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Mohammad Ali Tavallaei

Daniel Gelman

Michael Konstantine Lavdas

Allan C Skanes

Douglas L Jones

See next page for additional authors

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Authors

Mohammad Ali Tavallaei, Daniel Gelman, Michael Konstantine Lavdas, Allan C Skanes, Douglas L Jones, Jeffrey S Bax, and Maria Drangova

Design, Development and Evaluation of a Compact Tele-Robotic Catheter Navigation System

Mohammad Ali Tavallaei,^{1,2*} Daniel Gelman,^{1,2} Michael Konstantine Lavdas,^{1,3} Allan C. Skanes,⁴ Douglas L. Jones,^{1,5,6} Jeffrey S. Bax⁷ and Maria Drangova^{1,2,8}

¹Robarts Research Institute, Schulich School of Medicine & Dentistry, The University of Western Ontario, London, Ontario, Canada

²Biomedical Engineering Graduate Program, The University of Western Ontario, London, Ontario, Canada

³Mechatronics Engineering Program, The University of Western Ontario, London, Ontario, Canada

⁴Department of Medicine, Schulich School of Medicine & Dentistry, The University of Western Ontario, London, Ontario, Canada

⁵Canadian Surgical Technologies and Advanced Robotics, London Health Sciences Centre, University Hospital, London, Ontario, Canada

⁶Department of Physiology and Pharmacology, Schulich School of Medicine & Dentistry, The University of Western Ontario, London, Ontario, Canada

⁷Centre of Imaging Technology Commercialization (CIMTEC), London, Ontario, Canada

⁸Department of Medical Biophysics, Schulich School of Medicine & Dentistry, The University of Western Ontario, London, Ontario, Canada

*Correspondence to: Mohammad Ali Tavallaei, Imaging Research Laboratories, Robarts Research Institute, 1151 Richmond street, Western University, London, Ontario N6A 5B7, Canada.

Phone: (519) 663-5777 ext. 24096. Fax: (519) 663-3403. E-mail: atavall@robarts.ca

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Abstract

Background

Remote catheter navigation systems protect interventionalists from scattered ionizing radiation. However, these systems typically require specialized catheters and extensive operator training.

Methods

A new compact and sterilizable tele-robotic system is described, which allows remote navigation of conventional tip-steerable catheters, with 3-degrees-of-freedom, using an interface that takes advantage of the interventionalist's existing dexterous skills. The performance of the system is evaluated *ex vivo* and *in vivo* for remote catheter navigation and ablation delivery.

Results

The system has absolute errors of 0.1 ± 0.1 mm and $7 \pm 6^\circ$ over 100 mm of axial motion and 360° of catheter rotation, respectively. *In vivo* experiments proved the safety of the proposed tele-robotic system and demonstrated the feasibility of remote navigation and delivery of ablation.

Conclusion

The proposed tele-robotic system allows the interventionalist to use conventional steerable catheters; while maintaining a safe distance from the radiation source, they can remotely navigate the catheter and deliver ablation lesions.

Keywords

catheterization, image guided interventions, master-slave, tele-robotics, medical robotics.

Introduction

Cardiac catheterization is a widely accepted tool for the treatment and diagnosis of many cardiovascular diseases. These procedures are conventionally guided with fluoroscopic imaging. However, fluoroscopic imaging is a source of radiation that exposes the interventionalists and staff to scattered radiation on a daily basis, necessitating the use of leaded aprons for protection. These heavy radiation protection garments provide only partial protection (1-3) and their prolonged use is known to cause chronic neck and back pain (4,5). While proper training, improved imaging technology, and safety equipment have resulted in reduced exposure levels, scattered radiation exposure of staff continues to be a major safety concern; studies suggest that cumulative radiation exposure of staff is associated with a non-negligible lifetime risk of cancer (6,7) attributed to the excess radiation. Some of the safety measures aimed at reducing the exposure of staff to radiation – such as the separation of the control and procedure room in conventional catheterization labs (8) – can potentially disrupt the flow of an intervention and reduce the efficiency of the procedure by physically separating staff and hindering communication among them. These limitations of fluoroscopically guided catheter intervention procedures can be overcome by providing the interventionalist with the tools to remotely perform the catheterization directly from the control room.

Several remote catheter navigation systems (master-slave) have been developed that are now commercially available: Niobe (Stereotaxis Inc.) (9,10), Sensei (Hansen Medical) (11,12), Corpath (Corindus Vascular Robotics) (13), and Amigo (Catheter Robotics Inc.) (14). The user interacts with the Niobe system through a graphical user interface; this system then uses controlled magnetic fields to move and navigate a magnet connected to the tip of a catheter with 3 degrees of freedom (DOF) to follow the motion prescribed by the user. The Sensei system incorporates custom designed steerable catheters and sheaths to allow the remote manipulation of the catheters/ sheaths using a 3-DOF joystick. The Corpath system uses sets of rollers mounted on a rotating gantry to grip on to the catheter and rotate it, allowing for only 2-DOF to control catheters for vascular applications. The Amigo system allows for 3-DOF for the manipulation of standard-tip steerable catheters, which utilize rotary knobs mounted on the catheter handle for tip deflection, using a remote controller with push buttons.

Remote robotic catheter navigation systems have also been developed by several research groups. Wang *et al.* (15) developed a remote catheter navigation system with the ability to remotely manipulate a catheter with 2-DOF. In (16), a system for endovascular tele-operated access (SETA) is presented that incorporates haptic feedback and also has the ability to manipulate both the catheter and guidewire has been presented in (16); the SETA system also provides 2-DOF in catheter manipulation. Meng *et al.* (17) also introduce a remote controlled interventional robot that has 2-DOF and incorporates force feedback. Other master-slave systems that

allow for full 3-DOF in catheter manipulation have also been developed. Typically the interventionalist interacts with these systems using a joystick or a graphical user interface (18-20).

Developments by Thakur *et al.* (21-23) have taken advantage of the interventionalist's dexterous skills in remote manipulation of conventional commercial catheters; in this design approach the interventionalist directly applies push/pull and rotatory motions to a catheter traveling within a motion-sensing device. As a result, the system in (22,23) required minimal operator training and allowed for remote navigation using conventional and commercially available catheters. However, the former design only enabled catheter manipulation with 2-DOF, lacked the means to manipulate the catheter handle plunger for steering of the distal end, and did not allow for robot sterilization.

In this work, we addressed the limitations of (21-23) and developed a remote catheter navigation system (RCNS) that allows full 3-DOF in manipulation of conventional steerable catheters – specifically catheters of various diameters, with a plunger mechanism for distal tip deflection. The new master-slave system design continues to take advantage of the user's existing dexterity: the user pushes/pulls and rotates a catheter handle and rotates a knob similar to the manipulation of a conventional catheter handle. Another improvement in the presented system is that it allows for sterilization/replacement of components that come into contact with the catheter and also greatly facilitates catheter exchange. The developed system can potentially reduce the amount of radiation to the interventionalist, and facilitate procedure flow, by allowing the interventionalist to perform the navigation remotely (possibly directly from the control room). Furthermore, the proposed system can potentially increase catheter stability, motion precision and accuracy.

System Description

The RCNS is designed as a tele-robotic system. The robot (the slave unit) is composed of two sections: the handle manipulator (HM) and the catheter manipulator (CM). These two components work together to provide 3-DOF in catheter navigation. The interventionalist manually interacts with a master unit that takes advantage of their existing dexterous skills – relying on the push/pull, twist, and knob manipulations conventionally imparted on a catheter handle during navigation. The control system captures the motion imparted by the interventionalist on the master unit and, using the motor's encoder signal as feedback, controls the motors of the robot such that the user's applied input motions are replicated on the patient catheter. Using image guidance (such as fluoroscopic imaging) the interventionalist tracks the catheter position and remotely navigates it to the desired anatomical target. Figure 1 is a schematic diagram describing the interactions of the system components. The master unit, the slave robot and the control unit are explained in this section.

Figure 1.

