Use of ZFEN in Community Practice

The current state of treatment for complex abdominal aortic aneurysms in community practice using the Zenith Fenestrated stent graft.

BY JESSE MANUNGA, MD

In 1998, Anderson and colleagues performed the first clinical implant of a Cook Medical fenestrated stent graft to treat a high-risk surgical patient with a juxtarenal aortic aneurysm. Long before the publication of their experience with this novel technique in 2001,[1] the technology was being adopted by others and disseminated through workshops in Australia, Europe, and Southeast Asia. In the United States, it was embraced by Dr. Roy Greenberg, who began implanting fenestrated devices in August 2001 and later reported his experience in a cohort of 22 patients.[2] Over the ensuing decade, only a handful of United States academic centers with US Food and Drug Administration (FDA) approval of an investigational device exemption had access to this device. It was not until April 2012, after a prospective trial at 14 United States academic centers[3] that the FDA approved the commercial use of the Zenith Fenestrated (ZFEN) stent graft (Cook Medical) in the United States, giving community surgeons access to this device for the first time.

THE STATE OF VASCULAR SURGICAL PRACTICE IN THE UNITED STATES

With few exceptions, United States academic institutions continue to be the source of the next generation of physicians. Furthermore, these centers shape the future of medicine by serving as the preeminent engine in charge of evaluating and reporting outcomes of various conditions and procedures, including outcomes of industry-conceived new technologies. This trend will likely continue for the foreseeable future. However, the majority of vascular care in this country is and will continue to be delivered by community vascular surgeons—a group that currently encompasses two-thirds of the entire vascular surgical workforce.[4]

Unfortunately, reports on outcomes of surgical procedures performed by physicians in the community remain scarce, as the majority of vascular publications originate from the very institutions tasked with producing the next generation of vascular specialists. This scarcity is mostly driven by economics of medicine because the majority of community surgeons have productivity-based contracts with few to no incentives to embark on academic endeavors. Recent changes in medical payment are forcing many community physicians to become hospital employed, and thus they can negotiate contracts that are still based on relative value units but also include involvement in hospital leadership committees and, in some instances, reporting of clinical outcomes.

ZFEN EXPERIENCE IN COMMUNITY PRACTICE

A recent report on ordering trends suggests that academic medical centers remain the biggest implanters of ZFEN devices in the United States. However, the number of devices ordered by physicians in community practices nearly doubled from 2013 to 2014.[5] This growth rate was larger than that observed in academic practices during the same period of time. As an increasing number of community vascular surgeons continue to be trained every year, it is assumed that this trend will continue. However, several challenges continue to plague this group of physicians, as highlighted in the following sections.

Patient Selection

Patient selection is one of the most important determinants of clinical outcomes for every surgical procedure. For most physicians in community practice, fenestrated stent grafts continue to be reserved for high-risk surgical patients who are not candidates for open repair. This line of thought originates from the initial uncertainty surrounding the long-term performance of fenestrated devices. However, these devices have been implanted in thousands of patients around the world for the past 20 years, and several studies on their performance have shown that fenestrations have a long-term occlusion rate of < 2%.[6-8] These revelations have led many forward-thinkers in aortic surgery to start offering fenestrated procedures to both high- and low-risk surgical patients as long as the anatomy is suitable for such a repair. It is believed that the vast majority of physicians will come to share this philosophy as reports continue to show the excellent performance of these devices.

Device Design and Sizing

The next challenge after patient selection is device design and planning. Currently, Cook Medical requires a physician to perform a minimum of two cases before

being considered "signed off." Although this decision is left at the discretion of the proctor, most physicians are signed off after these initial two cases. This is largely due to the fact that the first two cases are performed with relative ease, because they are carefully scrutinized by experienced proctoring faculties and fall within the instructions for use (ie, a 4- to 14-mm neck with no thrombus or calcifications, limited neck angulation, and limited iliac artery tortuosity).

However, after implantation of the initial two cases, continued success of the endovascular complex aortic aneurysm program is based on the drive, dedication, vision, and clinical judgment of the lead physician(s) and the support from administration. Obtaining the proper CTA images (2-mm cuts) and meticulous analysis of the scans of every patient undergoing repair using a three-dimensional (3D) reconstruction workstation is paramount. Every CTA scan must be analyzed using centerline-of-flow measurements to determine lengths, angulations, clock positions, and arc lengths.

