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Early Experience with a Computerized Robotically Controlled Catheter System

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Abstract. ***Background:*** **Recently, the use of robotic assisted surgery has been utilized in cardiac surgical procedures. The use of robotics may offer benefits in precision, stability and control of instruments remotely. We report early experience with a novel remote robotic catheter control system (CCS).**

Methods: **We used a computerized robotically controlled catheter system that enables the user to remotely manipulate the tip of a catheter precisely in three dimensions. We tested the robotic catheter control systems ability to navigate within the heart and to make precise, rapid and repeatable movements. We compared the CCS with the ability of a standard quadripolar steerable ablation catheter placed in a deflectable sheath to navigate and make precision movements. Twelve *ex-vivo* porcine hearts were utilized to permit accurate measurements of navigation and precision. Eight targets were selected for navigation and precision testing. Time was measured for the catheter to reach the predefined target from a specific starting point to test navigation. In addition, time was measured to contact a discrete 0.8 mm target in order to test precision.**

Results: **The use of the CCS reduced the time needed for both navigation (8.5 ± 13.9 sec vs. 22.7 ± 26.7 sec, $p = 0.002$) and significantly decreased the time for precision targeting (10.1 ± 6.9 sec vs. 29.6 ± 26.4 sec, $p < 0.001$) in the specific RA and LA sites in the *ex-vivo* hearts.**

Conclusions: **The use of a computerized robotically assisted catheter control system is feasible and shows promise in rapid precision movement of the catheter. Further study is needed to elucidate the role of such a system *in-vivo* and in patient specific catheter ablation and mapping.**

Key Words. **catheter ablation, robotic assisted catheter movement**

Introduction

Recently the use of catheter ablation for the treatment of atrial and ventricular tachyarrhythmia's has increased as triggers and substrate of these rhythms can be mapped and ablated [1–4]. There have been significant technological advances with respect to the mapping of arrhythmic foci. Despite these advances, conventional ablation catheters remain limited in motion, with the ability for deflection in a single plane at a fixed radius. In some cases catheters with different curves may need to be used for a single ablation. Catheter motion is achieved by applying torque to the catheter shaft, this allows some side-to-side movement. Catheter motion may be limited by vessel tortuosity as well the use of long sheaths and occasionally catheter location in the heart. In addition, stable catheter contact with the endocardium may be compromised by heart motion and catheter compliance. This can make ablations of complex arrhythmias time consuming, and results in operator fatigue and increased exposure to fluoroscopy. All of these limitations in catheter movement and control as well as operator fatigue and fluoroscopy exposure may prove to be increasingly important as the mapping and ablation of more complex arrhythmias becomes standard.

Recently, the use of a magnetic tipped catheter that can be directed within a magnetic field has been demonstrated in mapping and catheter ablation [5–7]. This technology requires two large permanent computer driven magnets to be in place and may not be feasible for all electrophysiology laboratory settings. In addition, this technology may not be ideal for all patients with implantable devices such as implantable cardioverter defibrillators or pacemakers [6]. New catheter designs and new technologies for catheter navigation are needed to enable electrophysiologists to perform difficult ablations with the least amount of time and exposure to fluoroscopy, without compromising catheter precision, stability and ease of use.

During the last several years robotic technology has been used for a variety of surgical procedures [8–14]. Robotics can improve the precision,

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stability and dexterity of surgical procedures [15,16]. We report early experience with a computer driven, catheter control system (CCS) that has complete freedom of motion in three dimensions and steerability.

Methods

Twelve *ex-vivo* previously frozen porcine heart and lungs were held in stable position. Incisions were made over the right and left atrium to expose the underlying structures.

We compared catheter function of the CCS to a manually controlled steerable catheter placed within a deflectable sheath by evaluating navigation and precision motion to eight clinically significant pre-selected areas in the heart. On the right side these navigational targets included the high right atrium, tricuspid annulus, right atrial free wall, right atrial septum, right atrial appendage and right ventricular septum. On the left side these navigational targets included the left atrial appendage, mitral valve annulus and the pulmonary vein ostium. Time was measured on a stop watch for the catheter to reach the predefined target from the start point of the inferior vena cava-right atrial junction for the right sided targets, and from the start point of the intra-atrial septum for the left sided targets. For precision testing, the time was measured on a stop watch to contact a 0.8 mm electrode target that was placed at the discrete pre-selected target. For both navigation and precision, the time to each target was measured three times and the average time was used. Means were compared using a pared t-test. SPSS software was used for statistical analysis (SPSS 10.0, Chicago Il).