Master unit

The role of the master unit, Fig. 2, is to enable the measurement of the interventionalist's imposed rotational,

axial and catheter tip deflection manipulations on a standard interventional catheter. The master unit utilizes a catheter handle mounted on a linear slide. A rack and pinion mechanism coupled to a quadrature optical encoder (HEDS 5600, Avago Technologies, USA), with 1,000 counts per revolution, measures the relative axial position of the linear slide with respect to the base of the assembly. The handle and the deflection mechanisms of the catheter (knob) are both free to rotate independently along the axis that supports them. The position of the handle and knob are both measured using two additional optical quadrature encoders (HEDS 5600, Avago Technologies, USA). A Teensy 3.1 development board (PJRC, OR, USA) that incorporates a 32 bit ARM-architecture micro controller (MK20DX256VLH7, Freescale Semiconductor, Bermuda) is used for real-time quadrature decoding and streaming of the position data to the main control unit at 100 Hz. A simple user interface on the master unit allows for deactivation/activation of tracking. This feature permits readjustment of the handle position when the range of motion on the slide has been exceeded.

Figure 2.

Robot – slave

The slave unit, shown schematically in Fig. 3, is composed of the handle manipulator and catheter manipulator. The HM sits between the patient's legs, while the CM is positioned over the patient. The CM and HM are described below.

Figure 3.

Catheter Manipulator

The CM is designed to manipulate the catheter body directly. The design of the CM makes use of a differential gear mechanism to allow for radial and axial manipulation of the catheter with the source of actuation (two brushed-12V-DC motors) fixed. This design greatly reduces the size and inertia of the manipulator and permits easy disengagement of the manipulator from the body for sterilization or repair. Inside the structure is a set of parallel rollers that grip on to the catheter (active rollers); these rollers are pulled towards the catheter using two elastic bands and allow constant pressure on the catheter. These rollers are coupled to the differential gear mechanism through miter gears: the rotation of the rollers (with urethane coating) results in axial motion of the catheter, while the rotation of the base of the structure, results in the rotation of the entire assembly, and therefore provides rotation of the catheter body. To ensure future compatibility with use within an MRI scanner, the body of the CM was manufactured from Delrin®; and all gears were stainless steel or brass. Figure 4 illustrates the internal components of the CM (exterior housing hidden) and shows how the gears engage to achieve the desired function. With appropriate actuation of the differential gear mechanism (using two motors), one can control the radial and axial motion of the catheter arbitrarily. A further advantage of this design is that because adjustable shafts support the rollers, various catheter gauges can be accommodated without the need for any adjustment. Furthermore, the differential gear mechanism can easily be disengaged from the base (that supports the motors) for replacement or sterilization purposes.

Figure 4.

Mount

To enable arbitrary positioning of the CM, with respect to the patient, and to allow for access to various entry points, a mount was developed. The mount, illustrated in Fig. 5, is a simple stand, manufactured from Delrin® and PEEK, that supports the CM and allows the user to adjust the height and lateral position, as well as the roll and yaw angles of the manipulator.

Figure 5.

Handle Manipulator

Conventional steerable catheters have a plunger (or knob) on their handle that is used to deflect the catheter's distal end. The HM was designed to allow for the manipulation of this plunger. The designed HM, shown in Fig. 6, has a rotating gantry (coupled to a 12V brushed DC motor) on which the catheter is mounted. A winch and spring mechanism is used to push and pull the catheter plunger. The winch (actuated with a second DC motor) rolls a string that is connected to one end of a lever; the other end of the lever applies pressure to one side of the plunger. The other side of the plunger is supported by a spring. The spring stiffness is selected such that it allows for pushing back the plunger when the lever relaxes. This design allows both motors to remain stationary during operation. Most of the HM components are made of plastic using a 3D printer (Objet30 Pro, Stratsys, MN USA). The complete developed system is shown in Fig. 7.

Figure 6.

Figure 7.

Control Unit

The control unit of the RCNS system described in (22,23) was composed of three different components: encoder decoders, a computer and controllers. The positions of the two encoders of the master unit were first decoded and transmitted to a personal computer using commercially available encoder readers (E5S, U.S. Digital, WA). This reference motion was then relayed by the computer to two single-axis motion controllers (MVP, MicroMo, Clearwater, FL) so that the slave robot would follow the axial and radial position of the master. This control system was a non-real-time controller implementation that resulted in a relatively large delay of approximately 300 ms between the master and slave motion.

To reduce the delay in motion replication, a real-time servo control system is designed and implemented. The control unit comprises an Arduino Due development platform (Smart Projects, Strambino, Italy) that incorporates a 32-bit ARM-architecture microcontroller (SAM3X8E, ATMEL, California USA) together with a custom developed daughter printed circuit board that contains the DC motor driver integrated circuits (VNH5019, STMicroelectronics, Geneva Switzerland). The control unit communicates with the master unit to obtain the desired reference positions, and simultaneously measures the positions of quadrature incremental Hall-effect encoders mounted on each motor

(3200 counts per revolution). Using a proportional-integral-derivative (PID) control method, the processor calculates the appropriate control signal to reduce the error between the desired reference motion profile and the motor position, ultimately allowing for master-slave control of the robot. The PID controller was manually tuned to obtain a fast response with zero overshoot and offset.

System Evaluation

Evaluation in Laboratory Setting

Evaluation experiments were first performed in the laboratory setting to determine the accuracy of the RCNS to replicate prescribed axial in radial catheter motions. For these experiments, the patient catheter (7 F, Biosense Webster Inc., CA, USA) was confined to a 6-mm diameter acrylic tube that had a ruler aligned and attached to it.

Axial motion

Axial motion of ± 100 mm was imparted on the master's input handle to provide a reference position. The corresponding starting and stopping position of the patient catheter with respect to the ruler were recorded. Measurements were repeated 10 times for each direction.

Radial motion

To measure the accuracy of radial motion, a protractor was mounted on the end of the acrylic tube such that the catheter passed through its center. A mechanical "arrow" was connected to the tip of a catheter to enable measurement of the catheter angle with respect to the protractor. The input handle was rotated to $\pm 360^\circ$ and the corresponding angle of the patient catheter was measured. Measurements were repeated 10 times for each direction.

Plunger motion

To validate that the robot can provide a full range of motion for the plunger, the user rotated the plunger input of the master unit until the robot handle manipulator reached the maximum motion range and fully deflected the catheter tip. This was repeated multiple times.

Dynamic motion

Master and slave motion profiles were streamed to a personal computer at a rate of 30 Hz during 6 manual maneuvers, each approximately 1 minute in duration. Upon completion of the experiments the sampled master and slave profiles were interpolated, retrospectively in MATLAB, to a temporal resolution of 1 ms; the interpolated profiles were then cross-correlated (using the *xcorr* function in MATLAB, MathWorks Inc., Massachusetts USA) to determine the delay between each master and corresponding slave profile. The average delay for the 6 maneuvers was calculated for each DOF (axial and radial).

Evaluation in-vivo

Objective

The objective of the *in vivo* experiments was to demonstrate the safety and feasibility of remote catheter navigation and RF-lesion generation, using the described RCNS.

Animal Preparation

All animal studies were performed in accordance with institutional and national guidelines and approved by The University of Western Ontario Animal Use and Care Subcommittee. Three male pigs, weighing 30-40 kg, were used in this study; while a single animal would have been sufficient to demonstrate the *in vivo* feasibility of the RCNS, malfunction of equipment not related to the RCNS (RF generator, animal 1) and RCNS miscalibration (animal 2) required the use of additional animals.

Each animal was given an intramuscular injection of atropine (0.04 mg/kg) and Acepromazine (0.2 mg/kg) and premedicated with Telazol, reconstituted with 2.5 ml Xylazine (100 mg/ml) and 2.5 ml sterile saline administered at a dose of 0.03 ml/kg. Throughout the intervention, each animal was intubated and maintained under general anesthesia (1-2% isoflurane in O₂ and NO mixture). Anaesthetic and analgesia were monitored throughout the study. To access the vasculature, using the Seldinger technique, a 9 F introducer sheath (Fast-Cath, St. Jude Medical, St. Paul, MN, USA) was inserted into the right external jugular vein for the insertion of a 52 cm Active-Fixation pacing lead (5067, Medtronic, Republic of Ireland), which, when positioned into set locations, provided a navigation target. Two additional introducers were inserted into the right and left femoral veins. If the vessels could not be accessed percutaneously, a cut down was performed. The right femoral insertion point was prepared for use with the robotically operated catheter (RO_Cath) and the left femoral vein was prepared for use with a manually operated catheter (MO_Cath).

