



Evaluation of Robotic-Assisted Carotid Artery Stenting in a Virtual Model Using Motion-Based Performance Metrics

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Abstract

Purpose: Robotic-assisted carotid artery stenting (CAS) cases have been demonstrated with promising results. However, no quantitative measurements have been made to compare manual with robotic-assisted CAS. This study aims to quantify surgical performance using tool tip kinematic data and metrics of precision during CAS with manual and robotic control in an ex vivo model. **Materials and Methods:** Transfemoral CAS cases were performed in a high-fidelity endovascular simulator. Participants completed cases with manual and robotic techniques in 2 different carotid anatomies in random order. C-arm angulations, table position, and endovascular devices were standardized. Endovascular tool tip kinematic data were extracted. We calculated the spectral arc length (SPARC), average velocity, and idle time during navigation in the common carotid artery and lesion crossing. Procedural time, fluoroscopy time, movements of the deployed filter wire, precision of stent, and balloon positioning were recorded. Data were analyzed and compared between the 2 modalities. **Results:** Ten participants performed 40 CAS cases with a procedural success of 100% and 0% residual stenosis. The median procedural time was significantly higher during the robotic-assisted cases (seconds, median [interquartile range, IQR]: 128 [49.5] and 161.5 [62.5], $p=0.02$). Fluoroscopy time differed significantly between manual and robotic-assisted procedures (seconds, median [IQR]: 81.5 [32] and 98.5 [39.5], $p=0.1$). Movement of the deployed filter wire did not show significant difference between manual and robotic interventions (mm, median [IQR]: 13 [10.5] and 12.5 [11], $p=0.5$). The postdilation balloon exceeded the margin of the stent with a median of 2 [1] mm in both groups. Navigation with robotic assistance showed significantly lower SPARC values (-5.78 ± 3.14 and -8.63 ± 3.98 , $p=0.04$) and higher idle time values (8.92 ± 8.71 and 3.47 ± 3.9 , $p=0.02$) than those performed manually. **Conclusions:** Robotic-assisted and manual CAS cases are comparable in the precision of stent and balloon positioning. Navigation in the carotid artery is associated with smoother motion and higher idle time values. These findings highlight the accuracy and the motion stabilizing capability of the endovascular robotic system.

Clinical Impact

Robotic assistance in the treatment of peripheral vascular disease is an emerging field and may be a tool for radiation protection and the geographic distribution of endovascular interventions in the future. This preclinical study compares the characteristics of manual and robotic-assisted carotid stenting (CAS). Our results highlight, that robotic-assisted CAS is associated with precise navigation and device positioning, and smoother navigation compared to manual CAS.

Keywords

carotid stent/stenting, robotic-assisted surgery, motion analysis, endovascular treatment/therapy, peripheral vascular disease, performance metrics

Introduction

There is an increasing interest in endovascular robotic techniques in the treatment of carotid artery disease.¹ By translating the operator's hand movements to robotic movements, robotic assistance may contribute to a more accurate and stable endovascular manipulation. The robotic technique holds out the possibility for remote interventions, which would allow the geographical distribution of stroke services

to rural areas. Moreover, the operator performs the robotic phases of the procedure from a radiation-shielded workstation, thus the radiation exposure of the operator can be significantly reduced.^{2,3}

The CorPath GRX robotic system (Corindus, A Siemens Healthineers Company, Natick, MA, USA) is currently the only commercially available robot for endovascular use. Successful cases of robotic-assisted carotid artery stenting

(CAS) have already been demonstrated with this device in patients with carotid artery stenosis.⁴⁻⁶ The robotic platform allows the operator to perform well-controlled micro-movements both axially and rotationally, which offers safe navigation during endovascular interventions. Previous work has presented similar results between robotic-assisted and manual CAS in terms of perioperative outcomes, procedure-related complications, and procedural characteristics.⁷ However, quantitative measurements of endovascular tool motion may provide an appropriate alternative to evaluate the navigational properties of the robotic system.

High-fidelity endovascular simulators serve as a realistic platform for training, education, and device testing purposes and have already been used in studies evaluating aspects of the robotic performance in a remote setting.⁸ This study entails comparing the procedural characteristics and performance metrics of manual and robotic-assisted carotid artery interventions in a virtual model through the analysis of endovascular tool movements.

