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ANATOMIC FIXATION AND *ACTIVESEAL*TM

The Decade of Advancements
in Endovascular AAA Repair

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Technological Advances in Abdominal Aortic Aneurysm Treatment With Anatomic Fixation and ActiveSeal™ Platform

BY DAVID H. DEATON, MD

CHIEF MEDICAL OFFICER, ENDOLOGIX, INC. (IRVINE, CA)



Anatomic fixation has become the calling card of Endologix's AFX® system for treating abdominal aortic aneurysm repair. This technique provides two distinct advantages. First, the distractive or longitudinal migration force on aortic endografts occurs

largely as a result of the bifurcation of the endograft. By seating the endograft on the native bifurcation, this force is directly transferred to the patient's aorta at the bifurcation rather than to the aortic neck. As a result, the design of the endograft in the aortic neck can be solely focused on the other primary requirements of proximal sealing. Second, the advantage of preserving the native bifurcation allows future contralateral access for lower extremity intervention in patient populations with frequent comorbid infrainguinal occlusive disease. The articles in this supplement exemplify the benefits offered by Endologix's AFX Endovascular AAA System and VELA™ Proximal Endograft systems for abdominal aortic aneurysm repair.

In the first article, Jeffrey P. Carpenter, MD, explains the history and evolution of Endologix devices and how they changed the paradigm for modular endografts from iliac extension to proximal aortic extension, thus retaining the native bifurcation and allowing for proximal endograft designs focused on accuracy and sealing. He also touches on another primary innovation—attaching the graft material only at the top and bottom of the stent frame outside the stent. As a result, the graft material is free to conform to the aortic wall in a broad range of anatomies without the impediment of stent design or configuration. The introduction of the multilayer ePTFE material in the AFX device expanded the ability of the Endologix endograft platform to conform to the heterogeneity of mural disease and nongeometric anatomy that is frequently found in diseased aortas.

The evolution of the endograft design and the conformability of the fabric formed the foundation for ActiveSeal™ technology. ActiveSeal addresses the critical importance of a robust seal in the proximal neck to ensure adequate and definitive aneurysm exclusion. It incorporates both the original design of unrestricted fabric that is free to conform to the wall with the development of multilayer PTFE material with increased, “liquid-like” conformability to the aortic wall. This development further enhanced the ability to conform to the macroscopic effects of atherosclerotic disease on aortic geometry (i.e., noncircular lumens) and the more local effects caused by plaque irregularity and heterogeneity (i.e., ulceration, nonsmooth plaque surfaces, calcification).

Next, Raghu L. Motaganahalli, MD, and Alok K. Gupta, MD, discuss how to overcome thrombus-laden necks. Many current endograft instructions for use warn against use in thrombus-laden necks due to the effect of thrombus on fixation in devices requiring proximal neck fixation and its impact on oversizing and the potential to accelerate proximal neck dilatation. The AFX device avoids these potential impediments through its freedom from the requirement of proximal neck fixation and a wire-form stent structure that incorporates relatively low radial force over a broader range of diameters than other designs. Drs. Motaganahalli and Gupta outline the rationale for using AFX in thrombus-laden necks. By sizing the endograft to the true diameter of the aorta, regardless of the thrombus effect on blood flow lumen diameter, the natural history of thrombus resorption can occur gradually, with the stent “following” the thrombus resorption until it eventually reaches the tissue of the aortic wall. The lower reliance on radial force to establish a proximal seal also means that the thrombus is not disrupted during endograft implantation, avoiding intraoperative

embolization of the renal arteries or other critical arterial beds.

This article also discusses how the VELA proximal endograft continues the development of the original Endologix construct of aortic modularity by adding more precision during deployment. It accomplishes this goal through two different mechanisms. First, the new delivery system with the unique deployment mechanism provides the operator with a high degree of proximal and distal control over the endograft position, thus avoiding “blow back.” Second, the new proximal radiopaque marker band at the leading edge of the fabric gives a true three-dimensional insight into the graft positioning, and C-arm orientation. The multilayer ePTFE material on the VELA endograft extends the seal zone beyond what appears to be the “neck” on CT or angiography, thus capturing more surface area in the proximal sealing zone and enhancing integrity of the seal.

