

Getting Started With the Zenith Fenestrated Graft

The long-term success of this exciting new technology relies on proper patient selection, physician training, accurate sizing and assessment of anatomy, and delivering excellent patient outcomes.

BY JASON T. LEE, MD

The US Food and Drug Administration (FDA) approval of the custom Zenith Fenestrated graft (Cook Medical, Bloomington, IN) in the United States during the spring of 2012 was a significant step and evolution in the endovascular treatment of complex abdominal aortic aneurysms (AAAs) (Figure 1). Many centers had the capability of treating patients with various iterations of this device in their practice through the initial clinical trial,¹ physician-sponsored investigational device exemptions,^{2,3} or with physician-modified endografts,⁴ but widespread US experience with this particular device was limited. Although snorkel or chimney approaches have been increasing in popularity and reporting early success,^{5,6} long-term durability and patency data are still lacking. Because the Zenith Fenestrated graft gained significant utilization throughout Europe and Australia with excellent midterm outcomes⁷ in the treatment of short-neck juxtarenal aneurysms, there currently is great interest and early demand among US endovascular surgeons to have access to this newly approved endograft.

Our center had been a clinical trial site for the Zenith Fenestrated graft, but relatively strict anatomic inclusion criteria led to several patient exclusions, and we did not implant a device in the trial. When FDA approval was announced last spring, I was fortunate to be asked to participate in the first US training program as the technology was disseminated, giving our program the unique perspective as the first physician team to complete the FDA-mandated training and proctoring on the device, which we completed in the summer of 2012. The purpose of this article is to discuss the process our center went through in order to have full access to the device postapproval, how we prepared the operating room and angiography suite team to incorporate the technology into our practice, and some early lessons learned in setting up our fenestrated endovascular aneurysm repair (EVAR) program.

PHYSICIAN TRAINING

Training began even before participating in the 2-day mandated course in the form of reviewing the instructions for use (IFU) of the device and considering several patients for implantation. The IFU for this device requires an infrarenal neck of 4 mm or greater and those unsuitable for a nonfenestrated graft, which allows treatment of the short-necked aneurysms that are not treatable under the IFU for the standard Zenith Flex device (Cook Medical). Identifying several patients prior to attending the training course and bringing the DICOM CT data to analyze on the AquariusNet Intuition software package (TeraRecon, San Mateo, CA) was key to getting the most out of the training course. Much emphasis during the course was on the proper sizing and ordering of the custom Zenith Fenestrated device. I identified nine patients with aneurysms who had not yet been offered an endovascular solution to treat their AAAs at our institution due to various neck morphologic criteria.

Armed with these CDs, the course began with an introductory lecture about indications, instructions, and deployment sequences of the Zenith Fenestrated device. The bulk of the training course centered around working on computer workstations and performing three-dimensional (3D) analysis of the CT angiography (CTA) images we brought to the course of our own patients. If course participants did not have enough CTAs of their own patients, model patients were provided as standard training cases. Although I had already extensively used AquariusNet 3D software, as we routinely evaluate EVAR cases at our institution with it, the sequence and types of measurements necessary for the custom Zenith Fenestrated device were different and quite substantial.

As described throughout this supplement, understanding arc lengths, clock positions, and curved and multiplanar reformats are vital to accurately building the custom device. Because millimeters can make the difference between easy and challenging catheterization of

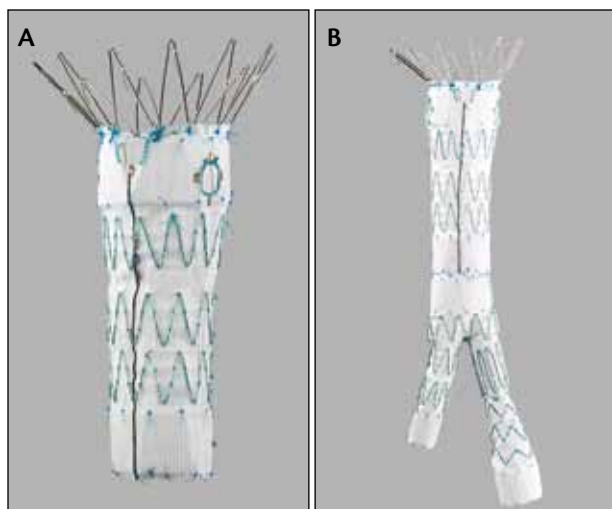


Figure 1. The proximal component of the Zenith Fenestrated graft (A). The distal component in place with an extension spiral Z limb to the left iliac (B).

renal arteries through fenestrations, as well as adequate perfusion through scallops, accurate sizing is paramount to optimal outcomes. I would estimate that even a relatively intermediate user of TeraRecon software initially requires 45 to 60 minutes per patient to make all the necessary measurements to order the device.

