

Infrarenal EVAR Technology Review

Steady evolution in device design and delivery has expanded endovascular repair to more patients, but further advancements are integral to this technology's future.

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The introduction of endovascular aortic repair (EVAR) revolutionized the care of patients with abdominal aortic aneurysms (AAAs).¹ Since then, additional studies have confirmed that procedure-related morbidity and mortality rates are significantly reduced with EVAR versus open repair.²⁻⁴

Since the first generation of endografts, progressive improvements in materials, fixation mechanisms, and delivery system profiles, as well as increased ease of use and expanded indications, have resulted in new technologies and improvements in preexisting technologies that initially proved to be flawed.⁵ In this article, we detail the various EVAR technologies that are currently or will soon be available (Tables 1 and 2).

CURRENT TECHNOLOGIES

Zenith Flex

The Zenith Flex AAA endovascular graft (Cook Medical, Bloomington, IN) is a modular bifurcated system consisting of self-expanding, stainless steel Z-stents sutured to a woven polyester graft material. The proximal uncovered stainless steel stent is barbed to provide active suprarenal fixation. The Zenith Flex device is delivered through 18- to 24-F sheaths, depending on graft size. The main body is mounted on the delivery system, and a push-pull technique allows for precise graft deployment with repositioning until the top-cap housing the suprarenal fixation stent has been

deployed in a separate step from main body deployment. The contralateral limb is cannulated, and iliac extensions are introduced to complete sealing. Zenith Flex is approved for use in patients with a minimal 15-mm infrarenal neck and angulation of $\leq 60^\circ$.⁶

Endurant

The Endurant AAA stent graft (Medtronic, Inc., Minneapolis, MN) is a modular bifurcated stent graft system composed of super-elastic nitinol stents secured to a high-density polyester fabric. Delivery and deployment of Endurant via the unique hydrophilic delivery system does not require an additional delivery sheath, and the system features a tip capture mechanism that enables precise positioning adjustments after deployment of up to three stent rings and enables controlled release of the suprarenal stent and anchor pins. The iliac limbs come in flared and tapered options, and the individual stents making up the main body and limbs are shorter for improved conformability. Endurant is approved for infrarenal necks measuring at least 10 mm and $\leq 60^\circ$ angulation.

Excluder

The Excluder AAA endoprosthesis (Gore & Associates, Flagstaff, AZ) is a modular bifurcated system composed of a helical construct of nitinol wire secured to an expanded polytetrafluoroethylene (ePTFE) and

fluorinated ethylene polypropylene graft. The system has active infrarenal fixation in the form of nitinol anchors and a proximal sealing cuff. The new C3 delivery system is designed to be a three-step process with the option for repositioning after deployment but before release of the active fixation stent. The Excluder device is approved for infrarenal necks measuring at least 15 mm and $\leq 60^\circ$ angulation.

AFX

The AFX Endovascular AAA System (Endologix, Inc., Irvine, CA) is built on the proven concept of anatomical fixation, wherein the bifurcated graft rests on the aortoiliac bifurcation. The proximal extension seals the aortic neck due to the radial force of the stents (traditional seal) and also due to an enhanced seal, called ActiveSeal. AFX is the only AAA device with stents

TABLE 1. CURRENT FDA-APPROVED DEVICES













Product Image	Device Name	Method of Measure	Available Main Body Sizes (Vessel Size Treated)	Available Iliac Limb Sizes (Vessel Size Treated)	Main Body Delivery Sheath Size	Fixation	Stent/Graft Material
	Zenith Flex (Cook Medical)	Outer-to-outer diameter	22–36 mm (18–32 mm)	8–24 mm (< 8–20 mm)	18–22 F	Active suprarenal	Stainless steel/polyester
	AFX (Endologix, Inc.)	Inner-to-inner diameter	22–34 mm (18–32 mm)	16–25 mm (10–23 mm)	17 F; 9 F contralateral	Anatomic fixation at bifurcation	Cobalt chromium/Strata (multilayer ePTFE)
	Endurant (Medtronic, Inc.)	Outer-to-outer diameter	23–36 mm (19–32 mm)	10–28 mm (8–24 mm)	18–20 F outer diameter	Active suprarenal	Nitinol/polyester
	Excluder (Gore & Associates)	Inner-to-inner diameter	23–31 mm (19–29 mm)	10–27 mm (8–25 mm)	18–20 F	Active infrarenal	Nitinol/ePTFE
	Ovation ^a (TriVascular, Inc.)	Inner-to-inner diameter	20–34 mm (16–30 mm)	10–22 mm (8–20 mm)	14–15 F	Active suprarenal; infrarenal sealing rings	Nitinol/PTFE
^a Humanitarian device exemption only.							