Materials and Methods

CorPath GRX

Participants completed robotic-assisted procedures with the CorPath GRX robot. The system is Food and Drug Administration (FDA)-cleared for percutaneous coronary and peripheral vascular interventions. It has been described previously.⁹ Briefly, the 2 main parts of the system are the bedside component and the control console. The operator manipulates the sheath, the guidewire, and the rapid exchange device separately with 3 joysticks. The joysticks allow us to perform axial and rotational movements with the endovascular instruments, and the operator can select from the various functions on the touch screen of the control console. These functions include active guide catheter control to stabilize the guide catheter, and automatic guidewire rotation (“rotate on retract”) for easier catheterization or lesion crossing. The bedside component consists of an extended reach arm, a robotic drive, and a single-use cassette. The endovascular devices are loaded into the single-use cassette that is attached to the robotic drive. This robotic drive receives the input from the control console, which results in the movements of the devices. The extended reach arm is mounted on the operating table and supports the robotic drive.

In the scenario of a clinical case, the control console is placed outside of the radiation field or in the angiographic

suite in a radiation-shielded workstation. As in this study the virtual simulation of the cases did not require any radiation exposure for the participants, the control console was next to the operating table (Figure 1). The virtual patient’s vital parameters, and live fluoroscopic and reference images were displayed on a monitor for the operator.

Study Participants

The institutional review board approved the study, and informed consent was obtained from the participants. Ten participants completed a total number of 20 manual and 20 robotic-assisted CAS in a high-fidelity endovascular simulator (AngioMentor; 3D Systems, Littleton, CO, USA).

Participants were senior vascular surgery residents (n=6), vascular surgeons (n=3), and a neurosurgeon (n=1). Two of the participants have used the robot in ex vivo navigational test runs. The remaining 8 participants have not used the robotic system before. None of the participants had completed CAS with the robotic system prior to the study.

All participants performed 2 manual and 2 robotic-assisted CAS with different anatomy in a random order (Figure 2). Cases were standardized: C-arm position and table position were adjusted for optimal visualization of the treated arteries. For each case, a fixed selection of guidewires, guide catheters, filter wire, stents, and balloons were provided.

Each participant received a description on the elements of the setup, including the endovascular simulator, the CorPath robotic system, functions of joysticks, and the control console. The steps of the procedures were also discussed. Each participant completed at least 1 practice procedure with the robot before beginning the session. Passive assistance was provided throughout the cases. An assistant handled the simulation platform as follows: adjusted the C-arm, placed the operating table in the virtual simulation, manually positioned the catheter and wire in the starting position, loaded and unloaded the devices from the robotic cassette, and selected the appropriate devices on the simulator’s screen.

Procedure

For both manual and robotic-assisted procedures, transfemoral access was gained, and the assistant placed the sheath in the orifice of the common carotid artery manually. Once