Experimental Setup

The RCNS was transported to the operating suite and positioned on the operating table. After the animal was prepared and positioned on the bed, the catheter mount was manually adjusted for the preferred entry position and orientation angle. The system was then turned on. The experimental setup is depicted in Fig. 8. All navigations were performed under fluoroscopic guidance using a portable x-ray system (OEC Elite 9900, GE HealthCare, Waukesha, WI, USA). The catheters used in this study were deflectable, 7 F, non-irrigated, D-type curvature catheters (BioSense Webster Inc., Diamond Bar, CA, USA). The RO_Cath was passed through the manipulator without engagement of the rollers in the CM or fixation of the handle in the HM unit so that it could be manually operated.

Both RO_Cath and MO_Cath were inserted manually into the right and left femoral veins, respectively, and guided up the inferior Vena Cava to be aligned with the apex of the heart, just above the diaphragm. The RO_Cath was then mounted on the robot.

Figure 8.

Procedure and Data Collection

The *in vivo* experiments were performed by an interventionalist with more than 15 years of experience in catheterization. The interventionalist had not used the RCNS

previously and was provided training instructions just prior to the start of the first animal experiments.

The first animal was used to evaluate navigation feasibility and compare navigation time between the RO_Cath and MO_Cath. To provide a target for catheter navigation, the pacemaker lead was inserted via the external jugular vein and navigated to 4 different locations during the experiment. These positions were in close proximity to the following anatomical landmarks: right atrial appendage (RAA), right ventricular lateral wall (RV-LW), right atrial low septum (RA-LS) and right ventricular outflow track (RV-OT).

Using fluoroscopic guidance, and when necessary verifying catheter tip position by repositioning the fluoroscopy unit between the left anterior oblique and right anterior oblique views), the interventionalist navigated the tip of the MO_Cath or RO_Cath towards the tip electrode of the pacemaker lead. Orthogonally positioned images were acquired and recorded to confirm the catheter tip had reached the target lead. The time to reach the target, as well as the radiation exposure and exposure time were also recorded. Following each manipulation, the RO_Cath/ MO_Cath was pulled back to the starting location above the diaphragm, the time was reset and the catheter was again navigated to the target. This experiment was repeated 4 times for each target for both manual and robotic modes of operation. The order sequence of robotic and manual navigation was randomly changed for navigation to each target, to prevent bias.

Time of navigation and exposure time for each anatomical target location were compared between the two modes of navigation (manual and robotic). For this comparison two-way repeated measures analysis of variance was used for data obtained from the same animal. All statistical analyses were performed using Prism™ (GraphPad Software Inc., San Diego, CA, USA) and $p < 0.05$ was considered significant.

The feasibility of RF lesion generation was evaluated in animal 3. For this experiment the interventionalist navigated the RO_Cath to 5 targets in the right side: high lateral right atrium, (HL-RA), right atrial appendage (RAA), right atrial septum (RAS), coronary sinus (CS), and the right ventricular lateral wall (RV-LW) and delivered 50 watts of RF power for 60 s. The right ventricle was selected as the final target as it is well known to be highly susceptible to RF-induced ventricular fibrillation in pigs. After the experiment, the pig was euthanized and the heart excised for validation of successful lesion creation.

Results

Evaluation in Laboratory Setting

Axial, Radial and Knob motion

Our measurements indicate that the error in axial positioning of the catheter is 0.1 ± 0.1 mm over 100 mm of manipulation. The radial error was $7 \pm 6^\circ$ over 360° of motion. As the PID controller has zero offset and overshoot, the primary source of this error is attributable to mechanical imperfections such as slippage and backlash.

The handle manipulator was capable of controlling the position of the plunger allowing for arbitrary deflection of the catheter tip; note that quantitative evaluation of the accuracy of catheter tip deflection is not possible because the amount of

deflection is dependent on many variables, including catheter, catheter age, ambient temperature etc. – what is important is similar tip curvature can be achieved when using the robot compared to manual knob manipulation. Overall, the proposed tele-robot allows for accurate remote position control of the catheter tip with 3-DOF.

Dynamic Motion

Representative profiles of dynamic motion profiles of the master and slave are presented in Fig. 9. Excellent agreement can be seen between the master and slave positions, both in the axial and radial directions. The average delay between the master and slave profiles was 35 ± 15 ms.

Figure 9.

Evaluation in-vivo

All 4 pacing lead targets were successfully reached with both the MO_Cath and the RO_Cath. Successful navigation was confirmed by obtaining two orthogonal fluoroscopic images, that both showed the catheter tip immediately adjacent to the target lead tip; Figure 10 shows a representative set of these images. Figure 11 shows the navigation time of each method to each of the four targets. Statistical analysis showed that the method of navigation had no effect overall on navigation time ($p=0.705$) or exposure time ($p=0.806$). Navigation attempts in the second animal failed as the misalignment of the mount resulted in excessive force on the catheter, therefore, limiting its proper actuation.

Large ablation lesions were clearly visible directly after excising the heart (animal 3) at all anatomical sites except for the lesion placed at the CS. Figure 12 provides visual confirmation of the created RF lesions.

In this compact design implementation the catheter may buckle in the space between the CM and HM units (when the catheter is retracted by the CM). However this buckling did not impede the catheter's motion during any of the experiments.

Figure 10.

Figure 11.

Figure 12.

Discussion

In this paper we have presented a tele-robotic system that allows for remote navigation of a conventional tip steerable tip catheter with 3-DOF. This study demonstrated, the feasibility and safety of the presented RCNS for remote catheter navigation and RF lesion generation *in vivo*. Without any prior training sessions, the interventionalist successfully navigated the RO_Cath to 4 different targets (4 times to each target for a total of 16 RO_Cath navigations) in the right side of the animal's heart. Statistical analysis showed no significant difference between the navigation times of manual vs. remote navigation. The interventionalist was also successful in creating ablation lesions with the RO_Cath at intended anatomical targets. Laboratory experiments showed the robot

to be accurate with an axial error of 0.1 ± 0.1 mm over 100 mm of motion and a radial error of $7 \pm 6^\circ$ over 360° of motion. Dynamic motion evaluation demonstrated that the robotic system has a very rapid response, with a delay of 35 ± 15 ms.

The presented robotic system is compact and easily accommodates conventional steerable catheters of varying external diameter. The unique design of the system allows for arbitrary positioning of the catheter manipulator at the desired point of entry, preventing buckling of the patient catheter between the robot and the introducer sheath. The system design also allows for catheter exchange in less than 2 minutes.

Since the presented compact RCNS uses the same general approach as that described in (22,23), the overall design continues to take advantage of the user's dexterous skills in the master unit. Furthermore, the addition of a handle deflection sensor/manipulator allows the interventionalist to directly manipulate a catheter handle in the master unit. Therefore, the currently presented RCNS has a negligible learning curve – interventionalists were able to operate the system without any prior training. The new robotic system also allows for simple disengagement of the differential gear mechanism (which comes in direct contact with the patient catheter) allowing for its replacement or sterilization; this was not feasible with the earlier system design.

Apart from the DC motors, all components of the presented robot are made of non-magnetic material. By replacing the DC motors with non-magnetic Ultrasonic motors (also non-magnetic) it is expected that the presented robot will be fully compatible with Magnetic Resonance Imaging (MRI), as has been shown with an earlier mechanical design (21). Therefore the presented robot design can also be used for remote catheter navigation under MRI guidance, as well as fluoroscopic imaging. Table 1 compares the main features of the presented RCNS in this paper to those of other robotic catheter navigation systems.

Table 1.

As was mentioned in the results section, the system delay was measured for multiple, representative, manual motion profiles. Because system delay is a function of frequency, a comprehensive analysis of the delay should be performed over multiple sinusoidal motion profiles, each at different selected frequency; such an evaluation will be considered in future studies. The experiments performed in this study represent a report of the effective delay over representative motion profile – each having a wide range of frequencies. Since no noticeable delay effects were observed during any of the experiments, we were satisfied that under representative use of the robot the measured effective delay was not of practical significance.

While the interventionalist was able to successfully navigate the catheter remotely and with high accuracy, the accuracy evaluated in the laboratory setting showed that there was a larger than expected discrepancy between the master and slave in the radial direction. This error was most likely caused by loosening of the motor shaft coupler (made of 3D printed material) that couples the motor to the rotating gantry

in the HM. This minor limitation can be overcome in the future (e.g. by utilizing material such as PEEK or aluminum).