In the next article, Kenneth Ouriel, MD, reviews emerging clinical evidence on the performance of the AFX Endovascular AAA System and the impact of the ActiveSeal endograft design. These studies demonstrate not only a 360° circumferential seal throughout the seal zone, but an extension of 360° seal into the aneurysm itself. Some degree of graft oversizing is a requirement for effective sealing in all endograft technologies. The implication is that in treating a 22-mm neck with a non-ActiveSeal 26-mm graft, the fabric will only seal in the oversized zone, as it is limited by the constrained stent structure (to which it is attached) from “following” the aortic diameter out to the full diameter of the endograft in areas of neck irregularity or taper. However, the highly conformable ePTFE material of the AFX system is not restricted by the stent structure and can “float” out to the nominal 26-mm diameter. This effectively provides a more comprehensive seal due not only to the conformability of the fabric, but also because it can “follow” the aortic contour, resulting in more surface area coverage

with longer effective seal zone length. This translates into better aneurysm exclusion, as demonstrated by the positive correlation between the apposition surface area and midterm aneurysm regression.

Finally, our last article is a roundtable discussion with Stuart Harlin, MD; Christopher LeCroy, MD; Fernando Kafie, MD; and Huey McDaniel, MD, who represent the Coastal Vascular and Interventional Center in Pensacola, Florida. The discussion revolves around the evolution of these partners’ individual practices toward bilateral percutaneous EVAR (PEVAR) and the motivations and barriers for PEVAR adoption. The group reflects on the technology advances and the PEVAR trial, a randomized clinical trial of PEVAR versus open femoral cutdown recently published in the *Journal of Vascular Surgery* and the resulting “on-label” indication for bilateral PEVAR when implanting the AFX system. The trial-validated “best practices,” coupled with robust hands-on experience under guidance from leading practitioners, form the basis of the Endologix PEVAR training program that the partners have attended (or proctored). With close to 80% of EVAR patients across the practice implanted percutaneously, the roundtable participants are now contemplating the provision of endovascular aneurysm repair in an outpatient setting if and when the clinical evidence, reimbursement, and other regulatory features affecting aneurysm repair fully support this major change in current practice.

We hope that you find the information presented in this supplement to *Endovascular Today* to be useful and informative, so that you may carry it forward into your own practice. ■



David H. Deaton, MD
Guest Chief Medical Editor

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.

BY JEFFREY P. CARPENTER, MD



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.

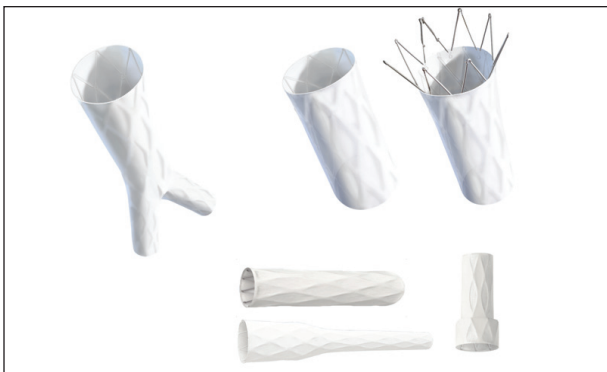


Figure 1. The AFX portfolio.



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

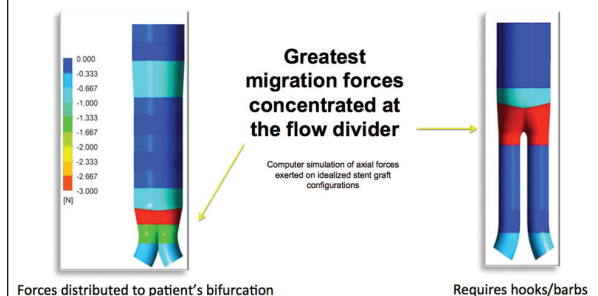


Figure 3. Phase I report: computer simulation of axial forces exerted on idealized stent graft configurations.¹³⁻¹⁵

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

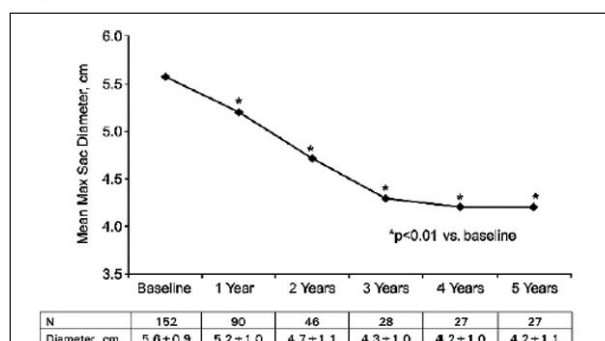


Figure 4. Aneurysm sac changes in an anatomic fixation cohort. Adapted from Carpenter et al, *JVS*, 2010.¹⁸

(Courtesy of Zvonimir Krajcar, MD.)