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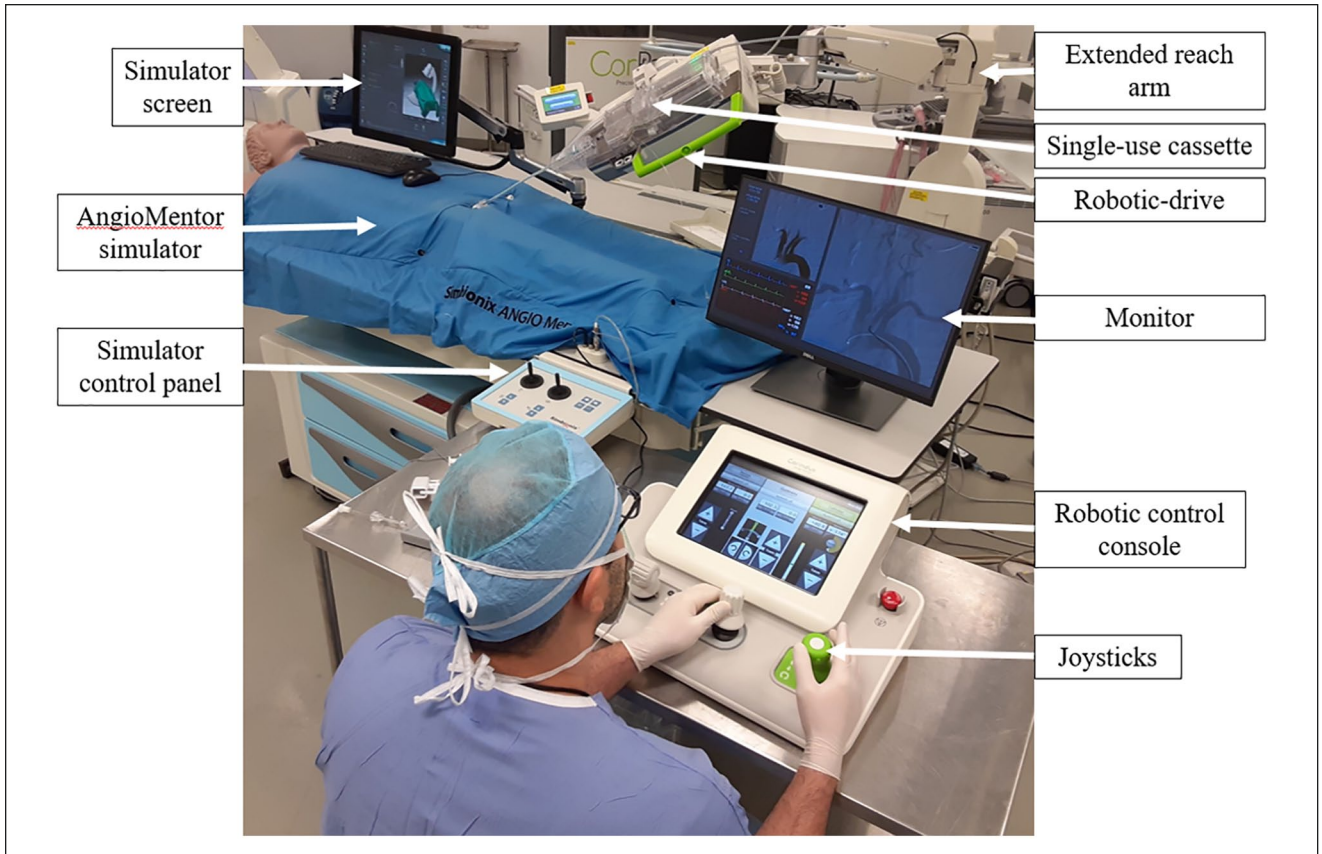


Figure 1. Layout of the interventional setup for the simulation.



Figure 2. (Left) Three-dimensional reconstruction image of the simulated aortic arch and supra-aortic branches. (Right) Aortic arch angiogram, contrast injected from the ascending aorta.

