ROBOTICS IN ELECTROPHYSIOLOGY PROCEDURES

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INTRODUCTION

With the advent of radiofrequency ablation in the early 1990's, clinical cardiac electrophysiology was transformed from a purely diagnostic discipline into a therapeutic one. Step by step, it was shown that common rhythm disorders could be safely and effectively treated by radiofrequency ablation. One by one, from Wolff-Parkinson-White syndrome, to atrioventricular nodal reentry, to common atrial flutter, supraventricular tachycardias were falling into the category of curable diseases.

Two rhythm disorders, however, have withstood this progress and remain challenging: atrial fibrillation and ventricular tachycardia associated with ischemic heart disease.

ATRIAL FIBRILLATION: ARE WE THERE YET?

Since the first description of atrial extrasystoles arising from the pulmonary veins as a cause of atrial fibrillation,[1] techniques have evolved to ablate the pulmonary vein ostia and adjacent areas to eliminate the disorder. But curing atrial fibrillation continues to be a challenge, both mechanistic and technical. Mechanistically, it is not clear that atrial fibrillation owes its existence solely to the pulmonary veins in all patients, and active research is being conducted to refine our understanding. Technically, ablating atrial fibrillation is one of the most demanding procedures in electrophysiology. First, it requires catheter manipulation in the left atrium, which implies a transseptal puncture with its associated risks, most commonly in duplicate (one for the ablation catheter, one for the multipolar mapping circular catheter). Second, catheter manipulation in the left atrium requires detailed familiarity with its three-dimensional arrangement (highly variable from patient to patient), and there is a complex, nonlinear relationship between manipulation of the catheter handle at the patient's groin and ultimate catheter tip motion. Third, the procedural end-point - electrical disconnection of the pulmonary veins and adjacent tissues - requires extensive radiofrequency applications in the pulmonary vein antra, as guided by a second multipolar circular catheter; precise catheter control and accurate and stable catheter positioning are critical for success. Fourth, there are significant risks associated with the procedure, and some are directly related to complex catheter manipulation in the left atrium. Ablating in thin atrial tissue, inadvertent ablation in the left atrial appendage can lead to left atrial tears that are prone to bleeding and cardiac tamponade during heavy anticoagulation.

It is in this context that robotic techniques seek to help. By providing extremely precise catheter manipulation, robotics promise to enhance the quality, safety, and speed of the procedure. Even so, the greatest limitation we face in achieving complete cure of atrial fibrillation is in our brain, not in our hands: our incomplete understanding of the disease has hampered our attempts to develop a universally effective ablation strategy. Unfortunately, robotics are subject to this limitation.

SCAR-RELATED VENTRICULAR TACHYCARDIA

A radically different problem arises in patients with chronic ischemic heart disease and other structural myocardial diseases. As a result of a prior myocardial infarction or other disease processes, scar tissue is generated. Such tissue is most commonly heterogeneous and contains viable myocardium that can sustain electrical propagation. During ventricular tachycardia, reentrant circuits involving propagation in myocardial channels within the scar can lead to syncope, sudden death, or repeated defibrillator shocks, since most of these patients have a previously implanted defibrillator. Most patients have multiple possible reentrant circuits and consequently multiple tachycardia morphologies. Elimination of ventricular tachycardia entails eliminating as many circuits as possible by ablating channels of viable myocardium within the scar or at least the exit points along the scar edge. Because some of these tachycardias are poorly tolerated hemodynamically, detailed mapping of the propagation patterns is often impossible.

