MAGNETIC NAVIGATION: A NEW GENERATION OF CATHETER-GUIDANCE TECHNOLOGY

Albert E. Raizner, M.D.
Methodist DeBakey Heart & Vascular Center, Houston, Texas

INTRODUCTION

Invasive cardiology began in the 1950s with the advent of cardiac catheterization for the precise diagnosis of cardiovascular disease. In the 1960s, invasive cardiology went into high gear with the application of coronary angiography to define the extent and location of obstructive disease within the coronary artery tree. Guidance of the catheters used in these diagnostic procedures relied solely on X-ray fluoroscopy and cine angiography. With the introduction of coronary angioplasty in the late 1970s, the era of interventional cardiology was born. Again, X-ray techniques provided guidance for the new catheters and devices developed not only for the diagnosis but also the treatment of cardiovascular disease. Thus, for five decades some of the greatest advancements in cardiovascular medicine relied on X-rays to provide visual guidance.

While an essential technology, X-ray guidance had numerous disadvantages. First, visualization of the heart required multiple two-dimensional projections to achieve a perception of three-dimensionality. Second, X-rays provided visualization and not true guidance, which relied on operator skills alone. Third, X-rays have the potential to injure both the patient and the laboratory personnel. The complexity of moderate interventional procedures requires increasing exposure to radiation.

MAGNETIC NAVIGATION

Magneric navigation represents a fundamentally new guidance rechnology. Magnetic fields are creared within and around the heart, which allow controlled orientarion of specially designed catheters and devices in the direction of the magnetic vector creared by these fields. Ir is imegrared into the X-ray system of the cardiac cathererization laboratory. As such, it adds an additional dimension of guidance above and beyond that afforded by X-ray technology alone.

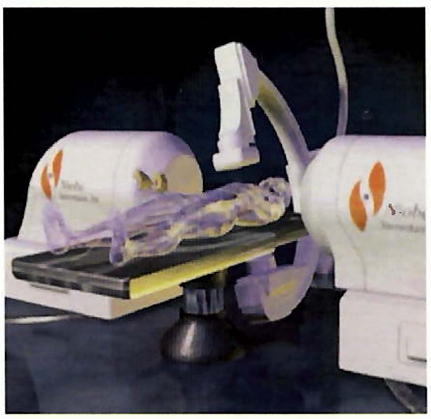

Figure 1. The permanent magnets are shown as they would be positioned around a patient in a cardiac cath lab. When not in use, the magnets are mechanically withdrawn away from the procedure field.

The Stereocaxis Magnetic Navigation System is comprised of three principal components:

1. The Niobe Magneric Navigation Sysrem consists of two permanent magnets (Figure 1), positioned on each side of rhe patient, which produce rhe magnetic field. By coordinating the position of these magnets, a magnetic vector can be created in any three-dimensional orientation. The patiem is positioned such that the heart is in the center of the magnetic field.
2. A family of guidewires and catheters incorporate a small magnet at the tip (Figure 2). When positioned within the magnetic field, the magnetic rip deflects in the orientation selected by the operator. Advancement of the guidewire or catheter by the operator moves the apparatus along the vector created by rhe magnetic field. The magnetic field, rather than the operator's manual manipulation, provides the direction of passage.
3. The "brains" of rhe system are a very complex and highly sophisticated series of software applications that control the position of the magnets in order to create the magnetic orientation desired by the operator. The software interface is digitally integrated with the each lab X-ray system. Digital reconstruction of angiographic images provides three-dimensional visu-

Figure 2. One of a family of guidewires developed for magnetic navigation. Note the metal magnetic tip at the end of the wire that can be directionally changed by the magnetic field.

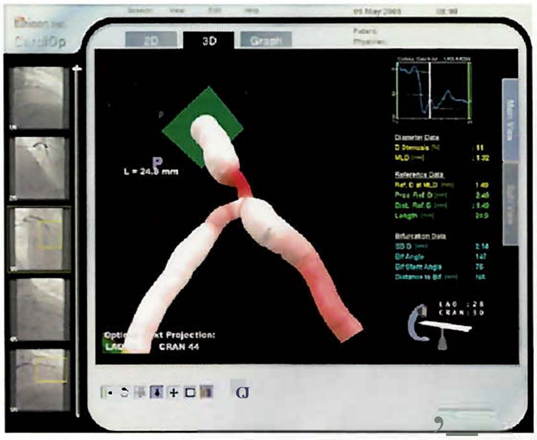

Figure 3. A three-dimensional reconstruction of a complex lesion in a bifurcating comnary artery. The vessel and lesion dimensions are calculated and served to guide device selection.

