Roy K. Greenberg, MD

An endovascular research thought leader, Dr. Greenberg discusses EVAR innovations and a need for new clinical trial initiatives.

How did your father and his work influence your path in medicine? My father's background is in architecture and engineering, and he was very analytical and processed as an engineer. This drove me to take a scientific approach to medicine with an engineering-type background. He focused on computer graphics and got me involved in doing some programming and working with 3-D image interpretation at an early age. And all of this now falls into place when I start to interpret CT scans, perform image manipulation, and meld reality (ie, a clinical scenario) with a virtual image.

How did you come to be Director of Endovascular Research at The Cleveland Clinic Foundation at this stage of your career, and how have you come to be involved in so many important clinical trials? I was recruited here to develop an endovascular research program by Ken Ouriel, MD, under whom I had trained in Rochester, New York. I think it's the fundamental background in science, imaging, and vascular surgery, with an intention to develop minimally invasive approaches that led to this pathway. Ultimately, these are likely to be the best ways for us to develop treatments for vascular patients, given the plethora of comorbid conditions and lack of ability to tolerate major operations. By developing more minimally invasive technologies, we're going to do patients a great deal of good.

How would you describe the role of industry in endovascular research today? It's too prevalent. I would like to see endovascular research take a more federally funded approach. It's very difficult to make any assessments on how patients should be managed based on industry-sponsored trials. It's easy to see whether a device is an acceptable option for a patient, but it's not easy to see whether a device is the best way to manage that patient.

On the other hand, industry plays a critical role in device development, and it's crucial for the device approval pathways, the research required for approval, and early development. However, as physicians, when we look at what device we should use and when, and which patients are appropriate for treatment, industry shouldn't have a part in that. That should be federally funded research. It would be great if the NIH had a directive toward looking at minimally invasive therapies in terms of redefining our treatment pathways.

The carotid stent trials are a perfect example. The CREST trial has taken a very long time to give us any answers, yet industry-sponsored trials have already led to the approval of carotid stents. Now doctors (and CMS) don't know which patients should be treated. Is there an indication to stent asymptomatic carotid disease? Should such patients be stented or undergo an endarterectomy? Similarly, industry-sponsored trials looking at whether an aneurysm should be treated are obviously grossly biased in favor of an inherent desire to increase treatment of aneurysms. That may or may not be the right thing for the patient, but such an industry-sponsored trial is too biased. Consequently, I believe that industry should be less involved in the choice of when and specifically how to treat a patient, keeping their directives primarily at whether a device is an acceptable option for that patient's therapy. The when and how should be decided by physicians.

Much of your recent work focuses on using fenestrated EVAR devices for treating large and complex aneurysms. In what ways do you see this procedure disseminating into more widespread use? When I treat patients with juxtarenal aneurysms, or even suprarenal or thoracoabdominal aneurysms, it is because I don't believe that they will do well with an open surgical approach. Therefore, I look for alternatives. Fenestrated devices provide one of those alternatives, and the other option is medical management; if the patient is so sick that he shouldn't have his aneurysm treated, then we don't treat him. We simply ensure that patients too sick to be treated are maximized on beta-blockers, have their hypertension controlled, and are taking a statin. However, a fenestrated device makes the most difficult infrarenal or juxtarenal aneurysm into a procedure that most patients can tolerate. The mortality associated with implanting an endovascular graft is really quite low (<1% at our institution).

In order to disseminate this option, we need to teach the

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adopting physicians how to best interpret imaging, which means sitting down at a 3-D workstation and using the imaging data to construct grafts so that you can reconstruct the flow, whether it's through the aorta or a visceral branch or internal iliac branch. The physician must become competent at looking at images orthogonal to a center line of flow, as well as doing appropriate length measurements, and orienting the visceral vessels. All of this relies on the physician having a fundamental understanding of the imaging. The difficulty with the fenestrated devices is that whoever plans them really has to perform the procedure. You cannot unlink the two—the physician must be trained in each of these steps. Physicians who master these abilities will be the next generation of vascular surgeons.

What else is on the horizon for endovascular aneurysm repair regarding the treatment of smaller versus larger aneurysms? Endovascular repair will ultimately supplant open surgery. Whether it's for smaller or larger aneurysms, I think is not as important, although I am not very aggressive in treating small aneurysms at this point in time. I also think advances in medical therapy will ultimately supplant endovascular repair. There have been several changes in terms of the perceptions of aneurysms among vascular surgeons and other specialists. Historically, we have always divided aneurysms as to juxtarenal, suprarenal, thoracoabdominal, thoracic, arch, and ascending, and according to those divisions, the procedures fell to one specialty versus another. Now, however, aneurysms are decreasingly identified by body cavity division; there is no need for hypothermic circulatory arrest for arch aneurysms treated with an endovascular approach. At this point in time, when we're considering an endovascular repair, access to the aneurysmal aorta is through a femoral incision, meaning that the procedure must be done by a physician who is competent at both imaging and implantation, and also someone who understands what risks the patient will face.

It is irrelevant whether the disease is in the abdomen or thorax, thus the historical boundary between vascular and cardiothoracic surgery will dissipate. However, judgement learned from both specialties must be conferred to all our trainees intending to treat abdominal aneurysms, thoracic aneurysms, or aortic dissections.

Which areas of innovation will provide the most exciting developments in the near future? Probably endovascular approaches to cardiac valves. This will be a very important adjunct, because the ability to deal with the aortic valve makes it possible to deal with the ascending aorta. At that point in time, the entire aorta is the domain of the interventionist. That's where we're heading.

What future research endeavors do you foresee undertaking? I need to make the devices we're developing that go into the branches and treat thoracoabdominals and arch aneurysms better and simpler. We've also developed a cardiac valve, which we have already put in one patient, and I expect to be working more with that technology in the near future.

The endovascular community has obviously undergone a great deal of change in the past several years. Which trends would you like to see progress, and which would you like to see halted? I think we need to concentrate on our training programs. What we're trying to do now in terms of the endovascular fellows is training them for the year 2000. They're getting endovascular experience, and they can do the basic procedures, but we're not training them for what we think the future of intervention holds. That would entail sophisticated training in MR, CT, and basic imaging issues, because as endovascular techniques become more and more sophisticated, the fusion of cross-sectional imaging techniques with interventions is going to be dramatic, and we have to be prepared to confront that. Surgeons' knowledge of the fundamental principles of radiology is grossly insufficient.

In order remedy this situation, we will need to somehow merge societies; the ideal interventionist will be someone who has a great deal of surgical training, as well as substantial imaging training, and good catheter-based training. Right now, we're training our surgical fellows very well in surgery, which of course is also in jeopardy to a certain extent, but we're really not training them well in imaging.

Many fellows graduating from programs do not have the ability to manipulate CT data, other than to scroll though axial or coronal images. We need to confront that issue before we can teach them how to even analyze complex aortic problems, much less treat them. I think that diagnostic angiography is dying, if it is not already dead. In that light, the next generation of interventionists needs to be able to read a CT scan or an MR image, looking for carotid lesions, intracranial lesions, lower-extremity occlusive disease, etc., and plan interventions on the basis of noninvasive imaging. I believe this blending of the specialties will undoubtedly occur, it's just a matter of when, and whether our societies can overcome the political obstacles.

Right now, everyone seems to be playing catch-up. Surgeons are trying to catch up to radiologists and cardiologists in terms of catheter skills, while IR folks are trying to understand and generate patient-care abilities. What really needs to happen is a leapfrog specialty, in which we all put our heads together and say we need to train some people who are able to work within the future of vascular disease, rather than the present or the past. ■