Thus, "substrate mapping," that is, delineation of the myocardial scar using three-dimensional mapping techniques, is commonly required. Performing such maps requires extensive manipulation of a catheter inside the heart, most commonly in the left ventricular endocardium but occasionally in the right ventricle or even the epicardial heart surface. In order to reach the left ventricle, the operator has to use either a retrograde aortic approach or a trans-

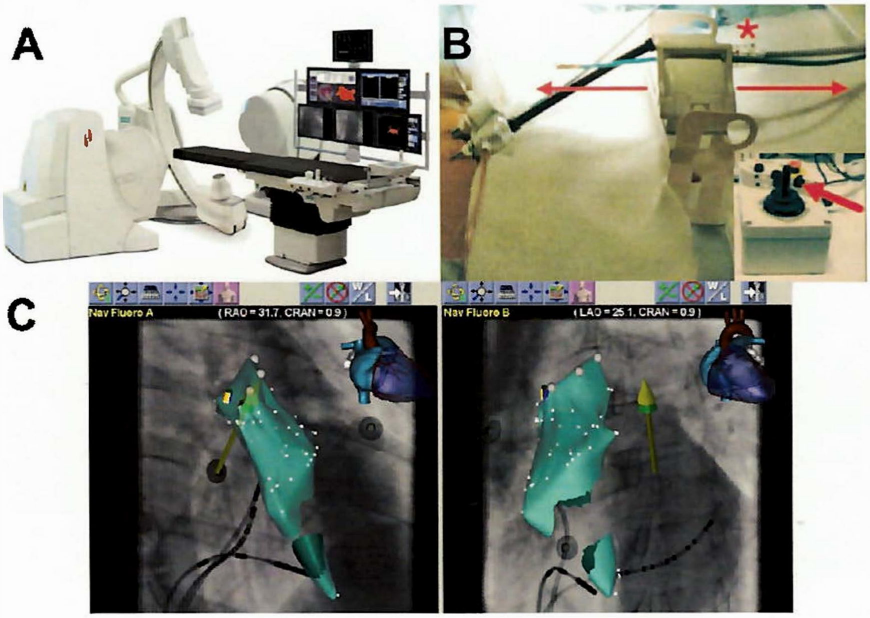

Figure 1. Stereotaxis magnetic navigation system.

A. Fluoroscopy table with two large magnets on each side.

B. Cardiodrive unit (red asterisk) that pushes and pulls the catheter as controlled by the joystick (insert, red arrow) at the physician's workstation.

C. Actual computer interface for selection of magnetic field orientation. The yellow green arrows represent the desired and actual magnetic field orientation (superimposed) in two orthogonal fluoroscopic views. The system is enhanced by integration of three-dimensional mapping data (green shape), in this case representing points in the right ventricular outflow tract.

septal, transatrial one, neither of which leads to a friendly or straightforward catheter manipulation.

The role of robotics

It is clear that the absence of direct catheter access into the left atrium or ventricle and the complexity of the three-dimensional geometry of these chambers pose a technical challenge on the operator and demand advanced dexterity. This challenge has been mitigated by new advances in robotics as we will discuss below. There are two competing robotic technologies currently approved that we will focus on in this review: Stereotaxis and Hansen Medical.

REMOTE MAGNETIC NAVIGATION: STEREOTAXIS

How it works

Stereotaxis, Inc. (St Louis, Mo.) developed a system that can drive the ablation catheter to specific locations. Two large permanent magnets are positioned inside two movable housings on both sides of the fluoroscopy table, in close proximity to the patient's chest (Figure 1A). They create a magnetic field (0.08 T) that includes the patient's heart. The system uses a special mapping and ablation catheter that contains a small permanent magnet on its tip (three magnets in its latest version). When inside the chest, the catheter comes under the influence of the outer magnetic field so that it aligns parallel to the magnetic field lines. When the outer magnets move, they change the orientation of the outer magnetic field, and the catheter is deflected to become aligned with the new magnetic field orientation. The user can change the orientation of such magnetic field with a resolution of 1° for angulation. Thus, the magnetic field orients the catheter tip and imprints a tendency towards a given direction. What ultimately moves the catheter to the desired locations is mechanically pushing and pulling the catheter by an automated system (Cardiodrive, Figure 1B) under the desired orientation of the magnetic field. To be effectively driven by the magnetic field, which exerts its influence solely in the catheter tip, the catheter body has to be necessarily soft and light so as to not oppose any resistance. Thus, all the usual components of ablation catheters, designed to enable the operator to deflect and torque the catheter, are absent. This also eliminates catheter stiffness, reducing the possibility of myocardial perforation and also the mechanical pressure exerted by the catheter while ablating tissue.

