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A leading cardiologist discusses his present research and projects, including simulation training, imaging modalities, and the creation of heart models.

What is the current focus of your research energy?

Our group's research effort is directed at the broad area of image guidance of cardiovascular procedures. This area of research can be explained by the definition proposed at a National Institutes of Health workshop on image-guided interventions (IGI). "IGI was defined as a patient encounter where images are obtained (within or immediately before a procedure) and used for guidance, navigation, and orientation in a minimally invasive procedure to reach a specified target under operator control." Our research group includes both interventional cardiologists and imaging scientists. We believe that research and development in the area of IGI has accelerated in the last 5 years due to several factors: medical imaging in many modalities has become highly developed and commercialized; post-processing of images is now routinely aided by the increase in computation power; and perhaps most importantly, the interventional community, including the medical device industry, has a greater appreciation of the critical importance of image guidance in both traditional procedures and many of the newer structural heart disease interventions.

What specific examples of image-guidance research are on going at your institution?

There are three imaging modalities on which we have focused our imaging research. In each we have formed a partnership with Philips Healthcare (Andover, MA) and, in fact, have an amazing team of imaging scientists from around the world working next to our three-dimensional (3D) imaging lab director, Dr. James Chen. The interface with the clinical environment is strong, such that the iterative process of development moves quite quickly. Our first area of focus was in x-ray imaging in the catheterization laboratory, which has dramatically changed now that the environment is digital, and computer workstations can do complex computations within seconds. Rotational angiography, the gantry rotating around the patient as images are captured, is a new acquisition technique applied to cardiac imaging that allows for very efficient image acquisition with less contrast and radiation. Furthermore, the data can be used for 3D reconstruction and then can be used by computer-based tools to help the interventionists perform many of the imaging tasks involved in an intervention. In simple terms, 3D information can now be routinely available, and this availability will help improve clinical outcomes.

Our second modality of interest has been cardiac computed tomography (CT). We do not look at CT as simply a diagnostic modality but as an imaging modality that provides unique 3D data to plan coronary and structural heart disease interventions. Much of our recent work has been taking the next step of importing CT data into the cardiac catheterization laboratory to guide interventions. This work has also involved Dr. Robert Quaife, head of our advanced cardiac imaging program.

More recently, we have been exploring the utility of real-time 3D transesophageal echocardiography in guiding structural heart disease interventions, such as mitral valve clipping in the EVEREST trial, atrial septal defect and ventricular septal defect closure, and mitral balloon commissurotomy. It is noteworthy that for the first time, we can navigate equipment and implant devices in a real-time 3D image. Previously, both ultrasound- and x-ray–based navigation have been performed using two-dimensional (2D) images. This major advancement in ultrasound guidance of interventions is significantly changing the way we organize the catheterization lab and assemble an interventional team. Dr. Ernesto Salcedo, director of our echocardiography laboratory, along with Dr. Quaife, have become true copilots of the interventions we perform.

You had a display of heart models at the recent TCT meeting made from medical images. What is this project about?

The aim of this project, lead by Dr. Michael Kim and Adam Hansgen, our expert in computer graphics, is to create clinically relevant computer and physical cardiac models from a patient's cardiac CT and magnetic reso-

(Continued on page 64)

(Continued from page 66)
nance (MR) images for use in procedure preplanning, device sizing and structure interaction, and education. We currently have the capability to generate full-color physical cardiac models, including the major vessels and prosthetic valves, with continuing development toward producing native valves. Models are currently produced with viewing holes to allow for visualization of the area of interest, although models can also be processed with unique specifications (removable sections, swinging doors, etc.). Furthermore, we are now developing expanded color processing, rubberized models, and IGES (initial graphics exchange specification) translation of surface models. Transforming medical images into the .stl file format that allows the 3D rendering of physical models is a very intensive process. Presently, we are steadily building a model library of various intracardiac defects, congenital abnormalities, aortic pathology, and valvular abnormalities.

How might medical simulation be used for percutaneous valve training? Are there any particular reasons why it might be beneficial?

Medical Simulation Corporation (Denver, CO), of which I am part-time medical director, has actively adapted simulation technology to train medical professionals in the growing area of percutaneous structural heart disease interventions, including valve implantation. Multiple medical device companies have learned that simulation training is important even during clinical trials before regulatory approval. It is critically important that the early lessons learned by the first-in-man interventions be transmitted to all investigators, and simulation plays a central role in helping even the most skilled interventionists safely and effectively make progress in the early learning curve. Many of these new procedures involve tasks never performed by interventionists, and thus training with simulation is especially needed. After device approval, simulation provides a means to train many professionals, physicians, and nurses, as well as the sales force. Without simulation, the early training experience has had to rely excessively on real patients. We all accept that experience increases procedural success and decreases complications. It is now clear that simulation-based training can be part of the process of gaining experience.

