David H. Deaton, MD

A prominent vascular surgeon shares his experiences with AAA devices, the PAD Coalition, and how surgery is a family business.

As an early adopter of endovascular aneurysm repair (EVAR), what were some of your experiences with early devices, such as Ancure? My earliest experience with EVAR was in February 1993, as a clinical fellow at UCLA. During that month, the first commercial aortic endograft procedure in the US occurred under the direction of Dr. Wesley Moore. This was the first EVT (Endovascular Technologies) endovascular graft, in a tube configuration, and during the subsequent year, EVT began development of a bifurcated graft. During the period of 1993 to 1994, a group of surgeons and engineers worked through a variety of technical issues in a large animal model to produce the first commercially viable bifurcated graft for clinical trials. I was fortunate to be included in that development team by one of my mentors at UCLA, Dr. William Quinones-Baldrich.

The underlying principles for the Ancure graft were, as much as possible, to change only the delivery of an aortic graft essentially identical to that used in open surgery. To that end, it had a series of hooks designed to replicate the function of sutures with transmural aortic fixation, and a bifurcated Dacron graft identical to the kind we would use in open aortic reconstruction. The graft performed well when it was implanted successfully, but as the first graft to come to the commercial market in 1999, with a largely untrained physician workforce, there was a steep learning curve to the implant procedure. Its relatively large delivery catheter diameter also caused significant difficulties in patients with smaller or heavily diseased iliac access vessels. In the end, it was withdrawn from the market for a variety of regulatory and economic reasons. My own experience with the graft was very positive. We continue to follow our Ancure patients, and thus far, none have required a chronic conversion. To my knowledge, the Ancure device has performed as well or better over a longer period of time than any other endograft. The validation of many of the principles embodied in the Ancure design is evidenced today by several grafts in clinical trials that employ transmural fixation and longitudinal flexibility.

Where does that development stand today? We are still learning a lot about what we can do with aortic endografts, their limitations, and their possibilities. I think it is important to remember that the open surgical procedure for aortic aneurysms underwent its own evolution that migrated from stiffer to more flexible prostheses, and from multistranded nonpermanent sutures to permanent sutures with very deep transmural fixation. Those early challenges for open aortic reconstruction and their solution have given us a very robust and durable procedure for open aneurysm repair that we hope to duplicate with the endovascular repair. A clear difference between the open surgical and the endovascular aortic graft is that the endovascular graft will be confined to an often tortuous and diseased anatomy. This necessitates radial support to allow limb patency but must also allow flexibility between the aortic neck, body, and limbs. Modular grafts address the operator's need for flexibility in addressing different anatomic requirements in the aortic neck and iliacs. The next generation will hopefully allow us to use a modular construction technique to create a functionally unibody graft inside the patient.

What was your involvement in the development of the TriVascular device, and what have you learned from that experience? The TriVascular device sought to address migration issues with transmural fixation and deliverability with a very small profile delivery system. It was unique in its application of a liquid fill solution that quickly hardened to fill rings in the proximal body and limbs of the graft that provided for anastomotic sealing and radial support in the limbs. At the time the TriVascular device (a unibody graft) was being conceived, the only alternatives available in the US were modular grafts. That is still the case today, with the exception of the Endologix PowerLink device. The intellectual appeal of the TriVascular device was very high. Its downfall was the inability to anticipate the myriad forces that an endovascular graft might experience in the enormous variety of human pathologic anatomies that are associated with aneurysmal disease.

(Continued on page 97)

(Continued from page 98)
The graft was designed beautifully for a certain set of circumstances and performed well in those circumstances. Unfortunately, in other circumstances that did not conform to the assumptions made in the design of the graft, stent fractures critical to the long-term success of the graft occurred in a variety of locations. One of the hallmarks of the development of endovascular aortic grafting is the poor record of preclinical testing, either on the bench or in animal models, to predict the events seen in the clinical arena. Improvements are being made, and several consensus conferences coordinated by the FDA have been convened to address these issues, but clinical trials remain vital to the safe development of this technology.

