Perspectives: Robotics in Practice

A discussion with experts who are exploring the utility and benefits of robotically assisted intervention in their practice.

Robotic technology continues to evolve and is increasingly becoming poised to impact practice. We spoke with Barry T. Katzen, MD, FACC, FACR, FSIR, who has experience with the Hansen Magellan system in the peripheral space, and Theodore L. Schreiber, MD, FACC, FSCAI, who has experience with the Corindus CorPath system in the coronary arena, about what robotics has brought to their practices.

Participants

Barry T. Katzen, MD, FACC, FACR, FSIR, is Founder and Medical Director of Baptist Cardiac & Vascular Institute and a member of Miami Vascular Specialists. He is also Clinical Professor of Radiology at the University of South Florida College of Medicine and Associate Dean of Clinical Affairs, Baptist Health at FIU Wertheim College of Medicine. *He has disclosed that he has no financial interests related to this article. Dr. Katzen may be reached at barryk@baptisthealth.net.*

Theodore L. Schreiber, MD, FACC, FSCAI, is President, DMC Cardiovascular Institute, and Leader of Cardiovascular Services, Tenet Healthcare Corp in Detroit, Michigan.
He has disclosed that he has no financial interests related to this article. Dr. Schreiber may be reached at TSchreib@dmc.org.

What is the role for robotics systems in interventional treatment?

Dr. Katzen: We are currently in the process of defining the role; it will be something that develops over time as we evaluate the utility of robotics in general. After watching the evolution of robotic technology over a couple of years, I began to see some work that was being done at Imperial College regarding the issue of catheter touches and what happens with manual catheterization as they did these catheter tracking experiments. I began to think that there may be some real benefit if you could reliably and predictably drive a catheter through the middle of an artery without injury and then position something in place for treatment, such as a guiding catheter or guide sheath; that would be much more stable than what we produce by manual palpation.

I became more interested in looking at how this could affect bread and butter catheterization. Is there some role in which robotics might actually alter work flow or bring meaningful benefit to the patient?

We began to explore a number of different applications and have performed a diverse group of procedures, including carotid stents, superior mesenteric arteries, visceral interventions, renal interventions, embolizations, contralateral hypogastric embolizations, and of course EVAR, which had been going on already.

There was an ah-ha moment for me. During an intervention in a patient with very complex type 3 aortic arch anatomy, we were able to place 6-F sheaths in both carotid arteries with the same device and wire, and were in a stable position in about 4.5 minutes. It was striking. Ultimately, we went in to place a carotid stent in one of the sides.

We're beginning to look at a clinical trial of some sorts, working with some of the other centers that are exploring this to try and define clinical benefit. I have a sense that robotics could benefit patients, staff, and physicians by reducing radiation dose, reducing procedure time, and increasing accuracy. But, we need to develop the trials to really prove that.

In today's world, we're asking interventionists who are less trained to do increasingly complicated procedures. Because of the reduction in diagnostic angio-

graphy and the competitive influences among multiple disciplines, everyone is coming into the field with less experience, but they are required to do more complicated procedures. Something that could make the procedures safer, more effective, and involve less trial and error could be very beneficial in that context.

Dr. Schreiber: Robotic coronary intervention has two obvious advantages. One is the avoidance of ionizing radiation and ergometric stress to the physician. The second is very precise positioning of the interventional device being used—angioplasty or stent. As has been demonstrated, improper stent positioning can lead to revascularization and myocardial infarction, so lowering the likelihood of these issues is a big benefit to the system.

I think the foremost role for robotics is to provide the strategy for the interventional team, for the patient to get less ionizing radiation exposure, and to alleviate the fear of our aging interventional physician population becoming disabled from spine issues from wearing lead.

What unique capabilities do robotic systems offer for interventional procedures?

Dr. Schreiber: Having no radiation exposure for the principal operator is unique. None of the newer lead shielding systems can cut radiation exposure to zero. The precision of the device is also unique.

Dr. Katzen: Robotics offer the ability to achieve controlled catheter delivery and deliver a device that is, generally speaking, much more stable than a conventional sheath for purposes of treatment. It's not something that's going to be used for diagnostic work.

The robotic catheter allows you to work in three dimensions, and stay within the center of the lumen. I believe it is much less traumatic than doing manual catheterization, but that needs to be proven.

What was your approach to implementing a robotic system into your practice, and what procedures did you start out performing robotically? How has your usage of the system evolved?

Dr. Katzen: In the beginning, we started with what others had done—EVAR, because it already uses large catheters. However, we quickly started considering the system for any complex intervention. We have performed approximately 40 cases now, consisting of a number of EVARs, renal artery embolizations, splenic artery catheterizations and embolizations, and very complex contralateral iliac artery aneurysm isolations/embolizations. We have delivered Amplatzer Occluders (St. Jude Medical, Inc., St. Paul, MN), coils, stent grafts, and stents, including renal and carotid stents via the robotic catheter.

