Design and Performance Evaluation of a Remote Catheter Navigation System

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***Abstract*—A novel remote catheter navigation system has been developed to reduce physical stress and irradiation to the interventionalist during fluoroscopic X-ray guided catheter intervention. The unique teleoperated design of this system allows the interventionalist to apply conventional axial and radial motion, as used in current practice, to an input catheter placed in a radiation-safe location to control a second catheter placed inside the procedure room. A catheter sensor (used to measure motion of the input catheter) and a catheter manipulator (used to manipulate the second catheter) are both presented. Performance evaluation of the system was assessed by first conducting bench-top experiments to quantify accuracy and precision of both sensed and replicated motion, and then conducting two experiments to evaluate the latency from sensed to replicated motion. The first study consisted of replicating motions of prescribed motion trajectories, while the second study utilized eight operators to remotely navigate a catheter through a normal carotid model. The results show the system has the ability to sense and replicate motion to within 1 mm and 1° in the axial and radial directions, respectively. Remote catheter manipulation was found to be operator dependent and occurred under 300 ms. Future applications of this technology are then presented.**

***Index Terms*—Catheter, catheterization, electrophysiology, fluoroscopic X-ray, image guidance, remote navigation, surgical robotics, telerobotics.**

I. Introduction

PERCUTANEOUS transluminal catheter-based interventional procedures have become the common practice for diagnosis and treatment of cardiac and vascular diseases, including electrophysiological conditions. These procedures typically use fluoroscopic X-ray images to visually assist the interventionalist during intravascular navigation and the final placement of the catheter. The high success rate of catheter-based interventions, combined with their minimal invasiveness, has lead to a significant increase in the number of procedures performed annually [1], [2]. As the number of procedures increases, radiation exposure to the medical staff has become a concern, as the effects of radiation exposure are well documented. Increased radiation training, proper utilization of safety equipment and improved imaging technology have helped reduce exposure levels [3]–[5]. However, these reductions may be offset by procedure complexity and other factors (such as interventionalist skill), which can increase exposure to the patient and medical staff [6]. In addition, the lead aprons and neck collars used to protect physicians and staff from radiation have been linked to the development of chronic back and neck pain [7], [8]. Reductions in radiation exposure and chronic pain would be achieved if percutaneous procedures could be performed from a location remote to the patient [9], and remote catheter navigation systems (RCNS) are being pursued to achieve this [10]–[13].

Catheter navigation systems developed by Negoro [12], Corindus, Inc. [10], Hansen Medical, Inc. [13]–[15], and Stereotaxis Inc. [11], [16]–[21] all employ a master-slave control architecture that uses a peripheral input device to control the remote catheter. The CorPath (Corindus, Inc., Auburndale, MA) and the Negoro system each employ a specialized mechanical transmission module to advance the catheter using the push, pull, and rotate technique; in Negoro's implementation [12], the interventionalist uses a joystick to control the remote catheter, whereas the CorPath system [10] allows the interventionalist to perform continuous motion with a joystick and discrete movements through a touch screen. The system offered by Hansen Medical, Inc. [13]–[15] (Mountain View, CA) uses input from a stylus to manipulate a remote catheter by a specialized, controllable catheter sheath and guidewire system. The Stereotaxis system (Niobe, St. Louis, MO) [11], [16]–[22] uses large permanent magnets mounted on mechanical arms that enable them to move and drive a small magnet placed at the tip of a guidewire through the vasculature. The path of this small magnet (corresponding to the catheter tip) is defined during the procedure by the interventionalist, who draws the intended 3-D path of the tip while sitting at a remote workstation.

Unlike the conventional bedside technique, which requires interventionalists to manipulate a catheter using their hands, employment of these remote navigation systems removes the catheter from the interventionalist's hands, thus removing his/her dexterous and intuitive skills from the procedure. Furthermore, the technological complexities of these systems may require long training times to ensure that the interventionalists

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are skilled in their use. For example, a study conducted by Schiemann *et al.* [23] demonstrated that equivalent navigation efficacy was achieved when comparing conventional navigation to remote navigation using the Niobe system in a glass phantom, after six months of interventionalist training on the system. Therefore, it should be beneficial if an RCNS incorporated the dexterous skill set of an experienced interventionalist during the procedure.

