Robotic Positioning of Standard Electrophysiology Catheters: A Novel Approach to Catheter Robotics

Bradley Knight, MD, Gregory M. Ayers, MD, PhD, Todd J. Cohen, MD

ABSTRACT: Background. Robotic systems have been developed to manipulate and position electrophysiology (EP) catheters remotely. One limitation of existing systems is their requirement for specialized catheters or sheaths. We evaluated a system (Catheter Robotics Remote Catheter Manipulation System [RCMS], Catheter Robotics, Inc., Budd Lake, New Jersey) that manipulates conventional EP catheters placed through standard introducer sheaths. The remote controller functions much like the EP catheter handle, and the system permits repeated catheter disengagement for manual manipulation without requiring removal of the catheter from the body. This study tested the hypothesis that the RCMS would be able to safely and effectively position catheters at various intracardiac sites and obtain thresholds and electrograms similar to those obtained with manual catheter manipulation.

Methods. Two identical 7 Fr catheters (Blazer II, Boston Scientific Corp., Natick, Massachusetts) were inserted into the right femoral veins of 6 mongrel dogs through separate, standard 7 Fr sheaths. The first catheter was manually placed at a right ventricular endocardial site. The second catheter handle was placed in the mating holder of the RCMS and moved to approximately the same site as the first catheter using the Catheter Robotics RCMS. The pacing threshold was determined for each catheter. This sequence was performed at 2 right atrial and 2 right ventricular sites. The distance between the manually and robotically placed catheters tips was measured, and pacing thresholds and His-bundle recordings were compared. The heart was inspected at necropsy for signs of cardiac perforation or injury.

Results. Compared to manual positioning, remote catheter placement produced the same pacing threshold at 7/24 sites, a lower threshold at 11/24 sites, and a higher threshold at only 6/24 sites (p > 0.05). The average distance between catheter tips was 0.46 ± 0.32 cm (median 0.32, range 0.13–1.16 cm). There was no difference between right atrial and right ventricular sites (p > 0.05). His-bundle electrograms were equal in amplitude and timing. Further, the remote navigation catheter was able to be disengaged, manually manipulated, then reengaged in the robot without issue. There was no evidence of perforation. Conclusions. The Catheter Robotics remote catheter manipulation system, which uses conventional EP catheters and introducer sheaths, appears to be safe and effective at directing EP catheters to intracardiac sites and achieving pacing thresholds and electrograms equivalent to manually placed catheters. Further clinical studies are needed to confirm these observations.

Key words: basic electrophysiology; electrophysiology mapping; robotic manipulation systems

Figure 1. The Catheter Robotics Remote Catheter Manipulation System (RCMS). Shown are the catheter manipulation unit (robot) and the user remote control handle (inset).

It is well known that technology for electrophysiology (EP) has advanced substantially over the past two decades to include the ability to map and treat arrhythmias that originate in any of the heart chambers, including the left atrium and the pulmonary veins via transseptal puncture. However, it is also known that successful EP studies are largely dependent on several factors: anatomy of the heart; ability to make good catheter contact with the endocardium during arrhythmia treatment; and the cardiologist’s ability and experience in accurately manipulating EP catheters. As a result, these procedures can be lengthy, especially when treating complex arrhythmias, which in turn can lead to physician fatigue and high cumulative radiation exposure. In order to reduce radiation exposure, radiation shields, such as lead aprons, are used by the physician and staff, but are burdensome and fatiguing.

There are currently two FDA-approved systems that reduce physician risk by allowing remote manipulation and positioning of EP catheters. However, both systems require a separate...
large workstation and the use of either a special catheter or large-diameter, long sheath to operate the remote system.\(^7\) One of these systems (Stereotaxis, Inc., St. Louis, Missouri) requires the use of a specially-designed magnetic EP catheter which communicates with an external magnetic field that encircles the patient’s torso. This substantially limits the use of this system due to the additional bulky equipment as well as the magnetic force, both which may be contraindicated for patients who are claustrophobic or obese.\(^7\) The second, newer system (Hansen Medical, Mountain View, California), uses a standard EP catheter, but encases everything but the catheter’s tip in a long, specialized 14 Fr deflectable sheath that actually manipulates the catheter.\(^9\)

