View-Synchronized Robotic Image-Guided Therapy for
Atrial Fibrillation Ablation
Experimental Validation and Clinical Feasibility

Vivek Y. Reddy, MD; Petr Neuzil, MD; Zachary J. Malchano, BS; Ragu Vijaykumar, BS; Ricardo Cury, MD; Suhny Abbara, MD; Jiri Weichet, MD; Christina D. McPherson, BS; Jeremy N. Ruskin, MD

Background—A robotic catheter navigation system has been developed that provides a significant degree of freedom of catheter movement. This study examines the feasibility of synchronizing this robotic navigation system with electroanatomic mapping and 3-dimensional computed tomography imaging to perform view-synchronized left atrial (LA) ablation.

Methods and Results—This study consisted of a porcine experimental validation phase (9 animals) and a clinical feasibility phase (9 atrial fibrillation patients). Preprocedural computed tomography images were reconstructed to provide 3-dimensional surface models of the LA pulmonary veins and aorta. Aortic electroanatomic mapping was performed manually, followed by registration with the corresponding computed tomography aorta image using custom software. The mapping catheter was remotely manipulated with the robotic navigation system within the registered computed tomography image of the LA pulmonary veins. The point-to-surface error between the LA electroanatomic mapping data and the computed tomography image was 2.1 ± 0.7 and 1.6 ± 0.1 mm in the preclinical and clinical studies, respectively. The catheter was remotely navigated into all pulmonary veins, the LA appendage, and circumferentially along the mitral valve annulus. In 7 of 9 animals, circumferential radiofrequency ablation lesions were applied per ostially to ablate 11 pulmonary veins. In patients, all of the pulmonary veins were remotely electrically isolated in an extraostial fashion. Adjunctive ablation included superior vena cava isolation in 6 patients, cavotricuspid isthmus ablation in 5 patients, and ablation of sites of complex fractionated activity and atypical LA flutters in 3 patients.

Conclusions—This study demonstrates the safety and feasibility of an emerging paradigm for atrial fibrillation ablation involving the confluence of 3 technologies: 3-dimensional imaging, electroanatomic mapping, and remote robotic navigation. (Circulation. 2007;115:2705-2714.)

Key Words: catheter ablation ▪ tomography, x-ray computed ▪ fibrillation ▪ imaging ▪ mapping

A number of approaches to catheter ablation of atrial fibrillation (AF) exist, including ostial pulmonary vein (PV) isolation, “extraostial” PV isolation, circumferential PV ablation without isolation, ablation of complex fractionated atrial electrograms, placement of linear ablation lesions, and ablation of autonomic targets.1-6 Although the ideal ablation strategy is still in evolution, it is clear that facile left atrial (LA)-PV catheter manipulation is important for safety and effectiveness.

Clinical Perspective p 2714

To facilitate intracardiac mapping and ablation, a series of technological advances have been introduced to the field over the past decade. The first and most significant was the introduction of real-time electroanatomic mapping (EAM) to precisely localize the catheter within the heart. More recently, the integration of high-resolution 3-dimensional (3D) computed tomography (CT)/magnetic resonance imaging with EAM permits real-time catheter manipulation within a more highly featured patient-specific anatomy.8,9 Despite the aid of this image-guided therapy paradigm, considerable technical skill is required for catheter manipulation. To this end, a remote robotic navigation system (RNS) has recently been developed.10,11 After a mapping/ablation catheter is placed within this 2-sheath system, a software interface is available at http://circ.ahajournals.org/cgi/content/full/CIRCULATIONAHA.106.677369/DC1.

© 2007 American Heart Association, Inc.

Circulation is available at http://www.circulationaha.org

DOI: 10.1161/CIRCULATIONAHA.106.677369
allows the operator to remotely manipulate this catheter tip with precision.

The present study examines the feasibility of combining this remote navigation system with both EAM and 3D CT imaging. The confluence of these 3 technologies was used in an experimental porcine model to assess the feasibility of safely navigating within the LA-PVs and performing circumferential PV ostial ablation. These data provided the experimental groundwork for subsequent view-synchronized remote LA-PV ablation in a series of AF patients.