Our group has addressed this need by developing a novel RCNS to manipulate percutaneous transluminal catheters from a location remote to the patient while allowing the interventionalist to apply conventional push, pull, and twist of a catheter's shaft during the remote procedure. To remotely navigate the catheter using this method, the interventionalist applies axial (push and pull) and radial (twist) forces to a catheter's shaft held inside a motion-sensing device, the sensed motion is transferred, via a computer console, to a second device, which replicates the motion along a second catheter's shaft. This method of catheter navigation via remote motion replication promises to provide a platform that incorporates the preexisting skills of an experienced interventionalist while maintaining the objective of reducing the occupational hazards associated with conventional bedside therapy.

In this paper, we describe this new RCNS. The custom mechanical design of the master device-–the Catheter Sensor (CS), the slave device-–the Catheter Manipulator (CM), and the software used to interface them are described in detail. The results of experiments performed to evaluate the accuracy and precision of sensed and replicated motion, as well as the latency in replicated motion are presented.

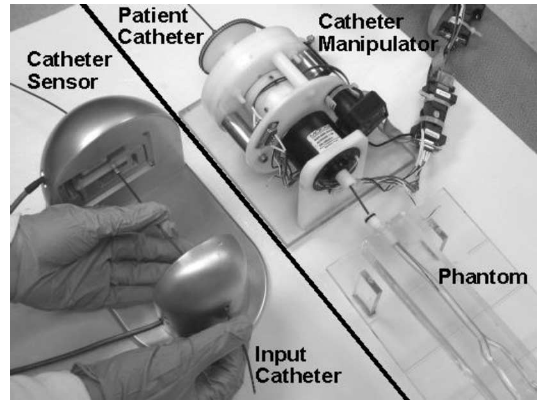

Fig. 1. Remote catheter navigation system: The interventionalist can pull, push or twist the input catheter inside the CS. Motion measured by the CS is then replicated with the patient catheter using the remotely placed catheter manipulator. Image feedback is provided by a standard fluoroscopic X-ray system (not shown).

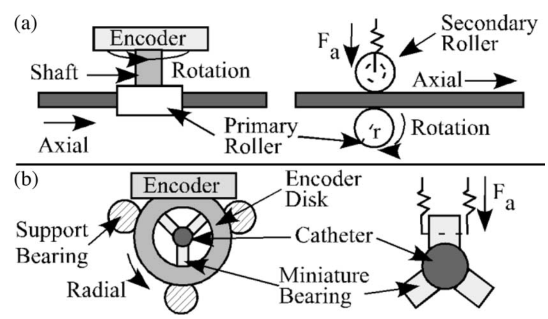

Fig. 2. Motion is measured by the CS in: (a) the axial direction by mechanically transducing the axial motion of the catheter to a rotation of the encoder disks shaft via friction between the catheter and primary roller; adjustment of a second passive roller ensures continuous contact between the catheter and primary roller, and (b) in the radial direction by rotating the radial optical disk through the sensor via three miniature bearings encased a housing which floats on three support bearings. Contained in each electromechanical sensor are springs that apply a force (F_a) to ensure the catheter does not slip in the apparatus.

II. System Description

The RCNS, shown in Fig. 1, was designed to consist of a CS (to be placed at a remote location) capable of measuring the axial and radial motions of an input catheter, a CM (to be placed at the patient bedside) capable of replicating the motions measured by the sensor, and a computer console that relays information between the sensor and manipulator. To ensure navigation with this system is appreciable with conventional bedside navigation, the following criteria were used in the design process:

1) the system should be compatible with generic 6–7 F (diameter: 2–2.3 mm) catheters, sizes common in interventional cardiology and electrophysiology procedures;
2) motion along the catheter's shaft (axial motion) and about the shaft (radial motion) should not be impeded by either the CS or CM;
3) accuracy of sensing and replicating axial motion: 1 mm (for a 1.5 m catheter);
4) accuracy of sensing and replicating radial motion: 1°;
5) latency of motion replication: <300 ms [24].

Detailed descriptions of each component are provided below.

A. Catheter Sensor

The prototype CS, previously described in [25], [26], and schematically shown in Fig. 2, is an electromechanical device that measures the axial and radial motion of the input catheter's shaft using two mechanically independent passive sensors. Each sensor contains a 2000 count-per-revolution quadrature encoder, mechanically coupled to the shaft of the catheter. Axial position of the catheter shaft is measured using a mechanical transducer that converts the axial motion of the catheter to a rotation of the shaft of an optical encoder (E5S, U.S. Digital, WA) using two rollers that mechanically couple to the catheter [Fig. 2(a)]. One of the rollers (the primary roller) is directly coupled to the encoder, while the second idler roller passively ensures continuous contact between the primary roller and catheter. The position of the second roller is adjustable to allow variable contact friction between the catheter and the primary roller. The rollers were manufactured from Delrin to ensure dimensional stability and low inertia. The axial position of the input catheter's shaft is determined as the product of roller circumference (40 mm) and digital encoder counts divided by the total number encoder counts (2000). In the current implementation, detection of a single-counter increment yields a motion sensitivity of 0.02 mm·count^{-1} in the axial direction.