There has been much interest about the connection of patent foramen ovale (PFO) and migraines. What recent evidence has there been to prove or disprove this link, and if the connection is there, how does this affect treatment options?

The connection between PFO and migraines has a variety of circumstantial links and anecdotal single-center and nonrandomized studies showing benefit from PFO closure. This being said, the pathophysiology link between closing the PFO and reducing the burden of migraine remains very speculative. I recently wrote an editorial in *Circulation* to accompany the publication of the first randomized trial (MIST) of PFO closure in a population of severe migraineurs refractory to conventional medications.[1,2] The trial was negative; that is, PFO closure provided no benefit, but the reasons are unclear and potentially include the trial design and aspects of the trial's execution. The bottom line is that, in 2008, PFO closure remains investigative for the treatment of migraines, and we need to await the results of several ongoing randomized trials. It looks like two large trials addressing PFO closure and the prevention of recurrent cryptogenic stroke will be finished this year and provide final results in 2009. Until then, PFO closure remains an exciting area of interventional cardiology but lacks the evidence base that would allow FDA approval and the confidence that it provides defined benefits with reasonable risk versus medical therapy.

How have 3D characterization and device performance had an impact on the treatment of PFO anatomy?

Recently, there has been a broad recognition of complexities of PFO anatomy. It is not a simple 2D flap but rather a 3D structure with multiple components, a dynamic structure that changes during the cardiac cycle, and a structure with patient-to-patient variability that has important implications for device performance. We see the importance of advanced medical imaging to study the dynamic anatomy of PFOs. We are using 3D transesophageal echocardiography, as well as making physical models, in our rapid prototyping project to provide a more comprehensive understanding of PFO anatomy. The next generation of PFO devices, some of which sit in the tunnel, will hopefully be better designed to conform to the patient's anatomy rather than using a rigid device that distorts the anatomy.

How does 3D coronary reconstruction go beyond standard imaging techniques?

Important properties of coronary artery disease and the coronary tree are 3D and are misrepresented in traditional 2D-projection images. For example, lesion length seems like a simple linear measurement, but the vessel is curvilinear and the 2D projection image frequently foreshortens the lesion, making it appear shorter than it really is. Other 3D features of importance include vessel tortuosity, essential to assess the deliverability of stent systems to distal lesions, and bifurcation angles, a geometric parameter that will be important to understand and quantify with new bifurcation stents.

More generally, 3D imaging puts the anatomy in its true geometric shape and lessens the burden on the interventionist to mentally process the multiple 2D images in his or her mind. There is no inherent advantage to 2D imaging; it simply is the history of medical imaging that 2D projection images came first, and we all had to learn how to deal with this very unnatural mode of visualizing structures.

Should a CT scan be the primary tool for detection of abnormalities in the coronary anatomy? Or should it be the first test, with subsequent tests (such as stress, angiography, etc.)

CT angiography (CTA) or MR angiography will eventually become the leading modality by which we perform diagnostic coronary imaging. Each has limitations, and despite CTA being further developed, there are limited clinical circumstances when CTA is a reasonable alternative to catheter-based coronary angiography. Most of these circumstances involve taking advantage of CTA accuracy when there is no significant coronary artery disease. But the future will bring CTA technology with better images with higher temporal and spatial resolution and, most importantly, with a lower radiation dose than current scanners. Assuming the completion of the needed multitude of well-designed validation studies and clinical outcomes studies, I expect CTA to be the primary tool for coronary imaging. For example, when the ST-elevation acute myocardial infarction patient arrives in the emergency department, the CTA will be performed in 5 minutes, and the interventionist will have the CTA images in the catheterization lab to guide the intervention with no diagnostic catheter-based imaging needed.

In December, CMS proposed to change the way coronary CTA is reimbursed. However, the decision has been finalized, and CMS will not set a national coverage policy restricting coronary CTA payments. Was this the right decision?

In my opinion, it was the right decision, and patients should continue to have access to this imaging modality. We do need to deal with the issues of high costs and financial incentives from physician ownership. We must move to the era when the choice of imaging modality is based on what is best for the patient, as documented in clinical studies. Furthermore, the indications for imaging need to be refined, and the appropriateness criteria developed by professional societies should be the guiding documents for clinicians—not coverage decisions from CMS. ■

1. Carroll JD. Migraine intervention with STARFlex Technology Trial: a controversial trial of migraine a patent foramen ovale closure. Circulation. 2008;17:1358-1360.
2. Dowson A, Mullen MJ, Peatfield R, et al. Migraine intervention with STARFlex Technology (MIST) Trial: a prospective, multicenter, double-blind, sham-controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache. Circulation. 2008;117:1397-1404.

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