Methods

This protocol was divided into 2 phases: the preclinical phase, including mapping/ablation in 9 pigs, which was approved by the Massachusetts General Hospital Subcommittee of Research Animal Care, and the clinical phase, which involved catheter ablation in 9 patients and was approved by the Massachusetts General Hospital Human Research Committee and the Homolka Hospital Ethical Committee.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

CT Imaging

Contrast-enhanced cardiac scanning was performed under general anesthesia on 9 normal pigs (25 to 50 kg) with a 64-slice CT scanner (Sensation 64, Siemens, Inc, Germany). Up to 7 days before the procedure, CT images were acquired with cardiac gating during a single breathhold at held expiration. Patient imaging was performed within 2 weeks of the procedure with a 16-slice CT scanner (Sensation 16, Siemens, Inc) with cardiac gating at end expiration.

Segmentation and 3D Reconstruction of the CT Imaging Data Sets

The LA-PVs and aorta were manually segmented separately with the research software package Cardiac++ (GE Medical Systems, Inc, Milwaukee, Wis). These segmented data sets were converted into 3D surface reconstructions (Magics, Materialise Inc, Ann Arbor, Mich). Then, the 3D models of the aorta and LA-PVs were imported into the image-guided intervention software (see Registration below).

The Robotic Navigation System

The RNS (Hansen Medical, Inc, Mountain View, Calif) consists of a “master-slave” electromechanical system that controls an internal steerable guide sheath and an external steerable sheath (Figure 1). The internal sheath contains 4 pull wires located at each quadrant; the range of motion includes deflection in 360° and the ability to insert/withdraw. The external sheath contains a single pull wire to permit deflection and to provide the ability to rotate and insert/withdraw. These movements allow a broad range of motion in virtually any direction. This steerable sheath system (SSS) can be used in the same way as conventional sheaths with different mapping/ablation catheters inserted through the guide lumen. Thus, with the mapping/ablation catheter fixed so that it just protrudes beyond the tip of the inner system, remotely driving the SSS translates to remote navigation of the catheter tip.

The SSS is attached to the remote robotic arm unit that can be fixed to the foot of a standard x-ray procedure table. A “3D” joystick allows the operator to remotely drive the catheter tip using a software interface. This interface translates movements of the joystick into the complex series of manipulation by the pull wires governing shaft motion. The operator can decide whether to individually manipulate the internal or external sheath.

Electroanatomic Mapping

EAM procedures were performed using a magnetic localization system (CARTO 7x, Biosense-Webster, Inc, Diamond Bar, Calif) with an EAM point location export function to permit real-time export of both any acquired EAM point and the real-time catheter tip location. With this EAM system,7 mapping was performed with a 4-mm-tip, 8-mm-tip, or saline-irrigated 3.5-mm-tip catheter (Navistar, DS Navistar, or Thermocool, respectively; Biosense-Webster, Inc).

Registration

A separate workstation with custom imaging software was used to combine the real-time EAM information with the preprocedural imaging data.8,9 This software can visualize, manipulate, and register the 3D CT images and EAM data. In addition to receiving real-time EAM catheter position information, the software also interfaces with the RNS. The RNS view governing the perspective used by the 3D joystick is sent to the custom software so that the registered 3D CT image also is displayed in an identical view. This view synchronization provides the operator an intuitive means to manipulate the catheter (see Figure 2).

As shown in Figure 3, the registration strategy first involves manual mapping of the endoluminal surface of the aorta using a retrograde aortic approach, which takes ~45 minutes.8 These EAM points were registered to the aorta 3D CT model using an “iterative closest points” distance minimization algorithm. With this initial registration pose, the LA was robotically mapped with careful attention to minimize chamber distortion from excessive catheter-tissue pressure. PV mapping was performed using the “vessel tagging” function to the level of the LA-PV junction. These additional LA-PV EAM points were incorporated into the registration algorithm to further refine the quality of the CT registration. The degree of registration error was calculated as the mean point-to-

Figure 1. The RNS. Various components of the RNS are shown. A, The mobile physician workstation and the robotic arm (circled) mounted to the foot of the x-ray fluoroscopy table. B, Example of the catheter tip shown just protruding from the tip of the inner sheath of the SSS; thus, maneuvering this SSS in effect translates to maneuvering the tip of the ablation catheter. C, The 3D joystick that the operator uses to maneuver the SSS. To better appreciate the movement of the SSS, see Movie I in the online-only Data Supplement.
Preclinical Electrophysiology Study

