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Research Letter

Performance of a Novel Miniaturized Robotic System in Percutaneous Coronary Intervention: A Preclinical Study

Scott Winsor, MD, Trisha Gomez, MD, Stacie VanOosterhout, MEd, Jessica L. Parker, MS, Ryan D. Madder, MD *

Frederik Meijer Heart & Vascular Institute, Corewell Health West, Grand Rapids, Michigan

In clinic use for more than a decade, established robotic systems have several limitations including their sizable footprint and large capital purchase required to establish a robotic percutaneous coronary intervention (PCI) program. This latter concern imposes a significant barrier to the further development of telerobotics because many rural hospitals, which stand to benefit the most from a telerobotic approach, may lack the capital funds to purchase a robotic system. To address these limitations, a novel miniaturized robotic system (m-robot), a fraction of the size and weight of other contemporary robotic systems, has been developed as a disposable, single-use endovascular robot. This study was conducted to evaluate the technical ability of the m-robot to perform PCI in a preclinical ex vivo model and to compare its performance with an established robotic system and manual control group.

The ex vivo model consisted of a high-fidelity endovascular simulator (VIST G7; Mentice) into which actual clinical devices (catheters, guide wires, balloons, etc) are inserted. Subsequent manipulations are displayed on a fluoroscopic monitor as corresponding movements of virtual devices within the vasculature of a simulated patient. The simulator allows an operator to perform PCI in different clinical scenarios each requiring the operator to manipulate real interventional devices in a manner akin to performance of PCI in vivo.

The m-robot (LIBERTY; Microbot Medical), in its current configuration, can advance, retract, and torque guide wires, microcatheters, and guide catheters. It has the potential to advance and retract balloons and stents, although these features are still under feasibility assessment. The m-robot is manipulated by a wireless handheld controller (Figure 1). Using rapid-exchange devices, all procedures were attempted by a single experienced robotic operator (R.D.M.) with the m-robot, manually, and with an established robotic system (CorPath GRX; Corindus). Outcome measures included procedural success (successful robotic delivery of guide wires, balloons, and stents to complete PCI of a target lesion without conversion to manual), wiring time (initial robotic manipulation of wire at tip of guide catheter to a prespecified distal segment of target vessel), and balloon/stent delivery time (initial robotic manipulation of device at tip of guide catheter to final delivery at the lesion).

Nonnormally distributed continuous variables are shown as median [25th percentile, 75th percentile]. Outcome metrics for the m-robot group were compared with the 2 control groups using a Wilcoxon rank sum test. Resulting *P* values were assessed at the .025 level for significance. Analyses were completed using SAS Enterprise Guide software version 7.1 (SAS Institute).

Ten consecutive and unique PCI cases were attempted in each of the 3 study groups. In all cases, the m-robot successfully performed PCI without conversion to manual (procedural success 100%). The m-robot delivered guide wires to target locations in a median of 27.1 [24.3, 41.6] seconds. This was not significantly different than guide wire delivery in the manual control group (36.9 [30.6, 52.0] seconds; $P = .34$) but was significantly faster than guide wire delivery by the established robotic system (62.3 [53.4, 72.0] seconds; $P = .0211$). Using the m-robot, device delivery times were not significantly different compared with manual for stents (5.2 [4.9, 10.8] seconds vs 7.8 [7.1, 9.2] seconds; $P = .62$) or postdilation balloons (4.2 [3.4, 4.8] seconds vs 5.2 [4.1, 7.8] seconds; $P = .08$) but were significantly faster than the established robot for stents (5.2 [4.9, 10.8] seconds vs 13.1 [11.3, 15.9] seconds; $P = .0058$) and postdilation balloons (4.2 [3.4, 4.8] seconds vs 8.3 [5.6, 10.0] seconds; $P = .0019$).

In this preclinical study, the m-robot demonstrated the technical capabilities to advance, retract, and torque devices in a manner necessary to perform PCI without the need for manual conversion. The m-robot delivered devices to prespecified target locations as efficiently as performed manually but faster than an established robotic system. The 60% reduction in wiring time observed with the m-robot compared with the established robotic system may be attributable to a faster maximum velocity of wire advancement with the m-robot. With both robotic systems, the velocity of device advancement increases proportionately to joystick tilt until the maximum velocity is reached. Whereas the maximum velocity with the established robotic system is only 12 mm/s, the maximum velocity is 40 mm/s with the m-robot. Each robotic system has a "turbo" function, which increases the maximum velocity of device advancement, but the "turbo" feature was not

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* Corresponding author: ryan.madder@corewellhealth.org (R.D. Madder).

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Figure 1.
Miniaturized robotic system. The miniaturized disposable robot (upper right) attaches to a bedside articulated arm mounted on the procedure table (left) and is controlled by a wireless handheld controller (lower right). The location for attachment of a catheter to the robot is shown (blue arrow). The handheld controller has a joystick and buttons for wire manipulation (red arrows) and a button for balloon/stent manipulation (green arrow).

utilized in this study. Although the safety of advancing wires at the higher speeds achievable with the m-robot requires testing in vivo, the higher speeds did lead to wiring times similar to those achieved manually.

The observations regarding device delivery times should be interpreted in the context of other potential advantages of the m-robot, including its smaller size, disposable nature, and comparative expense. Although controlled at the bedside in this study, the wireless design of the m-robot and its associated wireless controller may lend themselves to telerobotic applications. Prior studies have demonstrated that established robotic systems can be controlled remotely over contemporary networks, which have become sufficiently fast to support telerobotic PCI over great distances.[1,2] Future studies will be needed to evaluate if the m-robot can be similarly used to perform telerobotic PCI, albeit at a potentially lower expense. Taken collectively, these favorable preliminary observations made in an ex vivo model will serve as the foundation for future studies testing the technical performance of the m-robot in vivo.

Declaration of competing interest

Ryan Madder has received speaker honoraria from Abbott Vascular, Corindus, and Infraredx; has served as a consultant to Abbott Vascular, Angiowave Imaging, Corindus, Infraredx, Nanoflex Robotics, RapidAI, and SpectraWAVE; has received research support from Angiowave Imaging, Corindus, Infraredx, and Nanoflex Robotics; and serves on the advisory boards of Medtronic and SpectraWAVE.

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Ethics statement and patient consent

This manuscript does not report on patients or patient data.

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