With regard to the Aptus device, what is the present experience and what other applications are possible beyond AAAs? The Aptus device is probably a more faithful reproduction of the principles of open surgical aortic reconstruction than any endograft to date. The reason for this is that the seal and fixation functions are not only separate elements of the system, they are physically separate implant components. To that end, the endograft is deployed and held in place by the delivery catheter while a separate delivery catheter, delivered contralaterally, applies individual transmural staples to attach the graft to the aortic wall. As with sutures placed at the time of surgery, these staples are individually applied by the operator. While obviously performing a fixation function, they may also be used to address seal issues in irregular mural anatomy. The first clinical case, done outside the US, demonstrated that even a large proximal type I endoleak can be remedied by suturing down the side of the graft against an irregular aortic wall to seal it. The design of the staple and its transmural purchase allows a degree of fixation in the proximal neck that is well above anything that is available on the market today.

The spiral nature of the staples of the Aptus device provides a novel form of transmural fixation. Theoretically, it should not only hold the graft to the aortic wall but should also hold the wall to the graft, preventing further dilation of the aorta at the site of attachment. This is a characteristic shared with sutured anastomoses as well. Another unique feature of the Aptus device is the ability of the modular limbs to "lock" onto the main body once deployed. Once assembled, the graft functions mechanically as a unibody device. The division of the delivery system into two catheters (ie, one for the graft, one for the staples) allows for a very low profile without sacrificing any mechanical integrity in the form of thinner fabrics or metals. In my mind, the stapling procedure is the endovascular equivalent of sutures in open surgery. When we look at what the development of effective suturing techniques did for the evolution of open surgery, it is difficult not to be very excited about the possibilities of stapling for endovascular procedures.

From a more global perspective, all the devices currently on the market in the US have demonstrated excellent results, but I don't think anyone would say that the devices available today are perfect. Few surgeons would say that they have the confidence in endovascular grafts that they do in well-placed open surgical grafts. Our goal is that endovascular grafts fully attain the integrity associated with open surgical procedures.

In your opinion, what is the current state of carotid and peripheral endovascular interventions? There has been a tremendous amount of enthusiasm for these types of procedures, and I think we are still in the early stages of understanding when either open or endovascular techniques, or a combination of these techniques, are superior in a given clinical situation. My initial attraction to EVAR, and all endovascular techniques, was watching the first endovascular graft patient in 1993 be discharged shortly after the procedure with none of the usual morbidity associated with routine open AAA repair. The obvious morbidity saved with EVAR is enormous. The application of endovascular techniques to lower-extremity ischemia and renal artery stenosis has produced equally impressive reductions in acute morbidity and mortality. The "morbidity gap" between carotid endarterectomy and stenting is more difficult to differentiate, and it will be a long time before these therapies come into clinical equilibrium.

Most of our vascular patients are basically receiving palliative care. Many, if not most, will need more reconstructive procedures in the future as the disease process marches on. We are just beginning to impact the underlying disease process with new medications. With that in mind, we have to be careful the procedure we do today will not diminish our ability to treat the patient in the future. My final point relates to the the changes that occur in clinical practice as a result of technological advances. Vascular surgeons have worked over the last 20 to 30 years to develop a specialty separate and distinct from general surgery. During the last 10 years, it has become a relatively mature specialty, despite its lack of recognition by the medical establishment. One of the effects that the wealth of new endovascular procedures has is to de-specialize vascular care, as a large number of specialists without primary training in peripheral vascular disease or a pre-existing clinical practice in peripheral vascular patients enter the field. That is not to say that endovascular care by specialists

(Continued on page 96)

(Continued from page 97)
other than those trained in vascular surgery is not a good thing. What probably is a bad thing, is the increased treatment of patients by the "occasional" vascular specialist who primarily practices in other areas. The development of specialized care for vascular patients demands a focus on that patient subset and a commitment to both the clinical and technical care of those patients. I think we will see a maturation of those dedicated to vascular patients in other specialties similar to what has occurred in surgery over the last 30 years—a new subset of cardiologists, radiologists, and other specialists totally dedicated to the peripheral vascular patient. The practice of the future will benefit from the total dedication of its staff to the vascular patient and a wealth of professional training backgrounds. That will be a very good thing indeed.