Under general anesthesia, transseptal punctures were performed with fluoroscopic guidance either manually in standard fashion with a Brockenbrough needle or remotely with the RNS using a specialized transseptal needle under intracardiac echocardiography (ICE) guidance. When the puncture was performed manually, an exchange-length guidewire was used to pass the SSS into the LA. Remote LA-PV and right atrial (RA) mapping/ablation was performed with and without 3D CT image integration, respectively, but always with EAM guidance. At the conclusion of the procedure, the animals were killed, and the hearts immediately explanted and examined.

Clinical Electrophysiology Study

The clinical procedures were performed with conscious sedation. First, manual aorta mapping was performed as described above. Then, dual transseptal access was achieved using a standard 8F long transseptal sheath and a puncture performed remotely with the RNS under ICE guidance. Intravenous heparin was given before the transseptal punctures to achieve an activated clotting time >300 seconds. LA-PV mapping and registration were performed as described above with the 3.5-mm-tip irrigated catheter. Then, remote ablation lesions were placed to electrically isolate the PVs as ipsilateral pairs in an extraostial fashion. To minimize the possibility of esophageal damage, power was limited along the posterior LA to 30 W; elsewhere, power was titrated (20 to 70 W) to achieve a 5% to 10% drop in the impedance. The irrigation flow rate was 2 mL/min during mapping and 30 mL/min during ablation. Radiofrequency energy was terminated once the electrogram was no longer visible or after 60 seconds. A circular multielectrode mapping catheter (Lasso, Biosense-Webster Inc) was used to verify both entrance and exit block. Electrical PV isolation also was confirmed during the infusion of 20 μg/mL isoproterenol.

Figure 2. View-synchronized robotic mapping. A, The custom image processing workstation integrated the navigation, mapping, and imaging information. The 3D CT image was imported and registered to the real-time EAM system. Synchronizing the 3D imaging view to that of the RNS made intuitive cardiac mapping feasible. B, Movement of the catheter to the right on this posterior oblique view of the synchronized 3D CT image is accomplished by moving the 3D joystick in the same direction (yellow arrows). Accordingly, 3D view synchronization provides a facile means for cardiac mapping regardless of the perspective from which the chamber is viewed.
Results

Remote Porcine Atrial Mapping and Ablation With View-Synchronized 3D CT Imaging

After manual aorta mapping and registration with the CT scan, EAM of the LA was performed with 3D CT view synchronization. A total of 65 ± 29 LA EAM points (range, 25 to 119) were acquired (see Figure 4). Registration using the aorta EAM data alone resulted in an LA EAM point-to-surface error of 2.1 ± 0.7 mm; incorporation of the LA EAM data further refined the registration accuracy to an error of 2.0 ± 0.4 mm (P = NS). Thus, LA-PV image integration was highly accurate using the aorta EAM registration alone and guided robotic LA-PV mapping; inclusion of LA-PV EAM data had minimal impact on the registration accuracy. Despite the relatively small size of the porcine atria and the typical short distance between the transseptal puncture and the posterior LA wall, it was possible to enter and navigate into all 4 PVs in all animals; an example of the tubular renderings of the PVs is shown in Figure 4. Although difficult to quantify, the stability of the RNS allowed facile manipulation along the circumference of the mitral valve (note the perianular EAM points acquired in Figure 4) despite the characteristic vigorous motion of this annular region.

Through the use of either an 8-mm-tip or irrigated 3.5-mm-tip ablation catheter, periostial radiofrequency lesions were robotically placed in 7 of 9 animals. A total of 11 PVs were targeted for ablation: 7 right superior PVs and 4 left superior PVs. With the robotic system, a total of 13.6 ± 3.6 and 11.8 ± 1.3 lesions per PV were placed to periostially ablate the right and left superior veins, respectively. On postmortem pathological examination, no cardiac perforation was noted, and the radiofrequency lesions were uniformly situated at the PV ostia.

