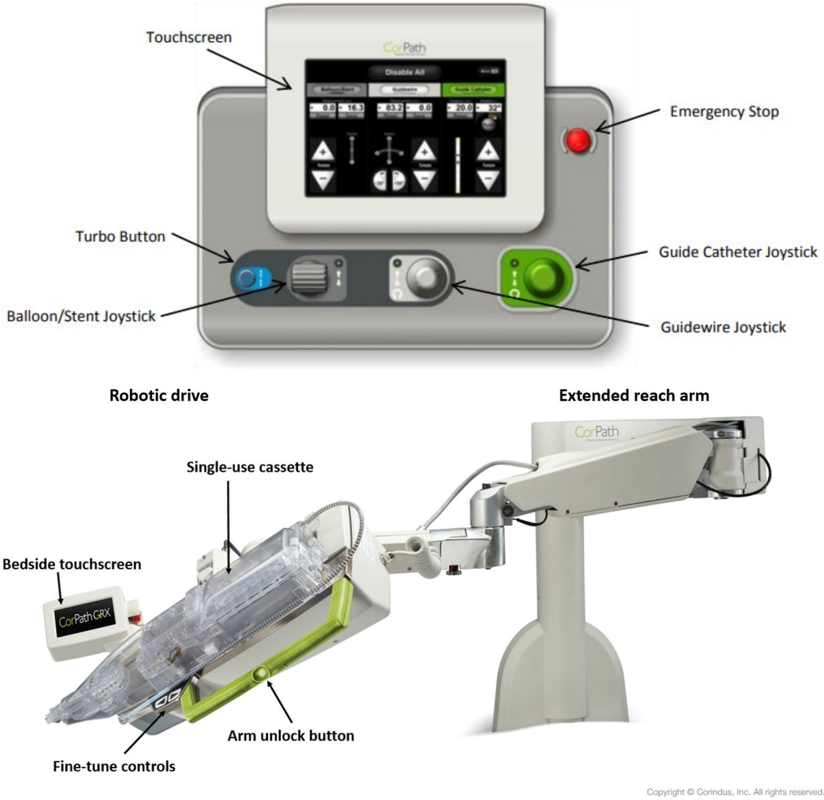

Figure 2. *CorPath GRX Workstation, and bedside component. The touchscreen displays the device coordinates and allows stepwise precision control of the endovascular tools. Three joysticks serve for device navigation.*

3.2. Study I – The effect of network latency on performance

Three interventional specialists participated in the study. Operators had extensive endovascular experience Peripheral arterial (femoral artery), neurovascular (external carotid artery), and coronary arterial navigation (Fig. 3) was performed by a vascular surgeon, neurosurgeon, and an interventional cardiologist, respectively. Specialists performed navigation only in their field of expertise.

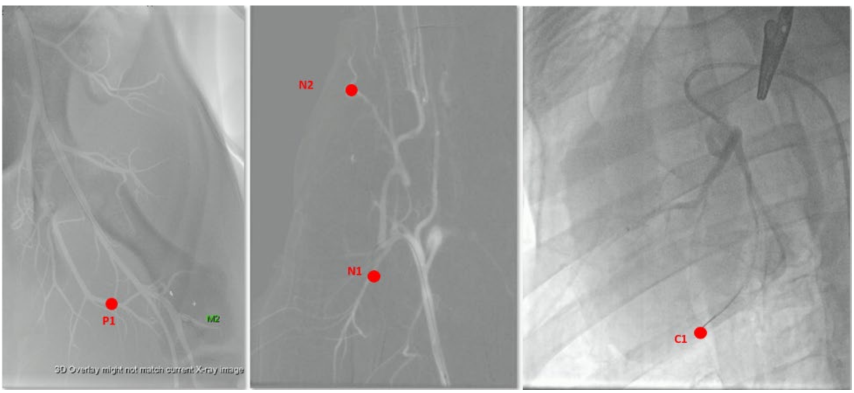

Figure 3. *Mask images from the porcine model. The navigational target vessels: distal branch of the deep femoral artery (P1), branch of the popliteal artery (P2), a branch of the lingual artery (N1), a branch of the facial artery (N2), and the diagonal branch of the the left anterior descending coronary artery*