The purpose of this feasibility study in dogs was to demonstrate safety and efficacy of a more simplified approach using, the Catheter Robotics Remote Catheter Manipulation System (RCMS, Figure 1). The RCMS is comprised of a mechanical catheter manipulator, or robot, and a remote control handle that enables the user to manipulate a standard, conventional, electrophysiology catheter through the full range of its 3 functions: insertion/withdrawal, deflection and rotation. We evaluated the ability of the RCMS system to allow the user to position an EP catheter in 5 target locations within the heart, and obtain adequate endocardial contact measured by pacing thresholds, while not causing untoward effects such as cardiac perforation or injury.

Materials and Methods

This study was conducted under a protocol that was reviewed and approved by the institutional review committee of the commercial animal facility in which the studies were performed. Six mongrel dogs (all male, weight 33 ± 2.6 kg) were used in this study. They were sedated with glycopyrrolate and propofol, and anesthesia was maintained with isoflurane according to standard operating procedures. Each animal was placed on a radiolucent procedure table. An arterial blood pressure cannula was inserted into the left femoral artery. Surface electrodes were placed to record the ECG.

The right femoral vein was cannulated under direct visualization with 2 standard 7 Fr sheath introducers. Two identical 7 Fr EP catheters (Blazer II; Boston Scientific Corp., Natick, Massachusetts) were inserted into the right femoral vein through separate sheath introducers and advanced to the right atrium. The first catheter tip was manually positioned in the right ventricular apex. The second catheter was then placed into the Catheter Robotics RCMS. This catheter was remotely maneuvered so as to approximate the location of the first catheter (the target site). When satisfactorily positioned, the pacing threshold was determined for each catheter. Three views of the catheters (AP, LAO and RAO) were recorded by cinefluoroscopy and stored on disk. This sequence was repeated at two right atrial sites (right atrial appendage, high right atrium and/or lateral right atrium) and an additional right ventricular site (either right ventricular outflow tract or high ventricular septum). During the study, the manual and robotically manipulated catheters were each rotated and withdrawn from the right ventricle until a His-bundle electrogram was recorded. His-bundle electrogram amplitude and intervals (AH and HV) were measured and compared. Lastly, once all the recording and pacing thresholds were measured, the robot was used to push the catheter to the point of buckling, once in the right atrium and once in the right ventricle.

After all data were collected, each animal was euthanized using sodium pentobarbital and potassium chloride. The chest was opened and the heart and lungs were excised. The pericardial sac was opened and observed for the presence of blood or fluid. The epicardial surface of the heart was observed for the presence of petechial hemorrhage. The cardiac chambers were then opened and visually observed for petechial hemorrhage and for any damage to the endocardial lining and cardiac structures. Lastly, the lungs were observed for signs of pulmonary embolus.

The distance between the catheter tips was measured by triangulation from the three fluoroscopic views using Osiris DICOM software. Pacing thresholds were compared using a sign test on the difference between the control catheter threshold and the robotic catheter threshold. All data are presented as mean ± 1 standard deviation.

### Results

Using the RCMS, the operator successfully positioned the EP catheter at all target sites in all animals. Once both catheters (manual and remote manipulation) were positioned, pacing thresholds were determined. Tables 1 and 2 show the pacing threshold and catheter tip distance differences for each site and

#### Table 1. Threshold difference – summary data.

<table>
<thead>
<tr>
<th>Intracardiac Sites</th>
<th>Threshold Control Catheter (mA)</th>
<th>Threshold Robotic Catheter (mA)</th>
<th>Mean Threshold Difference (mA)</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVA</td>
<td>0.76</td>
<td>0.83</td>
<td>-0.08</td>
<td>0.21</td>
</tr>
<tr>
<td>HRA</td>
<td>7.27</td>
<td>6.19</td>
<td>1.08</td>
<td>1.84</td>
</tr>
<tr>
<td>RAA</td>
<td>3.57</td>
<td>3.20</td>
<td>0.37</td>
<td>1.39</td>
</tr>
<tr>
<td>RVOT</td>
<td>0.65</td>
<td>0.52</td>
<td>0.13</td>
<td>0.15</td>
</tr>
<tr>
<td>Overall</td>
<td>3.26</td>
<td>2.69</td>
<td>0.38</td>
<td>1.17</td>
</tr>
</tbody>
</table>