Although 3D CT images of the RA were not available for use during these procedures, the RNS was used in concert with the EAM system to construct full RA maps in 3 animals. As shown in Figure 4, detailed RA mapping was possible without complications. Similar to the perivalvular stability observed on the left side of the heart, the catheter was easily manipulable circumferentially along the tricuspid annulus. The His bundle electrogram was identified in all animals.

Remote LA-PV Mapping and Ablation in AF Patients With View-Synchronized 3D CT Imaging

After manual aorta mapping and registration, the view-synchronized 3D CT scan guided detailed LA mapping; a total of 116 ± 49 EAM points were acquired (range, 60 to 193). When these additional LA points were incorporated into the registration scheme, the mean LA EAM point-to-surface error was 2.1 ± 0.3 mm. As with the experimental study, the view-synchronized CT scan allowed facile manipulation into the PVs, the LA appendage, and the mitral valve annulus in all patients. ICE imaging was performed manually to verify the proper localization of the catheter tip at each of these locations.

With the view-synchronized CT scan, an irrigated radiofrequency ablation catheter was robotically manipulated to perform extraostial PV isolation as shown in Figures 6 and 7. This was performed during sinus rhythm in 6 of 9 patients and during AF in 3 of the 9 patients. Along the posterior LA, the lesion set was extended to include a significant portion of the PV antrum; during ablation in this region, the maximum
amount of energy was limited to 30 W. During isolation of the left-sided PVs, lesions were placed on the PV side of the LA appendage–PV ridge. In all patients, the integrity of the isolating lesion set was confirmed by manually manipulating a circular mapping catheter into each of the PVs; entrance and exit conduction block was confirmed in all 36 PVs.

Adjunctive ablation lesions were placed in both the paroxysmal and persistent AF patients. In the paroxysmal patients, electrical isolation of the superior vena cava was attempted and successfully performed in 4 patients. Damage to the pericardiac right phrenic nerve was avoided by careful pacing before radiofrequency energy delivery. Cavotricuspid isthmus flutter was inducible in 1 paroxysmal AF patient; the mechanism was confirmed by entrainment from the isthmus. The robotically driven irrigated catheter was used to achieve bidirectional block across the cavotricuspid isthmus. A number of linear atrial lesions also were deployed in all 3 persistent AF patients: a cavotricuspid isthmus line, an LA “roof” line connecting the right and left PVs, and a mitral isthmus line (see Figure 8). Conduction block across each of these lines was achieved in all patients; for the mitral isthmus line, ablation within the coronary sinus also was required to achieve block in 2 of 3 patients. Finally, robotically driven ablation lesions also were placed at sites of complex fractionated activity, mostly along the left-sided interatrial septum, along the inferior wall, and at the base of the LA appendage. The rhythm converted to either sinus (1 patient) or an organized atrial flutter (2 patients) during catheter ablation in all 3 patients with persistent AF.

Clinical Synopsis

The overall “skin-to-skin” procedure time was 338±89 minutes (range, 260 to 480 minutes), and the total duration of x-ray fluoroscopy exposure to the patient was 29±14 minutes (range, 14 to 55; see the Table). A total of 63±17 ablation lesions (range, 45 to 104) were placed, some of which were “drag” lesions (ie, the ablation catheter was moved during ablation). The duration of time from the first to the last of these lesions was 180±75 minutes (range, 104 to 360 minutes). No acute or chronic complications related to the robotic system or procedure occurred, including thromboembolic complications such as stroke, pericardial effusion with tamponade (assessed by transthoracic echocardiography the day after the procedure), atrioesophageal fistula formation, and PV stenosis.

Discussion

The accuracy of mapping and ablation during catheter ablation of AF is limited in part by the patient-to-patient variability and complexity of the LA-PV anatomy and in part by the electrophysiologist’s ability to manipulate the ablation catheter manually to the desired intracardiac locations. To overcome these limitations, the present study examined the feasibility of combining preacquired 3D CT imaging with real-time EAM and robotic navigation. The fundamental utility of this combination is the ability to robotically navigate on a view-synchronized 3D CT rendering of the patient-specific LA-PV anatomy. In this study, the feasibility of this approach was demonstrated in a porcine experimental protocol, followed by a clinical series demonstrating safety and clinical utility.