Dr. Schreiber: We had a very rapid learning curve. The CorPath system (Corindus Vascular Robotics, Waltham, MA) is extremely simple to use. The main step in implementation was training the catheterization laboratory staff and designating one of my trainees as my principal assistant. I chose one of my fellows to be the robotic fellow, and he has had great expertise and ease in setting up the device. It doesn't necessarily have to be a fellow—at other institutions, it might be an experienced cardiovascular technologist. Our institution is a training program, so fellows assist the attendings in almost every case.

We started out with a handful of simpler cases and then worked ourselves up to the plateau of our learning curve with more complex cases. I have performed some complex percutaneous coronary interventions, and the results have been outstanding.

Was it difficult to implement the robotic system into your existing suite?

Dr. Schreiber: In our case, it was a major challenge. The room with the biggest number of square feet in our institution is also our hybrid room, where we implant transcatheter valves. In a way, we shot ourselves in the foot because the same room now has two competing sorts of cases. I would advise other programs to not put the robot in the same room where other various complex cases are performed.

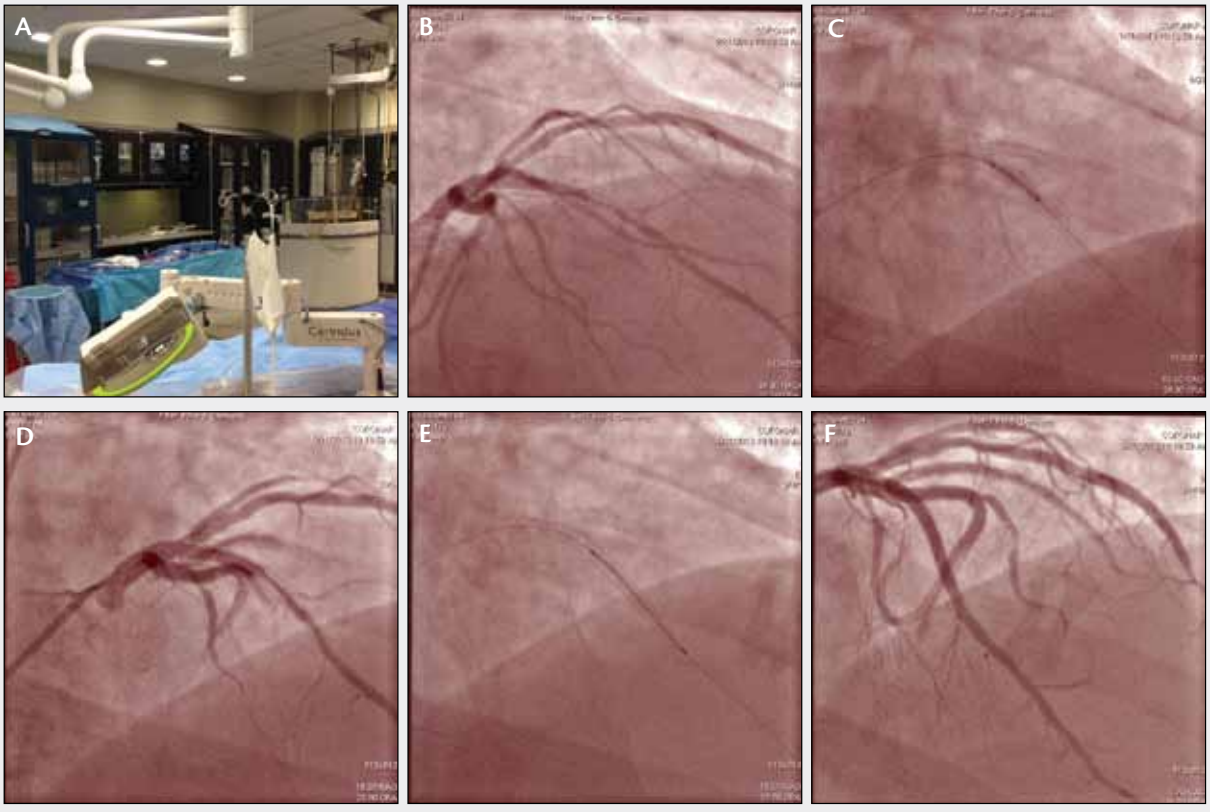
Our institution, Detroit Medical Center, Cardiovascular Institute, is fortunate to be opening a new heart hospital next summer. The robot will be in a different room than where it is now, so there will no longer be competition of the same room for various cases.

Dr. Katzen: There were some installation and ergonomic issues because the robotic arm, which is similar to a large elbow, takes up space at the end of the table. It adds weight to the table, so in some ways it could take away from the total weight capacity of the table.