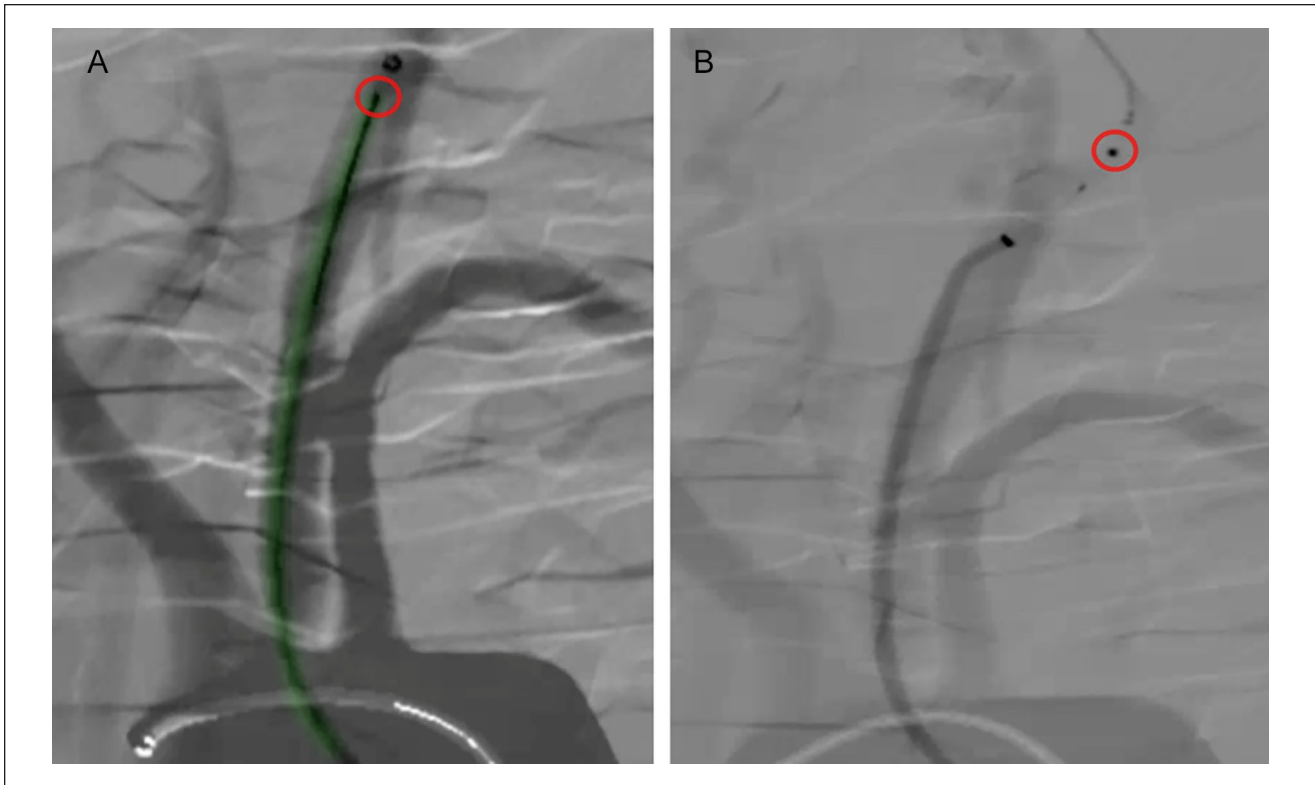


Figure 3. Intraoperative images from carotid artery stenting. Target for kinematic analysis is circled in red. (A) Navigation of the sheath in the common carotid artery with the guidewire highlighted in green. (B) Crossing the internal carotid artery lesion with the filter.

this starting position was achieved, the participant took over manually or with the robot. The following 5 procedural steps were observed: (1) navigation of sheath to the distal common carotid artery, (2) crossing the lesion in the internal carotid artery, (3) filter deployment, (4) robotic stent positioning and manual stent deployment, and (5) positioning of the postdilation balloon and manually performing the postdilation.

Measurements

Procedural success was defined as completion of the planned procedural steps individually, without any assistance in handling the devices or without the need of manual conversion during the robotic intervention. After completing each procedure, the simulator provided data of the overall procedural time, overall fluoroscopy time, residual stenosis, contrast dose, accuracy of stent positioning, movement of the opened filter wire throughout the procedure, and the accuracy of postdilation balloon positioning. The simulator software recorded the live images of the procedures (1080×1920; 25 fps) that were exported to a hard drive and were analyzed after concluding a session. During the post hoc video analysis,

procedural time and fluoroscopy time were noted separately for each procedural step. The time needed for device exchanges was not included in the overall procedural time.

Analysis of Tool Tip Kinematic Data

Procedural steps 1 and 2 were used for the analysis of tool tip kinematic data (Figure 3). The technique for the semi-automated image processing has been described before.¹⁰ Briefly, from the tangential velocity profile of the guidewire tool tip, we calculated spectral arc length (SPARC), average velocity, and idle time. Spectral arc length is a frequency-domain measure of movement smoothness and has been described to be a robust indicator of performance in endovascular tasks in ex-vivo models.^{11–13} The lower absolute value of SPARC is associated with smoother motion. Average velocity represents the speed of the tool motion. Idle time is defined as the amount of time that the tool tip remains stationary during a navigation task. Both average velocity and idle time have been shown to be accurate measurements of surgical proficiency. Due to data collection errors in 6 cases, only 34 of the 40 recorded case videos were used for the analysis.

Table 1. Simulator Metrics of Procedural Details.