You are involved with the PAD Coalition. What are its goals, and what has it done to increase awareness among both the physicians and patients? The PAD coalition has a development history of more than 6 or 7 years that originally started with the SIR's "Legs for Life" program outreach to broaden their scope by working with other specialties. This eventually resulted in a "summit" meeting 4 or 5 years ago at which the Vascular Disease Foundation took a leadership role as an organization that already had multispecialty leadership and whose roots were sown in patient advocacy. The impetus for the development of the PAD Coalition is the lack of awareness that the public and the primary care community have for peripheral vascular conditions. In essence, the goal is to increase the recognition of peripheral vascular disease as a consequence of the same disease process that is well-recognized in a patient's coronary arteries. We want to give PAD a "profile" among patients and primary care practitioners that breast cancer, coronary disease, and prostate cancer have today. This effort resonated with the staff at the NIH and, in conjunction with the PAD Coalition, they determined to have a national public relations campaign that would be funded by the NIH to increase awareness for peripheral vascular disease and the appropriate treatment of these patients. A large number of different specialties and professional organizations have come together to support this in a very unified way. The goal of the PAD Coalition is to match the NIH financial commitment by bringing industry and other interested parties to the table to work for a common goal.

What is your role at Georgetown University Hospital, and what are some of the challenges and goals you face? I moved to Annapolis in 1999, and I was in private practice for about 3 years. At that time, I received a call from Richard Neville, MD, who was the only vascular surgeon at Georgetown at that time to consider a transition to the burgeoning effort there. Georgetown had recently undergone a major administrative transition in which the University sold the hospital and all the clinical functions of the medical center to Medstar Health. That initiated a renaissance of the very long-standing tradition of clinical and academic excellence at Georgetown. The opportunity to build an endovascular program at Georgetown and to be part of a new and growing academic surgery program resulted in my transition to Georgetown. During the last 4 years, we have initiated essentially every endovascular procedure, including some relatively novel ones to complement the cutting-edge, lower-extremity revascularization work that Dr. Neville has pioneered. We initiated a program of clinical research and have participated in a variety of clinical trials in aortic, carotid, and lower-extremity disease. Today, we have four vascular surgeons in three hospitals with a goal to build a comprehensive vascular practice across a broad geographical region.

You come from a long line of surgeons, and you are married to one. Tell us about how you became a surgeon. I grew up Hickory, North Carolina, a town primarily known for furniture and textile production in western North Carolina. My maternal grandfather began practicing surgery in the 1920s. My father trained in general and thoracic surgery at Duke, practicing primarily vascular and general thoracic surgery. When he moved to Hickory from Duke, he performed the first aortic aneurysm repair done in that part of the state. Although he strongly encouraged me to look at a broad number of career choices, I ended up in medicine and finally surgery.

Our move to Annapolis, Maryland, was the result of an opportunity for my wife, a surgical oncologist, to start a Breast Center, and my fondness for sailing and Annapolis. We met as residents at a research lab at the University of Pennsylvania. At that time, we were both interested in pursuing careers in transplant surgery, and as we became more familiar with transplant surgeons and the lifestyles they lead, we realized that the demands of that specialty dictated that either transplant surgery or our relationship would have to go. Thankfully, she chose our relationship and me. We moved to Los Angeles to pursue fellowship training, she at the John Wayne Cancer Institute while I was at UCLA. During those fellowship years, she participated in the development of the sentinel node biopsy technique for breast cancer and has gone on to become one of the major proponents of that technique and its refinements, recently serving as president of the American Society of Breast Surgery. Although some of my vascular friends know me as Dr. Deaton, most know me as Mr. Dr. Tafra, a title of which I'm extremely proud. ■