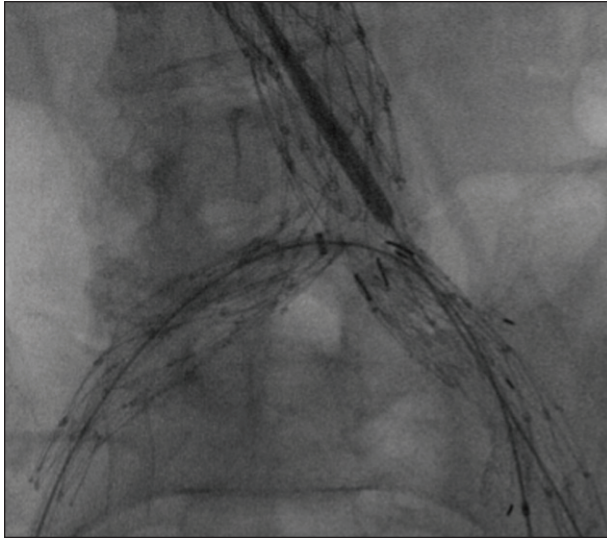


Figure 5. The crossover access technique through the AFX bifurcated unibody.

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
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® Quotion 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. ■

Jeffrey P. Carpenter, MD, is Professor and Chairman, Department of Surgery, Cooper Medical School of Rowan University in Camden, New Jersey. He has disclosed that he serves as a consultant to Endologix. Dr. Carpenter may be reached at carpenter-jeffrey@cooperhealth.edu.

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EVAR in Thrombus-Laden Necks

Unique applicability of the AFX® Endovascular AAA System and VELA™ Proximal Endografts.

BY RAGHU L. MOTAGANAHALLI, MD, AND ALOK K. GUPTA, MD



The significance of mural thrombus for procedural considerations and clinical outcomes of the endovascular repair of abdominal aortic aneurysms (EVAR) remains a

subject of much debate. Mural (or intraluminal) thrombus is a common finding in patients with abdominal aortic aneurysms.¹ The extent of the thrombus within the aneurysm sac has been associated with larger neck diameter,² accelerated aneurysm growth,³ and propensity for rupture.

Although computational flow dynamics studies suggest that thrombus reduces the shear stress on the wall of the aneurysm,⁴ such a reduction may not be significant in the presence of aneurysm tortuosity.⁵ At the same time, the aneurysm wall behind the thrombus has been found to be thinner,⁶ weaker,⁷ inflamed,^{6,7} and with reduced concentration of elastin fibers⁸ as compared to the thrombus-free segments of the wall, perhaps explaining the detrimental effect of the thrombus on aneurysm progression. Morphologically and histologically, the thrombus within the aneurysm sac remains highly dynamic, transitioning from a fibrin-based, disorganized structure to a collagen-based, organized structure after aneurysm exclusion,⁹ although both varieties appear to coexist through midterm follow-up, at least in patients with a stable aneurysm sac after EVAR.¹⁰

SIGNIFICANCE OF MURAL THROMBUS IN EVAR

The clinical data on the effect of mural thrombus within the aortic neck remain equally heterogeneous and lacking prospective, randomized evidence. Much of the available information is reported in either industry-supported studies or single-center EVAR experiences.¹¹⁻¹³ There is no uniformly accepted or reported definition of what constitutes significant thrombus at the proximal seal zone that compromises the outcome of EVAR. The analysis of early EVAR trials suggests protective proper-

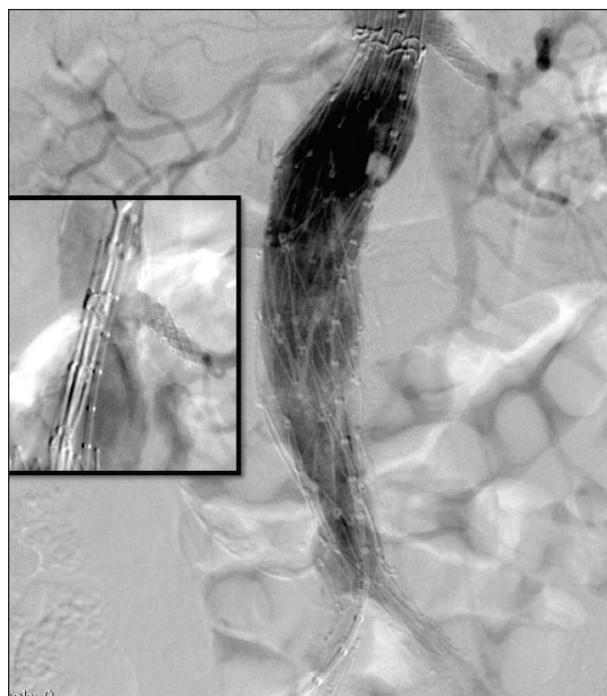


Figure 1. Deployment of the VELA Endograft in a reverse-tapered neck.

