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Robotic telestenting performance in transcontinental and regional pre-clinical models

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Abstract

Objectives: This study was conducted to evaluate the association of geographic distance with robotic telestenting performance by comparing performance measures in transcontinental and regional pre-clinical models of telestenting.

Background: Robotic telestenting, in which percutaneous coronary intervention (PCI) is performed on a remotely located patient, might improve PCI access, but has not been attempted over vast distances likely required to reach many underserved regions.

Methods: Telestenting performance was compared in regional (Boston to New York [206 miles]) and transcontinental (Boston to San Francisco [3,085 miles]) ex vivo models of telestenting, wherein a physician in Boston attempted robotic PCI on end-ovascular simulators in New York and San Francisco, respectively. PCI was attempted over both wired and fifth generation (5G)-wireless networks. Outcome measures included procedural success, procedural time, and perceived latency.

Results: Procedural success was achieved in 20 consecutive target lesions in the regional model and in 16 consecutive target lesions in the transcontinental model. The transcontinental model had a greater latency than the regional model over both wired (121.5 ± 2.4 ms vs. 67.8 ± 0.9 ms; $p < .001$) and 5G-wireless networks (162.5 ± 1.1 ms vs. 86.6 ± 0.6 ms; $p < .001$), but perceived latencies were graded “imperceptible” in all cases in both models. Transcontinental and regional models did not have significantly different procedural times over wired (4.1 ± 1.9 min vs. 9.0 ± 7.1 min; $p = .051$) or 5G-wireless (3.0 ± 0.6 vs. 6.3 ± 1.2 ; $p = .36$) networks.

Conclusions: Transcontinental robotic manipulation of coronary devices is now possible and was not associated with adverse performance compared to robotic telestenting conducted regionally.

KEYWORDS

robotic PCI, telehealth, telemedicine

1 | INTRODUCTION

Percutaneous coronary intervention (PCI) remains inaccessible for people living in geographically remote regions of the world.^{1,2} Robotic

telestenting, in which a physician uses a robotic system to perform PCI on a remotely located patient, has been proposed as a means to improve PCI access.³ The feasibility of telestenting has been previously demonstrated over relatively short distances, including over

approximately 100 miles in a pre-clinical *in vivo* study⁴ and subsequently over approximately 20 miles in five humans.⁵ In order for telesteinting to reach patients in many remote locations, it would need to be performed over much greater distances, yet whether existing networks are sufficiently robust to support telesteinting over vast distances remains unknown. This pre-clinical study was performed to evaluate the association of geographic distance with telesteinting performance by comparing performance measures in transcontinental and regional *ex vivo* models of telesteinting.

2 | METHODS

This study used previously described methodology^{4,6} to construct two experimental *ex vivo* models of telesteinting: a regional model and a transcontinental model. In each model, PCI was attempted on a commercial endovascular simulator system (ANGIO Mentor, Symbionix, Littleton, CO). The system simulates real-time PCI procedures and has an access site into which actual interventional devices, including guide catheters, coronary guidewires and balloon catheters, are inserted. After insertion, subsequent manipulations of these devices, such as advancement, retraction, and torquing, are detected by sensors in the simulator and displayed on a bedside fluoroscopic monitor as corresponding movements of virtual devices within the endovascularity of a simulated patient. The system contains software allowing an operator to perform simulated PCI on various target lesions in different clinical scenarios each requiring the operator to physically advance, retract, and torque real interventional devices in a manner akin to performance of PCI *in vivo*.

All PCI procedures were performed using a robotic system (CorPath GRX, Corindus, a Siemens Healthineers Company, Waltham, MA) consisting of a robotic control unit and a bedside robotic drive. In each model, the robotic drive was positioned adjacent to the PCI simulator and the robotic control unit was positioned with the interventional cardiologist at a location geographically remote from the PCI simulator. The robotic control unit and robotic drives were connected over a network to a respective target computer (Mobile RT, Speedgoat, Inc., Natick, MA) that each utilized a grandmaster clock and global positioning system antenna for synchronization of the robotic control unit with the robotic drive.