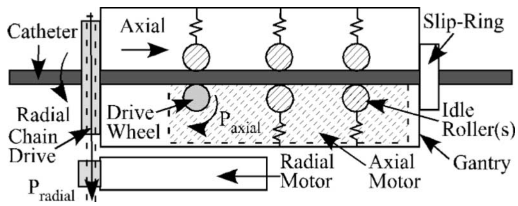

Fig. 3. Patient catheter is placed inside the catheter manipulator. Radial motion ((1): $\theta_{\rm CM}$) is achieved by rotating the slip-ring gantry by a servomotor via a sprocket gear and chain. Mounted on the slip-ring gantry is a second motor, which is used to actuate the catheter in the axial direction [(1): $a_{\rm CM}$] via a bevel gear and the drive wheel. A series of spring-loaded urethane coated rollers are placed inside the roller housing to grip the catheter. Each motor is controlled by a single axis motion controller (not shown).

To measure radial motion, the input catheter is used as the shaft to the radial encoder [Fig. 2(b)]. A cylindrical assembly is constructed to house the sensor components; three miniature bearings and the optical encoder. The three miniature bearings (diameter 4.8 mm) grip the catheter in the radial direction and hold it at the center of the encoder disk while allowing it to move freely in the axial direction; one of the miniature bearings is spring loaded to ensure continuous contact between the bearings and catheter. On the outer edge of the cylindrical housing assembly is a guide track, which in conjunction with three support bearings (diameter 9.52 mm) enables the catheter to freely rotate the optical disk through the optical sensor. The radial position of the catheter's shaft is measured directly by the encoder. In the current implementation, detection of a single-counter increment yields a motion sensitivity of 0.18° mm·count^{-1} in the radial direction.

B. Catheter Manipulator

The CM was designed to actuate the patient catheter using motion sensed along the shaft of the input catheter by the CS, and then applying that motion along the shaft of the patient catheter—a technique similar to the push, pull, and twist technique currently employed during manual bedside manipulation. Previous work [26] determining the kinematics range of a catheter encountered in routine interventional procedures was used to define the design constraints of the CM. Specifically, the following peak velocity and acceleration parameters were set as the design targets: 700 mm·s^{-1} and 30 000 mm·s^{-2}, respectively, in the axial direction; and 43 rad·s^{-1} and 1000 rad·s^{-2}, respectively, in the radial direction. These values exceeded the previously determined peak kinematics of: 300 mm·s^{-1} and 16 000 mm·s^{-2} in the axial direction, and 11 rad·s^{-1} and 500 rad·s^{-2} in the radial direction [26].

The prototype CM, illustrated schematically in Fig. 3, consists of an axial driver mechanism mounted within a slip-ring gantry. The axial-driver mechanism consists of a servomotor (Coreless-DC 2342, MicroMo, FL, USA) coupled to the catheter via a high-friction wheel (urethane 70 A, 1.27 cm diameter) through a 1:1 bevel gear; a secondary spring-loaded urethane idler roller mounted opposite the drive wheel acts to hold the catheter with sufficient frictional force. Contained in the gantry are two additional pairs of passively rotating spring-loaded urethane rollers that guide the catheter through the device. To ensure the catheter does not slip in the mechanism when actuated, springs were integrated into the design to provide an axial gripping force of 4 N and a radial gripping torque of 18 mN·m; these values were chosen to exceed the maximum axial force (2.5 N) and radial torque (14 mN·m) applied by interventionalists on a catheter in a previous study [26]. The entire slip-ring mounted gantry is rotated, via a sprocket-chain drive, by a second servomotor (Coreless-DC 3863, MicroMo, FL, USA), thereby rotating the catheter. Single-axis motion controllers (MVP, MicroMo, Clearwater, FL), which communicate with the computer console, drive the two servomotors.