	Manual	Robotic-assisted	p value
Contrast use (mL)	28 (10)	29 (15)	0.4
Movement of deployed filter wire (mm)	13 (10.5)	12.5 (11)	0.5
Postdilation balloon exceeded the margin of the stent (mm)	2 (1)	2 (1)	0.2
SPARC	-8.63±3.98	-5.78±3.14	0.04
Average velocity (pixel/s)	37.57±13.9	30.95±8.8	0.11
Idle time	3.47±3.9	8.92±8.71	0.02

Data are presented as median (IQR) or mean±SD. Two-sample *t* test or Mann-Whitney *U* test was used. Level of significance is $p < 0.05$. Significant results are in boldface.

Abbreviations: IQR, interquartile range; SPARC, spectral arc length.

Table 2. Results From Linear Mixed-Effects Model for Manual Versus Robotic Navigation.

	Sheath advancement to distal CCA	p value	Lesion crossing	p value
SPARC	F = 6.12	0.02	F = 2.61	0.12
Idle time	F = 6.26	0.02	F = 1.06	0.31
Average velocity	F = 2.55	0.12	F = 2.35	0.14

Abbreviations: CCA, common carotid artery; SPARC, spectral arc length. Significance level is $p < 0.05$. Significant results are in boldface.

Statistical Analysis

Continuous variables are presented as median [interquartile range, IQR]. The normal distribution of the variables was assessed by the Shapiro-Wilk test. For comparing the results of procedural time, fluoroscopy time, contrast dose, precision metrics (filter movement, accurate postdilation balloon positioning), and tool tip kinematic data between groups, 2-sample *t* test and Mann-Whitney test were used when appropriate. For the tool tip kinematic data, we applied a linear mixed-effects model using the calculated values of SPARC, average velocity, and idle time, using manual and robot-assisted navigation as the fixed-effect factor of interest. Degrees of freedom were approximated using the Kenward-Roger method. Results were considered significant at a p value ≤ 0.05 . For image preprocessing, we used MATLAB. For statistical analysis, STATA (StataCorp LP, College Station, TX, USA) and R were used.

Results

Procedural Outcomes

A total number of 40 carotid stenting procedures were performed by 10 participants. Each participant completed 2 manual and 2 robotic CAS procedures. Procedural success was 100%, and 0% residual stenosis was noted. Median contrast use was 29 [10] mL, and no significant difference in contrast use was shown between robotic and manual interventions.

The total procedural time was significantly higher during the robotic-assisted cases (seconds; median [IQR];

manual: 128 [49.5] vs robotic: 161.5 [62.5], $p=0.02$). However, fluoroscopy time did not show significant difference between manual and robotic-assisted procedures (seconds; median [IQR]; manual: 81.5 [32] vs robotic: 98.5 [39.5], $p=0.1$).

Precision During the Interventions

The simulator graded the positioning of the stent and the balloon accurately in all manual and robotic cases. Movement of the deployed filter wire did not show significant difference between manual and robotic interventions (mm, median [IQR]; manual: 13 [10.5] vs robotic: 12.5 [11], $p=0.5$). The postdilation balloon exceeded the margin of the stent with a median of 2 [1] mm in both groups (Table 1).

Tool Tip Kinematic Data

Results of tool tip kinematic data analysis are summarized in Tables 1 and 2. The performance metrics calculated during navigation with robotic assistance showed significantly lower SPARC values (-5.78 ± 3.14 and -8.63 ± 3.98 , $p=0.04$) and higher idle time values (8.92 ± 8.71 and 3.47 ± 3.9 , $p=0.02$) than those performed manually. The Average velocity was lower for robotic navigation than manual navigation, but results were not significant (Figure 4). Qualitatively, no difference was seen in the guidewire paths that were achieved for manual catheterization compared with the paths that were achieved with robotic catheterization (Figure 5). The offsets in the different tool paths are attributed to the view of the model being shifted between

