

Magnetic Attraction

More and more, interventional cardiologists are being drawn to an advanced steering system that is expanding their ability to diagnose disorders and deliver optimal care to patients with complicated problems of the heart and vasculature.

By Melanie Fridl Ross

For centuries, magnets have exerted a powerful pull on medical practice. And with today's sophisticated technology, scientific evidence of what they are really capable of doing has led to new discoveries and applications. One of the most exciting developments places the power of magnets at the heart of new inroads into percutaneous coronary interventions: Siemens and Stereotaxis have pioneered the AXIOM Artis® dFC Magnetic Navigation system, the first catheter and guidewire steering system of its kind. This technology is also used in the electrophysiology lab.

The system couples Siemens' advanced digital fluoroscopic imaging system, the AXIOM Artis dFC flat panel detector system, with Stereotaxis, Inc.'s NIOBE® Magnetic Navigation system to direct and digitally control catheters and guidewires along intricate paths within the heart and coronary vasculature. "Magnetic guidance provides interventional cardiologists and electrophysiologists with the ability to deliver care with potentially greater precision than standard manual techniques permit," says Dr. Neal S. Kleiman, M.D., director of the Cardiac Catheterization Laboratories at the Methodist DeBakey Heart Center and an

associate professor of medicine at the Baylor College of Medicine in Houston, Texas. The approach also helps physicians handle complex cases with increased efficiency, he says. That's especially important as the number and complexity of cardiac catheterization procedures performed annually continues to rise.

"It extends our options, and it probably means we can get to another 10 to 15 percent of patients – those patients who, because they couldn't have coronary intervention performed for one reason or another, might previously have had to take higher doses of medication or undergo bypass surgery," notes Kleiman. "The population undergoing coronary interventions potentially can be expanded with this device."

A Medical Milestone

Methodist incorporated the AXIOM Artis dFC Magnetic Navigation system into the catheterization lab about a year ago. Kleiman and his colleagues say it represents one of the most fundamental technologic developments in interventional cardiology in years – a unique and innovative advance in cardiac patient care. At least 23 clients worldwide have



THE NEXT GENERATION of magnets: tilting the NIOBE magnets supports projection in interventional cardiology with an angulation of up to 45 degrees LAO/RAO.

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Neal S. Kleiman, M.D.,
The Methodist DeBakey Heart
Center, Houston

installed the sophisticated system. Magnetic steering is especially promising for subsets of patients with complex disease or challenging anatomy who otherwise would not be good candidates for coronary intervention, Kleiman points out. These individuals make up a substantial proportion of the patients cardiologists see and include those with chronic total occlusions, multivessel disease, bifurcations, or difficult vascular anatomy, such as sharply angulated, tortuous small vessels, or long lesions.

“Basically, the magnetic navigation system is designed to help you direct guidewires into arteries or into portions of the heart that are difficult to access otherwise, for structural or anatomical reasons,” he says. Patients with structural heart disease or drug-resistant, difficult-to-ablate arrhythmias also could benefit. The technique, for example, could be used to help close atrial septal defects such as patent foramen ovale, to perform percutaneous mitral valve repair, or to carry out septal ablation with alcohol.

Precise Movement

The system is designed to make it easier for physicians to control the guidewire as it is positioned and threaded through the vasculature, making their movements much more precise. A standard wire-threaded catheter can only bend in a few directions. To reorient it in the heart’s anatomy, the physician must manually turn the entire guidewire. But these movements, initiated far from the tip of the wire, can be clumsy and imprecise, says Kleiman. Furthermore, excessive manipulation of the wire can cause it to distort or become kinked. In contrast, the guidewires used in the AXIOM Artis *d*FC Magnetic Navigation system are equipped with tiny magnets at the tip, which respond to an external magnetic field of a specific direction and magnitude. As a result, the physician can rotate the guidewire or catheter a full 360 degrees.

The system consists of two large, computer-controlled opposing permanent magnets set externally on either side of the patient. A fairly uniform magnetic field, approximately 15 centimeters in diameter and registering

about 0.08 Tesla at the patient’s chest, is created. (At the magnet’s surface, the field registers at 0.6 Tesla; in contrast, an MRI scanner typically ranges from 1.5 to 3 Tesla.) The distal tip of the magnets on the 0.014-inch guidewires or EP catheters responds to the field direction of the external magnets, making it steerable in any direction. The physician can maneuver within three dimensions using a navigation software console at the table side or remotely via the control room, helping to limit exposure to radiation.