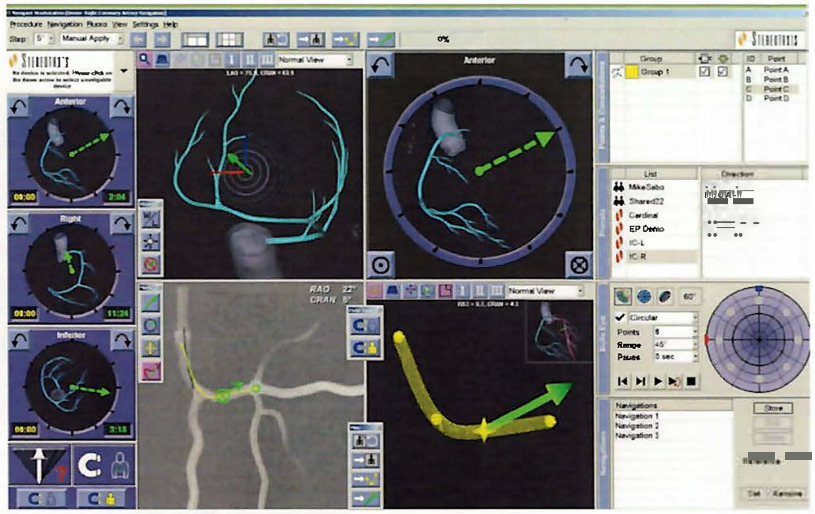

Figure 4. The panel seen by the operator that allows him to select the guidance program most suitable for that patient.

alization of coronary angiograms and, in addition, can create a unique endoluminal view as if one is traveling through the artery from within. In addition, the software allows for the importation of ocher sophisticated imaging technologies such as CT imaging. Consequently, three-dimensional CT images may also be utilized during these procedures.

APPLICATION IN CORONARY INTERVENTION

Advancements in incerventional cardiology have lead to the attempt to treat increasingly complex coronary stenoses. However, interventions are limited in certain anatomic lesion subsets in which placement of guidewires, balloon catheters, and scents is difficult or impossible. Torruous coronary arteries, severely angulated vessels, and chronic total occlusions are examples of lesions that pose particular problems with traditional current incervencional technology. Less complex coronary interventions can be facilitated by magnetic navigation by allowing the operator to change the angulation and orientation of the guidewire tip as it passes through the arterial tree.

In a typical coronary intervencional procedure, traditional coronary angiograms are first obtained in selected views. The target lesion is identified. Three-dimensional reconstructions of the target vessel and target lesion can be digitally created, and lesion and vessel dimensions can be measured for device sizing and selection (Figure 3).

The magnets are then rotated into position close to and on both sides of the patient. The patient's heart is fluoroscopically positioned in the center of the magnetic field. The operator selects from a visual panel (Figure 4) one of several software-driven guidance programs to perform the magnetic navigation:

1. In patients with more typical coronary artery anatomy, preset vectors guide the magnetic tip of the soft guidewire through the various segments of the coronary tree. This approach is used in patients with less complex lesions without unusual anatomic features.
2. Using traditional two-dimensional X-ray views, the operator selects a view that optimally profiles the target vessel and target lesion. The magnetic navigation system automatically recognizes chis field of view. The operator then selects the orientation of the magnetic vector as if looking at the face of a clock. For example, the magnetic rip of the guidewire can be positioned to face one o'clock, five o'clock, nine o'clock, etc. The tip orientation is changed as the wire is advanced along the course of the artery.
3. Using three-dimensional image reconstruction and road mapping, the guidewire is advanced along the arterial tree. At any given stopping point designated by the operator, the magnetic vectors are reoriented to follow the three-dimensional course of the artery (Figure 5).
4. In some situations, probing through a severe stenosis can be facilitated by visualizing the artery as if one were looking within the lumen and facing the stenosis. Slow circular movement of the magnetic tip in an expanding spiral allows probing for the lumen at the point of severe stenosis.

Regardless of which of the above techniques is used, once the guidewire passes the stenotic segment and is positioned distally in the artery, the interventional procedure is completed in the traditional manner by advancing balloon dilatation catheters and scents or other devices over the magnetically positioned guidewire.