In the both models, the interventional cardiologist and robotic control system were located in a laboratory in Waltham, Massachusetts, a suburb of Boston. In the regional model, the PCI simulator and robotic drive were located in a laboratory in New York, NY approximately 206 miles away from the interventional cardiologist. In the transcontinental model, the PCI simulator and robotic drive were located in a laboratory in San Francisco, California approximately 3,085 miles away from the interventional cardiologist. For each attempted PCI, a bedside technician at the simulator site manually advanced a 6 French guide catheter into the ascending aorta, positioned a 0.014 in. coronary guidewire at the tip of the guide catheter, and loaded the guidewire and a coronary balloon catheter onto the bedside robotic drive. All subsequent manipulations of the guide

catheter, guidewire, and balloon catheter were performed robotically, as controlled remotely by the offsite interventional cardiologist.

2.1 | Network connectivity

For each attempted PCI in the regional and transcontinental models, the robotic control unit and robotic drive were connected over either a wired network or a 5G-wireless network (Verizon Wireless, New York, NY). All cases were performed on a weekday during normal business hours. In the regional model, the wired network utilized public internet. In the transcontinental model, those cases performed over a wired network utilized a dedicated fiber connection for seven cases and utilized public internet in two cases. In the regional model, the interventional cardiologist was blinded to the network connection used in each case. In the transcontinental model, the intent was to blind the interventional cardiologist to the network connection used. However, while conducting cases in the transcontinental model, the interventional cardiologist was unintentionally unblinded to the network connection. Regardless of the network connection utilized in each case, connectivity between the robotic control unit and robotic drive was established using hardware firewalls (FortiGate, Fortinet, Sunnyvale, CA) and a virtual private network to secure and isolate device data within the network. Live simulated fluoroscopy images and hemodynamic waveforms from the PCI simulator were transmitted over the network to monitors in the interventional cardiologist's location. Audio and video communications between the interventional cardiologist and simulation laboratory personnel were established over the network using a telepresence system (Lifesize, Austin, TX).

2.2 | Outcome measures

Outcome measures for each telesteinting attempt included procedural success, procedural time, perceived latency score and latency impact score.⁶ Procedural success was defined as the successful robotic manipulation of guidewires and balloon catheters necessary to achieve stent deployment at the target lesion site without conversion to a manual operation. Procedural time was measured as the time from initial robotic guidewire manipulation to final robotic withdrawal of the guidewire from the coronary artery at the completion of PCI. The perceived latency score was graded by the interventional cardiologist as: 5 = imperceptible; 4 = noticeable but minor; 3 = noticeable; 2 = noticeable and major; 1 = unacceptable. The latency impact score was graded by the interventional cardiologist as: 5 = no impact; 4 = minor impact but acceptable performance; 3 = noticeable impact, loss in efficiency, but successful outcome; 2 = significant degradation, can complete procedure, but not desirable; 1 = unacceptable.

During each case the latency of the network connection was logged every 50 ms. Latency was defined as the sum of the time necessary for the robotic command signal to travel from the robotic controls to the robotic drive plus the time necessary for the fluoroscopic image to travel from the PCI simulator to the location of the

interventional cardiologist. In this manner, the measured latency represents the round-trip delay extending from the moment the interventional cardiologist manipulates the robotic controls to the moment the corresponding interventional devices are seen to move on the monitor being watched by the interventional cardiologist. In each PCI attempt, the network latency was reported as the mean latency recorded over the duration of each case.

2.3 | Statistical methods

Normally distributed continuous variables are shown as mean \pm standard deviation. Non-normally distributed continuous variables are shown as median (25th percentile, 75th percentile). Categorical variables are shown as count (% frequency). Categorical data were analyzed using Fishers Exact Test. To analyze the interaction between regional/transcontinental and network connection type the same tests listed above were used, but a Bonferroni correction was applied to adjust for the four p values being produced so the alpha was .0125. To analyze the remaining numeric variables (procedure time and mean latency) a two-way ANOVA analysis was completed

with an interaction variable between regional/transcontinental and connection type. To determine the pairwise comparisons a Tukey adjustment was applied to the p -values. All analyses were completed using SAS (SAS Enterprise Guide software, Version 7.1, SAS Institute Inc., Cary, NC).

3 | RESULTS

On October 24, 2019, telesteering was attempted in the regional and transcontinental ex vivo models. In both models, the interventional cardiologist and robotic control unit were located in a suburb of Boston. PCI simulators and robotic drives were located in New York and San Francisco in the regional and transcontinental models, respectively (Figure 1). In the regional model, telesteering was attempted in 20 consecutive target lesions over a distance of 206 miles, including 10 attempts over a wired network and 10 attempts over a 5G-wireless network. In the transcontinental model, PCI was attempted on 16 consecutive target lesions over a distance of 3,085 miles, including nine attempts over a wired network and seven attempts over a 5G-wireless network.