“If you remember high school physics, the magnetic field has a vector that is directed in three dimensions,” Kleiman explains. “Using the computer, you rotate the magnets so you can alter the vector of the magnetic field. You can adjust the external magnetic field so that it deflects the catheter tip in a direction that enables you to get to your target, to get around bends, without the difficulty you otherwise might face.” Kleiman says that this can be a real advantage, considering a coronary artery may only be less than 3 to 3.5 millimeters in diameter at its widest point, and that’s in a large individual. The magnetic-assisted intervention system helps appropriately scale down operator movements at the tip of the guidewire. “Every time you go like that,” he says, motioning as if he were threading the guidewire, “you’re making a big, clumsy movement to the wire. Imagine if from the control room you could scale it down. Let’s say, for example, that if you move five centimeters, the tip of the wire only moves a half centimeter. It would be much less clumsy. That’s what robotics are about.”

The system’s software can help the physician reorient the guidewire or catheter tip using preset parameters: one panel might display vector calculations formulated from average anatomical dimensions for each coronary artery, for example. The computer also can create an individualized three-dimensional track for navigation through the target vessel. Magnetic-assisted interventions may prove especially helpful for treating chronic total occlusion, Kleiman states, because they can



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construct a view of the blocked artery as if you were traveling within it, making it easier to identify small channels through which the catheter can be threaded. Physicians can also store data regarding the exact angulation of the wire during a procedure, permitting them to reorient guidewires and catheters precisely the way they were previously positioned, if the need arises. Images displayed on the system's flat panel detector are high resolution and provide superior clarity.

Magnetic guidance is helping to speed up particularly difficult cases involving extreme tortuosity, which often are unsuccessful using traditional methods, Kleiman says. The system can help direct turns in the vessel exceeding 90 degrees, or help guide the wire through a series of tight turns in quick succession. And because the tip of the wire is so carefully controlled, the procedure can be

virtually atraumatic. "Could we do it another way?" he muses aloud. "It would be very time consuming, and there is a significant failure rate."

When magnetic steering is not desired, the magnets simply swivel unobtrusively to the side.

A Bright Future

The need for advances such as magnetic-assisted interventions is likely to continue to grow in the coming years, Kleiman believes. "Two things are happening: first of all, the population is getting older, and second of all, our tools are getting better," he says. "As a result, case complexity is increasing every year. So I think we're going to find this kind of device is really only a first step into robotics. I think you'll find an increasing need for it. We're not at the point where we can have a



THE EFFICIENT and intuitive system handling improves the workflow in the electrophysiology laboratory. The navigational functions can be performed remotely from the control room.

cup of coffee and push a couple of buttons, but someday we might get there.”

Benefits of the Method

Kleiman reiterates that traditional catheterization techniques may be inadequate for some patients with complex arterial obstructions in difficult-to-reach locations, making their condition impossible to treat with standard angioplasty. Many of these patients end up undergoing bypass surgery or resorting to higher doses of medication long term. Now coronary interventions may prove to be a welcome option for an increasing number of them, he says. In the future, magnetic navigation might even be

used for improved targeting of gene and stem cell therapies, he predicts. First, though, practitioners will have to learn the ins and outs of the technology and grow comfortable with using it. Kleiman says there is a steep learning curve. But he is convinced that once it is mastered, practitioners will likely find that the more difficult the case, the more time saved. That’s because the method is so useful for complex situations that would otherwise pose a time-consuming challenge to perform manually. “It’s as if you went home and found a Ferrari in your garage,” he says. “The first year, it would not get you to work quicker. You’d be driving more slowly, even if the road might



THE UNIQUE PROCEDURE was designed to make cumbersome and time-consuming conventional guidewire steering a thing of the past.

be straight. You'd be cautious about getting the doors dinged. But eventually you'd get out of your garage and make turns very quickly and get to work in considerably less time." Kleiman states that magnetic navigation has been responsible for an 86 percent successful guidewire placement rate out of 51 lesions treated at Methodist using the new approach. Median placement time was 9 minutes, and total procedure time averaged 64 minutes. With additional patient experience, he's confident that those numbers could even improve. As the technology for magnetic-assisted interventions continues to evolve, other treatment advances in the realm of interventional cardiology are likely

to follow close behind, Kleiman predicts. "I think it was a wise decision to bring this new technology to our institution," he says. "We are a tertiary referral center, and we get a lot of complex cases. Part of our responsibility is to take on some of these challenges. Having this system has been a positive thing for both us and our patients."

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