During *in vivo* navigation experiments with the second animal, the robot faced a calibration issue. Due to poor adjustment of the mount, the sharp angle of entry into the pig's right femoral vein was not fully compensated. As a result the catheter was pulled towards the introducer at a sharp angle at the point where it exited the manipulator. This in turn had forced the catheter to slip out of the roller's grip. Readjustment of the catheter and the mount fixed this issue. While such a sharp entry angle is unique to porcine models, and is unexpected for human subjects, the catheter has to be confined to the center of the manipulator (e.g. with a narrow tube), to prevent any such slippage or complications in the future. Alternatively, a more versatile mount can be developed that accommodates a larger range of motion in the orientation of the CM.

Our implementation did not include haptic feedback for the interventionalist, because of the requirement to use standard (off-the-shelf) catheters. In conventional manual catheterization there is limited force feedback from the catheter-vessel contact and the friction between the catheter and introducer further distorts this force (24), resulting in the interventionalist relying primarily on visual feedback. Recent developments in catheter design have introduced force sensors at the tip of the catheter (e.g. TactiCath, Endosense, SA, Switzerland). This force information can be displayed to the interventionalist or, in future implementations, can be utilized by the robot for automatic force regulation during ablation.

The presented robot manipulates conventional steerable catheters of various gauges and with a plunger steering mechanism. The robot can potentially facilitate the operation flow of an electrophysiology lab, by allowing the interventionalist to be with the staff in the control room, facilitating communication and eliminating the need for continuous wear of heavy lead protection, as well as allowing the interventionalist to remain seated during the navigation procedure. Although, the presented robotic system must undergo further preclinical and clinical studies to validate its efficacy, the initial results, presented in this paper, are highly promising.

Conclusion

We have introduced a tele-robotic system that allows 3-DOF for remote navigation of conventional steerable catheters of different gauges. *In vivo* evaluation of the tele-robotic system demonstrated feasibility of remote catheter navigation and ablation and showed that the navigation method had no significant effect on navigation time. The presented system facilitates catheterization and allows the interventionalists to remotely perform the navigation procedure from a safe distance, minimizing exposure to radiation.

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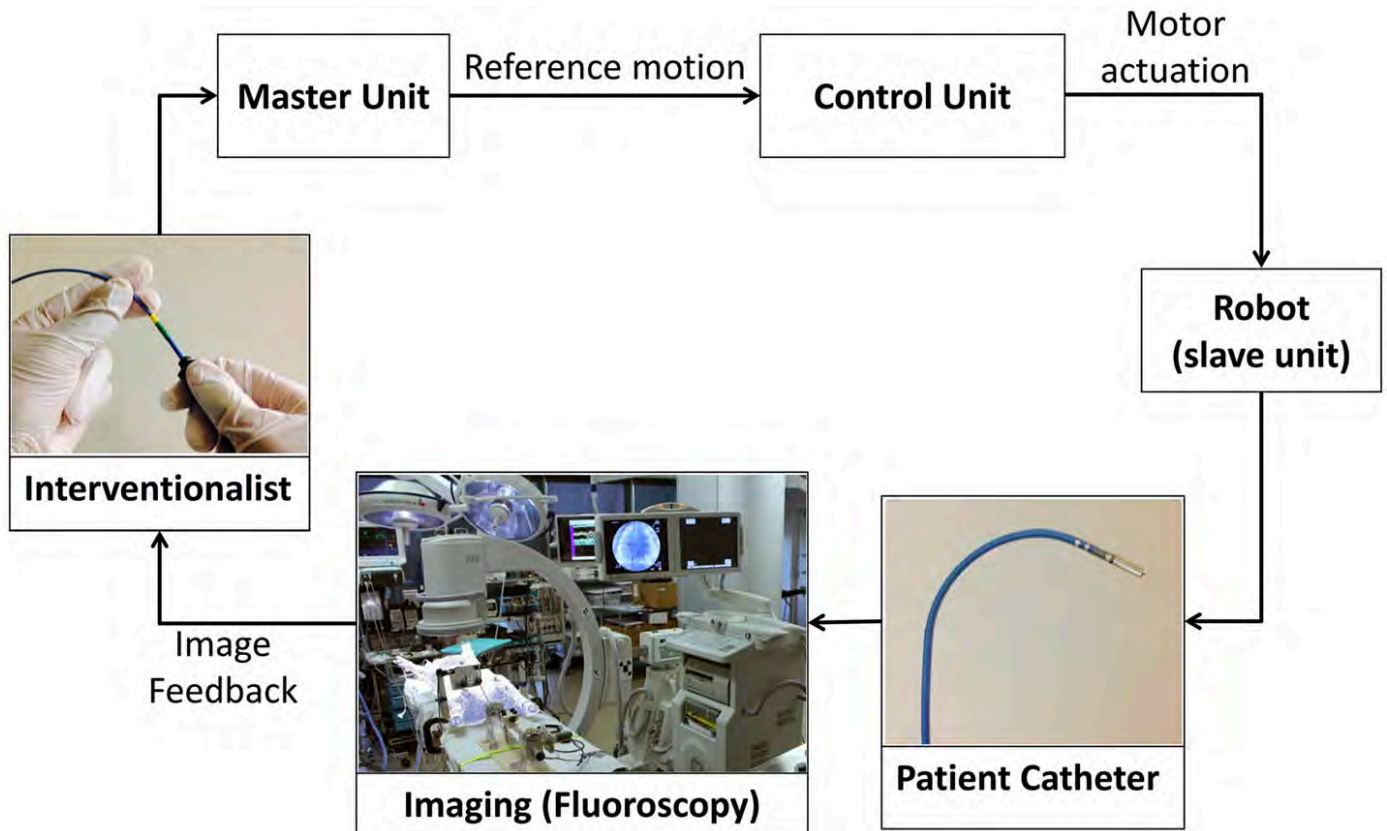


Figure 1. Schematic diagram of the system, displaying the workflow and interactions of the different components.