Regional clinical specialists, as well as core faculty, who are experienced with the Zenith Fenestrated device are obviously part of the training course and provide invaluable tips and tricks to successful analysis of CTA data and ordering of the appropriate endograft components (see the *Tips and Tricks for Getting Started With the Zenith Fenestrated Graft* sidebar). Based on my experience at the training course and performing 21 cases in the first 6 months after approval, measuring and sizing at least six cases and discussing them with the faculty at the course is a reasonable goal for understanding the process. As previously indicated, prior experience with TeraRecon software potentially shortens the learning curve. Not having access to TeraRecon software at one's institution puts the surgeon at a particular disadvantage for this device, as the clinical specialists, support from Cook Medical, and the server to share in creating 3D measurements are all based on this software platform.

The final part of the physician training course involved hands-on device deployment under fluoroscopy on a tabletop model to understand the general steps in completing a case with the Zenith Fenestrated device. Again, faculty course leaders and clinical specialists who are well versed in these cases provided key pearls as to the most efficient sequence of steps, types of catheters and equipment necessary, and the general nuances of visualizing the device markers during the case. This hands-on demonstration was one of the key components of the training, and even watching your other training course

colleagues perform their own hands-on deployment was extremely informative.

From that point on during the training, the physician should have developed a list of catheters, balloons, sheaths, and ancillary endovascular equipment to successfully plan out their required two proctored cases. Participants at the training course should try to plan and size and get signed off on by the faculty course leader for one, if not both, of their required proctored cases. This process involves uploading the CTA data to the central server, sizing and measuring the case, reviewing the case with your local clinical specialist, and then having a faculty proctor independently review the case to provide advice and confirmation of the device order. The training course is an ideal environment to speed up this process should you have an anxious patient anticipating repair with the Zenith Fenestrated device.

SETTING UP YOUR TEAM

Most, if not all, surgeons going through the Zenith Fenestrated graft training process will already have extensive experience with routine EVAR and perhaps even more complex EVAR. The planning and orchestration of a "fenestrated EVAR" case requires adequately trained staff, slightly more patience on the surgeon's side, and some additional time. One of the helpful tips I learned from the training program was to discuss some of the upcoming changes with the operating room and angiography suite staff. The list I created of additional catheters, wires, balloons, and sheaths was printed, laminated, and attached to our hybrid operating room wall. We changed our scheduling system so we could book a fenestrated EVAR case, and the staff would know to pull the additional ancillary equipment.

We met with our key nursing personnel to discuss the additional time and extra equipment that was to be expected during the learning phase with the Zenith Fenestrated graft. I met with our purchasing managers in the angiography suite to ensure that they understood that these were custom-ordered devices to be charged to a particular patient. Although all hospital policies are different, understanding this process might be new to many surgeons. Because the devices are manufactured in Australia and then shipped locally, a purchase order must be set up ahead of time. Making sure your hospital staff understands this process will make the ordering and delivery of devices more streamlined. Speaking with your billing and finance officers is recommended, as there are new "G-codes" as of April 2013 for billing of fenestrated cases. Ensuring that the program is financially viable is obviously a local issue, but this can cause problems if it is not acknowledged early on.

My own personal bias for performing these cases is that they should be done in a hybrid endovascular suite with fixed imaging. Being acquainted with the visualiza-

TIPS AND TRICKS FOR GETTING STARTED WITH THE ZENITH FENESTRATED GRAFT

- Identify several patients who might be candidates and bring their DICOM data to the training course.
- Familiarize yourself with 3D workstation software for imaging manipulation and discuss the feasibility of purchasing/leasing TeraRecon software with the hospital or radiology department.
- Meet with your operating room and angiography suite staff, nurses, technologists, and inventory purchasers to prepare them for this new technology.
- Choose routine cases for your first several Zenith Fenestrated graft cases that include good iliac access, minimal tortuosity and angulation, and straightforward renal anatomy.
- Consider prewiring the renal arteries to mark the positions of the ostia or use imaging overlays.
- Anticipate difficult renal cannulations and have backup plans of how to advance devices through the fenestrations and into target vessels.
- Do not hesitate to create better iliac access via open or endovascular conduits.

tion of the markers on the device for accurate placement, as well as the potential amount of fluoroscopy time needed to perform the case, makes using a portable C-arm potentially unsafe and inefficient. Preliminary data are accumulating that use of a hybrid room is safer, even for routine EVAR.⁸

For surgeons who perform EVAR with an assistant, surgical partner, or trainee, familiarizing the group with this procedure is also important. Several additional steps and attention to detail so that sheaths do not slip, wires stay in place, and devices deploy accurately are key changes compared to more routine EVAR. Debriefing with your assistants and empowering your partners to size up their own cases allows further education in the rollout of this exciting new technology.