TABLE 2. EVAR DEVICES NOT YET AVAILABLE IN THE UNITED STATES^a

Product Image	Device Name	Method of Measure	Available Main Body Sizes (Vessel Size Treated)	Available Iliac Limb Sizes (Vessel Size Treated)	Main Body Delivery Sheath Size	Fixation	Stent/ Graft Material
	Zenith Low Profile (Cook Medical)	Outer-to-outer diameter	22–36 mm (18–32 mm)	10–24 mm (8–20 mm)	16–17 F	Active suprarenal	Nitinol/ polyester
	Fortevo Endograft With HeliFX EndoAnchors ^b (Aptus Endosystems, Inc.)	Inner-to-inner diameter	22–32 mm (19–29 mm)	11–22 mm (9–20 mm)	16–18 F	Active endo-anchor infrarenal	Nitinol/ polyester
	Incraft (Cordis Corporation)	Outer-to-outer diameter	22–34 mm (17–31 mm)	10–24 mm (7–22 mm)	13 and 15 F	Active suprarenal	Nitinol/ polyester
	Treovance (Bolton Medical, Inc.)	Outer-to-outer diameter	20–36 mm	8–24 mm	18–19 F	Active suprarenal and infrarenal	Nitinol/ polyester
	Anaconda One-Lok (Vascutek Ltd.)	Inner-to-inner diameter	21.5–34 mm (17.5–31 mm)	10–23 mm (8.5–21 mm)	20–23 F (OD)	Infrarenal (with fixation hooks)	Nitinol/ polyester/ tantalum
	Aorfix (Lombard Medical Technologies)	Inner-to-inner diameter	Maximum 33 mm	Maximum 22 mm	22 F	Active	Nitinol/ polyester
	Nellix (Endologix, Inc.)	N/A	16–36 mm	8–35 mm	17 F	Complete aneurysm sac sealing	Cobalt chromium/ biostable PEG-filled sacs

^aInvestigational devices. Limited by Federal (or United States) law to investigational use.

^bNote: HeliFX EndoAnchors available separately and approved for use with AneurX, Endurant, Talent, Excluder, and Zenith.

(made of cobalt-chromium) on the inside of the graft material. They are stitched only at the proximal and distal ends to allow movement of the graft material outside of the stents.

ActiveSeal is achieved because of the independence of the stent from the conformable STRATA ePTFE graft material, which apposes the vessel lumen under blood pressure, to provide more wall contact. The AFX delivery system is a major enhancement of the IntuiTrak delivery system that makes the implant procedure easy. For all sizes available, delivery is via a 17-F hydrophilic introducer sheath (19 F OD) with a novel valve for improved hemostasis. The device delivery system allows for unilateral cutdown and 9-F contralateral percutaneous access. While AFX is currently available in the US and in Europe, the IntuiTrak system with the Powerlink graft is available in rest of the world.

Ovation

The Ovation abdominal stent graft system (TriVascular, Inc., Santa Rosa, CA) is still under investigation but is approved for use in the United States under a humanitarian device exemption. The device is a bifurcated trimodular system composed of nitinol stents and PTFE graft material. The main body is delivered via a 14- to 15-F (OD) sheath and has active suprarenal fixation. Rings in the proximal sealing zone are inflated with a polymer to achieve a robust infrarenal seal that conforms to thrombus and/or calcium in the aortic wall. The main body is available for treating necks as small as 16 mm and as short as 7 mm. The ultra-low-profile delivery system allows patients with small-caliber vessels to undergo EVAR when clinically indicated.

WHAT IS ON THE EVAR HORIZON?

Lower-Profile Devices

Zenith Low-Profile

Currently under investigation, Cook Medical's Zenith low-profile AAA endovascular graft has a 16-F introducer system and is constructed using nitinol stents, as opposed to stainless steel, with a thinner polyester graft material. In the low-profile system, the suprarenal fixation stent is no longer contained within a top cap, which is meant to simplify delivery and minimize top cap recapture complications, such as proximal graft disruption.⁶ The active suprarenal fixation of the previous Zenith device is the same, but the 16-F delivery allows EVAR to be considered in patients with iliac lumens as small as 6 mm.

Incraft

The Incraft ultra-low-profile AAA system (Cordis Corporation, Bridgewater, NJ), also under investigation

in the United States, is mounted on a 13- to 15-F integrated delivery system. The graft is composed of 1-cm nitinol stent rings and low-porosity polyester graft material. It is a three-piece modular bifurcated system with an active suprarenal fixation stent not contained in a separate top cap. The graft has the unique capability of in situ length adjustment up to 2 to 3 cm bilaterally and an active locking mechanism between the main body and limbs to minimize type III endoleaks.