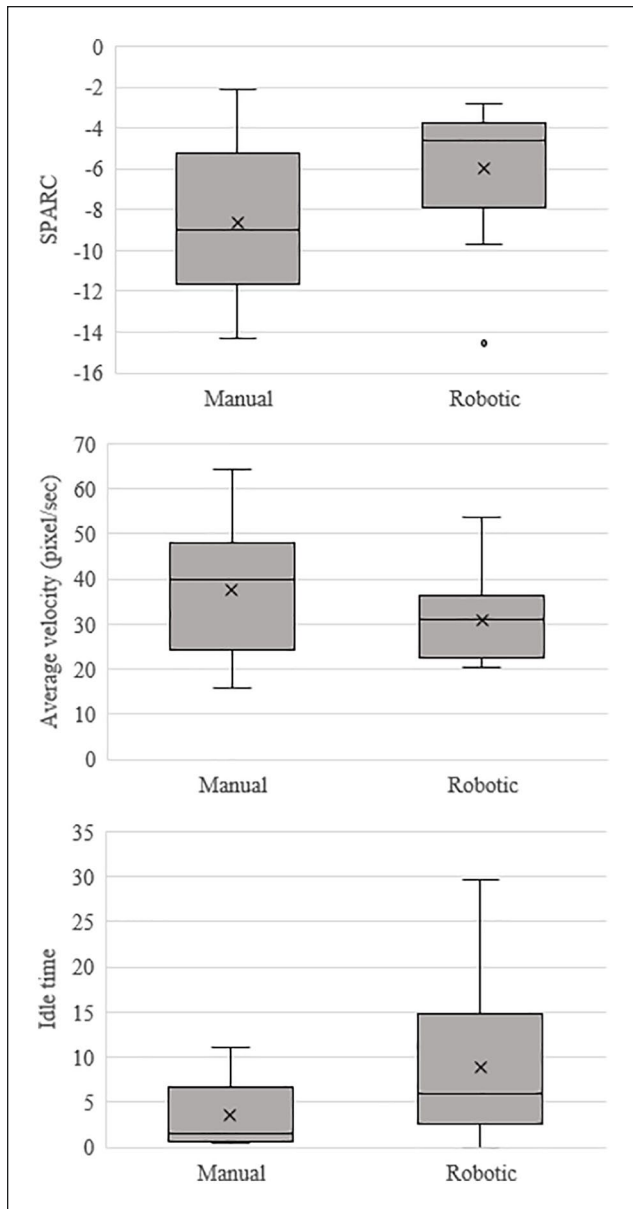


Figure 4. Box plots presenting the results of tool tip kinematic data analysis. SPARC, spectral arc length (lower absolute values associated with smoother motion).

tasks as the participants positioned the simulated fluoroscopic image of the anatomy using the C-Arm controls on the AngioMentor. The C-arm controls shift the simulated image along the X- and Y-axes and define the origin point for the tool tip coordinates extracted from the recordings.

Discussion

The aim of this study was to compare robotic-assisted and manual CAS in a high-fidelity virtual model through quantitative metrics derived from endovascular tool tip

kinematic data, stent positioning, balloon positioning, and open filter wire movements. The observations of this study show that open filter wire movements and postdilation balloon positioning did not differ significantly between the 2 modalities, and that stent positioning was accurate in both groups. Robotic-assisted navigation in the common and internal carotid artery was associated with significantly lower SPARC values and longer amounts of idle time. Lower SPARC values indicate smoother motion, which is likely a result of the effective motion stabilization provided by the robot. The longer amounts of idle time can be explained by the design of the control console and the lack of routine with the robot. The operators are used to the manual control of a coaxial system and have an extensive routine in manipulating the devices simultaneously. However, the robotic control console provides 3 joysticks to navigate the endovascular tools, which requires completely unusual movements from the operator to complete the same task. Therefore, the operators tended to make more pauses with one device, to readjust the other one. The absence of differences in paths traversed by the guidewire for the 2 cases is not surprising. In some of our other works, we have noted that path length is not a metric that shows correlation to expertise.¹⁴ Rather, it is the motion-based performance metrics (SPARC, average velocity, and idle time) that capture tool tip movement smoothness that is associated with better navigational task performance.

Interventionalists successfully completed all robotic-assisted CAS simulations, which demonstrates the intuitive nature of the robotic platform. Stent positioning was accurate with both manual and robotic control. Open filter wire movements and postdilation balloon positioning did not differ significantly between the 2 modalities. These similar results outline that, in terms of precision, manual and robotic CAS are comparable.