ties of the thrombus at > 25% of the neck circumference,¹² whereas analysis of a large, prospective, single-center cohort with the same endograft systems (Zenith [Cook Medical], Talent [Medtronic, Inc.], AneuRx [Medtronic, Inc.], and Excluder [Gore & Associates]) found thrombus on > 50% of the neck circumference to be a statistically significant predictor of perioperative complications.¹³

The natural concerns about establishing the proximal seal in the aortic neck with a heavy thrombus burden include acute type I endoleak (particularly when the resulting flow channel has an irregular and/or tapered morphology), migration, embolization, and renal thromboembolic events. The most recent comparison of outcomes in patients with and without neck thrombosis

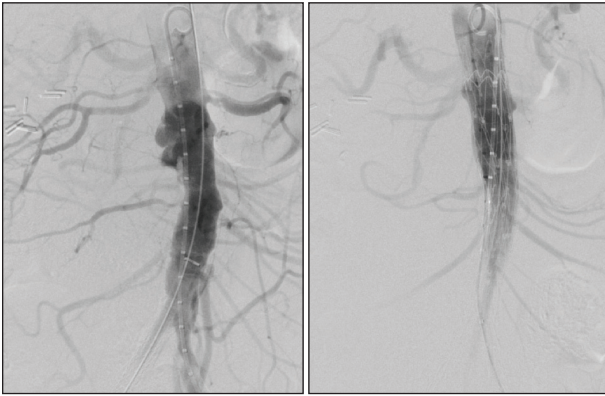


Figure 2. Deployment of the VELA Proximal Endograft in a severely calcified neck.

identified a statistically significant univariate effect of thrombus on migrations, but not on the endoleaks or renal outcomes.² The effect of thrombus on migrations lost significance in multivariate analysis when the use of active fixation endografts was considered. On the other hand, because the majority of active fixation endografts available on the market utilize a suprarenal component, the use of such devices in the presence of suprarenal thrombus may portend an incremental risk of renal dysfunction and distal embolization, as recently suggested.¹⁴

Provided there is proper procedural placement of the device, the infrarenal neck thrombus is trapped between the healthy aortic tissue and the fabric of the device and resolves over time, thus making it unlikely to contribute to the long-term risk of thromboembolism. Positive remodeling of the aortic neck has also been reported with resolution of thrombus in patients with proximal attachment-site thrombus.² Overall, with current-generation devices, EVAR in patients with significant thrombus in the proximal neck should be considered routine, conditional to detailed assessment of the axial and circumferential distribution of the thrombus, appropriate device fixation, and minimal intraprocedural manipulation without multiple reconstraining and repositioning steps.¹⁵

ENDOLOGIX SYSTEM IN THROMBOTIC NECKS

Use of the AFX® Endovascular System (Endologix) in proximal necks with significant thrombosis provides an additional degree of procedural flexibility and is supported by extensive clinical evidence. The system is based on a combination of the high-columnar-strength bifurcated unibody and proximal endografts. The bifurcated component is anatomically fixated on the native aortic bifurcation and inhibits proximal migration without the need

for active fixation features.¹¹ The design of the proximal endograft is optimized for maximum sealing using a highly conformable, exoskeletal, multilayer expanded polytetrafluoroethylene material attached to the stent only at the proximal and distal ends. The pressure gradient between the aorta and the excluded sac pushes the graft material against the luminal surface and beyond the outline of the stent, extending the effective seal length.¹⁶

The AFX System's instructions for use permit up to 32% oversizing of the proximal endograft, making it an ideal platform for treating necks having varying luminal diameter changes, characterized as conical and reverse conical (Figure 1). The unrestricted graft fabric that is externally mounted on the stent allows the implant to conform to atherosclerotic (Figure 2) and thrombus-laden (Figure 3) necks. Quite fittingly, the Endologix anatomical fixation IDE trials consistently enrolled a substantial number of patients with thrombus-laden and reverse-tapered necks (41% and 69%, respectively); this prevalence profile is consistent with that observed in the contemporary, unselected cohort¹⁶ and has yielded excellent acute results that have been shown to be durable long-term.^{11,17}

