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Initial Experience With AFX

Advanced Anatomical Fixation

BY MATTHEW JUNG, MD

Over the last decade, endovascular technologies have brought significant benefits to thousands of patients with abdominal aortic aneurysms (AAAs) around the world. Each year, with new advances in endovascular aneurysm repair (EVAR) devices, outcomes continue to improve, and more patients are successfully treated.

The newest advance in EVAR technology comes from Endologix, Inc. (Irvine, CA) with the introduction of the AFX endovascular AAA system that was recently approved by the US Food and Drug Administration for commercial use in the United States. With a low-profile hydrophilic sheath, next-generation expanded polytetrafluoroethylene (ePTFE) graft technology, and a precise deployment mechanism for accuracy, the device system offers a promising new technology for EVAR patients. As the name implies, AFX is based on the proven concept of anatomical fixation, which has been shown to provide exceptional clinical outcomes while preserving the aortoiliac bifurcation.¹

We describe our initial results using the AFX endovascular AAA system for EVAR.

DEVICE DESCRIPTION

The stent graft is constructed of a cobalt chromium alloy self-expanding stent with STRATA ePTFE graft material. STRATA is produced using proprietary technology that results in a highly conformable and durable material that facilitates aneurysm sealing. The material was originally developed for the Endologix Ventana™ fenestrated stent graft (an off-the-shelf device restricted to investigational use only and not approved for commercial use in the United States or internationally). Based on the exceptional properties of this material in bench and nonclinical testing, its application was extended to AFX for use in the endovascular repair of infrarenal aneurysms. Unlike other commercially available EVAR devices, the graft material is attached only at the proximal and distal ends of the stent. This design allows the graft material to move independently from the stent, thereby conforming to the aortic anatomy and extending into the proximal and distal seal zones as illustrated in Figure 1.

AFX is provided in a variety of diameters and lengths to treat aortic necks from 18 to 32 mm in diameter and

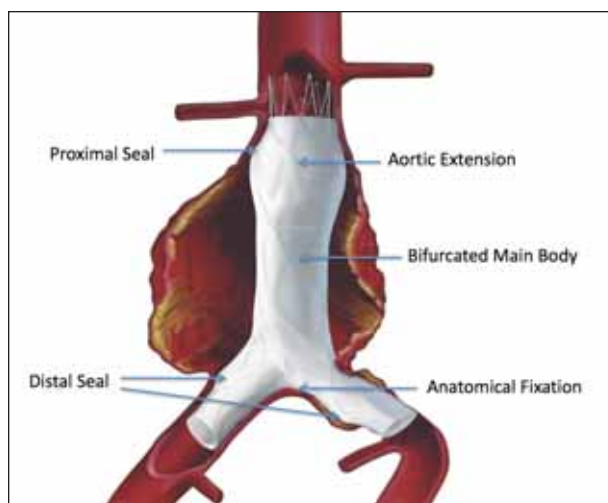


Figure 1. Principle of seal with STRATA ePTFE.

common iliac arteries from 10 to 23 mm in diameter. All of the stent grafts are delivered on the ipsilateral side through a 17-F hydrophilically coated introducer sheath and dilator. Unique to this device, the contralateral limb is precannulated and accessed with a 9-F sheath, which is beneficial for patients with limited or difficult access on one side. The aortic extensions are available in infrarenal and suprarenal configurations and are delivered using a deployment dial feature that allows precise placement.

CASE STUDY

An 80-year-old man presented with a history of hypertension, prostate disease, and surgical brain tumor resection. Computed tomography (CT) angiography revealed a saccular AAA measuring 55 mm in diameter with an aortic neck diameter of 19 mm (Figure 2). The lengths of the aortic and most caudal renal artery to aortic bifurcation were 19 and 85 mm, respectively. Notably, this patient had a high-grade stenotic lesion in the right common iliac artery (Figure 3). Under general anesthesia, using a retrograde puncture of the left common femoral artery, a 0.035-inch angled Glidewire (Terumo Interventional Systems, Somerset, NJ) was passed, and a 9-F sheath (Terumo Interventional Systems) was placed for contralateral access. The right common femoral artery was accessed surgically, and a 0.035-inch AUS 2

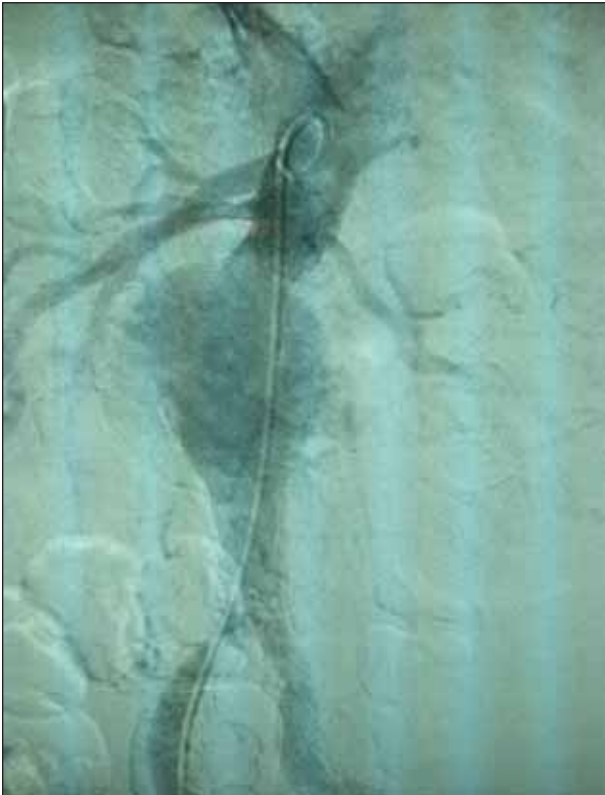


Figure 2. Intraoperative angiogram showing the complete AAA anatomy.

guidewire (Cook Medical, Bloomington, IN) was placed in the aorta. Intraoperative arteriography was used to confirm CT scan measurements. The repair was planned with a 22-mm AFX bifurcated stent graft having 60-mm body length and 40-mm limb length and a 25-mm AFX suprarenal aortic extension having 75-mm covered length. Upon heparin administration, the 17-F AFX introducer system was advanced over the guidewire into the right femoral access site. Despite the presence of the stenotic lesion, access was uneventful, and the introducer sheath was easily maneuvered past the bifurcation and into the aorta.