The challenge is that a large number of community vascular surgeons do not have access to 3D workstations and rely on industry representatives to size cases for them. Although most representatives have been thoroughly trained and can be trusted to perform the job well, it is the physician's responsibility to ascertain the sizing accuracy of devices that are implanted in patients. One way of addressing this challenge is by investing the time required to learn programs such as 3mensio (Pie Medical Imaging), a software available to all of Cook Medical's clinical representatives who are willing to help physicians size cases with them rather than for them. The other option is to take advantage of TeraRecon's complimentary short-term software access. Although this is a short-term fix, we have successfully used it at our institution prior to convincing administration that purchasing the program was a worthwhile investment.

Surgical Team, Ancillary Tools, and Postoperative Care

The impact of surgeon and hospital volume on outcomes has been well documented and should not come as a surprise. Having an experienced team is extremely important for the success of an endovascular complex aortic aneurysm program. This team should not only include a creative and astute lead surgeon(s) with excellent endovascular skills, especially with visceral artery interventions, but also a dedicated support staff. At my institution, we have two techs for these cases, one of which has scrubbed nearly all of our cases and serves as the lead tech for the program. This tech's involvement is invaluable, and the program would not be what it is without him. In addition, a comprehensive inventory of wires, catheters, balloons, sheaths, and stents is key to the successful implantation of fenestrated devices. We have previously reported on a comprehensive list of helpful ancillary tools for endovascular aortic aneurysm repair.[9]

Postoperatively, the majority of patients treated with ZFEN can be admitted to the general floor, provided nurses are trained on how to care for them. This is certainly the case in our practice, where over the last 2 years, the

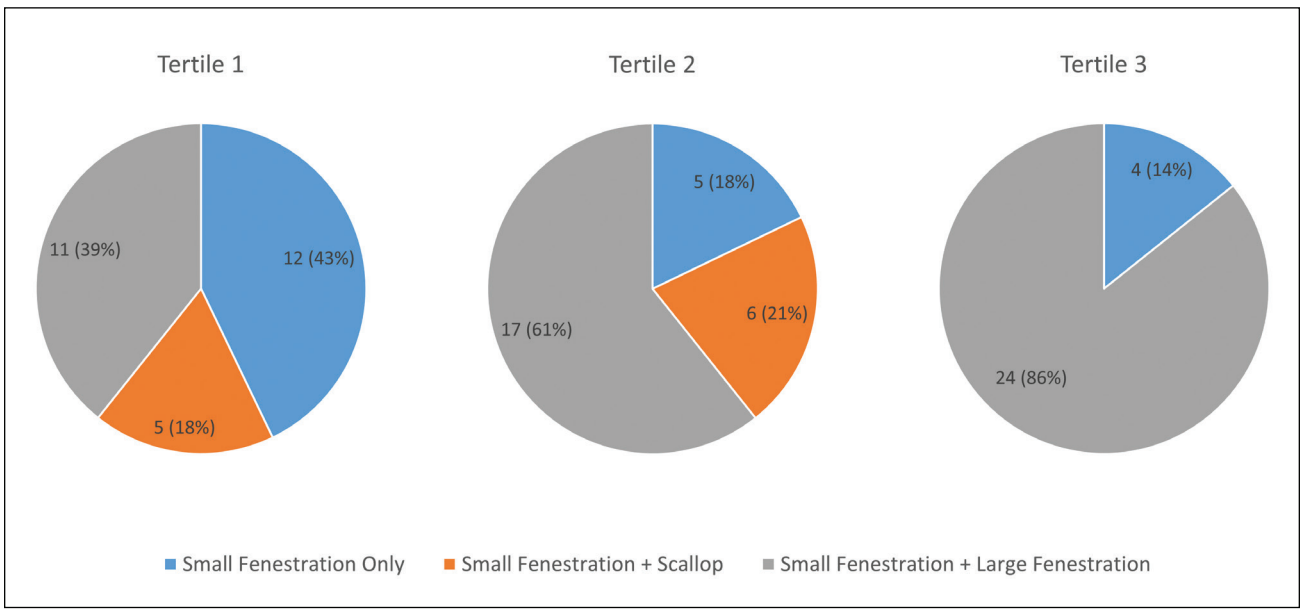

Figure 1. Pie chart showing the trend in device configurations with time in our practice. Note that over time, we have come to favor maximizing the seal zone, with fewer two-vessel fenestrations and more three-vessel fenestration configurations.