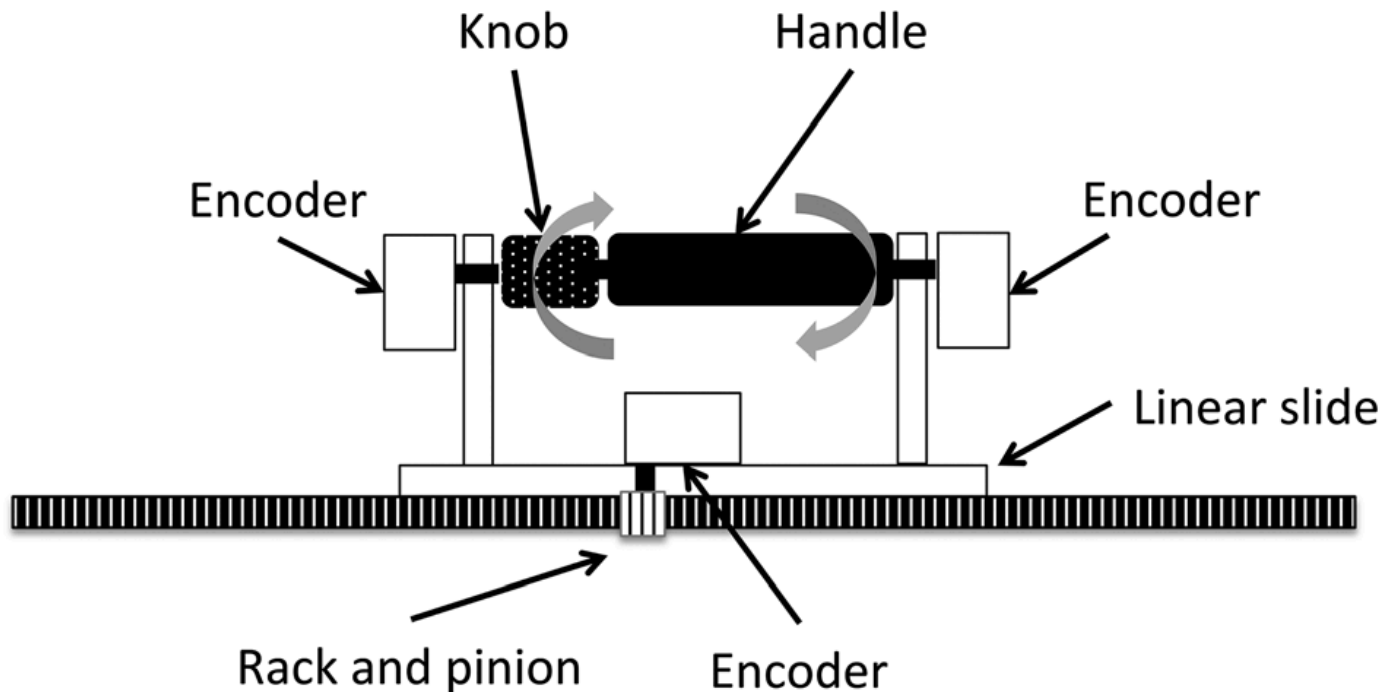
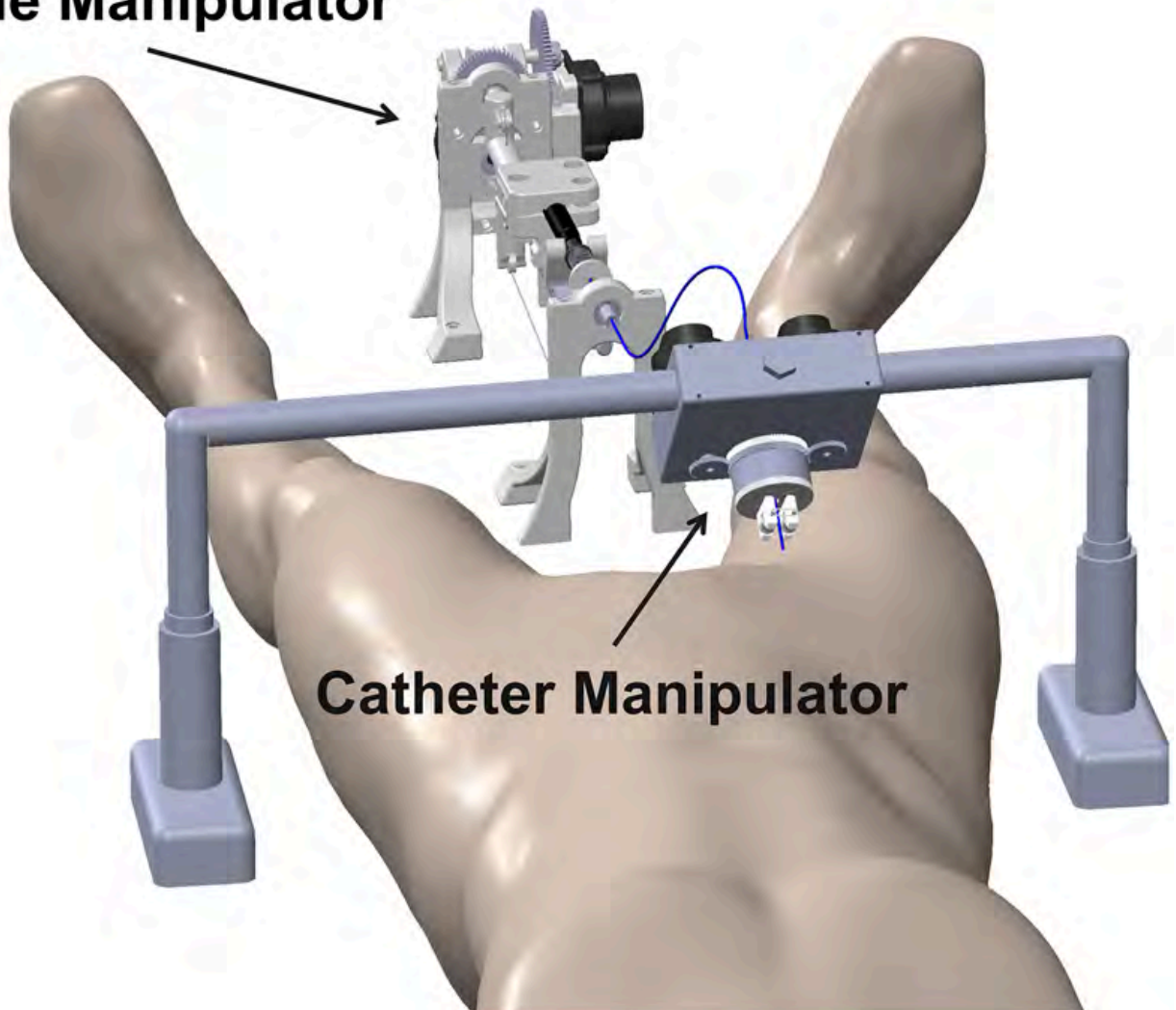


Figure 2. Schematic diagram of the master system is shown. The master unit allows for measurement of the user's input for axial motion, radial motion and tip steering (for manipulation of plunger or knob).

Handle Manipulator



Catheter Manipulator

Figure 3. The slave robot is shown. In the example setup, the catheter manipulator is positioned over the patient and the handle manipulator between the patient legs.

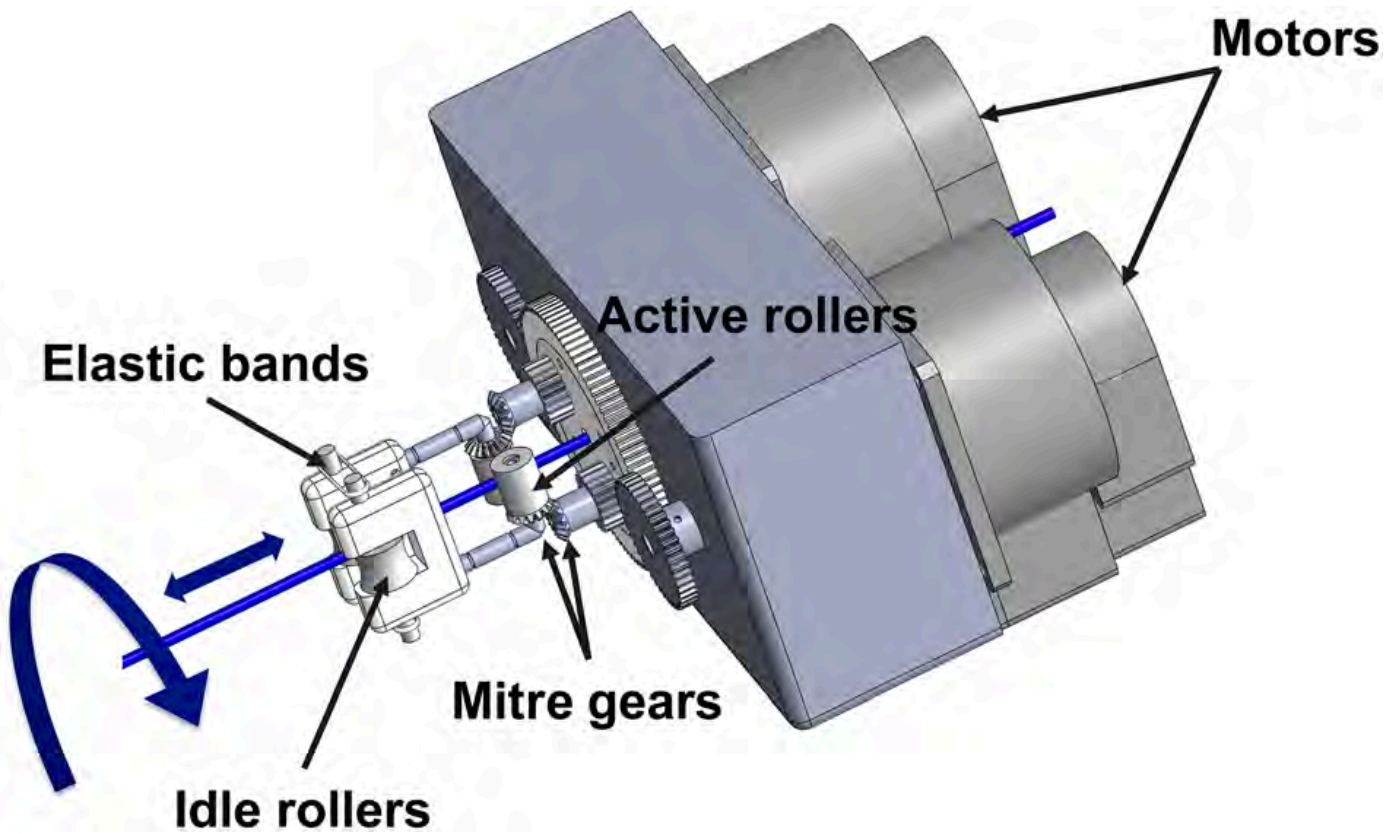


Figure 4. The internal mechanism of the catheter manipulator and the motions it can impart on the catheter are illustrated. The external components in the center of the manipulator are hidden to better illustrate the differential gear and adjustable roller mechanism.

