

The Staying Power of Anatomical Fixation and ActiveSeal™ Endograft Architecture

In the unforgiving environment of the abdominal aorta, Endologix technology stands the test of time.

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Since the introduction of endovascular repair and the associated improvement in perioperative morbidity and mortality when treating patients with abdominal aortic aneurysms (AAAs), matching the long-term durability of the repair to that of open surgical procedures has remained a clinical and technological challenge.

Furthermore, migration, endoleaks, and occlusions drive the need for long-term postoperative surveillance and secondary interventions, offsetting the initial benefit of endovascular repair. The abdominal aorta accepts approximately 70% of the cardiac output, and the resultant forces produce a hostile and dynamic environment for any endoprosthesis.

Commonly used endograft designs with shorter bifurcated bodies and longer iliac limbs elevate the flow divider from the native bifurcation, subjecting the endograft to caudal and lateral migration forces mid-aneurysm^{1,2} and increasing hemodynamic impedance of the aorta.³ Use of active fixation elements (e.g., hooks and barbs) in endograft designs significantly reduces the incidence of outright migra-

tion failures, but requires careful consideration of the aortic neck anatomy and endograft oversizing.^{4,5}

The radial force induced by oversizing is critical for establishing proximal seal in most of the endograft systems, yet the effect of that force on progressive neck dilation and risk of type Ia endoleaks remains a subject of controversy.^{4,6} The presence of a narrow distal aorta creates yet another challenge in accommodating two competing iliac limbs, creating conditions for iliac limb kinking, infolding, and subsequent distal occlusions.

ANATOMIC FIXATION FOR PREVENTION OF PROXIMAL MIGRATION

An alternative endograft architecture has been proposed by Endologix. In clinical use in Europe since the late 1990s,^{7,8} Endologix endografts gained US Food and Drug Administration approval in 2004 and are now available under the AFX® trademark. The AFX system consists of bifurcated unibodies with short, integrated iliac limbs; suprarenal and infrarenal proximal endografts; and straight, stepped, or tapered iliac limb extensions (Figure 1). The implant is delivered using a dedicated 17-F introducer sheath on the ipsilateral side and an auxiliary 9-F introducer sheath on the contralateral side.

The Endologix system was clinically validated and obtained a specific indication for bilateral percutaneous EVAR based on the results of the only prospective, multi-center, randomized trial comparing the safety and effectiveness of percutaneous EVAR versus the surgical cutdown approach.⁹ All AFX endografts feature a high-columnar-strength cobalt chromium stent frame with highly conformable multilayer expanded polytetrafluoroethylene material external to the stent.

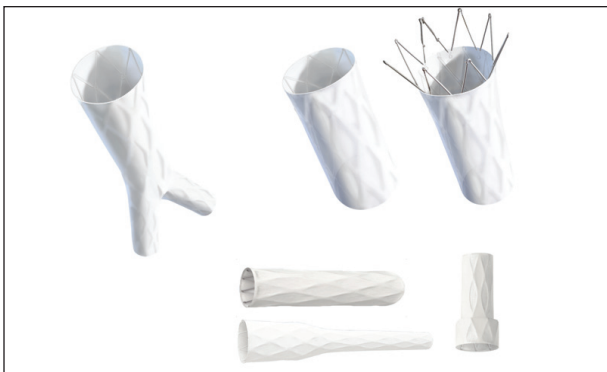


Figure 1. The AFX portfolio.



Figure 2. Postoperative CT scan showing the AFX System placed on the narrow aortic bifurcation.