Challenging Anatomy

Additional investigational technologies have focused on eliminating the need for secondary procedures that have been demonstrated to add cost to the endovascular approach.⁷ These technologies also seek to address patients who currently fall out of the realm of the "acceptable endovascular candidate," either due to infrarenal necks < 15 mm, angulation > 60°, or if the diameter of infrarenal aorta is not compatible with the smallest available devices (ie, 18 mm by AFX) or exceeds the largest of the commercially available implantable devices (currently the 36-mm Zenith and Endurant grafts).

Treovance

The Treovance device (Bolton Medical, Inc., Sunrise, FL) offers both suprarenal and infrarenal active fixation and a self-described highly flexible design meant to conform to tortuous anatomy and improve fixation in highly angulated necks. The graft is a modular bifurcated design composed of nitinol stents sutured to woven polyester. It is unique in its design in that it allows treatment of necks as short as 10 mm, if angulated ≤ 60°, and can treat up to 75° of angulation in necks that are at least 15 mm long. The delivery system is 18- or 19-F in outer diameter. The device within has a separate clasp mechanism that holds the barbed suprarenal stent, allowing for repositioning after deployment until the clasp is released. The stent graft has barbs for infrarenal active fixation in addition to the suprarenal fixation.

Anaconda One-Lok

The Anaconda One-Lok AAA stent graft system (Vascutek Ltd., Inchinnan, United Kingdom) is currently an investigational device in the United States. It is composed of a short bifurcated body with infrarenal fixation by the means of eight hooks. A range of contralateral and ipsilateral iliac leg configurations can be subsequently docked into the bifurcated body to treat a range of anatomies. Cannulation is facilitated by a preloaded wire and magnet system.

Aorfix

The Aorfix device (Lombard Medical Technologies, Oxfordshire, UK) is composed of nitinol rings on a polyester graft fabric. The neck is “fishmouthed” for the potential of transrenal placement and barbed to allow for active fixation. The proximal seal zone is 8 mm, and the circumferential rings increase conformability. The device is currently in trial (PYTHAGORAS) to evaluate its use in highly angulated necks up to 90°. The limbs are designed to actively interlock with the main body to simulate a one-piece graft once completed.

Fortevo

Addressing what can be the Achilles’ heel of EVAR for infrarenal aortic aneurysms, the Fortevo AAA endograft system (Aptus Endosystems, Inc., Sunnyvale, CA) uses the HeliFX Aortic Securement System (Aptus Endosystems). Endoanchors introduced separately from the main device secure the proximal fixation site to mimic the securement of the surgical anastomosis in open repair. Each anchor is a single piece of MP35N LT (nickel, cobalt, and chrome) with a conical tip meant to mimic an SH1 needle tip. Each anchor measures 4.5 mm in length X 3 mm in diameter. The Fortevo is a modular bifurcated graft system with positive interlocking iliac limbs, all composed of nitinol stents and a low-porosity polyester graft material.

A case series from The Netherlands also demonstrated the successful use of the anchoring device in a secondary procedure to treat type I endoleaks, as well as the compatibility of the device for use across multiple endograft devices.⁸ The ANCHOR (Aneurysm Treatment Using the HeliFX Aortic Securement System Global Registry) is currently being compiled with investigators in Europe and the United States.

Nellix

The Nellix endovascular system (Endologix, Inc.) is an investigational endovascular aneurysm sealing (EVAS) system addressing a broad array of patients including those with proximal neck anatomy deemed unsuitable for currently available endovascular devices due to juxtarenal or pararenal aneurysmal changes. EVAS represents the next generation of AAA therapy and is intended to treat more anatomies than currently approved endovascular stent graft devices. It is the only technology whose operating principle is centered on sealing the entire aneurysm sac. The Nellix device consists of cobalt chromium stents delivered via 17-F sheaths. Around the stents are sacs that are subsequently filled with biostable polyethylene glycol material that forms to seal the aneurysm sac. The anatomical

Endografts on the horizon propose interesting improvements in profile, fixation, and aneurysm exclusion.

requirements for patients to be enrolled in the clinical investigations include neck length \geq 5 mm, neck diameter of 16 to 36 mm with maximum aortic blood flow lumen diameter of \leq 60 mm, and common iliac artery diameter of 8 to 35 mm.

CONCLUSION

Arguably the endovascular era is still in its infancy. As medical technologies evolve, vascular surgeons will tackle a greater number of challenging anatomies with greater durability. Demonstrated here are a number of advanced technologies offering solutions to challenging anatomy. Still available are the workhorse grafts that provide a broad range of solutions; however, endografts on the horizon propose interesting improvements in profile, fixation, and aneurysm exclusion. ■

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