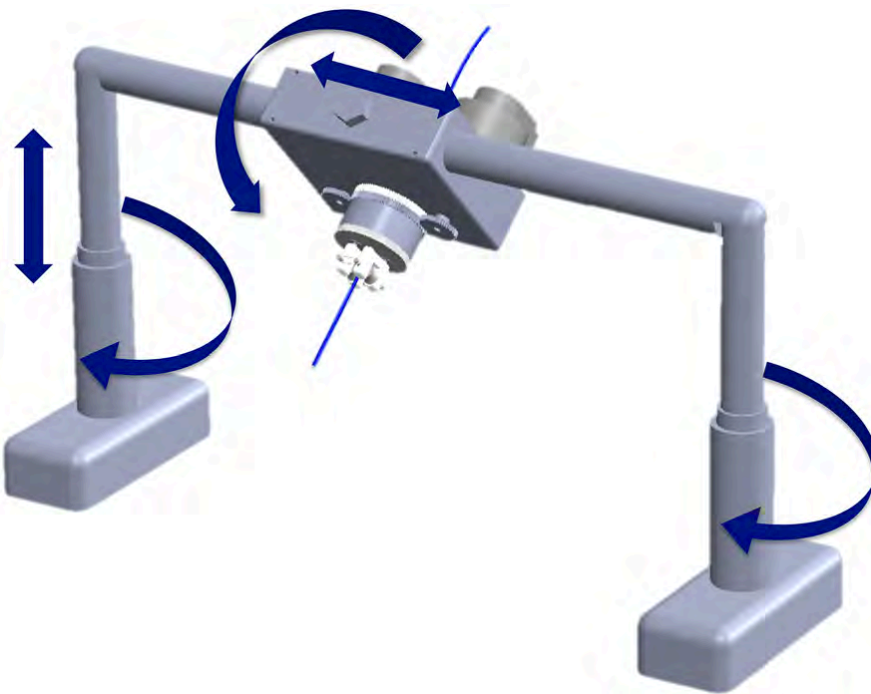


Figure 5. The mount of the catheter manipulator. The manually adjustable positions and orientations are indicated by the arrows.

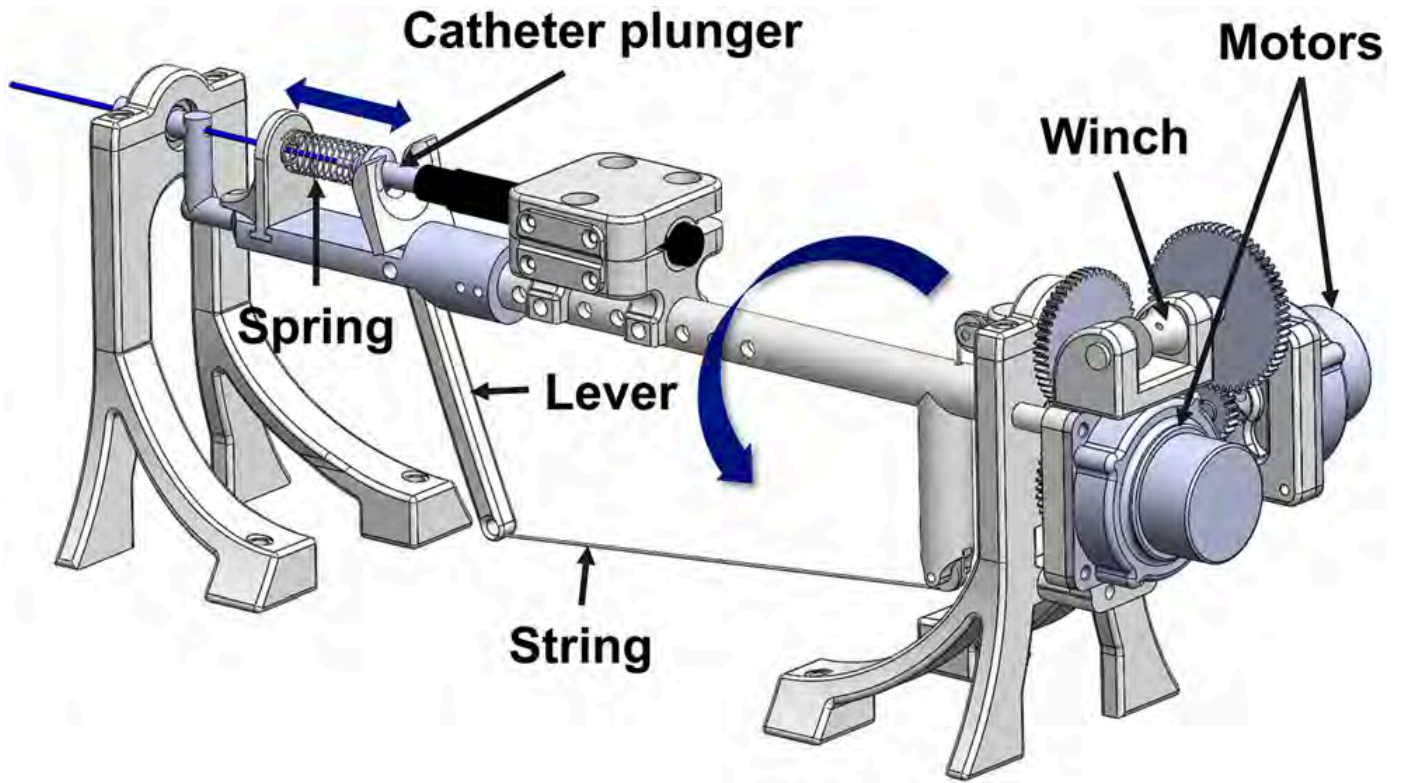


Figure 6. The handle manipulator and its controllable motions are shown. One motor controls the position of the plunger knob via a string, winch, and a series of gears; the other rotates the catheter handle.

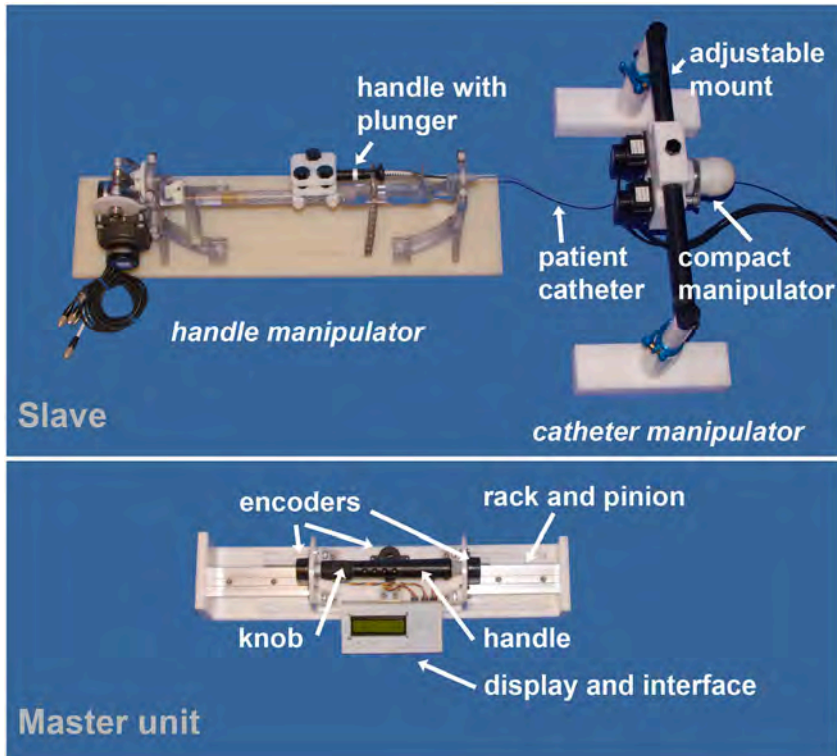


Figure 7. The master and slave units are shown side by side.