The magnetic field orientation is selected by the operator guided by an imaging system. In its most basic form, a remote console consisting of two orthogonal fluoroscopic views is used. The computer displays a vector in these two views. This vector is the direction of the magnetic field. The operator changes the magnetic field direction in three dimensions by moving the vector in the fluoroscopic views. Additionally, the operator advances or retracts the catheter in order to reach the desired location in 1-3 mm steps. Newer versions of the system effectively integrate the catheter manipulation interface with the three-dimensional mapping system, which significantly enhances its flexibility. Figure 1C shows integration of fluoroscopy imaging, with three-dimensional mapping of the right-ventricular outflow tract, with the orientation of the magnetic field (green-yellow arrows). Thus, the operator can intuitively select the direction of catheter orientation in three dimensions with minimal radiation exposure.

Clinical Data

The system was shown in animals to accurately direct an electrophysiology catheter to prespecified anatomical targets without affecting its ability to record electrical signals and deliver radiofrequency lesions.[2] Shortly after animal validation,2 Faddis et al.

conducted the first human studies using Stereotaxis remote magnetic navigation: they validated the system's ability to manipulate the catheter and direct it to >200 prespecified anatomical targets, and they showed, in seven patients with supraventricular tachycardias (SVT), that the catheter could deliver effective radiofrequency lesions and SVT cure.[3]

Ernst et al.[4] demonstrated successful ablation of atrioventricular nodal reentrant tachycardia in 42 patients, an experience that was reproduced by Thornton et al.[5] Similar successful experiences have been reported using Stereotaxis for the ablation of accessory pathways,[6] focal atrial tachycardia,[7] and atrial flutter.[8] Most recently, a randomized comparison of remote magnetic versus manual catheter manipulation for ablation of SVT has shown decreased fluoroscopy time (17.8 min versus 27.1 min, $p<0.05$) but similar success and complication rates and total procedural times.[9] Aside from the fact that the operator manipulates the catheter sitting down and free from radiation exposure, remote magnetic catheter navigation has failed to demonstrate significantly improved outcomes in the treatment of these SYTs compared to conventional catheter use.

Atrial fibrillation ablation was envisioned as the procedure most likely to benefit from the use of Stereotaxis. Pappone et al. described their initial experience[10] using remote magnetic navigation in 40 patients undergoing circumferential pulmonary vein ablation (CPVA) to treat atrial fibrillation. They showed that after a learning curve (-12 cases), the system could be used to deliver the left atrial lesions intended, with similar procedural times compared to control standard procedures. The authors did note decreased ablation times in the right-sided pulmonary veins when using Stereotaxis (16.5 min versus 25.5 min, $p<0.001$). Such encouraging results proved the effective catheter manipulation by the system but did not prove its ablative efficacy. It is important to keep in mind that the procedural endpoint was solely a decrease in local electrogram amplitude in the ablation sites circumferentially in the pulmonary vein ostia without seeking isolation and that no clinical outcome data were reported. DiBiase et al. reported their experience in 45 patients: delivering a CPVA lesion set with Stereotaxis was successful but only lead to pulmonary vein isolation in four veins in four patients (8%), and in the remaining 92% no pulmonary vein disconnection was detected in any vein, despite wide area ablation in the pulmonary vein antra. Most concerningly, charring on the catheter tip occurred in 33% of the cases.[11] Charring is a phenomenon that occurs when radiofrequency energy leads to excessive heating of the tip, which leads to blood coagulation. If patients had persistent pulmonary vein connection, conventional isolation was performed with a manually maneuvered catheter in the right PV antrum (22 patients) or both antra (23 patients). On follow-up, 90% of the patients that did not have all pulmonary veins disconnected had recurrence, showing that a lasting effect was only achieved when the full procedure was performed manually. Of note, widely discrepant letters to the editor have followed publication of these data.[12, 13]

