What Is Your Preferred EVAR Device and Why?

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All seven of the commercially available abdominal aortic endograft devices perform well when used within the confines of their instructions for use. Unfortunately, unfavorable anatomy tends to present a challenge for all endovascular specialists. In these situations, a thorough knowledge of the limits of one or two endografts is essential to improve device performance. Three endograft features in particular are desirable for endovascular aneurysm repair: active proximal fixation, accurate deployment, and controlled delivery of a modular device. With that being said, the Cook Zenith Endograft (Cook Medical, Bloomington, IN) has become my workhorse aortic endograft. One of the most desirable features is the delivery system. The hydrophilic kink-resistant Flexor introducer sheath (Cook Medical) works well in very challenging iliac anatomy. The flexible sheath design, combined with the lubricious surface, facilitates device insertion and tracking while allowing a controlled deployment. The deployment mechanism of the Cook Zenith endograft promotes accurate and precise endograft placement—the graft lands where it is supposed to land. Combining accurate deployment with active suprarenal fixation facilitates abdominal aortic aneurysm (AAA) repair in patients with challenging proximal necks. Active proximal suprarenal fixation appears to minimize the risk of endograft migration and type I endoleak occurrence. The modularity of the Cook endograft expands treatment options by allowing the physician to make changes on the fly. The main body comes in various lengths (112 to 179 mm) and a wide range of diameters (22 to 36 mm). The numerous sizing options for the Zenith main body are matched by a wide variety of lengths (39 to 122 mm) and diameters (9 to 24 mm) of Spiral-Z iliac stents (Cook Medical). This combination is unparalleled for off-the-shelf treatment of AAA and iliac artery aneurysms.

Familiarity with the three-piece modular Cook Zenith endograft has expedited access to more advanced endograft devices, which include the custom-made and off-the-shelf fenestrated and branch devices. Ultimately, a thorough understanding of the benefits and limitations of one or two endograft devices creates a higher level of confidence for the implanting physician, which may improve patient outcomes.

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Dr. Ellozy has received honoraria from Medtronic, Inc.

We are currently using fourth-generation devices to treat AAAs. With more than 20 years of clinical experience with endovascular repair, the characteristics of the ideal stent graft have been identified. The optimal prosthesis needs to be durable, conformable, trackable, precise, and it must come in a broad range of diameters and lengths. Postoperative limb patency and device imaging are also important considerations. All of these factors play into the choice of graft.

When planning a case, I obtain all the measurements first. The proximal seal zone is of primary importance, and it is the first criteria I use to choose a device. I will rule out a device if I feel that it may not tolerate the tortuosity of the neck or if I am concerned about the durability of the repair. The distal seal zone is the next issue of concern. Iliac limb diameter and conformability can influence the choice of device. Once I am deciding between a limited number of devices, I will then use profile as a discriminating factor. Finally, with everything else being equal, I try to choose the device that can successfully treat the aneurysm with the fewest number of components.

At present, there are seven stent grafts that are commercially approved in the United States for the treatment of AAAs. They are, in order of approval by the FDA, the AneuRx (Medtronic, Inc., Minneapolis, MN), the Excluder (Gore & Associates, Flagstaff, AZ), the Zenith Flex AAA endovascular graft (Cook Medical), the AFX endovascular system (Endologix, Inc., Irvine, CA), the Talent AAA device (Medtronic, Inc.), the Endurant II (Medtronic,

Inc.), and most recently, the Ovation abdominal stent graft system (TriVascular, Inc., Santa Rosa, CA). All of the current devices treat straightforward anatomy very well. Personally, I think that they are all comparable in efficacy in straightforward anatomy with good access vessels.

If I had to choose only one device to have on the shelf, I would go with the Endurant II device. The 36-mm device treats up to a 32-mm neck. It has a clinical indication for a 1-cm neck, and it tolerates neck angulation very well. The delivery system is small and trackable. However, I do have two main concerns with the device. First, if there is severe tortuosity of the visceral aorta, care must be taken when removing the delivery system. Second, because the device is fairly low profile, the limbs can be deployed in calcified and stenotic iliacs. After implantation, once aneurysm exclusion is confirmed, the limbs should be ballooned from the level of their overlap in the sac down to the distal seal zone. The completion angiogram needs to be carefully analyzed for any stenosis of the limbs to avoid late limb thrombosis. Keeping these issues in mind, our institutional results with the Endurant device have been excellent overall.

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With the evolution of aortic stent graft devices over the last 20 years, it is now far easier to choose a device that is ideally suited for specific anatomic configurations. Although most patients can be treated with many of the commercially available endografts, there are particular instances when I'm biased to a specific device based on either published data, delivery profile, delivery trackability, device conformability/flexibility, accuracy of deployment, and/or anatomic constraints. My largest experience is with the Gore Excluder and Cook Zenith devices. Both have undergone generational changes over the years; however, the essential elements are largely unchanged, and both have been reliable, durable, and functional solutions for many patients.