RVA = right ventricular apex; HRA = high right atrium; RAA = right atrial appendage; RVOT = right ventricular outflow tract/high ventricular septum; SD = standard deviation

#### Table 2. Distance between catheter tips – summary data.

<table>
<thead>
<tr>
<th>Intracardiac Sites</th>
<th>Mean (cm)</th>
<th>SD</th>
<th>Min (cm)</th>
<th>Max (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVA</td>
<td>0.56</td>
<td>0.44</td>
<td>0.13</td>
<td>1.16</td>
</tr>
<tr>
<td>HRA</td>
<td>0.42</td>
<td>0.36</td>
<td>0.13</td>
<td>0.97</td>
</tr>
<tr>
<td>RAA</td>
<td>0.37</td>
<td>0.19</td>
<td>0.21</td>
<td>0.66</td>
</tr>
<tr>
<td>RVOT</td>
<td>0.48</td>
<td>0.33</td>
<td>0.16</td>
<td>1.05</td>
</tr>
<tr>
<td>Overall</td>
<td>0.46</td>
<td>0.33</td>
<td>0.13</td>
<td>1.16</td>
</tr>
</tbody>
</table>

Min = minimum; Max = maximum; RVA = right ventricular apex; HRA = high right atrium; RAA = right atrial appendage; RVOT = right ventricular outflow tract/high ventricular septum; SD = standard deviation
catheter tip location. Overall, there was no significant difference in thresholds achieved between manual and robotic placement of the catheters ($p > 0.05$). The mean difference in pacing threshold was $0.38 \pm 1.17$ mA. The site with the largest difference was in the HRA where the robotic manipulation threshold was lower than manual by $1.08 \pm 1.84$ mA. It should also be noted that the variability of pacing thresholds within each method was also greatest at this site, possibly due to difficulty in assuring adequate contact with either catheter manipulation method.

Comparing the control and robotic catheter placement sites, thresholds were lower using robotic manipulation at 11/24 sites, the same at 7/24 sites, and higher at only 6/24 sites. At sites in the right ventricular apex (RVA) and right ventricular outflow tract (RVOT), both control and robotic manipulation resulted in thresholds greater than 1 mA in only 2/12 sites, and these were the same sites for both methods. At all sites where the threshold with one method of catheter manipulation was greater than 1 mA, it was consistently above this level for the other method. In 5/24 threshold comparisons, the difference in threshold for one method versus the other exceeded 1 mA. In 4/5 the robotic manipulation threshold was lower and in 1/5 the manual manipulation threshold was lower.

For each site, the distance was measured between the catheter tip positioned manually and the one positioned by robotic manipulation. Table 2 provides a summary of the distances between the catheter tips for each intracardiac site tested along with the minimum and maximum catheter tip distances. Using the robot, the operator was able to position the catheter tip to within 1 cm of the manually positioned catheter tip in all but 3/24 instances. The average distance between catheter tips was $0.46 \pm 0.33$ cm (median 0.32, range 0.13–1.16 cm). There was no difference between right atrial and right ventricular sites with respect to the difference in the location of the catheter tips for the two methods of manipulation ($p > 0.05$).

In each animal, His-bundle electrograms were recorded using both manual and robotic manipulation. Figure 2 compares a His-bundle electrogram recorded with manual manipulation to a similar recording in the same animal after catheter placement using the RCMS. The mean His-bundle electrogram amplitude was $0.25 \pm 0.09$ mV and $0.24 \pm 0.02$ mV for the manually and robotically positioned catheters, respectively. The AH and HV intervals were $83 \pm 12$ and $33 \pm 8$ msec for the manually positioned catheters, and $78 \pm 6$ and $36 \pm 7$ msec for those robotically positioned. The electrogram amplitude or intervals were not significantly different for the two methods ($p > 0.05$).