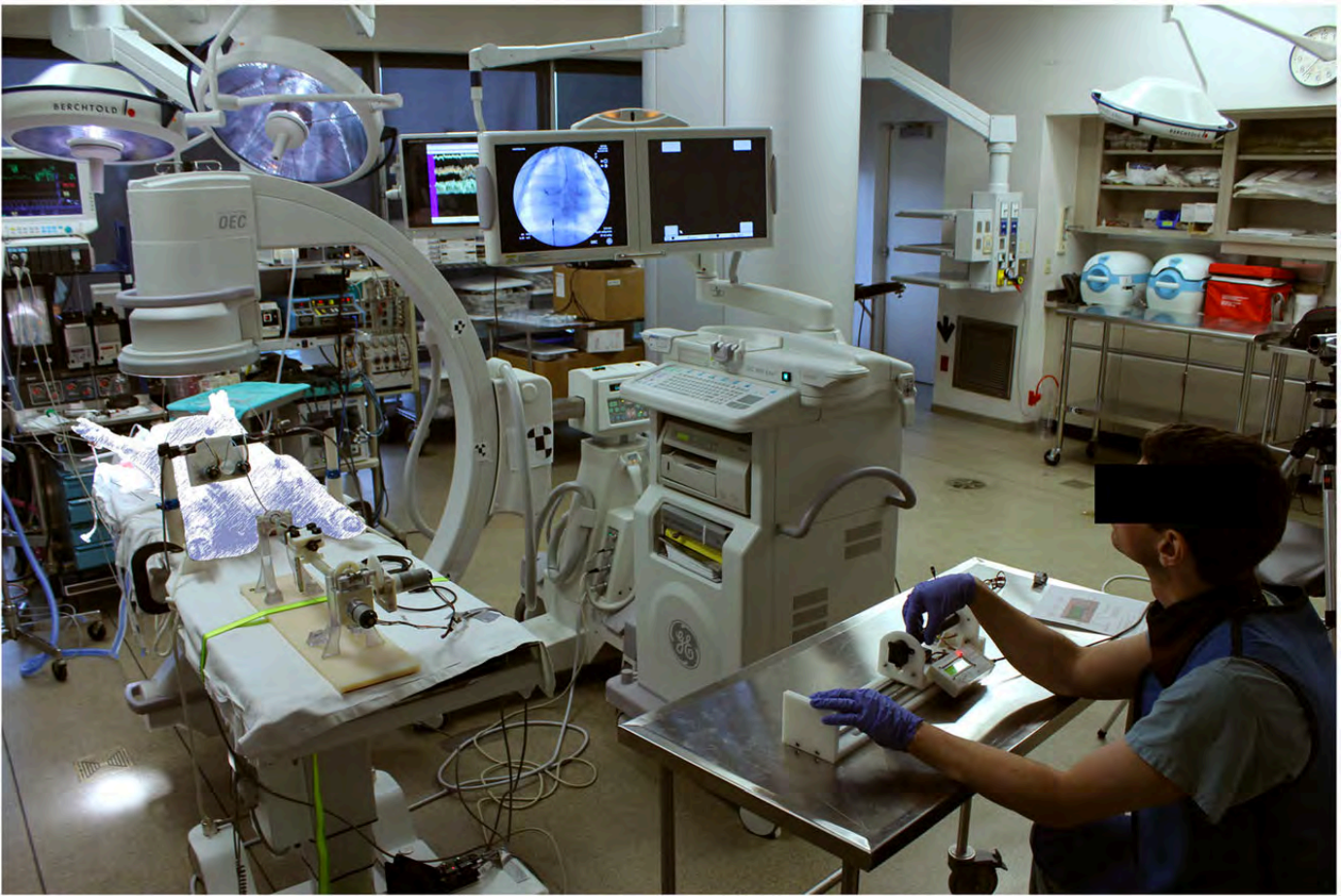


Figure 8. The system setup at the experimental operating suite at CSTAR, London, Ontario. The robot is setup on the animal bed (on the left). By manipulating the master unit, the interventionalist (on the right) remotely controls the robot under fluoroscopic guidance.

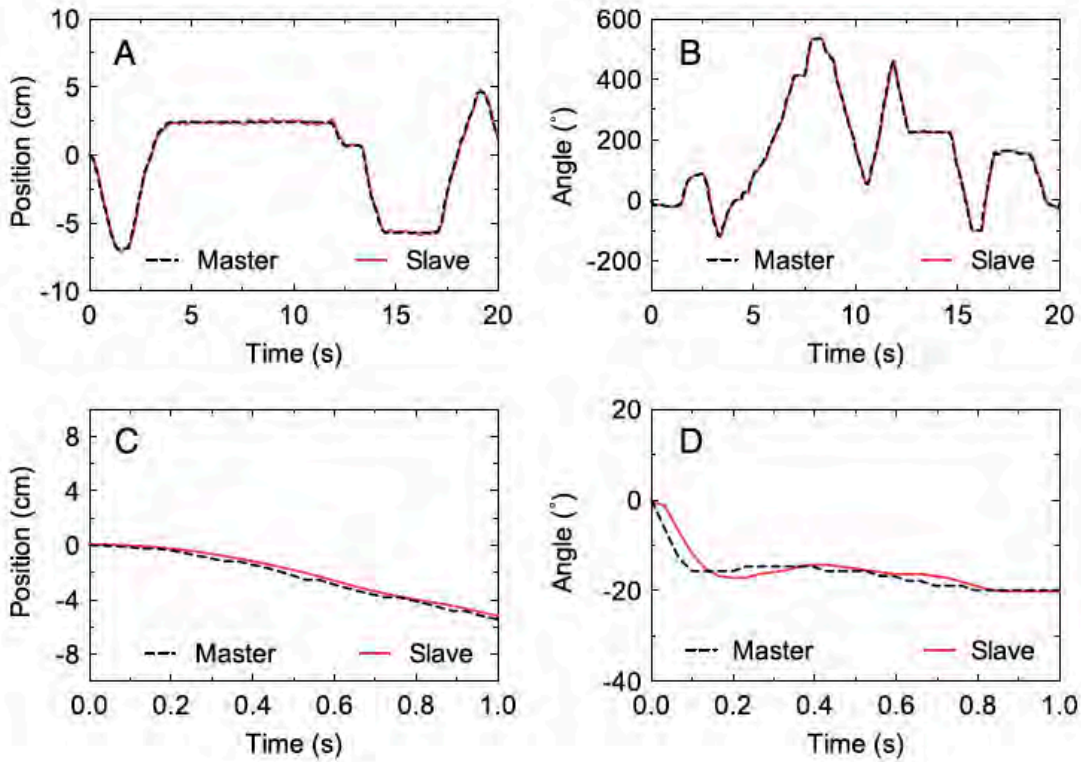


Figure 9. Example manual motion profiles of the master and slave are shown as a function of time: The catheter's radial and axial motion, calculated from encoder counts are shown in a) and b) respectively; c) and d) are magnified versions of the first second of the profiles in a) and b), respectively, to illustrate the small delay in the response.