Ventricular tachycardia ablation has also been successfully performed with Stereotaxis. Several small case series have documented its utility in structurally normal hearts.[14, 15] However, it appears most useful when approaching scar-related ventricular tachycardia. As described above, such tachycardias require the use of three-dimensional mapping systems to achieve a detailed delineation of the myocardial scar and its endocardial (and sometimes epicardial) edges. Such mapping usually entails long, tedious catheter manipulation, demands high operator dexterity, and is usually associated with prolonged fluoroscopy times. Ray et al. showed in an animal model that remote magnetic catheter navigation could assist in the complex scar mapping, dramatically reducing the fluoroscopy times required (56 versus 244 seconds) without compromising the quality of the map.[16] The same group of investigators showed that, in patients with symptomatic ventricular tachycardia, complete endocardial and epicardial scar mapping could be achieved with mean fluoroscopy times of 27 and 18 seconds! Although ablation of the tachycardias commonly required the use of a manual, open-irrigation catheter, the procedural improvement is undisputable. Figure 1 shows an example.

Personal perspectives

The system requires an enormous investment in equipment (-$1 million) and construction (-$1-3 million); not only are the large magnets and associated hardware expensive, but the installation requires extensive construction in the cardiac catheterization laboratory to reinforce and magnetically isolate the room. Once installed, the biggest limitation is the unimpressive ablative capability of the ablation catheters. In our experience at the Methodist DeBakey Heart & Vascular Center, we have performed ablations of atrial fibrillation in 41 patients using the Stereotaxis system. While the performance of the navigation system has been outstanding, effective ablations have consistently required the use of a conventional manual open irrigation catheter in all cases, making the system less than self-sufficient. On the other hand, our experience with scar-related ventricular tachycardias has been quite satisfactory: the system continues to be extremely valuable when performing substrate mapping in scar-related ventricular tachycardia, dramatically decreasing fluoroscopy time and facilitating that part of the procedure, although ablation is still performed manually. It is expected that catheter improvements, including the release of an open irrigation catheter (announced for the first quarter of 2009), will enhance the ablative capability of the system and expand its uses.

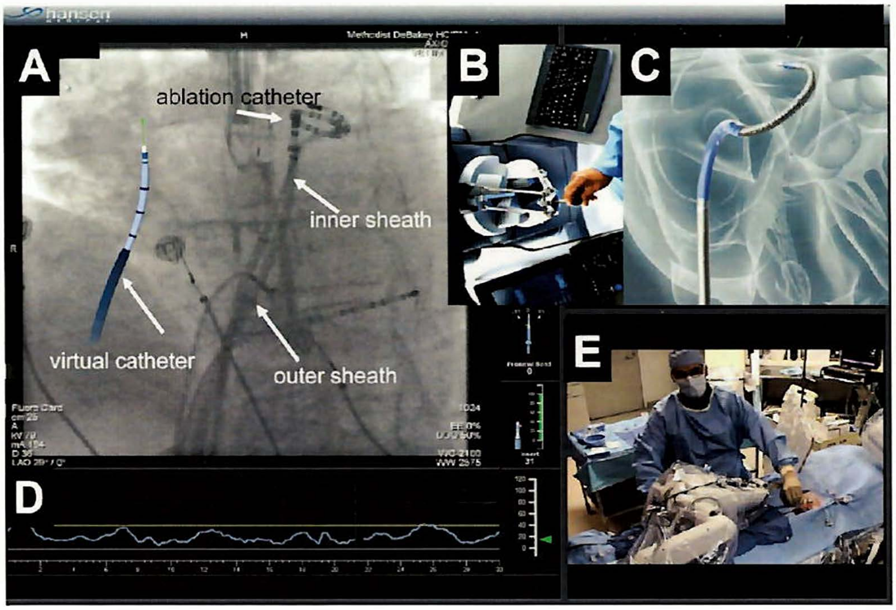

Figure 2. Hansen robotic system

A User interface. The operator uses a fluoroscopic view to guide catheter manipulation

B. Motion of the handle is directly translated to the catheter as seen in the chosen fluoroscopic view.

C. Catheter sheath deflections are transmitted to the robotic catheter and are shown in the virtual catheter. The operator can compare them with the actual catheter motion seen in fluoroscopy.