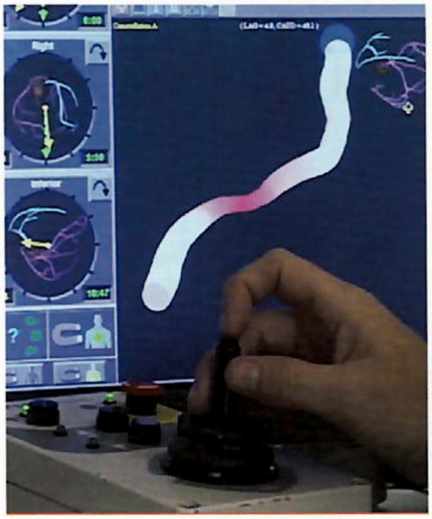

Figure 5. The operator can direct the magnetic navigation system to automatically change magnetic vectors based on the three-dimensional orientation of the artery at any given site.

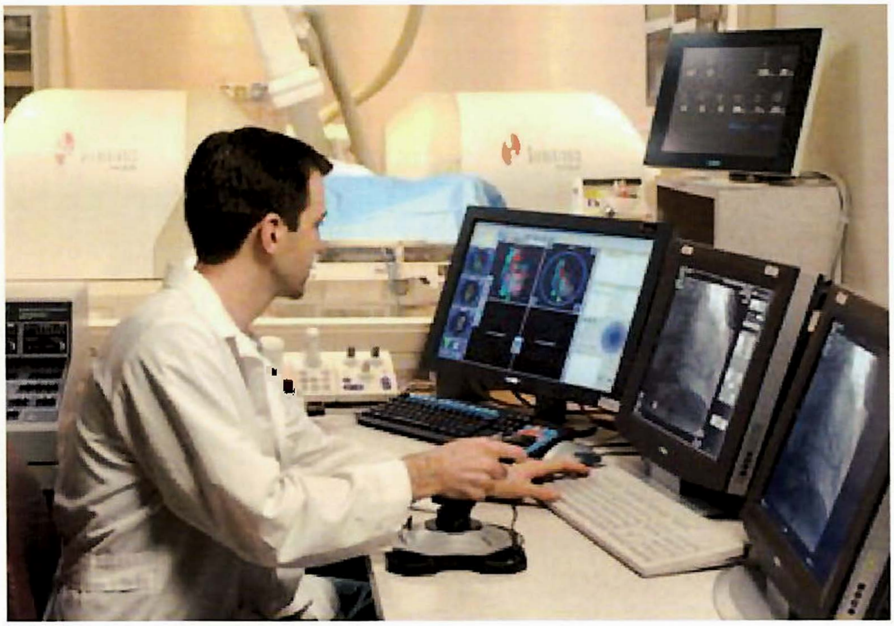

Figure 6. The future potential to operate the Magnetic Navigation System by remote control is illustrated.

APPLICATION IN CARDIAC ELECTROPHYSIOLOGY

The Stereotaxis Magnetic Navigation system is particularly well suited for the diagnosis and treatment of both common and complex arrhythmias. Successful ueatmenc requires precise catheter positioning chat can be achieved more consistently using computerized magnetic navigation. Traditional mapping and ablation techniques require the use of relatively stiff catheters in order to orient and direct these devices to the target location. With magnetic navigation, softer, more flexible catheters are used and guided into position. Reproducibility of catheter position can be achieved, if needed, by device passage utilizing che same magnetic vectors. Merging magnetic navigation with sophisticated three-dimensional catheter location sensing cechnology offers the potencial to provide safer catheter passage to more precise locacions within che hean. A family of mapping and ablation catheters is in development.

FUTURE DIRECTIONS

Currendy, magnetic navigation is in its early stages of development. Refinements in guidewire and catheter technology are proceeding vigorously. Additionally, exciting developments in operational software offer the potential for new and expanded uses of magnetic navigation. The integration of magnetic navigacion with other imaging technologies such as cardiac CT and CT coronary angiography provides the opportunity ro further expand che diagnoses and creatment of patients with cardiovascular disease.

The integration of several imaging and guidance technologies may be particularly helpful in treating patients with a totally occluded coronary arcery. Since the occlusion prevents angiographic visualization of the distal artery, current interventional treatment frequently requires "blind" manipulation of the catheter beyond the occlusion. In contrast, CT coronary angiography provides visualization of the course of the distal vessel. CT imaging combined with magnecic navigation may prove to be a safer and more effective approach to the interventional treatment of patients with occluded coronary arteries.

Finally, magnetic navigation has the potential to be a cruly robotic technique. Conceivably, the operaror could sic in a nearby or even remoce control room managing che magnetic navigation syscem (Figure 6) and utilizing a mechanical catheter advancer to assist in che intervencional task.