FIGURE 1 Regional and transcontinental models of telesteering. A geographic overview of the regional and transcontinental experimental models used in this study is depicted on the map. In both experimental models, the interventional cardiologist and robotic control unit were located in a suburb of Boston (lower right photo). PCI simulators and robotic drives were located in New York and San Francisco in the regional and transcontinental models, respectively (lower left photo). In this manner, the interventional cardiologist in Boston used a robotic system to manipulate coronary guidewires and balloon catheters in New York and San Francisco in a manner necessary to perform PCI on a simulator. In the regional and transcontinental models, telesteering was performed over both wired (blue line) and 5G-wireless (orange line) networks. 5G, fifth generation; PCI, percutaneous coronary intervention [Color figure can be viewed at wileyonlinelibrary.com]

Procedural success was achieved in all lesions in both models. Telestenting performance measures in each model are presented according to network connectivity in Table 1. The transcontinental model had a greater latency than the regional model over both wired (121.5 ± 2.4 ms vs. 67.8 ± 0.9 ms; $p < .001$) and 5G-wireless networks (162.5 ± 1.1 ms vs. 86.6 ± 0.6 ms; $p < .001$; Figure 2). Despite measurably higher latency values in the transcontinental model, perceived latency scores were graded as a 5 ("imperceptible") in all cases in both models.

The greater distance characteristic of the transcontinental model was not associated significantly different procedural times compared to the regional model for cases performed over wired (4.1 ± 1.9 min vs. 9.0 ± 7.1 min; $p = .05$) or 5G-wireless (3.0 ± 0.6 vs. 6.3 ± 1.2 ;

$p = .36$) networks. Wired network connectivity was characterized by a lower latency than 5G-wireless connectivity in both the regional model (67.8 ± 0.9 ms vs. 86.6 ± 0.6 ms; $p < .001$) and the transcontinental model (121.5 ± 2.4 ms vs. 162.5 ± 1.1 ms; $p < 0.001$; Figure 2).

4 | DISCUSSION

In this study, interventional coronary devices in San Francisco were robotically manipulated in real-time by an interventional cardiologist in Boston, thereby demonstrating, for the first time, that remote robotic manipulation of coronary interventional devices is currently

TABLE 1 Telestenting performance measures in the regional and transcontinental models according to wired or 5G-wireless network connectivity

	Regional			Transcontinental				
	Wired	5G-wireless	<i>p</i> value*	Wired	5G-wireless	<i>p</i> value**	<i>p</i> value***	<i>p</i> value****
Target lesion location								
Left main	1 (10.0)	1 (10.0)	1.0000	0 (0.0)	0 (0.0)	1.0000	1.0000	1.0000
LAD	4 (40.0)	4 (40.0)	4 (44.4)	3 (42.9)				
Left circumflex	4 (40.0)	4 (40.0)	4 (44.4)	3 (42.9)				
RCA	1 (10.0)	1 (10.0)	1 (11.1)	1 (14.3)				
Procedural time (min)	9.0 ± 7.1	6.3 ± 1.2	.4184	4.1 ± 1.9	3.0 ± 0.6	.9497	.0507	.3620
Latency (ms)	67.8 ± 0.9	86.6 ± 0.6	<.0001	121.5 ± 2.4	162.5 ± 1.1	<.0001	<.0001	<.0001

Abbreviations: LAD, left anterior descending artery; RCA, right coronary artery.