The RNS

One of the potential advantages of the RNS is increased and more precise instinctive control of the catheter tip. Existing catheters (that have only a single- or dual-deflection mechanism) require a significant degree of operator skill and experience to efficiently navigate the
LA-PV anatomy. The SSS attempts to address this challenge by providing an instinctive catheter control mechanism; movement of a simple 3D joystick is electronically transduced to a 1:1 movement of the catheter tip. Alternatively, the movement can be decimated to provide a greater degree of control (ie, physical movement of the joystick by 1 cm can be decimated 4:1 to result in only a 0.25-cm movement of the catheter tip). This provides a degree of control not easily achieved with a standard manually driven catheter.

**Clinical Procedural Details**

<table>
<thead>
<tr>
<th>Patient</th>
<th>AF Type</th>
<th>AF Duration, y</th>
<th>LVEF, %</th>
<th>Ablation Lesion Sets</th>
<th>Procedure Time, min</th>
<th>Ablation Time, min</th>
<th>Fluoroscopy Time, min</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Persistent</td>
<td>3</td>
<td>81</td>
<td>PVI + SVC + CTI + MI + Roof + CFAE</td>
<td></td>
<td>345</td>
<td>188</td>
</tr>
<tr>
<td>2</td>
<td>Paroxysmal</td>
<td>0.67</td>
<td>86</td>
<td>PVI + SVC</td>
<td></td>
<td>306</td>
<td>152</td>
</tr>
<tr>
<td>3</td>
<td>Persistent</td>
<td>3</td>
<td>70</td>
<td>PVI + SVC + CTI + MI + Roof + CFAE</td>
<td></td>
<td>360</td>
<td>205</td>
</tr>
<tr>
<td>4</td>
<td>Paroxysmal</td>
<td>12</td>
<td>67</td>
<td>PVI + SVC</td>
<td></td>
<td>480</td>
<td>167</td>
</tr>
<tr>
<td>5</td>
<td>Paroxysmal</td>
<td>2</td>
<td>36</td>
<td>PVI + CTI</td>
<td></td>
<td>260</td>
<td>155</td>
</tr>
<tr>
<td>6</td>
<td>Persistent</td>
<td>20</td>
<td>60</td>
<td>PVI + SVC + CTI + MI + Roof + CFAE</td>
<td></td>
<td>300</td>
<td>177</td>
</tr>
<tr>
<td>7</td>
<td>Paroxysmal</td>
<td>2</td>
<td>65</td>
<td>PVI</td>
<td></td>
<td>270</td>
<td>114</td>
</tr>
<tr>
<td>8</td>
<td>Paroxysmal</td>
<td>10</td>
<td>60</td>
<td>PVI + SVC</td>
<td></td>
<td>240</td>
<td>104</td>
</tr>
<tr>
<td>9</td>
<td>Paroxysmal</td>
<td>0.5</td>
<td>62</td>
<td>PVI + SVC</td>
<td></td>
<td>480</td>
<td>360</td>
</tr>
</tbody>
</table>

LVEF indicates left ventricular ejection fraction; PVI, electric PV isolation; SVC, electrical superior vena cava isolation; CTI, cavitricuspid isthmus line; MI, mitral isthmus line; Roof, LA roof line; and CFAE, complex fractionated atrial activity.

Figure 5. Echocardiographic monitoring of robotic navigation in humans. The RNS screen and simultaneous intracardiac echocardiographic images are shown. The blue icon of the SSS is shown overlying the real-time fluoroscopy images. The transseptal puncture is shown in A; the transseptal needle is seen across the interatrial septum into the LA on the ICE image. B, The SSS has been used to remotely navigate the ablation catheter to the cavitricuspid isthmus to ablate typical atrial flutter; ICE imaging reveals the tip of the ablation catheter (arrow) at the level of the tricuspid annulus. C, The ablation catheter has been remotely maneuvered to the superior aspect of the left inferior PV; by placing the ICE catheter within the coronary sinus to visualize the LA, the tip of the ablation catheter (arrow) and the circular mapping catheter are seen.
Robotic navigation is controlled by the clinician to direct the catheter tip to a desired location on the basis of feedback from the standard imaging modalities currently used to guide electrophysiology procedures: fluoroscopy and EAM technologies. Of importance, although existing mapping/ablation catheters typically have only single- or dual-deflection capability, the range of motion by the SSS is considerably greater. Because the inner guiding sheath has 4-quadrant deflection capability, it can navigate in virtually any direction. One limitation is a single fulcrum for these deflections. To overcome this limitation, the deflection and rotation capability of the