0. Force sensor (Intellisense®); the catheter tip is pushed forward and backward at 4 Hz and the resistance is sensed and displayed to avoid excessive tissue pressure.

E Bedside robotic arm that transmits catheter motions.

ROBOTIC CATHETER REMOTE CONTROL: HANSEN

How it works

The Sensei™ Robotic Catheter Control System (Hansen Medical, Mountain View, Calif.) has several components. The robotic catheter is a multidirectional deflectable hollow sheath (Artisan catheter, Hansen Medical) through which any mapping or ablation catheter can be inserted. The sheath has four embedded wires (in the north, south, east, and west positions) and multidirectional deflectability is achieved by varying tension on these wires, a process that is computer-controlled. The catheter is inserted in the patient's heart and connected to an arm (remote catheter manipulator) at the patient's bedside that hooks to the sheath's wires. The robotic sheath is inserted through an outer sheath with unidirectional deflectability that provides stability and allows the entire system to rotate. The physician workstation is located remotely and consists of a computer, an instinctive motion controller, and monitors that display fluoroscopy data, three-dimensional mapping data, intracardiac echocardiography data, and force sensing data. The operator integrates imaging data (from fluoroscopy or three-dimensional mapping) and maneuvers the instinctive motion controller in the desired direction of the particular imaging used. The computer translates this maneuvering into actual motion of the catheter. When using fluoroscopy as the imaging guide, the computer uses an inclinometer placed in the fluoroscopy's image intensifier to know the specific projection being used and deliver the appropriate catheter motion that marches the operator motion of the instinctive motion controller. In its current form, the system is not suited for left-ventricular mapping.

Al-Ahmad and colleagues showed in explanted hearts that the system allowed for rapid, reproducible, and precise catheter motions to reach specific anatomical targets.[17]

Clinical Data

Ablation of atrial fibrillation has been the major focus of Hansen's use. Marrouche et al. reported in abstract form the first human experience using the system in seven patients with supraventricular tachycardia: all seven were successfully ablated; manipulation included crossing the interatrial septum (through a patent foramen ovale) and left atrial navigation in two patients; and there were no complications.[18] Saliba et al. showed that the transeptal puncture could be effectively performed in dogs using the system.[19]

The system's utility in ablation of aerial fibrillation was first reported by Reddy et al. in a study that combined animal validation followed by demonstration of effective pulmonary vein antral isolation in nine patients.[20] Most recently, Saliba et al.[21] reported a multicenter international case series of 40 patients undergoing pulmonary vein antral isolation for atrial fibrillation. Robotic catheter manipulation allowed effective pulmonary vein antral isolation in all patients, thus the procedural success was excellent. Procedure and fluoroscopy times were 163 ± 88 min and 64 ± 33 min, respectively). Long-term reported arrhythmia-free success was 85%. There were two cases of cardiac tamponade due to perforation, a number that exceeds (doubles) the reported incidence in manual cases. Thus, it appears that the system can help the electrophysiologist "do the job," but it is unclear what advantages are provided, except for operator comfort and less exposure to radiation. Head-to-head comparison of robotic versus manual ablation is needed to delineate the improvements provided by the system.

Personal perspectives

The system is comparably cheaper (-$400,000) than Srereotaxis and does nor require any special construction in the cardiac cathecerizarion laboratory. We have used ic ac che Methodist DeBakey Heart & Vascular Center co perform 38 ablation procedures. Manipulation is intuitive, and ablation is enhanced by excellent catheter stability and tissue contact. Three instances of cardiac camponade occurred bur were resolved with pericardiocentesis without major consequences. These were related to excessive ablative power and excessive catheter pressure. Adjusting ablative power, enhanced image integration with three-dimensional mapping systems, and passing the learning curve will help eliminate these complications. The system performs very well and simplifies catheter manipulation. Once again, only head-to-head comparisons with the conventional manual catheter manipulation will cell whether a significant improvement in procedural success is afforded.

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