Ultimately, the combination of anatomic factors and device features dictate the ideal stent graft choice. When faced with excessive proximal neck tortuosity, I find the Medtronic Endurant device and the Excluder to function quite well. Both deploy accurately—the Excluder with the C3 delivery system and the Endurant with the "tip capture" mechanism—and conform well to the angulation of the proximal neck, providing good wall apposition and proximal sealing. These two devices are also preferred in cases of extreme iliac artery tortuosity, and due to its delivery trackability and device conformability, I have begun to incorporate the Zenith device as well for iliac tortuosity, with the introduction of the Zenith Z-stent iliac limbs. In circumstances when the distal aortic neck is small (< 18 mm), rather than use an aorto-uni-iliac device, I prefer using the Endologix AFX stent graft system. This avoids problems with contralateral gate cannulation and kinking of two large iliac limbs. Lastly, at our institution, we perform all endovascular aneurysm repair procedures using the "preclose" technique and thus favor devices with lower profiles whenever feasible.

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The latest generation of FDA-approved devices for infrarenal AAA repair has its advantages and disadvantages based on the patient's anatomy and the clinical situation. I have used all of the available devices and usually select the Gore Excluder device (with C3 delivery system) and the Medtronic Endurant device.

The Gore Excluder device with the C3 delivery system has improved my accuracy in proximal deployment. I believe that I can be very aggressive in gaining every millimeter of aortic neck with the ability to have a "mulligan." I have been able to treat some complex anatomy knowing that I can adjust the final positioning of the device. I have used the C3 system for both proximal movement and distal movement in order to perfectly position the device based on the renal artery anatomy. Also, the device can be adjusted for ease of cannulation, but I have not used this aspect of the device very often. The long-term data associated with the Excluder are great and give me the confidence that I am providing my patients with an excellent repair.

I also enjoy the accuracy of the proximal deployment with the Endurant. This device has been an outstanding evolution of endograft technology. I think that the suprarenal fixation is valuable in certain circumstances, and I like

the fact that the device is approved to treat an infrarenal neck length of 10 mm. The delivery system is very trackable and allows me to treat difficult iliac artery anatomy, which is not true with some of the other available devices. The 2-year data are now available from the US investigational device exemption study, and they are outstanding.

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In the context of supporting a vascular residency training program, I want our fellows to get a broad-based experience that includes all of the commercially available aortic devices. This supports our goal of graduating fellows who have developed their aortic endovascular skills using a variety of devices, so they should feel confident when they enter practice. To support this philosophy at Penn, we have established and supported a corporate supply chain system that allows us to maintain a diverse inventory of aortic stent grafts on consignment, all of which are relatively aligned with regard to cost.

It is difficult to make a strong, data-driven argument favoring one EVAR device over another. All of the commercially available devices have gone through numerous iterations over time; looking at 5-year pivotal trial data has demonstrated robust clinical outcomes without indicating device superiority or inferiority.

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My first response to this question is, "Whatever graft fits the patient's anatomy best." I have always used an anatomy-directed approach for device selection and sizing to take advantage of the fact that each of the available AAA stent graft systems has certain features that make it uniquely applicable in different situations.

With that said, the Endologix AFX aortic stent graft system differs from the other approved EVAR systems in several ways. It features the only unibody main body component, in contrast to the usual two- or three-component modular design. The device is placed directly onto the aortic bifurcation, providing secure anatomic fixation, eliminating main body graft migration, and essentially relining the distal aorta and common iliac arteries. The base component is then complemented by an aortic extension cuff that is available in either an infrarenal or transrenal option that provides seal through radial force and the ability of the compliant expanded polytetrafluoroethylene (ePTFE) graft material to accommodate irregularities in the aortic wall. Fixation and seal are then addressed independently by key features of the graft system.

The AFX system handles irregular neck anatomy well with its tolerance to oversizing. The 34-mm-diameter aortic extension is approved for a ≥ 23-mm neck diameter, so the surgeon can be aggressive with oversizing in cases of reverse-tapered or ectatic, irregular neck morphology. This, combined with the compliant ePTFE fabric, allows treatment of the challenging neck with less fear of a resulting type IA endoleak. These concepts also apply to iliac ectasia and distal seal.

The prevalence of a narrow distal aorta (< 20 mm) associated with AAA may be as high as 65%. In these situations, relining the aortic bifurcation with the AFX device is more appealing than trying to squeeze two limbs side-by-side through the small calcified lumen or switching to an aorto-uni-iliac stent with a femoral-femoral bypass. Relining provides the ability to more aggressively postdilate the bifurcation to ensure an adequate-flow lumen and lower limb occlusion rates.

Finally, the main body device and aortic or iliac extensions are delivered through a single 17-F ID hydrophilic access sheath without the need for exchanges. The contralateral side is managed through a 9-F sheath that is approved for standard percutaneous access and makes AFX the lowest-profile system currently available. The system can therefore be used in patients with small, diseased iliac access vessels without the need for a conduit, especially in patients with severe asymmetric disease on one side that can be safely traversed without the need for a larger limb delivery sheath. This low-profile design and single indwelling delivery sheath also make AFX particularly well suited for percutaneous delivery (PEVAR). Recently presented results from the PEVAR trial showing favorable outcomes using a preclose technique as compared to standard femoral cutdown should provide AFX the first on-label indication for fully percutaneous EVAR. ■