**p* value is for comparison of wired vs. wireless in the regional model.

***p* value is for comparison of wired vs. wireless in the transcontinental model.

****p* value is for comparison of regional vs. transcontinental on wired network.

*****p* value is for comparison of regional vs. transcontinental on wireless network.

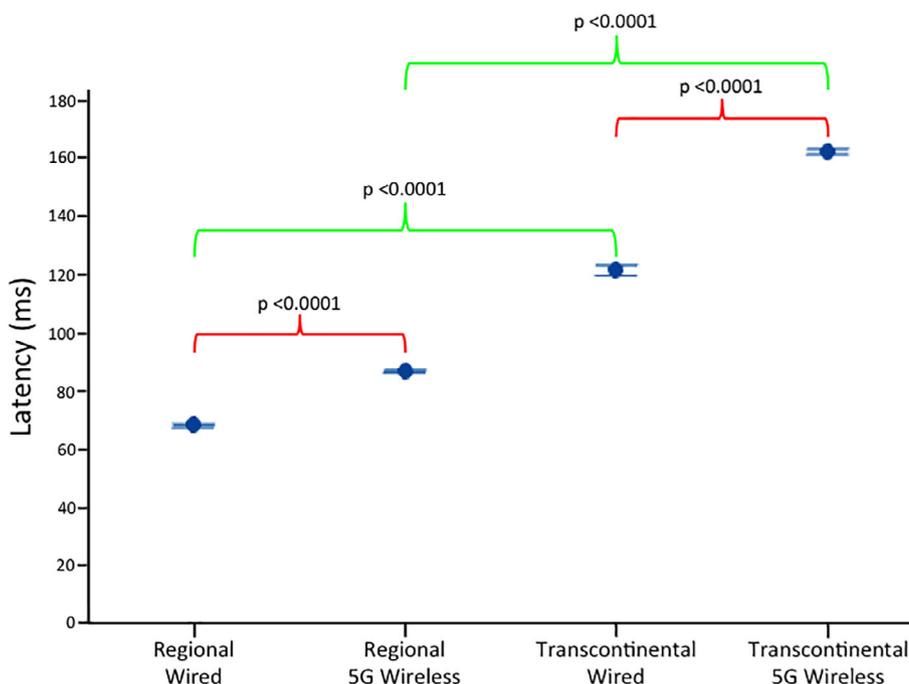


FIGURE 2 Network latency across wired and 5G-wireless networks in the regional and transcontinental models. Mean latency values (blue dot) and 95% confidence values (blue bars) are shown in the regional and transcontinental models for cases performed on wired and 5G-wireless networks. Latency was significantly higher for 5G-wireless connectivity compared to wired networks in both models (red brackets). Network latencies in the transcontinental model were significantly higher than those of the regional model for both wired and 5G-wireless networks (green brackets). 5G, fifth generation [Color figure can be viewed at wileyonlinelibrary.com]

possible over distances exceeding 3,000 miles. This observation is incremental to our previous work in remote robotics that demonstrated the ability to robotically manipulate coronary devices *in vivo* over a distance of approximately 100 miles.⁴ The present study extends these prior findings by demonstrating the distance over which a robotic arm can be successfully manipulated without perceived latency is at least 30-fold greater than the distance of the prior study.⁴ Notably, telesteering performed over a distance of 3,085 miles in the transcontinental model was not associated with significant differences in procedural success, procedural time, or perceived latency compared to telesteering performed over a distance of 206 miles in the regional model. This finding suggests contemporary network infrastructure within developed countries could be sufficient to eliminate any perceptible impact of geographic distance on remote robotic manipulation of coronary devices. This observation further supports the premise that the distance separating a patient and physician may be irrelevant when conducting telesteering as long as the network connecting their respective locations exceeds a yet to be determined threshold of performance. Although only accomplished in an *ex vivo* model, these observations may expand the geographic reach of telesteering capabilities.

4.1 | Implications of wireless connectivity in remote robotics

This study also demonstrates for the first time that remote robotic manipulation of coronary devices is now possible using wireless network connectivity. Accordingly, a 5G-wireless network supported telesteering attempts in both a regional and transcontinental fashion without perceived latency by the operator. The implication of these observations is that telesteering, which has previously only been studied over wired networks,⁴⁻⁶ may no longer require a wired network connection, but rather may eventually be performed at any location having a sufficient quality-of-service wireless signal. The ability to perform telesteering wirelessly may further increase the geographic reach of telesteering.

It is remarkable the round trip latencies of signals traveling between Boston and San Francisco on the wired and 5G-wireless networks used in this study were approximately 122 and 163 ms, respectively. Although significantly longer than those in the regional model, the latencies in the transcontinental model were substantially below the 400 ms threshold previously shown to be perceptible in remote robotic wiring of coronary arteries *in vivo*.⁶ This likely accounts for the observation that latency was imperceptible to the operator in the transcontinental model and did not significantly impact telesteering performance measures. This observation is also consistent with prior data showing delays of up to 300 ms do not exert a significant impact on procedural performance in telesurgery.^{7,8}

To overcome the longer latencies characteristic of previous wireless networks, 5G-wireless networks are under development to enable transmission of larger amounts of data at faster speeds. Despite these improvements over older generations of wireless

technology, 5G-wireless transmission speeds are not expected to surpass those of wired networks. This concept accounts for the observation that 5G-wireless connections in this study were characterized by significantly higher latencies than those of wired networks in both the regional and transcontinental models. It is important to note that although the latency of 5G-wireless connectivity was greater than wired connectivity, the latency values measured using 5G-wireless remained substantially below the 400 ms threshold previously shown to be perceptible in telesteering.⁶ Hence, the 5G-wireless network used in this study was sufficiently robust to transmit signals across the continent to enable remote robotic manipulation of coronary devices without latency being perceptible by the operator.