The position of the patient catheter's shaft is determined by the gear ratios of the bevel and sprocket gears used, the internal gear ratios of the servomotors, and the radius of the urethane rollers and are described by

$$P_{\rm patient}[a_{\rm CM}, \theta_{\rm CM}] = \left[\frac{2\pi \text{counts}_{\rm CM-axial} r_{\rm CM}}{k_{\rm axial}\text{cpr}_{\rm CM}} \quad \frac{2\pi \text{counts}_{\rm CM-radial}}{k_{\rm radial}\text{cpr}_{\rm CM}}\right]. \quad (1)$$

In the prototype CM, the calculated values of the constants $k_{\rm axial}$ and $k_{\rm radial}$ were 3.3 and 16.5, respectively. The drive roller radius ($r_{\rm CM}$) was 6.35 mm, the number of encoder counts per revolution ($\text{cpr}_{\rm CM}$) was 2000; $\text{counts}_{\rm CM\text{-}axial}$ and $\text{counts}_{\rm CM\text{-}radial}$ are the respective number of digital encoder counts of the axial and rotational components. Based on this CM configuration, the smallest motion that can be imparted on the patient catheter is 0.006 mm·count^{-1} and 0.011°·count^{-1} in the axial and radial directions, respectively.

C. Computer Console

Control of the CM and CS is achieved through a computer console (1 GHz dual Athlon, Linux kernel 2.16.15) via RS-232 serial communication. Control software was implemented using C++; to enable simultaneous motion control in the axial and radial directions, device control was multithreaded. The axial and radial motions measured by the CS are substituted for $P_{\rm Patient}[a_{\rm CM}, \theta_{\rm CM}]$ [defined above: (1)] and solved to determine the corresponding position of the CM in motor space [(1): $\text{counts}_{\rm CM\text{-}axial}$, $\text{counts}_{\rm CM\text{-}radial}$). The position of each CS component is sampled at 20 ms intervals; the corresponding velocity and acceleration values are determined and commands are then issued to the CM controllers at 60 ms intervals. This sampling strategy was used to optimize update time while minimizing motion jitter. The motion controllers are provided with position, velocity, and acceleration by the console and then use a trapezoidal motion profile [27], in conjunction with a PID control loop, to drive the patient catheter [28].

III. Methods

A. Evaluation of Catheter Sensor

The axial accuracy of the CS in measuring axial motion was evaluated by advancing a 6 F catheter (Viking, BardEP, MA), containing four 2-mm-long electrodes, inside a 2.4-mm (3/32 in) diameter straight acrylic tube while monitoring the catheter position using a calibrated fluoroscopic X-ray system (MultiStar, Siemens, DE). The catheter was advanced, and then retracted, in the CS in 25-mm increments (approximate) over a 300 mm range. At each catheter position, five radiographic images (FOV/FOV$_{\rm eff}$: 40/36-cm, image matrix: 880 $\times$ 880, technique: 73 kVp and 47 mA) were obtained. Following correction for pincushion distortion [29], the five radiographs were averaged and the catheter's axial position was determined by calculating the weighted centroids of three catheter-shaft electrodes [30]. These values were compared with the corresponding position reported by the CS and accuracy was calculated as the average difference between CS-measurement and the radiographically derived position. These measurements were first performed to determine any deviation in the primary roller radius from the nominal value, thereby generating a calibration constant to linearly scale axial measurements; experiments were then repeated to determine the CS accuracy.

To evaluate axial measurement precision, an acrylic rod with a flat end was placed inside the 2.4-mm (3/32 in) diameter acrylic tube; the end of the rod was used to mark the position to which the catheter would be advanced. The catheter was advanced through the CS into the guide tube until it made contact with the acrylic rod; the position reported by the CS was then recorded. The procedure was executed over a 60-mm range, repositioning the rod at 10 mm steps, at each position five independent CS measurements were made. Measurement precision of the CS was calculated as the standard deviation of the error in the measured position.

The accuracy and precision of radial position measurements were evaluated using a 2-mm diameter carbon-fibre rod in place of the 6 F catheter. This substitution was made to avoid measurement errors introduced due to the elastic properties of the catheter. Placed on the rod's end was a 12.7-mm (0.5 in) diameter cylindrical sleeve with a flat edge precision machined into the cylindrical surface. To evaluate accuracy and precision, the rod was rotated until the flat edge aligned with a gauge block (type 516-423-26, Mitutoyo, Inc., Japan), and a reading was acquired by the CS. Accuracy was evaluated by obtaining measurements at 180° increments over 1080°, and then calculating the mean error in the measurement. Radial measurement precision was evaluated by rotating the rod by 360° ten times, recording the CS measurement, and then calculating the standard deviation.