The catheter control system consists of a computerized "master" input device that translates the operator's movement of a handle via an electromechanical patient side "slave". This remote catheter manipulator controls the tip of a guide catheter that fits a standard ablation catheter in its lumen (Fig. 1). The guide catheter can be used in the same way as conventional guide catheters, with different diagnostic and therapeutic catheters, inserted through the guide catheter thru-lumen to perform mapping and/or ablation. This control is provided via a "Master-Slave" electromechanical system that controls a guide catheter by digitally translating the hand motion of the user who sits at a remote computer console enabling the guide catheter to move to any target that the user defines.

For the manually controlled catheter system, a standard steerable ablation catheter (Blazer II, Boston Scientific, Natick, MA or Marinr, Medtronic INC., Minneapolis, MN) was placed within a deflectable sheath (Naviport® 40 mm curve, Cardima, Fremont CA) and was used for navigation and precision testing.

Results

The CCS was able to reach all targets. Although we did not specifically test for tissue contact, tissue contact appeared to be at least as good as with a standard catheter system. There was no observed mechanical perforation or damage to the tissue using either system.

In comparing the between the CCS and the standard catheter system with respect to overall navigation and precision, the average time for navigation and precision to a total of 135 right and left sided targets using the CCS was 9.2 ± 11.4 seconds as compared with 25.9 ± 26.7 seconds using the standard catheter system to reach 99 right and left sided targets ($p < 0.001$).

The average time for navigation to 75 right and left sided targets using the CCS was 8.5 ± 13.9 seconds as compared with 22.7 ± 26.7 seconds using the standard catheter to reach 54 right and left sided targets ($p = 0.002$) (Fig. 2). There was no statistical difference in navigation to 46 right sided targets using the CCS when compared to navigation to the 36 right sided targets using the standard catheter (8.6 ± 17.1 seconds vs. 16.7 ± 21.2 seconds, $p = 0.16$). Navigation to 29 left sided targets using the CCS resulted in significantly decreased average time as compared with navigation to 18 left sided targets using a standard catheter (8.4 ± 6.5 seconds vs. 34.9 ± 32.7 seconds, $p = 0.002$).

The average time for precision movement of the CCS to 60 right and left sided targets was 10.1 ± 6.9 seconds as compared with 29.7 ± 26.4 seconds for precision movement using the standard catheter to 45 right and left sided targets ($p < 0.001$). Using the CCS resulted in significantly decreased average time to 30 right sided targets when testing precision movements as compared with the 36 precision targets using the standard catheter system (12.3 ± 8.5 vs. 22.4 ± 15.6, $p = 0.007$). Precision to 30 left sided targets using the CCS also resulted in significantly decreased average time as compared with precision to 9 left sided targets using the standard catheter (7.8 ± 3.9 seconds vs. 58.9 ± 39.5 seconds, $p = 0.004$).

Discussion

The use of robotics in medicine offers many potential advantages that include stability, precision and the ability to perform procedures remotely