The flow divider of the bifurcated component of the AFX system is placed directly on the native aortic bifurcation (Figure 2), using what has become known as anatomic fixation to counter migration forces acting at the bifurcation (Figure 3).² The columnar strength of the bifurcated and proximal endograft stents transfers support at the bifurcation to the aortic neck, inhibiting proximal migration and development of type Ia endoleaks. A dramatic effect of anatomic fixation on migration and endoleak development was observed in early European experience⁸ and was reconfirmed in a large cohort of the US Food and Drug Administration pivotal trial patients, with up to 5-year follow-up.¹⁰ There were no migrations, conversions to open repair, AAA ruptures, or aneurysm-related deaths. The aneurysm sac diameter decreased or remained stable in 93% of the patients (Figure 4).

Obviation of the contralateral gate cannulation step during deployment of the AFX system also makes it uniquely suitable in cases of saccular and bilobed aneurysms, as well as in anatomies with narrow distal aortas, where this step becomes technically challenging, if not unfeasible. The presence of the single graft lumen in narrow distal anatomies, as well as the fully supported iliac limbs with highly conformable graft material on the outside of the stent, are the most likely explanations for the extremely low 1.3% rate of distal occlusions observed in clinical trials.¹⁰ With 17% to 25% of the patients undergoing EVAR presenting with concomitant peripheral arterial disease,^{11,12} the probability of subsequent peripheral interventions in this patient group remains nontrivial. Preservation of the native aortic bifurcation using the AFX bifurcated unibody enables performing such interventions

Migration Forces of Fixation Designs for Infrarenal EVAR

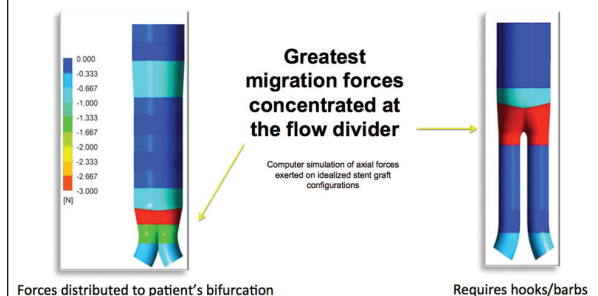


Figure 3. Phase I report: computer simulation of axial forces exerted on idealized stent graft configurations.¹³⁻¹⁵

using a traditional crossover technique, rather than a more challenging antegrade approach (Figure 5).¹⁶

ACTIVESEAL IN PROXIMAL AORTIC NECKS

The inhibition of proximal migration by anatomic fixation of the bifurcated unibody on the native bifurcation allows optimization of the proximal endograft design for sealing performance. In the AFX system, this is accomplished by placing the highly conformable multilayer expanded polytetrafluoroethylene graft material external to the stent and restricting attachment locations to the top and the bottom of the stent frame. When the stent frame is compressed within the proximal (as well as distal) landing zone, the material can move independent of the stent and conform to the arterial wall under the gradient between the aorta and the excluded sac, effectively extending the graft-wall apposition, as is often observed on completion angiography. The ActiveSeal concept has recently been quantified in terms of the apposition seal length and total apposition surface area in a core lab analysis of 37 patients from the retrospective observational cohort at two United States centers.¹⁷ In that analysis, the effective seal length exceeded the anatomic neck length in 54% of the patients by an average of 5.1 mm. Importantly, along with the anatomic neck length, the apposition surface area was the only additional

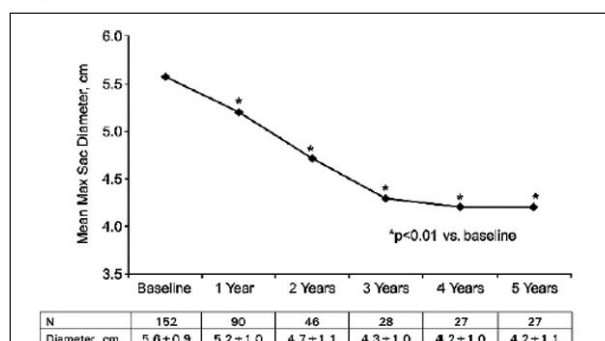


Figure 4. Aneurysm sac changes in an anatomic fixation cohort. Adapted from Carpenter et al, *JVS*, 2010.¹⁸

(Courtesy of Zvonimir Krajcar, MD.)