Each operator performed robotic-assisted navigation. Their task was to drive the guidewire tip to the preselected vascular target marked on their monitor. Robotic command latencies (delays) ranging from 0 to 1000 ms (0, 150, 250, 400, 600, 1000 ms) were randomly added. Operators were blinded to latency times. A navigational run was defined as the wire advancement from the tip of the sheath until the wire tip reaches the preselected vascular target. After each run, the operator was asked to score the perceived latency (1=imperceptable, 5=too long) and how the latency impacted the procedure (1=no impact, 5=unacceptable to complete.

A domestic cross, female swine (49 kg) was used. Whenever the observed arterial bed was accessed, angiography was performed from the sheath. The navigational target vessels were marked based on the angiographic image.

3.3. Study II - Remote interventions for peripheral vascular disease

Remote peripheral vascular interventions were simulated from a long geographic distance. The study included two locations. The remote operator was a vascular surgeon was navigating the robot from the robotic workstation (Houston

Methodist Hospital Medical Center – "remote"), while the robotic arm was located 44 miles away (Houston Methodist Hospital Woodlands – "patient side").

An endovascular simulator was used to simulate five superficial femoral arterial cases TASC II (Trans-Atlantic Inter-Society Consensus Document II) A and B. 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.

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. The remote operating physician and the bedside technician were interviewed after each pocedure and rated the quality of the communication on a 1 (unacceptable) to 5 (ideal) scale. The AngioMentor endovascular simulator (3D Systems, Israel) was used.

4. Results

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

A total of 65 robotic-assisted guidewire navigation attempts were included. Added network latencies varied from 0 to 1000 ms. The procedural success was 100%.

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. 4). 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). 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. 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. When comparing the baseline latency to latencies of 400 ms and above, both procedural impact and perceived latency scores have significantly increased.

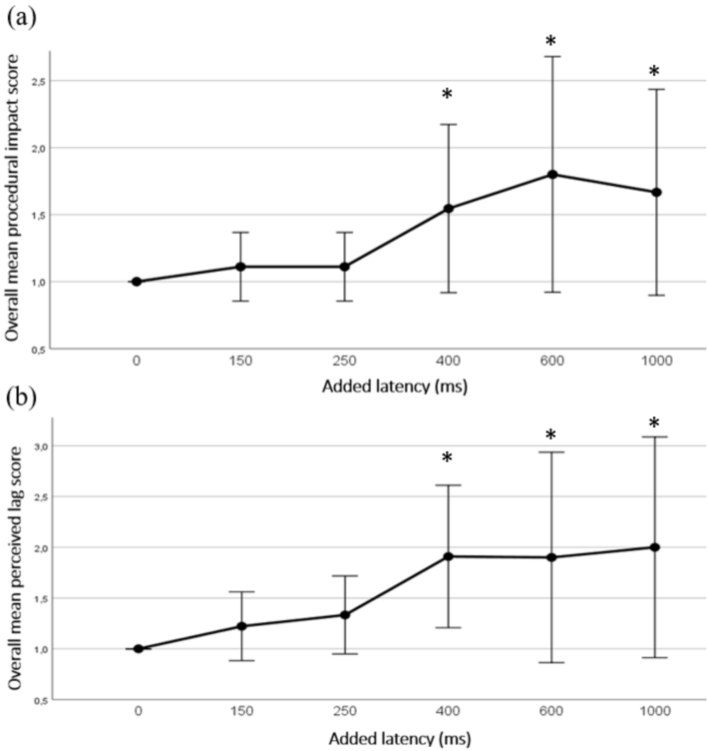

Figure 4. *Line graphs of procedural impact and perceived latency scores (a) Overall procedural impact score (mean±SD) with different added command latencies (ms), (b) Overall perceived latency score (mean±SD) with different added command latencies (ms). Statistically significant values are marked with asterix (*) (57)*

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%.

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 1) 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).

Audiovisual communication feeds were 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 1. *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. 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 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.

6.1. Publications with relevance to the current work

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