The AFX bifurcated device was prepared and advanced over the guidewire into the hemostasis valve of the introducer sheath and into the aorta. The contralateral limb wire was also advanced through the introducer sheath and guided over the aortic bifurcation to create a crossover, a key attribute of the anatomical fixation method. After unsheathing, the bifurcated stent graft was deployed at the bifurcation using the control cord mechanism. The delivery system was removed, leaving the introducer sheath in place.



Figure 3. Intraoperative angiogram showing the high-grade stenosis of the right common iliac artery.

Balloon angioplasty of the right limb and common iliac artery was performed using a 12-mm X 4-cm balloon (Cordis Corporation, Bridgewater, NJ) before introduction of the proximal extension delivery system. The extension was precisely deployed at the intended infrarenal location. The extension delivery system was removed and exchanged for another 12-mm X 4-cm balloon that was used for balloon angioplasty of the stent graft junction with the iliac arteries. Final angiography (Figure 4) revealed no endoleaks and excellent seal proximally and distally. All visceral arteries remained widely patent. The left femoral percutaneous access site was closed with a StarClose closure device (Abbott Vascular, Santa Clara, CA).

All wires and sheaths were removed, and the right femoral artery and groin incision were closed using the standard technique. Heparin effect was reversed with protamine sulfate. Because this was our first case using the AFX system, we took great care in verifying and reverifying positioning and device deployment at each step. The fluoroscopy time was 18 minutes with a volume of 139 mL of contrast media used; the total proce-



Figure 4. Final intraoperative angiogram showing vessel wall conformability and proximal seal with STRATA ePTFE.

duration time was 116 minutes. The patient tolerated the procedure well and was discharged from the hospital on postoperative day 1 with no adverse events reported to date. He resumed work in 4 days and is enjoying an active lifestyle as a small business owner.

DISCUSSION

We have extensively used anatomical fixation for the treatment of a variety of AAA anatomies with excellent short- and long-term success rates. This implantation technique provides device stability while preserving the aortic bifurcation for future crossover endovascular interventions. This is significant because the concomitant finding of lower limb occlusive disease has been reported in 20% to 40% of patients presenting with AAAs.² Although technology advances in delivery systems and device availability have occurred in recent years, the AFX system provides further unique clinical benefits.

The conformability of the STRATA graft material is seen in the sealed proximal neck, which is achieved without the need for ballooning. This is illustrated in an intravascular ultrasound image (Figure 5) in which the

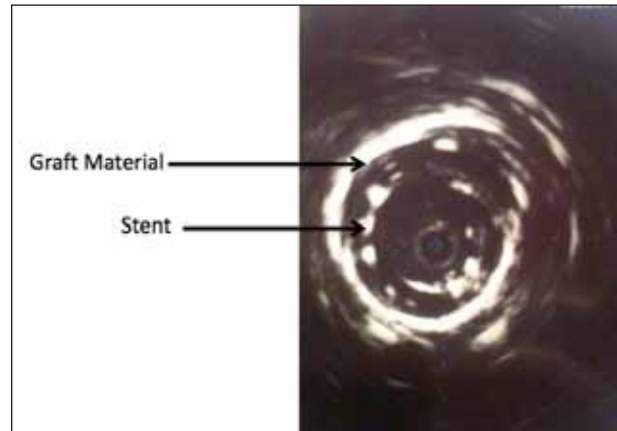


Figure 5. Intraoperative intravascular ultrasound imaging showing the unique sealing characteristics of the STRATA ePTFE.

graft material is observed to conform to the aortic anatomy while the stent is constrained in a narrow section just above the aortic bifurcation. We theorize that the ability of the graft material and stent to work independently may provide greater graft wall contact and enhancement of seal zones.

Also noteworthy was the achievement of access using the introducer system in an artery having a high-grade stenotic lesion. The combination of lower-profile, hydrophilic coating, and pushability design features made this portion of the case very simple. Lastly, the precise deployment of the proximal extension was made possible by the new dial mechanism, which is a very nice upgrade from the previous system.

SUMMARY

The AFX endovascular AAA system provides new design features that performed very well in our initial clinical experience. In particular, we believe that this low-profile 17-F introducer system and STRATA graft material could have a very positive effect on the treatment of AAA patients. Broader clinical experience is needed to further evaluate the application of the AFX system, a third-generation device in AAA repair. ■

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1. Carpenter JP, Garcia MJ, Harlin SA, et al. Contemporary results of endovascular repair of abdominal aortic aneurysms: effect of anatomical fixation on outcomes. *J Endovasc Ther.* 2010;17:153-162.
2. Axelrod DA, Diwan A, Stanley JC, et al. Cost of routine screening for carotid and lower extremity occlusive disease in patients with abdominal aortic aneurysms. *J Vasc Surg.* 2002;35:754-758.