B. Evaluation of Catheter Manipulator

The accuracy and precision of the CM were evaluated using the calibrated CS. Consistent with the CS experiments, a 6-F catheter was used for all axial experiments and a carbon-fibre rod was used for all radial experiments. Prior to evaluating the accuracy and precision of the CM, a series of experiments were performed to characterize the mechanical backlash of the CM. In the axial direction, mechanical backlash was measured by moving the catheter from 0 to 100 mm then back to 0 mm, ten times in succession. The difference between the start position and final position, as reported by the CS, was divided by the total number of iterations to determine error per direction change. The backlash error was then software corrected. This process was repeated iteratively until the final error was under 1 mm. In the radial direction, the methodology to calculate the mechanical backlash was similar; rotating the carbon-fibre rod from 0°–360°, ten times, and then adjusting the backlash constant until it was under 1°.

To evaluate the accuracy of axial motion, the catheter was advanced by the CM through the CS in 25-mm increments over a range of 400 mm at a speed of 10 mm$\cdot$s^{-1}; readings of the catheter position were made at each increment. To evaluate axial precision, the catheter was advanced to the 40 mm position, ten times, and the standard deviation of the error in the position was calculated. These measurements were first performed to determine any deviation in the drive roller radius ($r_{\rm CM}$), thereby generating a calibration constant to linearly scale $a_{\rm CM}$ in (1), then repeated to determine the CS accuracy.

Radial position accuracy was evaluated by rotating the carbon-fibre rod at a rate of $1^\circ\cdot$s^{-1} over a range of 720°, with measurements taken using the CS at 45° increments. To evaluate precision, the catheter was rotated 360° ten times, recording the radial position using the CS at each trial.

C. Evaluation of Lag in Replicated Motion

Two studies were performed to evaluate the lag time between the sensed and replicated motion. In the first study, the CS was replaced with a data file containing prescribed motion profiles (step, square, ramp, and triangle) in order to remove human factors from the experiments. For the step and square motion profiles, the manipulator was instructed to move the catheter from rest to a prescribed position (up to 350 mm in the axial and 350° in the radial directions) then return back to the original position (square response only, after a 9-s rest at the prescribed position). For the ramp and triangle motion profiles, the manipulator was instructed to move the catheter at a prescribed constant velocity; velocities up to 350 mms^{-1} or 350° s^{-1} in the axial and radial directions, respectively.

In the second study, eight operators with no interventional experience, or experience using this catheter navigation system, were provided with 10 min of training on the system. They then proceeded to navigate a 6-F catheter through an acrylic model of a normal carotid artery [31]; the operators were instructed to navigate the catheter from the common carotid to the internal branch, retract the catheter into the common carotid, then direct it into the external carotid. Inexperienced operators were chosen because in a previous study [26] they were shown to manipulate catheters with higher kinematics than experienced interventionalists. Each operator repeated the procedure 12 times in succession, under direct visual feedback. Fluoroscopic imaging was not used in this case, because the type of feedback mechanism was not expected to affect the measured lag of the RCNS. In both studies, the catheter navigation system logged the motion profiles of both the input catheter and the patient catheter.

To determine the lag in replicated motion, the input and replicated motion profiles were resampled at 20 ms intervals, and then filtered (10th-order rectangular low-pass filter $F_{\rm cutoff} = 2.5$ Hz) to remove frequencies in the replicated profile that are the result of "on-the-fly" motion profile generation,

TABLE I
RESULTS, ACCURACY, AND PRECISION OF THE CATHETER SENSOR AND CATHETER MANIPULATOR

	Catheter Sensor		Catheter Manipulator	
	Axial (mm)	Radial (°)	Axial (mm)	Radial (°)
Accuracy	0.04	0.10	0.07	-0.18
Precision	±0.14	±0.15	±0.11	±0.33

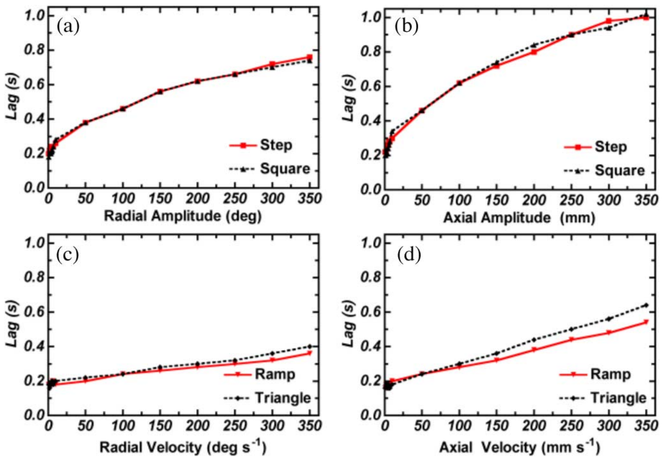

Fig. 4. Measured replicated motion lag time using known motion profiles: (a) step/square response in the radial direction, (b) step/square response in the axial direction, (c) ramp/triangle response in the radial direction, and (d) ramp/triangle response in the axial direction.