Figure 6. View-synchronized catheter ablation. In this patient with paroxysmal AF, external posterior views (A, D) and endoluminal views (B, C) of the left-sided PVs are shown. The irrigated ablation catheter is shown during ablation along the posterior LA wall (A, B) and at the ridge between the left superior PV and the LA appendage (C); this latter lesion completed extraostial electrical isolation of these left-sided PVs (also shown in D). In A, the arrow indicates the tip of the ablation catheter. LSPV indicates left superior PV; RSPV, right superior PV; LIPV, left inferior PV; and RIPV, right inferior PV.

Figure 7. View-synchronized catheter ablation of paroxysmal AF. The end point of the ablation procedure is shown in this patient with paroxysmal AF. The 2 top left images are posterior and anterior views of the 3D CT image with the superimposed ablation lesions (red dots); the color represents a sinus rhythm activation map projected onto the 3D image (red indicates earliest activation; purple, latest activation). The top right image is a posterior view of the baseline electroanatomic bipolar voltage map with the superimposed ablation lesions; the amplitude cutoff for purple is 1 mV. The preablation and postablation electrograms within each of the pulmonary veins using a circular mapping catheter confirm electrical isolation; pacing from within the PVs also confirmed exit block (not shown). Abbreviations as in Figure 6.
external sheath provides a moveable fulcrum from which the inner sheath is manipulated.

**View-Synchronized LA-PV Mapping and Ablation**

The workflow for CT-EAM registration was similar to that used previously by our group. A manually derived EAM of the aorta was registered to the corresponding 3D CT reconstruction. At this point, the registration is largely complete, so LA-PV mapping can be performed atop a view-synchronized 3D CT image. Although difficult to quantify, the initial experience with porcine LA-PV mapping emphasized the intuitiveness of this view synchronization (ie, the capability for the operator to move the catheter tip to the left by simply moving the 3D joystick in the same direction regardless of the orientation of the view being used). Given the small size of the porcine LA, the ability to robotically create accurate and realistic renderings of the LA-PVs is itself an important result. The ability to place periostial PV ablation lesions also was established in this initial experimental phase. Porcine RA mapping was performed to generate realistic renderings of the chamber. Because a 3D CT rendering of the RA was not available, view synchronization was not used. Instead, the RNS and EAM views were manually oriented to the same cardinal view. For example, both could be placed in a standard anterior view so that a rightward movement of the 3D joystick results in a similar rightward movement of the catheter tip on the EAM screen. One qualitative observation from these mapping studies was the stability of the catheter tip when positioned at various intracardiac locations such as the His electrode and atrioventricular valve annuli.

The clinical experience with view-synchronized LA-PV mapping and ablation was similarly favorable. Although only a limited number of subjects were included, the variety of LA ablation lesion sets normally deployed clinically was evaluated. For example, an important procedural end point to catheter ablation of paroxysmal AF is electrical isolation of the PVs, an end point achieved in all patients in the present study regardless of whether the ablation was performed during sinus rhythm (n=6) or AF (n=3). Although a circular mapping catheter was used to confirm electrical PV isolation, it was not necessary to manipulate this mapping catheter constantly during lesion delivery. In the typical procedure workflow, after the circular catheter was manually placed in a PV, this catheter was not manipulated until both ipsilateral PVs were electrically isolated robotically with the ablation catheter. Then, the circular catheter was moved manually to the other ipsilateral PV to verify isolation, followed by movement to the contralateral side to monitor robotically driven isolation of those veins. Thus, ablation could be completely performed remotely and by a single operator. Electrical superior vena cava isolation was similarly performed.