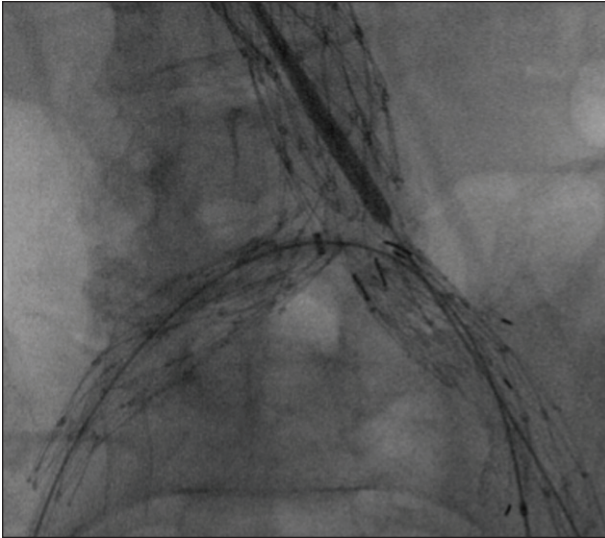


Figure 5. The crossover access technique through the AFX bifurcated unibody.

statistically significant univariate predictor of early sac regression.

Contrary to the common misconception, the ActiveSeal effect relies on the compression of the stent frame rather than distention of the graft material, which is both highly stable (< 5% distensibility) and highly impermeable. The radiographic appearance of ActiveSeal endografts on intra-procedural and follow-up imaging is somewhat unusual and may require the education of the radiology staff. The latest generation of the Endologix ActiveSeal design, the VELA™ Proximal Endograft, has recently been released in the United States and features a fully circumferential radiopaque marker sewn into the proximal edge of the graft material, adding further distinction to the unique appearance and properties of the device.

With graft material external to the stent and radial forces calibrated to optimize the ActiveSeal effect without concerns for migration, the VELA endograft allows for the broadest range of oversizing and the fewest number of the distinct graft diameters to cover the entire spectrum of treatable aortic necks (Table 1). In addition to inventory management ramifications, the liberal oversizing guidelines provided by the device instructions for use enable on-label treatment of necks with significant change of the diameter along the length, including reverse conical, thrombotic/calcified, and irregular necks. The high prevalence of such anatomies in routine practice, as well as a recent observational cohort,¹⁷ warrants strong consideration of Endologix technology in many of those patients.

SUMMARY

The last 20 years have witnessed a revolution in endovascular treatment of patients with AAAs, with many endograft concepts emerging and disappearing from the

TABLE 1. RECOMMENDED OVERSIZING FOR PROXIMAL COMPONENTS FROM DIFFERENT ENDOGRAFT MANUFACTURERS

	Proximal Size (mm)	Aortic Diameter (mm)																
		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Endologix® VELA™ Proximal Endograft System	25																	
	28																	
	34																	
Medtronic Endurant® Stent Graft System	23																	
	25																	
	28																	
	32																	
Gore Excluder® AAA Endoprosthesis	23																	
	26																	
	28.5																	
	31																	
	35																	
Cook® Zenith Flex® AAA Endovascular Graft	22																	
	24																	
	26																	
	28																	
	30																	
	32																	
TriVascular® Quition Prime™ Abdominal Stent Graft System	20																	
	23																	
	26																	
	29																	
	34																	

clinical landscape. The abdominal aorta is an unforgiving environment, and only select designs have proven staying power. The safety and effectiveness of the unique endograft architecture developed by Endologix has been studied in six multicenter, prospective clinical trials, involving more than 790 patients treated at both community and academic centers. As new evidence and design refinements continue to emerge, the basic principles of active fixation and ActiveSeal will find growing acceptance in the clinical community and utility in broad patient populations. ■

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