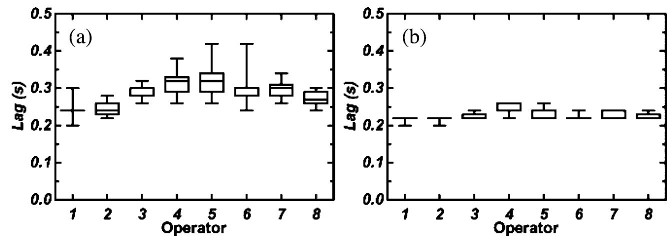

Fig. 5. Measured motion lag when different operators remotely manipulated the catheter through a carotid bifurcation. Motion lag in the (a) radial direction tended to be higher with more variability than the motion lag in the (b) axial direction. Plotted data are the median, lower median, upper median, and range of measured lag times for 12 trials per operator.

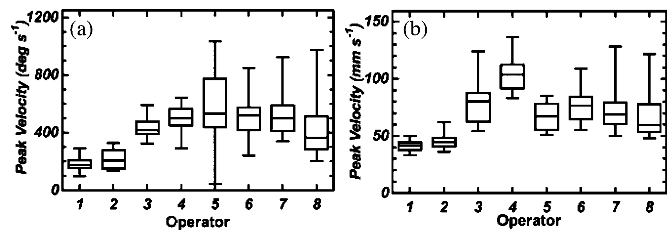

Fig. 6. Peak velocity in the (a) radial and (b) axial directions. Plotted data are the median, lower median, upper median, and range of calculated peak velocity for the 12 trials per operator.

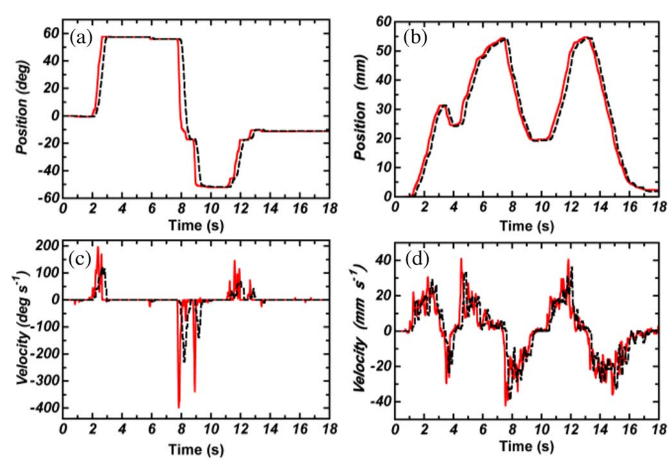

Fig. 7. (a) Radial motion profile, (b) axial motion profile, (c) radial velocity, (d) and axial velocity observed during remote catheter navigation through the normal carotid model (Operator 6, trial 10). The solid line represents motion of the input catheter, while the dotted line is the motion of the patient catheter. In the axial direction, replicated velocity is fluid with the input velocity (c), in contrary to replicated velocity in the radial direction (d), which is visually intermittent.

which occurs at 16.7 Hz. The cross-correlation between motion profiles was then calculated using the *xcorr* function in Matlab (R2007b, MathWorks, Inc., MA). To determine if the lag in replicated motion was operator dependent, lag-time results were compared using one-way ANOVA, performed using Prism V4 (GraphPad Software, Inc., CA).

IV. RESULTS

A. Evaluation of Catheter Sensor

The measured calibration constant for axial motion was 1.0062 mm·mm^{-1}. Listed in Table I are the measured accuracy and precision for the CS.

B. Evaluation of Catheter Manipulator

The measured mechanical backlash was 0.17 mm in the axial direction. Mechanical backlash was not observed in the radial direction. An axial calibration constant of 0.94923 mm·mm^{-1} was observed for the axial drive mechanism. The accuracy and precision of the CM, measured after backlash correction and calibration, are listed in Table I.

C. Evaluation of Lag in Replicated Motion

The lag in motion replication using prescribed motion profiles, shown in Fig. 4, demonstrates a dependency on the amplitude of the requested motion, as well as the requested velocity and acceleration. A minimum system lag of 0.18 s was observed in all cases. As expected, the lag was greater when the prescribed motion profile included larger accelerations (Fig. 4: step and square profiles versus ramp and triangle profiles).