Robotic-assistance for endovascular interventions offers an enhanced radiation protection for the operator without the need for wearing a heavy lead apron.² A high success rate is reported with robotic-assisted coronary and peripheral arterial interventions,^{2,15} and early feasibility studies with robotic-assisted CAS are showing promising results.⁴⁻⁶ Carotid artery stenting is considered to be an alternative option of carotid endarterectomy in selected patient groups with carotid artery stenosis.^{16,17} Patients with carotid artery stenosis are treated by multiple specialties, such as vascular surgeons, interventional radiologists, neurosurgeons, and cardiologists. Based on the Nationwide Readmissions Database, 57 273 CAS procedures were performed between 2010 and 2015.¹⁸ The stroke risk of CAS remains high; The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) trial¹⁹ reported a periprocedural stroke rate of 4.1% associated with CAS, which significantly exceeds the periprocedural stroke rate of carotid endarterectomy, which is the current gold standard treatment of carotid

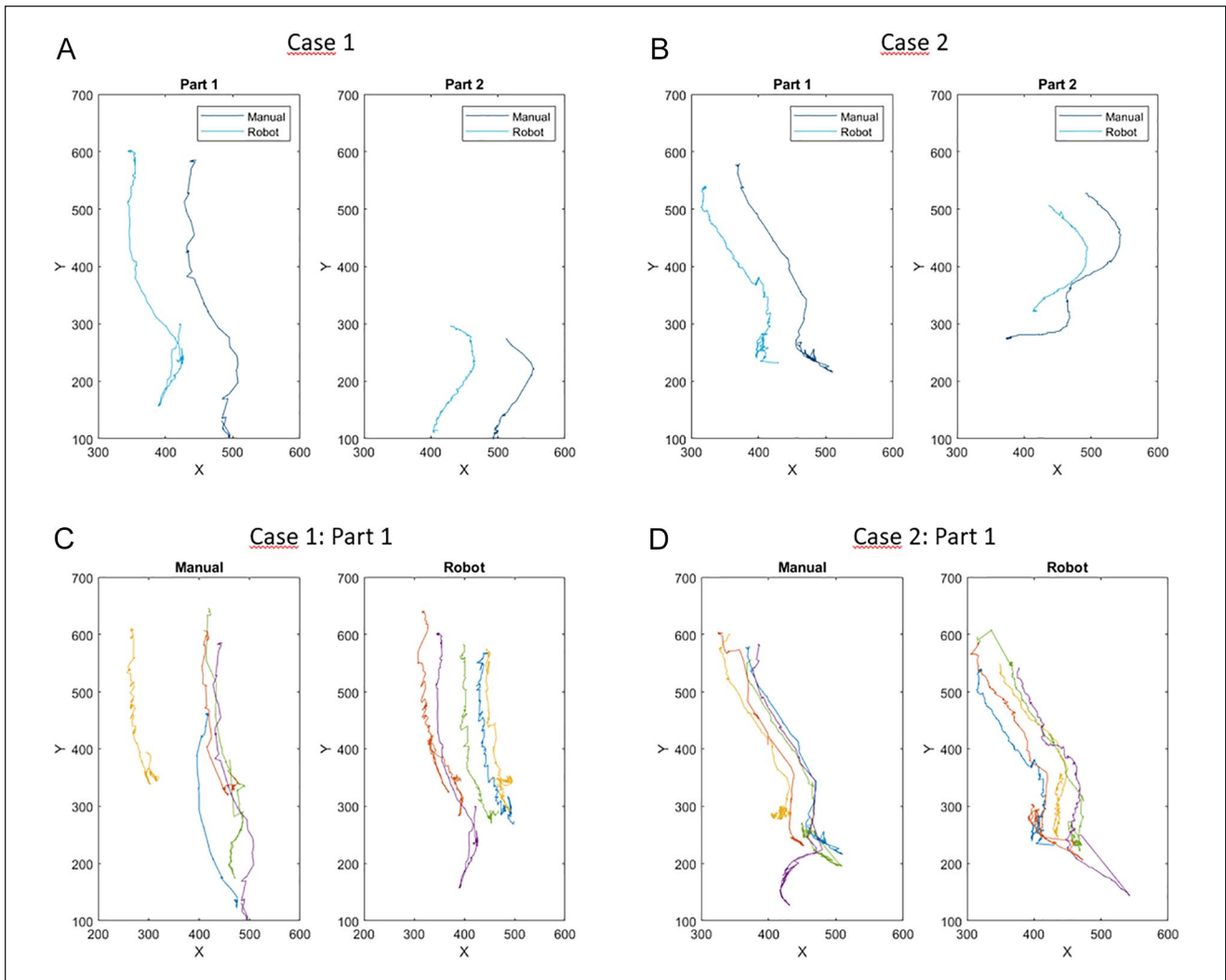


Figure 5. Comparison of manual and robotic navigation trajectories for a single participant for each case (A, B) and for a subset of participants who performed part 1 of both cases (C, D). Values are in units of pixels. Part 1 refers to the navigation of sheath to the distal common carotid artery. Part 2 refers to the lesion crossing in the internal carotid artery.

artery disease. Intraoperative transcranial Doppler (TCD) observations^{20–22} described endovascular navigation in the aortic arch, common carotid artery catheterization, lesion crossing, balloon predilation, stent crossing of the lesion, stent deployment, and stent postdilation to be associated with high embolization risk during CAS. By translating the operator's hand movements to smoother motion, robotic technology could potentially play a role in more precise endovascular navigation, which ultimately may result in lower intraprocedural distal embolization.

Aortic arch and common carotid artery catheterization are physically possible with the CorPath GRX system, but may require manual conversion.⁷ Moreover, Kim et al²³ described that common carotid artery catheterization with a 7 to 8 Fr guide catheter and a guidewire only, without a diagnostic catheter, is associated with a higher incidence of

new embolic signals in diffusion-weighted imaging, compared with arch navigation with the additional use of a 4 to 5 Fr catheter (ie, Headhunter). The currently available CorPath GRX system does not allow the coaxial use of a guide catheter and a diagnostic catheter at the same time, therefore robotic common carotid artery catheterization was not studied.