4.2 | Potential future applications

According to a recent policy statement from the American Heart Association, telehealth services are presently underutilized in the management of cardiovascular disease.⁹ Robotic telesteering, which is an interventional extension of telehealth and has been shown to be feasible in an *in vivo* swine model⁴ and in humans,⁵ is being developed as a possible means to disseminate interventional expertise to address geographic disparities in PCI access. This may be relevant particularly since the low penetration of PCI in many regions has been associated with an increased risk of adverse outcomes among patients with acute coronary syndromes.¹⁰ In this regard, Bueno et al recently demonstrated marked variation in coronary revascularization rates at the country, regional, and hospital-level, and that these differences were associated with all-cause mortality at 2 years.¹⁰ Furthermore, the development of robotic telesteering capabilities may be timely considering an impending shortage of interventional cardiologists has been predicted in the United States.¹¹ Although the present study involved the remote manipulation of endovascular devices intended for the coronary bed, the results may have applications for the performance of endovascular procedures in other vascular beds. When considering this possibility, it should be noted that significant geographic disparities exist in the management of critical limb ischemia¹² and stroke,¹³ both of which are amenable to treatment with endovascular procedures. Future research is needed to determine if the approaches developed to perform robotic telesteering in the coronary arteries could be adapted to treat critical limb ischemia and stroke remotely.

4.3 | Limitations

The present study is limited by its small sample size and the performance of procedures by a single operator. It is critical for future studies to investigate the perception of latency in a larger number of procedures and operators. The use of an *ex vivo* model rather than an *in vivo* model represents another limitation. Clearly the manipulation of coronary devices and the performance of PCI on a simulator are not equivalent to those in a diseased human coronary artery. The PCI procedures performed in this study involved the treatment of

relatively simple lesions. The ability to treat complex coronary lesions with remote robotics has not been studied to date. It is possible that a learning curve existed within the models and that performing multiple cases in each model led to familiarity that may have influenced the procedural duration results. The study is further limited considering the interventional cardiologist was not blinded to the network connection for all cases in the transcontinental model. The connection of three major cities in this study, rather than a remote rural area, represents another limitation. The successful demonstration of manipulating a robotic system over a 5G wireless network in this study does not address the current limited availability of access to 5G wireless networks, particularly in rural areas. Furthermore, many hospitals in rural communities around the world may lack access to high quality networks. Whether existing network infrastructure in many rural areas, wherein patients may stand to benefit most from remote robotic interventions, is sufficiently robust to support telesteinting remains unknown. The study is also limited since latency is not the only network characteristic to consider in the development of telesteinting. Other factors, including network jitter, the impact of network traffic, and data security remain major concerns for the performance of long-distance telesteinting in humans. Regarding the impact of network traffic, it should be noted this study was conducted during normal business hours on a weekday. Whether internet traffic outside of normal business hours would impact telesteinting performance remains unknown. Finally, this study did not evaluate other potential obstacles likely to be encountered in the implementation of telesteinting into clinical practice. One such obstacle not yet studied is the uncertainty regarding required medical personnel and their level of expertise onsite with the patient. Additional studies are needed in this regard.

5 | CONCLUSION

The present study demonstrates remote robotic manipulation of coronary devices is currently possible over distances of >3,000 miles. Robotic telesteinting in the transcontinental model was not associated with adverse performance compared to telesteinting in the regional model. Although only accomplished in an ex vivo model, the result of this study may increase the geographic reach of telesteinting capabilities.

CONFLICT OF INTEREST

Ryan D. Madder receives research support, speaker honoraria, and serves on the advisory board of Corindus, A Siemens Healthineers Company. Kalyna Sconzert, Yao Li, Nicholas Kottenstette, Abigail Madsen, John-Michael Sungur, and Per Bergman are employees of Corindus, A Siemens Healthineers Company. All other authors have nothing to disclose.

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