In the second study, all operators were successful in navigating the catheter into both the internal and external carotid arteries. The replicated motion lag is plotted in Fig. 5, for the radial (a) and axial (b) directions. Average lag times in the radial and axial directions were 0.28 $\pm$ 0.04 s (range: 0.2–0.36 s) and 0.23 $\pm$ 0.01 s (range: 0.2–0.26 s), respectively. Statistically, significant differences in the measured lag times were observed between operators ($P < 0.0001$) in both the axial and radial directions.

V. Discussion

The RCNS described in this paper uses a novel method to control the catheter: remote navigation via motion replication. This navigation method promises to enable interventionalists to use their highly developed dexterous skills to remotely maneuver the catheter, potentially reducing radiation exposure and physical stress during long procedures. The current implementation of the RCNS was designed for use with 6–7 F catheters, commonly used in electrophysiological procedures, but is easily adaptable for catheters of different sizes. The performance evaluation of the RCNS demonstrated the system's ability to sense and replicate catheter motion within the intended specifications (accuracy better than 1 mm and 1° in the axial and radial directions, respectively). The reported accuracy and precision in motion sensitivity and motion replication, in addition to using the dexterous skills possessed by the interventionalist should enable rapid acceptance of this technology while maintaining the remarkable success of conventional catheter-based intervention.

The response time between sensed and replicated motion is an important characteristic of any teleoperated system. The minimum achievable lag with the current implementation of the system was 180 ms, attributable to the inherent communication lag between the CS and the CM. However, longer lag times were observed when motion profiles, requiring increased velocities and accelerations, were executed by the CM, as shown in Figs. 4 and 5. Specifically, the observer study demonstrated that the lag times measured for some operators were significantly longer, and in the radial direction lag times of as much as 360 ms were measured. In comparison, motion lag in the axial direction varied only by 60 ms between all operators. There are two related factors that explain this operator-dependent increase in the radial direction lag time. First, inspection of the motion profiles in the radial direction demonstrated that operators who navigated the remote catheter with longer, and more variable lag times (Fig. 5), tended to apply higher peak velocities (Fig. 6) than operators with lower and less variable lag times (e.g., operator 5 versus operator 2). Second, the ability to visualize changes in catheter orientation and position also influences the motion profile, and thereby, the measured lag time: in the axial direction, changes in the position are easily perceived, while changes in the radial orientation of the catheter are obscured both by the catheter's radial symmetry and its deformability. This inability to visualize the radial orientation of the catheter seemed to result in a *move–wait–visualize–repeat* mode of navigation in the radial direction, instead of moving and visualizing the catheter *simultaneously*, which occurs in the axial direction. Inspection of the recorded axial and radial velocities of the operator's motion profiles supports this hypothesis; an example motion profile, shown in Fig. 7, illustrates smoothly varying motion in the axial direction [Fig. 7(b) and (d)] and intermittent motion in the radial direction [Fig. 7(a) and (c)]. The lack of perception of the radial motion of the remote catheter observed in these studies is consistent with catheter navigation and visualization in clinical practice, where motion applied to the proximal end of the catheter is not fully transferred to the distal end, and rotation about the catheter's axis is poorly perceived in the fluoroscopic images. Overall, these results suggest that lower lag times are achievable when the operator navigates the catheter using smoother motion. Furthermore, our earlier study [26], comparing catheter kinematics while operated by novices and experienced interventionalists, demonstrated that experienced interventionalists navigate catheters with lower peak velocities and peak accelerations than inexperienced users, suggesting that, in a clinical setting, the lag times will be dominated by the inherent communication delay, which, in future implementations, can be decreased using a more sophisticated communication strategy. Nonetheless, even the lag times observed with inexperienced users are still within the previously defined limit of 300 ms, established by Fabrizio *et al.* [24] as the maximum acceptable image-display latency needed to ensure safe remote surgical manipulation.

The simplicity of the experiments performed to evaluate mechanical backlash and the phantom used to determine lag in replicated motion represent limitations of this study. Correcting mechanical backlash was iteratively performed until ten changes in direction resulted in an observed error of less than 1 mm and 1° in the axial and radial directions, respectively. Increasing the number of directional changes may result in a larger discrepancy between the starting position and final recorded position, as quantization effects of the backlash correction factor become more apparent. Although this may occur, the iterative error per direction change is very small and may not be perceived by the operator, who, in practice, will use fluoroscopic X-ray imaging as position feedback of the patient catheter.