In addition to PV and superior vena cava isolation, ablation of chronic AF typically involves the ablation of other targets such as sites of complex fractionated activity and placement of linear lesions like the LA roof and mitral isthmus lines, all

---

**Figure 8.** View-synchronized catheter ablation (Abl) of persistent AF. Remotely created electroanatomic bipolar voltage maps are shown in the left posterior oblique (A) and right anterior oblique (B) views; the amplitude cutoffs for red and purple are 0.1 and 1.0 mV. The registered 3D CT image with superimposed ablation lesions also is shown in a left posterior oblique view (C). The baseline AF rhythm converted to typical atrial flutter after electric isolation of the PVs, placement of LA roof and mitral isthmus lines, and ablation of sites of complex fractionated atrial activity along the base of the LA appendage and the LA septum. The mechanism of the flutter was confirmed by entrainment from the cavotricuspid isthmus; ablation lesions were remotely placed to create bidirectional conduction block. In another patient with persistent AF, the electroanatomic bipolar voltage map is shown in a posterior view in D; note again the characteristic preexisting low-voltage region along the posterior wall. After PV isolation, ablation of sites of complex fractionated atrial activity, and an LA roof line, ablation of the mitral isthmus was begun. After LA endocardial ablation, epicardial ablation from within the coronary sinus (CS) was robotically performed; note the SSS within the coronary sinus in the inset. During ablation at this coronary sinus location, the rhythm terminated to sinus (E).
of which were successfully performed in the present study. The electric continuity of the lines was verified by differential pacing. However, the small number of patients studied precludes an assessment of the relative effectiveness of robotic linear lesion creation with manual linear lesion formation. A larger experience is required to fully appreciate the effectiveness of robotic chronic AF ablation.

Both the overall procedure and ablation times during these studies were considerable. However, it is important to recognize that completion of the ablation lesion sets was not the only goal of these procedures. A considerable amount of time was expended for detailed robotic mapping of the LA-PVs, collecting data to assess the quality of image integration, and verifying tissue contact during selected ablation lesions using ICE. The time spent for these various maneuvers was not separately recorded, but the overall procedure times would certainly have been shorter if the only goal was ablation to isolate the PVs or to place linear lesions.

The Safety of View-Synchronized Robotic Ablation

No complications were observed either during or after the ablation procedure. However, a number of potential complications are worth discussing. First, the size of the SSS mandates that careful attention be paid to achieving hemostasis after removal. Second, one of the important qualitative advantages of robotic ablation appears to be the relative stability of the catheter tip. However, this could prove to be a disadvantage if excessive catheter pressure/power is applied to the tissue during ablation; in this situation, one may anticipate a greater chance for critical subsurface heating, leading to impedance “pops” and cardiac tamponade. This suggests the importance of future work in 2 areas: developing strategies for sensing tissue contact pressure and assessing the amount of power that should be delivered on the basis of the degree of contact. Third, no clinical evidence of esophageal damage could be observed in the present study, but neither intraoperative esophageal temperature monitoring nor postprocedural esophageal endoscopy was performed. Fourth, embolism-related stroke related to either thrombus or air did not occur, probably because, although various radiofrequency ablation catheter designs were used in the experimental phase, only the irrigated catheter was used clinically—in large part because of its improved safety profile for thromboembolism.

Finally, catheter-related perforation of the heart did not occur. Because this was the first clinical experience with AF ablation, view synchronization with 3D CT images was used in all cases, a fact that may have contributed to the favorable safety record in the present study. However, it would be inappropriate to interpret this to mean that view synchronization is necessary to perform robotic LA mapping and ablation. Note that porcine RA mapping was performed without view-synchronized CT images, and in other preliminary clinical work, we have performed AF ablation without CT synchronization (unpublished observation, V.R. and P.N.). Similarly, other CT image registration strategies may prove clinically useful. Ultimately, although the present study establishes that robotic LA-PV mapping and ablation are feasible, the clinical superiority of this paradigm remains to be proved. Ultimately, randomized comparisons of robotic image-guided therapy with standard approaches are necessary to definitively establish its utility.