System safety was excellent; there were no adverse events during the conduct of the study. When the remotely manipulated catheter was advanced with robotic manipulation until the catheter buckled, there was no evidence of the catheter tip extending beyond the cardiac silhouette, nor was there a change in blood pressure or fluoroscopic evidence of cardiac tamponade. Blood was not observed in the pericardial fluid in any animal. Gross pathologic examination of the heart demonstrated no significant hemorrhage into the tissue or evidence of damage to intracardiac structures. There was no evidence of pulmonary embolism. Lastly, the remotely manipulated catheter could be removed from the robotic system, manually manipulated and then replaced into the robot within seconds and without difficulty, all without removing the catheter tip from the heart.

**Discussion and Conclusions**

The current study of the Catheter Robotic system confirms the feasibility of remote manipulation of conventional EP catheters and introducer sheaths. In addition, this study shows that adequate tissue contact can be achieved with remote manipulation. This study also shows that remote manipulation was accurate for the placement of EP catheters using remote manipulation the operator was able to position a catheter tip within
millimeters of a target catheter that had been manually placed. Lastly, this study was able to demonstrate the safety of remote catheter manipulation. No complications such as cardiac tamponade, bloody pericardial effusion or endocardial injury were observed. In addition, the catheter could be rapidly removed from the robot (manual override feature), allowing the operator to quickly gain manual control of the catheter if for any reason this should be necessary. The system design preserves the normal safety mechanism of catheter buckling when excessive force is applied to the catheter handle during either remote or manual manipulation. Other systems that encase almost the full length of the catheter in a rigid steerable sheath lose this important characteristic.

In addition to this study, there have been two reports of similar systems that were designed to utilize standard introducer sheaths and catheters. In 2005, Cohen described an early prototype of the Catheter Robotics system that consisted of a catheter feeder and a remote control device. Cercenelli and colleagues tested a prototype telerobotic system in 3 animals and reported that their system was capable of reducing right atrial mapping times when compared with manual manipulation. The latter study was performed with very early prototype systems where the authors stated that additional development and in vivo testing would be required before clinical use. Despite showing basic proof of concept, neither report evaluated the clinically important parameters of tissue contact and the precision by which remote manipulation could reach specific target positions within the atria and ventricles.

Unlike the 2 other commercially available robotic systems, the Catheter Robotics RCMS allows the physician to select the best catheter for the purpose and allows the catheter to retain its typical operating characteristic when in use during the study. The RCMS applies forces only to the catheter handle and thereby utilizes the standard catheter mechanisms developed for catheter manipulation: deflection, rotation, and catheter advancement and withdrawal. Other systems, however, apply forces to the catheter by other means, making the catheter a more passive element in the system. For the Stereotaxis system, force is delivered to the catheter tip by a directed magnetic field, while an external shaft drive serves to insert and withdraw the catheter. In the Hansen system, steering is accomplished by delivering force through control wires in a proprietary 14 Fr sheath, leaving the protruding catheter tip a passive element with very high axial stiffness. Additionally, both systems have control stations that are large, comparable in size to standard computerized EP workstations, and utilize nontraditional user interfaces with the catheter (computer screen GUI or joysticks). By comparison, the Catheter Robotics system does not have a control station, but instead uses a handheld remote control that closely resembles a standard catheter handle. Additionally, the available systems tend to be expensive, while the simplicity of the Catheter Robotics system has the promise of a less costly robotic alternative. Lastly, in the Catheter Robotics system, the catheter’s handle and shaft can be quickly disengaged from the robot (without removing the catheter from the patient’s body), allowing the catheter to be manually manipulated. The catheter can subsequently be re-engaged within the robot to switch back to remote manipulation. All this can be achieved without affecting the sterility of the catheter.

In conclusion, the Catheter Robotics RCMS can be used to position the tip of a standard, commercially available EP catheter at sites typically evaluated during an EP study. The system provides and maintains appropriate tissue contact necessary to obtain pacing thresholds equivalent to those obtained with manual catheter manipulation. Complex maneuvers such as recording the His-bundle electrogram can be reliably and easily accomplished. The RCMS retains the safety features of a standard EP catheter, namely that the system does not inhibit or alter the buckling property of the catheter when excessive axial force is applied to the handle. Lastly, it allows the catheter to be quickly switched between robotic and manual manipulation without losing the position of the catheter tip or breaking the sterility of the catheter. Clinical trials in man are planned to confirm the results of this animal study.

References