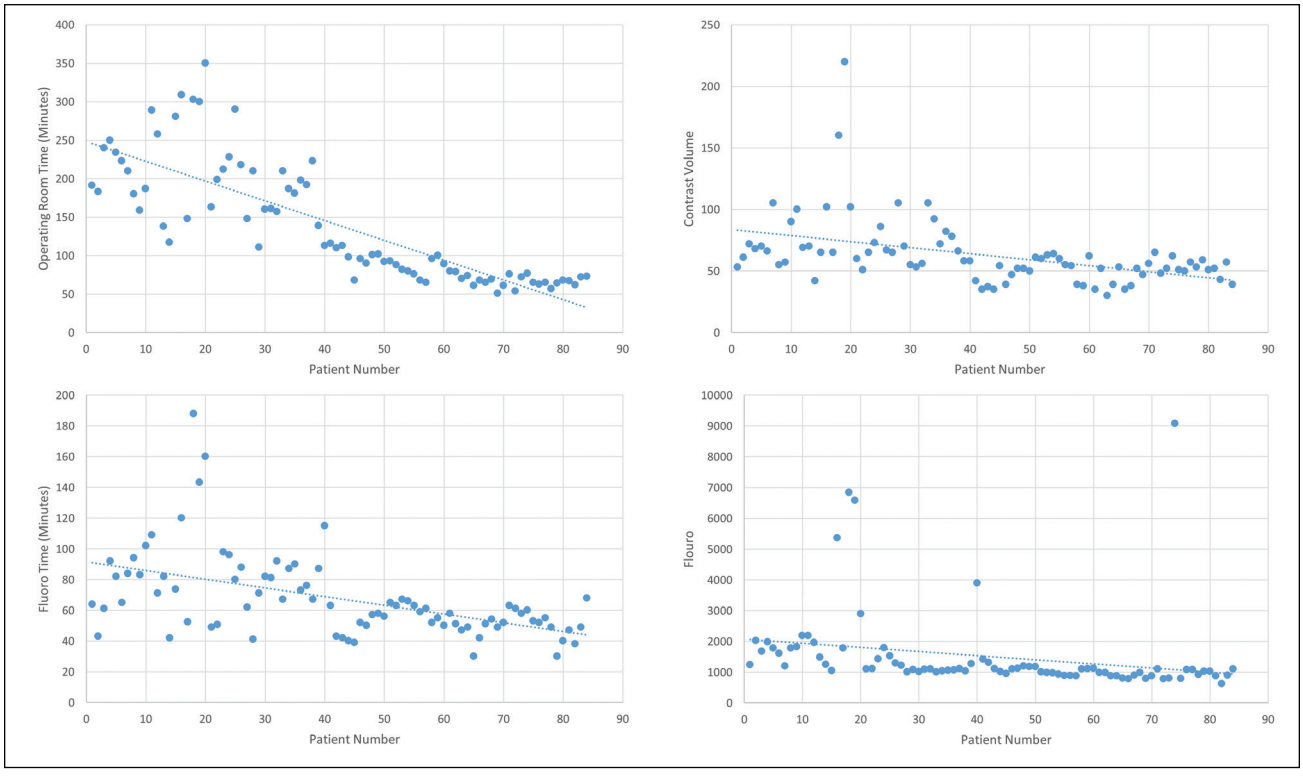

Figure 2. Scatter plots demonstrating a trend in procedure time, contrast volume, fluoroscopy time, and volume as experience was gained.

majority of our patients are admitted directly to the general floor after the repair procedure and discharged home 2 days later. Lactate, complete blood count, and basic metabolic panels are drawn postprocedure and every day that the patient is in the hospital. We prefer to keep the Foley catheter in place the first 24 hours to closely monitor urine output. Postoperative CTA of the abdomen and pelvis is performed prior to discharge in patients with normal renal function, which allows us to address any type I or III endoleaks that might have been missed intraoperatively.