THE FIRST TWO CASES

To be “signed off” for Zenith Fenestrated graft use after completing the physician training course, you must complete two observed cases with a faculty proctor. Choosing these first two cases can be a source of some difficulty for many, but some relatively simple rules apply. First and foremost, the case must fit within the IFU, meaning a modest neck of 4 to 14 mm should be present to ensure that the device behaves and acts the way it was meant to be utilized. Challenging anatomy that would cause early cases to be more complicated with longer operative times includes severely angulated necks, neck thrombus,

downward-angulated renal arteries, narrow distal aortas, iliac tortuosity, and poor external iliac access.

There will be enough challenges during Zenith Fenestrated graft training involved with using a new device, achieving familiarity with the steps, and ancillary help, so choosing an anatomically challenging case can potentially lead to compromised results. Active discussion prior to your first case with the faculty proctor provides invaluable insight into completing the case safely and effectively. Newer imaging technology that can be extremely helpful includes fusion software to provide overlays of the anatomy on the screen while trying to cannulate. When still in the learning curve, I prefer the technique of prewiring both renal arteries with 0.018-inch wires through multiple punctures in the contralateral sheath to mark the renal ostia. This allows clear visualization of the target renal arteries when catheterizing through the small fenestrations. An added benefit of the prewired renal arteries is the occasional misaligned proximal body and the ability to inflate a balloon at the renal ostium to deflect away the fabric to allow successful catheterization.

THE NEXT SEVERAL CASES AND HOW TO PREPARE YOUR PRACTICE

After two successful cases and being signed off by the proctor, there remains much potential to expand your practice and referral network. Our team developed a streamlined process for evaluation and local recruitment of these patients with challenging EVAR anatomy. Personal calls to local surgeons and primary care physicians informing them of our new access to the Zenith Fenestrated device immediately generated several referrals, and the word spread relatively quickly. This not only garnered referrals for more Zenith Fenestrated graft cases, but even for more routine cases that were treated with standard EVAR. Certainly, an unintended consequence is now the referral of cases that are clearly not suitable for the Zenith Fenestrated device, which includes “no-neck” aneurysms, thoracoabdominal aneurysms, and reintervention for previously placed endografts.

Perhaps the most challenging part of the next several cases after one has been “signed off” is that planning and sizing has to be done independently from that point on. Anticipating every angle, curve, or challenge is difficult at best and, to reiterate an earlier point, requires full access, comfort, and experience with the TeraRecon software. Now, we can complete the usual measurements for routine Zenith Fenestrated graft cases in under 20 minutes, but some uncertainty remains in how the renal angulations can affect cannulations and how iliac tortuosity can misalign or twist a proximal piece when inserted. Although the Zenith Fenestrated graft is a dramatic improvement in the current endograft technology

and allows for the treatment of more challenging neck anatomy, further refinements are already underway, and next-generation fenestrated and branch technology is in the pipeline. The rollout and dissemination of the Zenith Fenestrated device has helped with the process of physician training, emphasizing reliance on imaging and sizing, and stressing the technical skill set necessary to successfully treat these patients.

SUMMARY

Like all new devices, the long-term success of this exciting new technology will be predicated on careful patient selection, adequate physician training, expert sizing and assessment of anatomy, and delivering excellent patient outcomes. The endovascular surgeon remains the key stakeholder and provider of this care and should remain at the forefront of the learning, teaching, and development of future fenestrated technology. Attention to detail and the precision in planning and sizing cannot be overemphasized. The process of training was purposefully developed to be comprehensive with several checks and balances and perhaps should serve as a model as EVAR technology continues to be refined.

The early experience with the Zenith Fenestrated graft has been very successful from a patient treatment standpoint, yet challenging in that multiple resources

were necessary for programs to be launched. The expertise of several colleagues and proctors nationally to share in their experience, as well as my local partners and ancillary staff, has been extraordinary as we shepherd in this next wave of advanced EVAR treatments. ■

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