A Clinical Look at EVAR

W. Anthony Lee, MD, principal investigator of EVAR trials past and present, believes that control, accuracy, and reliability are the three key features that separate a great device from a good device.

As someone who has served as a principal investigator for numerous trials involving different endovascular aneurysm repair (EVAR) device manufacturers, is it difficult not to let your bias through within the confines of a scientific study examining only one device? In other words, if a patient is accepted into a trial and meets the inclusion criteria, what do you do if you would prefer to use a different device based on your personal predilections?

Dr. Lee: Although admittedly the very purpose of a clinical trial is to gather evidence in support of the safety and efficacy of a new medical device, most experienced operators instinctively have a pretty good sense whether a new device is structurally and mechanically sound. Nearly 2 decades since the first EVAR, there is a lot of collective knowledge to draw from. I think most investigators would not participate in a clinical trial if he or she did not believe that the device would work. At the end of the day from a purely ethical standpoint, when I enroll a patient in a trial, I must believe at some level that the device is at least as good as, if not superior to in some respect, a commercially available device or another investigational device for the particular patient and his or her anatomy.

When you are performing an EVAR procedure outside of a clinical trial setting, how do you decide which commercially available device to use?

Dr. Lee: In general, I think all of the commercial devices perform quite well with good short- and long-term outcomes when used within their Instructions for Use. That said, the reality of most tertiary-care referral centers is that many of the patients do not have ideal anatomies and have no other options than endovascular treatment or no treatment. I believe that it is in these adverse situations that critical differences in device performance can be seen. Although there are many attributes that can be discussed about an endograft system, in my opinion, control, accuracy, and reliability are the three key features that separate a great device from a good device. I must also add that although much of the research and development has historically focused on the endograft, there is no question that the delivery system is every bit as important. It should be obvious that no matter how great an endograft is, if an operator cannot deploy it accurately and reliably, the endograft will become just another piece of endotrash in the aorta.

> "The perivisceral aorta is clearly the next frontier in EVAR."

There is currently some debate as to the appropriateness of physicians having any financial conflicts of interest related to the products they use. However, EVAR is a field in which physician investigators often work very closely with industry on the design of next-generation devices. To what degree do you think such relationships, when disclosed, are acceptable if not necessary?

Dr. Lee: It is difficult not to make my answer sound somewhat self-serving because I, like many of my colleagues, have such relationships. I think these relationships are absolutely critical to the development of next-generation devices, and contrary to those fueling the

debate, these relationships and physician integrity are not mutually exclusive states. The engineers with whom I have had the privilege to work over the years were some of the brightest people that I have ever known, but they openly thirst for clinical guidance and feedback from operators. No amount of benchtop testing and thought experiments can substitute for some good ol' fashioned pulling, squeezing, and twisting by a pair of clinically experienced hands. It is sometimes quite apparent when devices are developed with or without broad clinical input. I believe that a device company should encourage (even better, mandate) its engineers to devote at least 20% of their efforts to interacting with physicians and observing cases.

> "Nearly 2 decades since the first EVAR, there is a lot of collective knowledge to draw from."

Having worked with numerous EVAR systems, do you think there are significant differences among the devices currently approved for use in the United States?

Dr. Lee: Besides the obvious physical differences such as modular versus unibody, active versus passive fixation, and suprarenal versus nonbare-stent constructs, critical differences among devices become manifest in adverse anatomies. In these cases, all the features of an endovascular device must work together as a single system to provide control, accuracy, and reliability to the operator and for the patient. In this regard, I believe there are devices that offer these qualities in a consistent manner at the expense of slightly increased complexity that can be overcome with use and experience. On the other hand, simplicity at the expense of control and accuracy is a poor compromise.

What can you tell us about the design and goals of the Zenith Iliac Branch Device clinical trial?

Dr. Lee: I serve as the global principal investigator for the Zenith Iliac Branch Device trial in which the Connection endovascular covered stent will be used (Cook Medical, Bloomington, IN). The first phase will be an international multicenter feasibility study in the use of the Connection stent to bridge the side branch of the endograft to the hypogastric artery. After successful approval, the Iliac Branch Device will offer an invaluable endovascular option for patients with aortoiliac aneurysms, who are currently managed either with a surgical hypogastric bypass or intentional occlusion of the hypogastric artery with resultant risk of ipsilateral buttock claudication.

What clinically useful information can be learned from trials that are suspended or terminated due to device failures or otherwise suboptimal results? Often, these results are not published or widely disseminated.

Dr. Lee: Yes, that is a failure of our entire culture of medical reporting. Negative results are generally perceived as less interesting and unfavorable, and are therefore more difficult to get published. I think much can be learned from such "failed" trials, but this depends on the diligence and integrity of the sponsoring companies in performance of a comprehensive root-cause analysis. In a perfect world, these data would be disseminated so that other would-be inventors and engineers will not make the same mistakes, but in reality, the information is a closely guarded intellectual property. For the public at large, unless they have experienced the failure mode(s) directly, the information is typically disseminated by hearsay.

What do you believe is the next horizon for technological breakthroughs in the EVAR field?

Dr. Lee: The perivisceral aorta is clearly the next frontier in EVAR. To look at the history of endovascular therapy, the industry first started with the infrarenal aorta and then jumped to the descending thoracic aorta conveniently skipping the most complicated segment in the middle. Despite the frustratingly slow dissemination of fenestrated/branched technologies in the United States, with thousands of implants already performed worldwide, the technology can no longer be considered novel or new. But in the current form, it is principally limited by the need to custom manufacture each device. The challenge for the industry in the next decade will be to move beyond the renal arteries and bridge the gap between the thoracic and abdominal aorta using an off-the-shelf solution. It is interesting to note the growing emergence of unconventional techniques such as homemade fenestrations and chimney stents, which is surely proof positive of a real unmet need. ■

W. Anthony Lee, MD, is Associate Professor of Surgery with the Division of Vascular Surgery and Endovascular Therapy at the University of Florida College of Medicine in Gainesville, Florida. He has disclosed that he is a paid consultant to and receives grant/research funding from Cook Medical and Medtronic, Inc. Dr. Lee may be reached at (352) 273-5484; anthony.lee@surgery.ufl.edu.