One of the potential benefits of robotics is reduced radiation exposure for the physicians and staff. How important is this to you?

Dr. Katzen: I think it's huge, and to the patient as well. For my purposes, I like getting everyone away from the table, including the techs and nurses. I go to a remote sitting station where I can control the entire environment—I can remotely move the table and C-arm, shoot x-rays, rotate the robot, and advance the catheters.

ROBOTICS IN THE CORONARY ARENA: THE CORPATH SYSTEM



The operating room setup with the CorPath vascular robot (A). Diagnostic angioplasty showed a severe (85%) tubular in-stent restenosis of the patient's left anterior descending stent (B). The lesion was successfully crossed using a rebotically navigated guidewire followed by robotic angioplasty using the CorPath robot (C). Postangioplasty angiography showed improvement in in-stent lesion severity (D). A drug-eluting stent was successfully navigated to the index lesion (E). Postdeployment angiography showed a well deployed stent with no significant residual stenosis amd TIMI III flow (F).

Reducing radiation exposure is a major focus of quality now in our institute. It's one of our important dashboards, and we're working on this in all aspects of the endovascular arena.

How did you and your staff find the learning curve for a robotic system?

Dr. Schreiber: It's a very rapid learning curve. Everybody adapted to it very easily.

The training process was actually pretty intense. We had Corindus bring in their staff for a full week. The first couple of days were with the company directors, doing didactic sessions of both physician users and the technical and nursing staff. Then for the rest of the week, they brought out the technical specialists, and we trained other physicians, with myself as the principal operator.

The Corindus staff is extraordinarily forward-looking, eager to help, and very responsive, so it's been a positive experience for us.

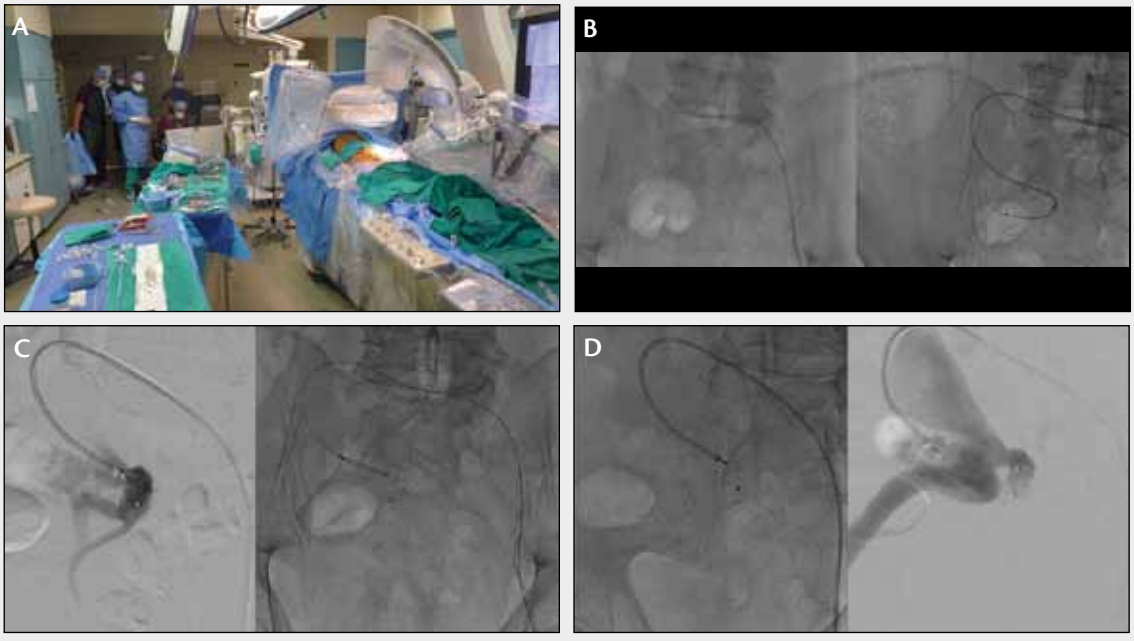
Dr. Katzen: There is a very elaborate training program developed by Hansen Medical (Mountain View, CA), the manufacturer of the Magellan peripheral vascular robotic system, which includes a fundamental understanding of preparing the device as well as operation of the robotic catheter system. In practice though, the techs handle all of the set up and preparation.

In terms of learning the movements of the robot, even as someone who is not a "video game" guy, I found it very intuitive and adapted to it immediately.

How do you explain the role of the robot to patients? What is the reaction to the concept?

Dr. Katzen: I tell them that we are going to use an FDA-approved robot that I think will bring a specific

ROBOTICS IN THE PERIPHERAL SPACE: THE MAGELLAN SYSTEM



The Magellan robot setup in the operating room (A). The remote sitting station allows the operator to control the table and C-arm, shoot x-rays, rotate the robot, and advance the catheters. The robot cannulating the right hypogastric artery (B), and performing right hypogastric artery embolization (C). Completion (D).

advantage. They ask if they will feel anything different, to which I tell them no. Most patients primarily care about the end result. We try to educate the patients about the procedure and the device because we believe they will be an important piece of where this goes in the long-term.