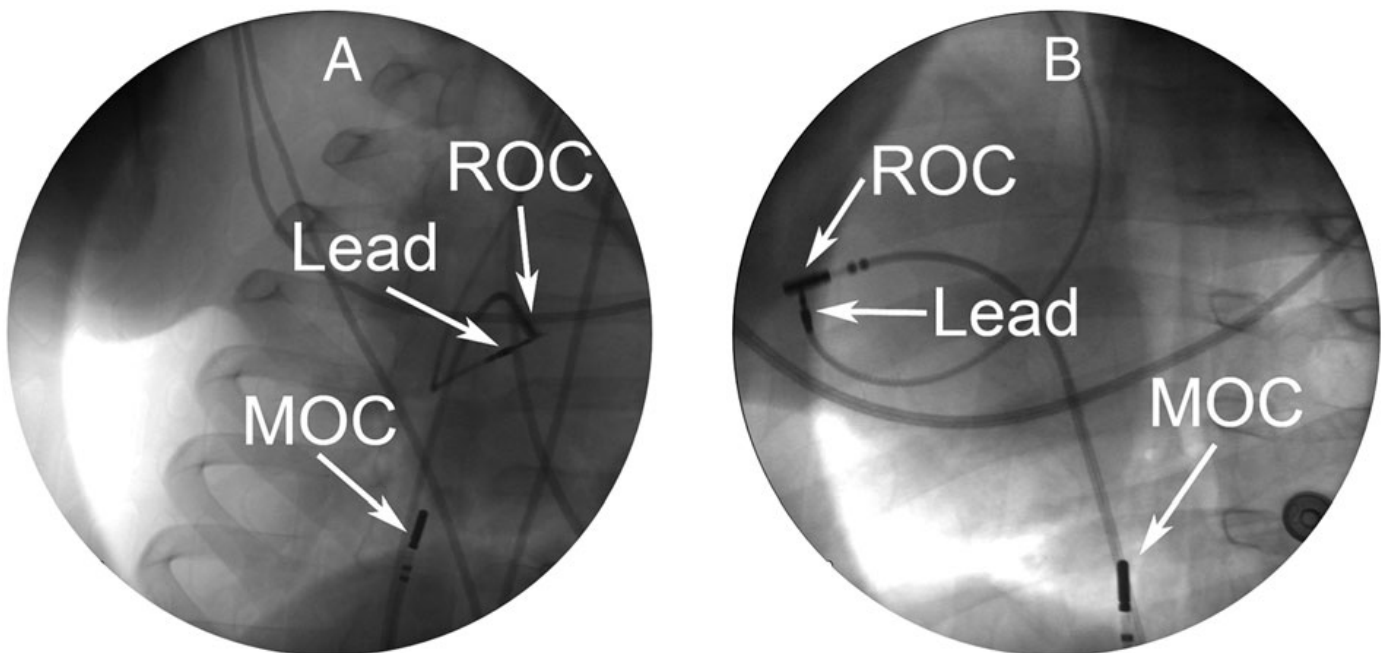


Figure 10. Radiographs of the catheter and lead in the animal heart. a) image obtained at 45° right anterior oblique (RAO) angle b) image obtained at 45° left anterior oblique angle (LAO). Both perpendicular images clearly show the contact between the catheter tip and the lead.

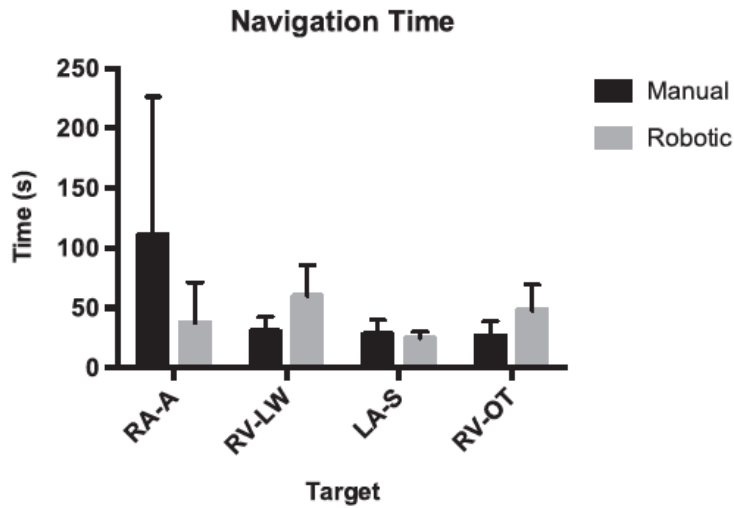


Figure 11. Navigation time to four targets using both the manual and robotic method. No statistically significant difference between the two methods was observed ($p=0.705$).

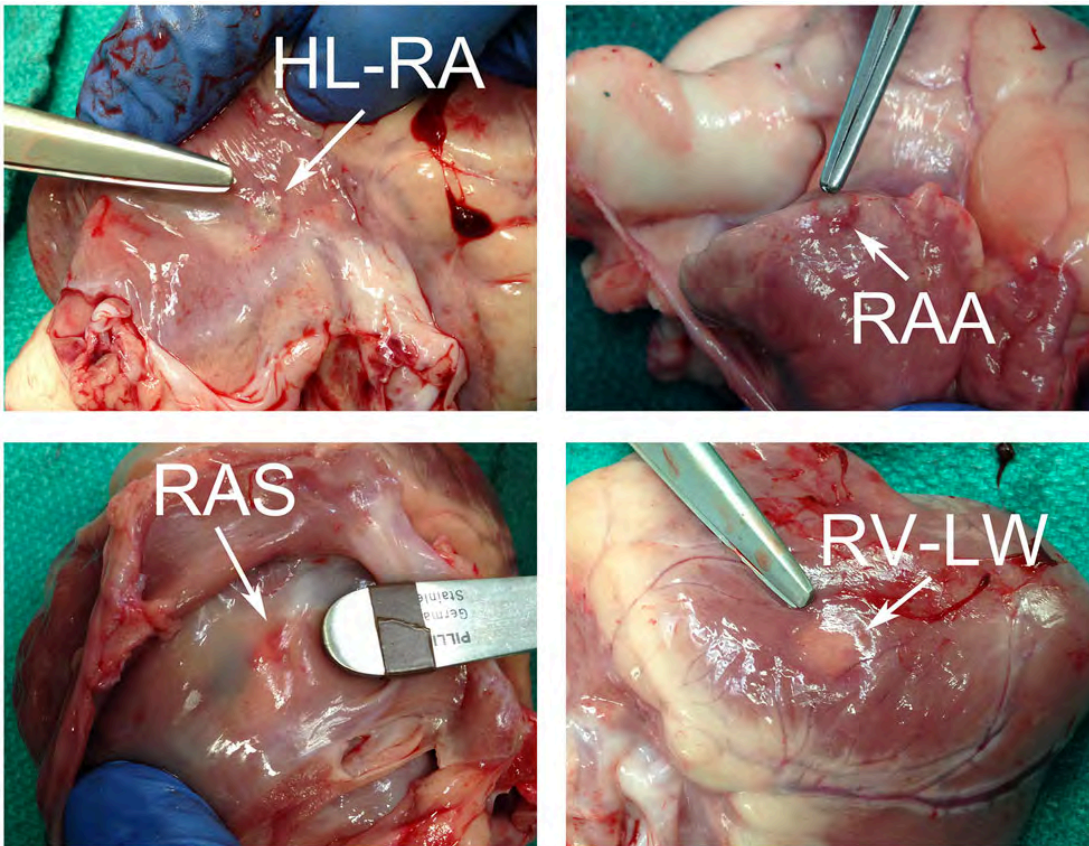


Figure 12. Visual confirmation of the created RF lesions. Lesions created on the HL-RA, RAA, RAS, and RV-LW are shown (arrows).

Table 1. Comparison of the RCNS presented in this paper with other robotic platforms.

Remote catheter navigation systems	3-DOF	Intuitive interface	Utilizes commercial catheters	Made of non-magnetic material (for MRI guided interventions)	Manipulates steerable catheter handles with plunger mechanism	Manipulates steerable catheter handles with knob mechanism	Navigation accuracy
RCNS	✓	✓	✓	✓	✓	×	Axial: 0.1 ± 0.1 mm Radial: $7 \pm 6^\circ$
Niobe (9,10)	✓	×	×	×	×	×	Estimated <1 mm from target
Sensei (11,12)	✓	×	×	×	×	×	Not available
Corpath (13)	×	×	×	×	×	×	Not available
Amigo (14)	✓	✓	✓	×	×	✓	Not available
Thakur <i>et al.</i> (22)	×	✓	✓	×	×	×	Axial: <1 mm Radial: $<1^\circ$
Tavallaei <i>et al.</i> (21)	×	✓	✓	✓	×	×	Axial: 1 ± 0.8 mm Radial: $2 \pm 2^\circ$
Wang <i>et al.</i> (15)	×	×	✓	×	×	×	Axial: <0.5 mm Radial: Not available
Srimathveeravalli <i>et al.</i> (16)	×	×	✓	×	×	×	Axial: <0.4 mm Radial: Not available
Meng <i>et al.</i> (17)	×	×	✓	×	×	×	Axial: <1.3 mm Radial: Not available
Marcelli & Cercenelli <i>et al.</i> (18,20)	✓	×	✓	×	✓	×	Axial: 0.2 ± 0.1 mm Radial: $1.4 \pm 0.8^\circ$
Park <i>et al.</i> (19)	✓	✓	×	×	×	✓	Not available

* A user interface that takes advantage of the interventionalists existing natural dexterous skills and ergonomic preferences.