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A world leader in endoluminal treatment of aortic disease discusses the evolution of TAA grafting and the Zilver PTX trial.

How has the transition from University of Stanford School of Medicine to University of Virginia Health System been for you?

The transition has gone well. I'm blessed that the surgeons here are also incredibly superb. The cardiac surgery program at the University of Virginia is phenomenally busy, and we have two great vascular surgeons as well. Between the interventional radiology team—there are six of us now—the surgeons, both cardiac and vascular, and our hospital support, we have a unique situation in terms of exploring some of the next phases of this technology. These include hybrid procedures where the anatomy does not fit strict instructions for use for standard, fenestrated, and branched devices.

In terms of the latter, which are custom fabricated devices, there are a number of questions, not the least of which is whether you can make a business out of it. I think some people have started doing hybrid procedures combining less-invasive open surgery with stent grafts. At our institution, a number of our surgeons are adept at exploring these opportunities. This week alone, we are doing three arch debranching procedures with stent grafts over the arch and bypasses coming from the ascending aorta. From the very beginning, this whole area of thoracic endografts has defied pre-existing dogma. Who would have thought that you could cover the entire thoracic aorta with an internal graft, obliterating the ostia of all the intercostals and not make the patient paraplegic? Who would have thought that you can cover the subclavian artery and not have the left arm of the patient become ischemic? And now, the idea of taking patients to the OR, performing a sternotomy, and taking a bifurcated graft off the ascending, and then placing a stent graft over the entirety of all the arch vessels is, in reality, not such a big deal and does not overly perturb the constitution of an individual patient. We are sending these patients home in the same time-frame as patients who have a simple through-the-groin procedure without any relocation or hybrid portion of a procedure. It is a little different, and it takes patients a bit more recovery time if you are going to do the same thing in the abdominal aorta for the visceral branches. However, for the arch branches, we are getting a lot of experience, and I believe people are saying they can wait a bit longer for the branch grafts to come because this is working well and patients are tolerating it. Everyone is getting more experienced because the alternatives of the customizable, octopus-like branches are just not available to most people. It may turn out that this alternative, which was born out of necessity, may turn into something that is more mainstream.

How would you describe your early experiences with endovascular TAA repair?

When I went to Stanford about 15 years ago, I was first introduced to a number of different considerations regarding the thoracic aorta. I worked with some superb cardiac surgeons who had a long history of aortic repair. In 1991, I asked Juan Parodi, MD, and Tim Chuter, MD, to come to Stanford and participate in an informal symposium on the new field of stent grafting, which at that time was really only being applied to the abdominal aorta. Dr. Chuter and I did an animal case with a prototype single-piece device. After that, it seemed obvious that we had a bountiful supply of thoracic aortic cases and started thinking about patients who were not really surgical candidates. We thought there was an opportunity to translate this technology to the thoracic aorta, with some modifications. We performed our first human case in July 1992. We made the initial grafts ourselves out of Z-stents and woven polyester graft material that we customized to the patient's anatomy and sterilized. We treated 103 patients, and that experience somewhat validated the procedure. From that, a number of commercial ventures began to initiate, and things progressed. The cases were always done jointly between interventional radiology and cardiovascular surgery.

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Looking at the past, what can you say about the future for this procedure?

We are really just scratching the surface in terms of the range of applications for the thoracic aorta as opposed to the abdominal aorta, where the single focus is on degenerative aneurysms—the garden-variety infrarenal aneurysm. In the thoracic aorta, we have been initially focusing on aneurysms, and the first device that has been FDA approved, the Gore TAG device (W. L. Gore & Associates, Flagstaff, AZ), has an indication for descending aortic aneurysms. There is a whole range beyond that—whether it is intramural hematoma, dissections, acute trauma, giant penetrating ulcers—where this needs to be vetted and trialed. In the future, I assume that we will see devices custom designed for these different applications, rather than one-design-fits-all, and from that we will be able to see what devices can best meet the challenge of these individual pathologies.

I think 5 years from now there will be a number of different devices with various features that will allow the interventionist to individualize the device for the patient. It may not be customized for the exact individual anatomy, but certainly more customized than we have now for the patient's anatomy, tortuosity, and pathology in the thoracic aorta.

The next application for the thoracic aorta stent graft technology will probably either be trauma or dissection, and I think both of the lesions are very ripe for developing designs of stent grafts that are focused on the pathology. I think it is also very easy to do some trials in this area, both with trauma and especially acute dissection. A trial in this county that I think the NIH and others are interested in potentially supporting would be stent graft treatment of patients with uncomplicated type B dissection within 3 months of onset of symptoms compared to optimal medical therapy alone. I think only a non-industry supported trial could do this and carry it out 5 or 10 years to see the long-term results and possible benefits.

What can you tell us about your experience implanting the first in-man, FDA-approved TAA graft?

It was a milestone for W. L. Gore & Associates and a number of individuals who had worked long and hard at this. The actual implantation of the device was no different than the ones we had been investigating, so it was not particularly technically challenging. But, in terms of being involved in the first FDA-approved implantation of the device, it was very special, and served as a milestone in the development of the technology.

As the Principal Investigator for the Zilver PTX trial, which has been underway since September 2004 and investigates the effectiveness of drug-eluting stents in the SFA/femoropopliteal segment, what can you tell us about its progress?

There have been 30 patients enrolled, which is a nice milestone. Initially, we had 10 sites up and running, and we now have 30 enrolling sites. When the overall enrollment reaches 60, the FDA will evaluate all the results to-date, looking specifically for any safety issues, and then if the safety and efficacy are supported, they will allow us to go forward and enroll about 300 total patients. As the PI, I am not able to look at the interim results.

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Do you anticipate DES success for treatment of PVD to mirror its positive results in the coronary anatomy? It is unclear, but we will not know until we try. There are some obvious fundamental differences. The lengths of lesions that we will target in the SFA and the infrainguinal vessels are so much longer than coronary lesions. Obviously drug dosing is a consideration when you are treating 30 cm to 40 cm of vessel as opposed to 1 cm of vessel. Clearly, the hurdle gets a little higher. In addition, the actual platform for the delivery of the drug is also fundamentally different. In the coronaries, you will use balloon-expandable stents. In the periphery, you will be using self-expanding stents; loading the drug, and ensuring that is stays on during the deployment process in a self-expanding format. It is important to make sure that this translation is identical to the type of treatment that is being supplied in the coronaries. Longer vessels, wider-diameter vessels, and vessels that require a different type of stent platform are not inconsiderable challenges. In the coronary circulation the results are phenomenal, and were from the beginning. I think it might be ambitious to expect that we could duplicate those results right out of the box in the peripheral vessels. But you never know unless you try, and that is why I think that the Zilver PTX trial from Cook Incorporated (Bloomington, IN) will at least show us the path that we will start out on. ■