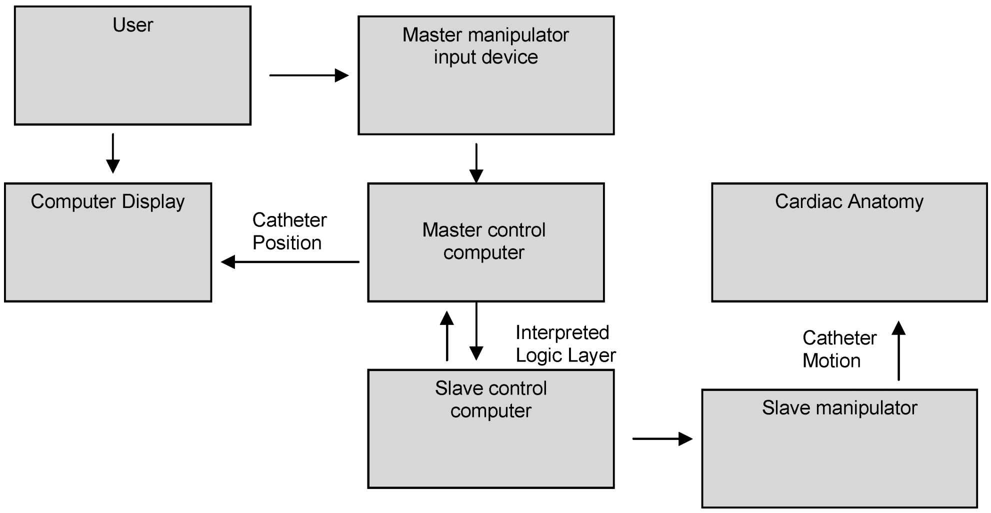

Fig. 1. *A schematic diagram demonstrating the CCS input and output.*

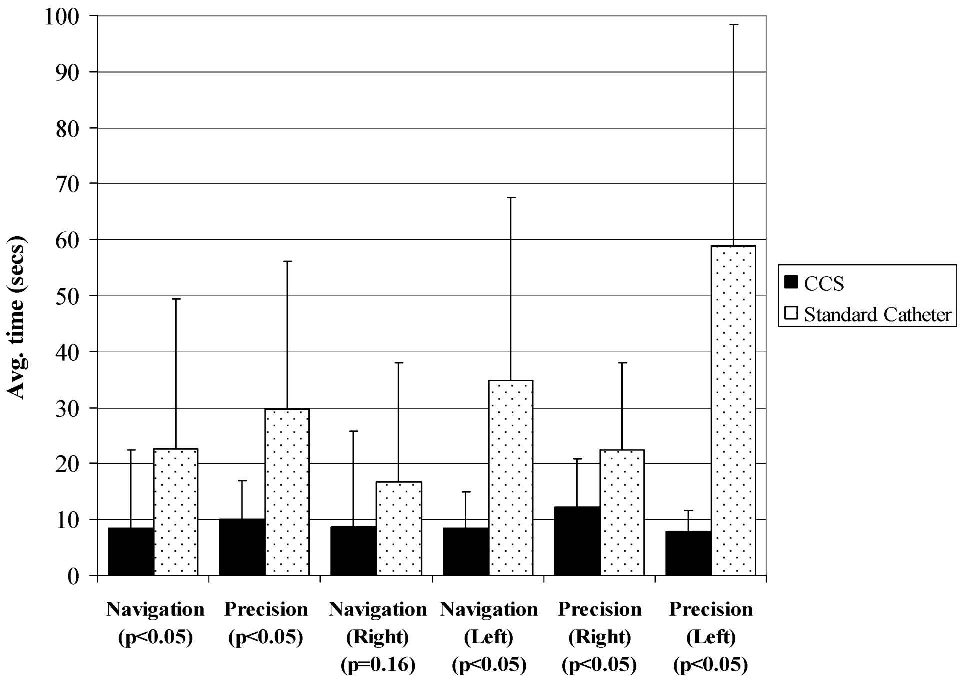

Fig. 2. *Graph of average time for the CCS as compared with the standard catheter system in overall navigation and precision, as well as navigation and precision in right and left sided targets.*

[8,16,17]. Robotics thus far have been limited to use in surgical procedures with great success [8, 16]. This is the first report of a fully computerized robotically controlled "master-slave" catheter system for use in cardiac catheterization and electrophysiology. In this report, the use of the CCS for both navigation and precision movements in the *ex-vivo* hearts was significantly faster than use of a standard catheter in a deflectable sheath. This is likely a result of a greater range of motion with the CCS than with the standard catheter and deflectable sheath. In order to reach a target with the CCS the operator needs to adjust the controller to aim the tip of the CCS in the direction of the target, whereas with a standard catheter in a deflectable sheath the operator needs to make a series of movements that require adjusting the radius of curvature as well as the

amount of manual torque on the catheter or sheath shaft in order to reach a given target. Existing catheters require a great deal of skill and experience to efficiently navigate to chosen targets and establish contact at those sites. The CCS is designed to facilitate the electrophysiologist's ability to control and precisely manipulate and position catheters within the cardiovascular system. One of the key advantages of the CCS is increased control of the catheter tip. The robotic catheter control system allows for complete freedom of motion in three dimensions for the tip of the catheter. This type of motion may have several advantages over standard catheters such as the ability to navigate with precision that is not limited by a fixed catheter radius of curvature or the ability to apply torque. In addition, use of a robotically controlled CCS may limit the amount of exposure the fluoroscopy and limit the fatigue associated with prolonged ablation procedures. This technology may also enable more electrophysiologists to perform ablations such as left atrial ablations for atrial fibrillation treatment. For example, a left atrial ablation could be carried out remotely with computerized assistance to help move the catheter and create appropriate sets of lesions. Our study is limited by the use of *ex-vivo* hearts, and do not reflect the challenges of using a catheter in a beating heart including the simulation of tortuous anatomy. In addition we did not examine motion to ventricular sites. Our study was not designed to determine risk of perforation, and although we did not see any damage to tissue or perforation in this study, further *in-vivo* study will be needed to examine this issue.

Our results demonstrate the ability to precisely navigate and control a catheter remotely. We demonstrate that catheter motion is both rapid and accurate with the ability to reach a small target in seconds. Further investigation into the use of this technology in-vivo will be important in evaluating this system for routine use.

In conclusion, use of a robotically controlled catheter is feasible and may offer potential benefits in precision mapping and complex radiofrequency ablation.

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