Furthermore, the phantom used in the motion lag study presented a simpler path trajectory than those commonly encountered in clinical practice, which require maneuvering of the catheter through tortuous vessels and tight curvatures (e.g., vessel selection through the aortic arch). Softening of the catheter, which occurs due to contact with warm blood, and catheter navigation in a wet environment were also not mimicked in the presented experiments, although the effect of manipulating a wetted catheter should be neutralized using an introducer sheath, which stops the backflow of blood along the catheter. The experiments performed were intended to measure the lag imposed by the system's inherent characteristics (i.e., inertia, communications delay, and control parameters), as well as the motion sensitivity and motion replication of the system. Extensive experiments addressing the system performance under more physiologically relevant conditions, as well as directly comparing remote catheter navigation versus conventional catheter navigation, are the subject of future studies.

The prototype RCNS was designed for compatibility with generic 6–7 F catheters; catheter sizes used commonly during interventional electrophysiology procedures, but in its current implementation it does not contain the mechanics required to manipulate deflectable tips found on some electrophysiology catheters. The mechanical mechanisms used to deflect these catheters are not standardized and thus would require a specialized mechanical device for compatibility with each different deflectable catheter type. In addition, the compatible catheter sizes (6–7 F) are larger than catheter sizes found in routine interventional cardiology and interventional neuroradiology procedures, which are typically 4–5 F. Utilizing this system with smaller catheters will require modifying the mechanism that grips and actuates the catheter in the CM, as well as the electromechanical sensors in the CS. The CM is predominantly composed of Delrin, an easily machinable low-cost plastic, which provided a cost-effective method to demonstrate the proposed method of remote catheter navigation. However, Delrin cannot be placed in an autoclave, thus limiting the ability to easily sterilize and reuse the CM. Future versions of the RCNS will address these concerns.

The RCNS presented has many potential advantages over commercially available systems. Unlike magnetic catheter navigation [11], where large permanent magnets are used to orient the catheter, thereby removing biplane imaging capabilities, limiting oblique projection views to $\pm 30^{\circ}$, requiring magnetic shielding in the procedure room, and requiring specialized catheters, the RCNS presented can be easily integrated into existing fluoroscopic suites. The current system also uses generic catheters, with performance characteristics known to the interventionalist, during remote navigation. Most other commercially available remote navigation systems utilize joystick-type input devices to navigate the remote catheter, and all but the device described by Negoro *et al*. [12], manipulate the remote catheter without providing tactile sensation to the interventionalist. Because of the flexible nature of catheters, external forces applied to the catheter during catheter guidance occur when the tip of the catheter pushes directly into tissue or when twisting the catheter pushes its body against the vascular wall. In both situations, the external forces applied to the catheter are not fully transferred to the interventionalist but instead result in catheter deformation. The operator uses these visual cues (sometimes termed “image haptics”) during catheter guidance, and we expect that the ability to exploit prior dexterous skills during remote catheter navigation, as provided by our RCNS, may provide added benefit over navigation systems employing joysticks or other nonintuitive master devices [10], [13]–[15].

The system description and performance evaluation provided here demonstrate the ability of the RCNS to accurately sense and replicate catheter motion within acceptable lag. Performance validation of this system *in vivo* is required. The diagnosis and treatment of cardiac arrhythmia is an ideal choice, as these procedures use 6–7 F catheters, and these procedures can be long, enhancing radiation exposure and fatigue to the interventionalist. Application of this system during other interventions; such as vascular angiography or placing balloon/stents to open stenosed arteries is possible, but for each application, the logistics of this technology must be examined to ensure patient safety and positive clinical outcome. Further investigation and developments are underway to address these issues.

VI. Conclusion

The RCNS presented is a unique platform that provides the interventionalist with the ability to use their dexterous skills while performing catheter-based interventions from a location remote to the patient. The present study has demonstrated the system’s ability to accurately sense and replicate catheter motion with acceptable lag. Combining accurate motion replication with the system’s ability to easily integrate within existing facilities promises to make this RCNS a cost-effective approach to reducing interventionalist’s radiation exposure and physical discomfort. In the future, utilizing this system to perform a range of catheter-based interventions *in vivo* is required to establish the limitations of this technology in clinical practice.

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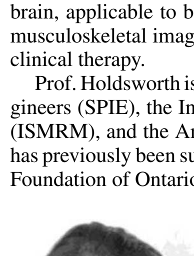

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