THE MINNEAPOLIS HEART INSTITUTE AT ABBOTT NORTHWESTERN HOSPITAL ENDOVASCULAR PROGRAM

Like many others, we initially struggled to find ideal candidates for fenestrated stent grafts and get buy-in from partners and hospital staff. We had the great fortune of having the trust and support of our chairman who believed in our ability to build this program even though we were fresh out of fellowship. After countless talks to operating room nurses, cath lab techs, anesthesia staff, advanced practice providers, and intensive care unit and surgical floor nursing staff, we implanted the first fenestrated stent graft in Minneapolis/St. Paul, Minnesota, in December 2013—the initiation of our endovascular complex aortic aneurysm repair program.

The majority of low-risk surgical patients with complex abdominal aortic aneurysms (cAAAs) are still treated by open repair in our practice. However, since December 2013, we have endovascularly treated over 84 high-risk surgical patients with cAAAs using the ZFEN stent graft. Five patients underwent repair with local or spinal anesthesia, including one who presented with a ruptured aneurysm.[10] The mean Society for Vascular Surgery/American Association for Vascular Surgeon Comorbidity Severity Score for our cohort was 15 (range, 13–17). Fifty percent of patients were American Society of Anesthesiologists class III or IV. A total of 226 visceral arteries were incorporated in this cohort, with only one renal artery lost as a result of dissection while attempting fenestration cannulation. The majority of patients (97.6%) were discharged directly home 2 days after repair, with only two patients requiring nursing home placement. Further analysis revealed a trend in our practice: there was a move away from offering two-vessel fenestrated devices. This shift resulted in the vast majority of our patients being treated with three-vessel fenestrated devices than any other configuration (Figure 1). With

increasing experience, we noted a decrease in procedure time and radiation dose even as case complexity increased (Figure 2).

Even in this high-risk surgical group, the rate of major adverse events in our cohort was 13.1%, mortality was 2.4%, and all but two patients were discharged directly home 2 days after repair. Our outcomes are in line with contemporary reports from high-volume academic centers that have a reported 30-day mortality of 1% to 5% and a major adverse event rate of 14% in patients treated with fenestrated stent grafts.

CONCLUSION

Advances in medical therapy are enabling people with multiple comorbidities to live longer, and vascular surgeons are being tasked to care for these patients. Because community surgeons deliver the majority of vascular care in the United States, it is imperative that these physicians are equipped with tools needed to effectively care for these patients. Community vascular surgeons are increasingly embracing repair of cAAAs with ZFEN stent grafts. This technology will likely become the treatment modality of choice for all patients with suitable anatomy once it is fully disseminated. ■

1. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. J Endovasc Ther. 2001;8:3-15.
2. Greenberg RK, Haulon S, Lyden SP, et al. Endovascular management of juxtarenal aneurysms with fenestrated endovascular grafting. J Vasc Surg. 2004;39:279-287.
3. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428.
4. Perler BA. We care. J Vasc Surg. 2016;64:1197-1211.
5. Simons JP, Shue B, Flahive JM, et al. Trends in use of the only Food and Drug Administration-approved commercially available fenestrated endovascular aneurysm repair device in the United States. J Vasc Surg. 2017;65:1260-1269.
6. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg. 2013;57:926-933.
7. Martin-Gonzales T, Mastracci T, Carrell T, et al. Mid-term outcomes of renal branches versus renal fenestrations for thoraco-abdominal aneurysm repair. Eur J Vasc Endovasc Surg. 2016;52:141-148.
8. Panuccio G, Bisda T, Berekoven B, et al. Performance of bridging stent grafts in fenestrated and branched aortic endografting. Eur J Vasc Endovasc Surg. 2015;50:60-70.
9. Manunga JM, Oderich GS, Bjellum KE, Bjellum KM. Managing endovascular inventory. In: Oderich GS, ed. Endovascular Aortic Repair: Current Techniques With Fenestrated, Branched and Parallel Stent-Graft. Cham, Switzerland: Springer International Publishing; 2017:215-231.
10. Manunga J, Titus J. Regional anesthesia as the anesthetic of choice for high-risk surgical patients undergoing repair of juxtarenal aortic aneurysms with fenestrated stent grafts. J Vasc Surg. 2017;65:1820-1822.

Jesse Manunga, MD
Department of Vascular and Endovascular Surgery
Minneapolis Heart Institute at Abbott Northwestern Hospital
Minneapolis Heart Institute Foundation
Minneapolis, Minnesota
(612) 863-8900; jesse.manunga@allina.com
Disclosures: Consultant to Cook Medical.