Prior Experience With Remote Navigation

On the use of the robotic system, 1 ex vivo and 1 in vivo canine study exist. However, both of these simply report movement to various general regions in the heart (eg, right ventricular outflow tract, left ventricular septum), not precise locations. Thus, creating full EAMS of the atrial chambers (in both animals and patients) represents a qualitative demonstrative leap. Second, it is important to recognize that electric PV isolation has never been described using this particular RNS. Furthermore, although a single clinical report exists on the use of an alternative remote magnetic navigation system for AF ablation, it is important to note that the procedural end point in that report was not electrical PV isolation in the standard electrophysiological sense. Instead, its end point was “>90% reduction in the bipolar electrogram amplitude, and/or peak-to-peak bipolar electrogram amplitude <0.1 mV inside the line”. Thus, this is not only the first report of electrical PV isolation using this particular RNS but also the only report of electrical PV isolation using any remote navigation system, robotic or magnetic. Third, the concept of CT view-synchronized remote image-guided therapy is, to the best of our knowledge, unique and has never been reported, including the aforementioned AF ablation study with the magnetic navigation system. On the other hand, a number of reports have been published on using the magnetic navigation system to map and ablate the slow pathway or accessory pathways in patients with supraventricular tachycardias.

Study Limitations

It is important to recognize that a leftward movement of the 3D joystick does not always translate to an exact leftward movement in the in vivo situation. As with manual catheter movement, anatomic obstacles must be properly negotiated. In addition, the resistance exerted by contact with the cardiac tissue alters whether the catheter tip will arrive at the exact location desired by the movement. However, this limitation was not restrictive enough to preclude achieving all of the mapping and ablation objectives of the present study.

Although certain technical limitations of manual mapping are overcome with robotic mapping, one must still master other skills required to perform remote mapping, including how to use the software for the RNS. Robotic mapping also requires the purchase of an additional expensive piece of equipment, which may not be feasible for any given institution.

Although only 2D ICE is currently available clinically, strategies are being developed for 3D ICE imaging. When available, these may be incorporated into the procedure to further minimize radiation exposure to the patient. However, to fully capitalize on these advancements, future iterations of the RNS will require a means for separately manipulating the 2D/3D ICE catheter in tandem with the ablation catheter.

Sources of Funding

This work was supported in part by Hansen Medical, Inc and a National Institutes of Health K23 award (HL68064) to Dr Reddy.
Disclosures
Dr Reddy has served as a consultant to Biosense-Webster, Inc. Drs Reddy and Neuzil have received research support from Hansen Medical, Inc. Dr Abbara serves as a consultant to E-Z-EM, Inc, and is on the speakers’ bureau for Siemens Medical Systems, Inc. The other authors report no conflicts.

References

CLINICAL PERSPECTIVE
The past decade has seen a tremendous evolution in our understanding of how to treat atrial fibrillation with catheter ablation. However, these scientific advances have not been widely applied in clinical practice, in part because of the technical expertise required to safely and effectively perform the procedure. Significant patient-to-patient variability and complexity to the left atrial and pulmonary venous anatomy exist, and manual manipulation of the ablation catheter to these locations can be challenging. To overcome these limitations, this study examined the feasibility of performing atrial fibrillation ablation by remote robotic navigation of the catheter on a view-synchronized 3-dimensional computed tomographic rendering of the subject-specific left atrial pulmonary vein anatomy. The initial porcine experimental phase (9 atrial fibrillation patients) established that this paradigm could be successfully applied to perform all of the major aspects of catheter ablation of paroxysmal or chronic atrial fibrillation: electrical PV isolation in an extraostial fashion, isolation of the superior vena cava, and linear atrial ablation of typical and atypical atrial flutters. Although the ideal ablation strategy to use in any given patient is still in evolution, this study demonstrates the safety and feasibility of an emerging paradigm for atrial fibrillation ablation involving the confluence of 3 technologies: volumetric 3-dimensional imaging, real-time electroanatomic mapping, and remote robotic navigation. Technological advances such as these will likely pave the way for a more generalized use of catheter ablation to treat this troublesome arrhythmia.
View-Synchronized Robotic Image-Guided Therapy for Atrial Fibrillation Ablation: Experimental Validation and Clinical Feasibility


_Circulation._ 2007;115:2705-2714; originally published online May 14, 2007; doi: 10.1161/CIRCULATIONAHA.106.677369

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2007 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/115/21/2705

Data Supplement (unedited) at:
http://circ.ahajournals.org/content/suppl/2007/05/11/CIRCULATIONAHA.106.677369.DC1

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation_ is online at:
http://circ.ahajournals.org//subscriptions/