I have had several cases that were easier because we used the robot, but without quantifying it, it's very hard to communicate that message to a patient.

I am trying very hard not to oversell this technology, either from a marketing point of view or a clinical point of view. I am very excited about it, but I'm also very concerned about being considered a champion for the technology without having specific and defined benefits.

On the other hand, I think that this is a technology that is important for people in my profession to evaluate and establish value, moving from potential to real benefits. This is part of the innovation evolution pipeline, which frequently winds up with unanticipated benefits. But without exploration, we will never learn.

Dr. Schreiber: The patients' reactions are always enthusiastic. As you know, the word "robotic" for our population connotes an almost anomalous, divine implication that the technology is better than what was there before. A lot of the public believes that it is better, and I think in many cases for robotic technology—but not all cases—it is better than the conventional, more open approach.

We explain to patients that the difference here is that a physician delivers the equipment more precisely and more deliberately using robotic technology, which actually amplifies physicians' vision and refinement of motions. Without exception, the patients have all been accepting.

What clinical research is ongoing or planned related to robotic systems?

Dr. Katzen: It is important that we try to generate level one data through appropriate trial design and execution. There have been a number of randomized trials in simulators, animal models, and glass models, where one operator uses a manual catheter and another does it robotically. They all universally show that robotic delivery is better. The question is, how do we prove that there is benefit in humans? That's what we're struggling with right now.

As more investigators get involved, we're trying to put our heads together and figure out what clinical

questions need to be asked. It's much more complicated than a question of "a robot can do it better than your hands."

Obviously, putting a 5-F catheter into a straight aorta with manual palpation and one wire and one catheter will not be enhanced by robotics. But as the technology relates to treatment procedures, I think there may be benefit. We need trials that compare fluoroscopy and catheter times.

I am also interested in wall hits, particularly around arch angiography. Dr. Nick Cheshire's group at St. Mary's London, Imperial College has done some interesting work with video tracing in models where they can calculate wall hits from real fluoroscopy. They have shown examples of an interventionist trying to catheterize an innominate artery; the catheter moves all over the place. Then they show the robot, which basically makes a straight line into the carotid. It's pretty impressive.

Dr. Schreiber: We are commencing a protocol for use of the robotic device via radial access, and commencing our own program to explore use of the robotic device for peripheral angioplasty; however, this is currently off-label. We are also a part of the Corindus PRECISION registry, which recently enrolled its first patient.

How do you see robotic systems evolving and what are some potential future applications for robotics in endovascular?

Dr. Schreiber: I think as technology gets better, the setup will be quicker. In an emergency situation, as a very experienced operator, I can do conventional angioplasty in less time that it takes the robotic procedure to be done. But of course, I get all the radiation and there is some lack of precision in delivery using conventional technique.

The Corindus device is already a pretty mature device, but the opportunity for much quicker setup is there, and it will be one of the technical advances that I'm sure will be delivered within the next several years.

Dr. Katzen: We're working with first-generation technology. Right now, when you look at the complexity of movements that occur between the leader of the sheath and the wire, there's a whole host of complicated movements that occur in three dimensions. The next-generation devices will essentially be able to recreate almost any catheter shape.

I think there is potential here to use robotics and image fusion in some way to reduce or eliminate contrast and to more safely deliver devices placed in the body.

How has implementing a robotic system impacted your practice and patient care?

Dr. Katzen: It has added a lot of excitement. It certainly has added cost. We're being very conservative about promoting the system in terms of driving volume, but likely that will start at some point. We did not get it for that purpose, but we are very proud of our innovation pipeline here at Baptist Cardiac & Vascular Institute. I think there's a positive perception in the community about robotics and probably unrealistic expectations based on what's happened in surgical robotics. We're in that stage now, where I'm certain it's going to bring value of some sort, but we're working hard to define it.

Dr. Schreiber: It has reduced my radiation exposure because I do selected cases using this device. I think that from a public relations point of view, the Detroit Medical Center has been recognized as the leader in the area for robotic intervention and has certainly helped our prominence and reputation.

What economic impact does a robotic system have on your practice?

Dr. Schreiber: The economic impact has been a mild positive by attracting some additional cases. The capital cost is substantial—there is the cost of the device, disposables, and the startup cost. Over the course of several years, we expect to recoup capital cost of the device via a combination of fewer stents per case overall and by having more precise positioning. Also, having one less physician that is incapable of doing angioplasties because he needs a back operation is a big gain.

I think the net economic effect over the course of several years is going to be quite positive. ■