High-fidelity virtual endovascular simulators are validated for training and skill assessment.^{24–26} With these simulators, users can perform cases with multiple anatomical morphologies and different lesion types without the burden of radiation exposure. In this study, the simulator served as a platform wherein the same cases could be repeated in a standardized environment; therefore, we were able to evaluate solely the navigational performance of the participant and the treatment modality. Rolls et al^{27,28} used a similar

method to evaluate catheter path length in CAS with varying anatomical complexity. The simulator metrics provide an objective and quantitative evaluation of the operator's performance immediately after concluding the case. Among other parameters, these metrics were used to compare the 2 interventional modalities.

Robotic-assisted endovascular procedures typically take more time than conventional endovascular procedures due to the setup time and the additional device exchange time required. In this study, we did not register the setup time or device exchange time. Rather, we focused only on the time of robotic manipulation. The results demonstrate comparable procedural and fluoroscopy time with both manual and robotic control. It is important to mention the additional operative cost when performing robotic-assisted endovascular procedures. The CorPath GRX system's approximate price range is between \$480 000 and \$650 000, with an additional \$400 to \$750 cost per procedure for the single-use cassette and accessories.²⁹

The low number of participants is a limitation of the study. The complications during interventions could not be evaluated because assessment of complications is not integrated into the simulator model; however, the simulator allowed for the standardized comparison of the groups. This study only evaluated straightforward CAS cases, and due to the standardization of the procedures, no therapeutic decisions were made by the operators. Still, we were able to objectively evaluate and compare the navigational performance of the participants.

Conclusion

Robotic-assisted CAS shows precise stent and balloon positioning. Procedural characteristics are comparable with manual CAS. Navigation in the common carotid artery is associated with smoother motion and higher idle time values. These findings highlight the accuracy and the motion stabilizing capability of the endovascular robotic system.

Authors' Note

Previous presentations: Parts of this work has been presented at the 43rd Annual International Conference of the Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (October 31—November 4, 2021; Virtual)

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Declaration of Conflicting Interests

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