Unique among the EVAR devices, the Endologix proximal endografts, now marketed as VELA™ Proximal Endografts and featuring a circumferential graft line marker, are available in both suprarenal and infrarenal configurations (Figure 4). The analysis of renal outcomes in Endologix IDE patients found no difference between patients with suprarenal and infrarenal endografts,¹⁸ providing rare insight into the ongoing discussion about the variability of device selection and implantation strategy, as well as exclusion of the patients with significant thrombus in the neck.¹⁹

The recent introduction of the VELA Proximal Endografts and delivery system further increased the utility of this technology in complex and, specifically, thrombotic necks. During implantation, the two proximal segments of the VELA endografts (either suprarenal or infrarenal) are retained by the expanded polytetrafluoro-

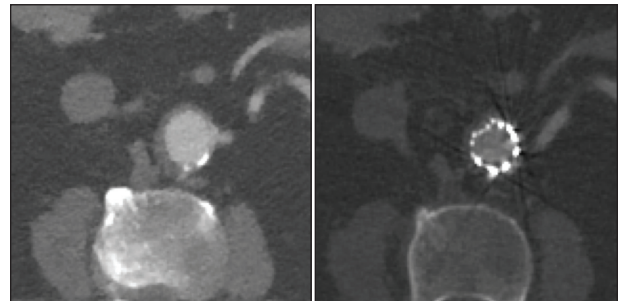


Figure 3. The VELA Endograft in a thrombus-laden neck, pre- and postprocedural axial CT scan.

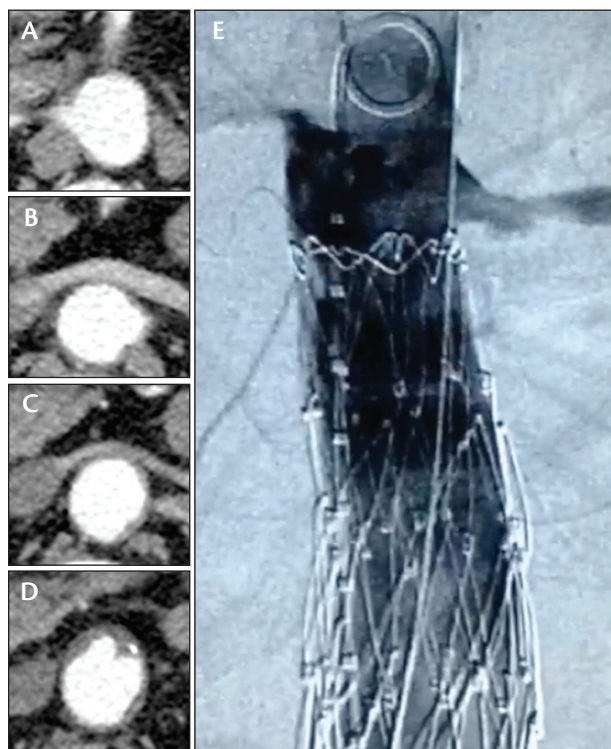


Figure 4. Progressive increase in aortic thrombus load and results of abdominal aortic aneurysm repair using the VELA infrarenal endograft. Suprarenal aorta (A), juxtarenal aorta (B), aorta on the level of lowest renal artery (C), aorta 10 mm below the level of lowest renal artery (D), and completion angiogram (E).

roethylene release sleeve and are deployed only once the position of the graft has been stabilized after unsheathing the middle section of the stent.²⁰ The new delivery system and the circumferential graft line marker allow for a highly predictable and precise location of the graft in the aortic neck, obviating the need for significant cranial or caudal position adjustment while in full or partial contact with the thrombus-laden aortic lumen, which carries an associated risk of renal or distal thromboembolism.

Based on the available data, the option of either suprarenal or infrarenal proximal extension in association with a distal unibody design that sits on an aortic bifurcation provides protection against distal graft migration.¹¹ This flexibility of the deployment approach and graft configurations provides the implanting physicians with options to customize the implantation strategy of the VELA Proximal Endograft in accordance with the patients' anatomic characteristics and their own clinical sensitivities.

CONCLUSION

The clinical evidence supports the safety of EVAR in patients with significant mural thrombus at the proximal aortic neck. Risk of device migration, renal dysfunction, and embolic complications, which are known complications of thrombus at the proximal seal zone, can be minimized by proper device selection and detailed procedural planning. The AFX System's architecture with the VELA Proximal Endograft fulfills multiple criteria when planning endovascular repair in patients with thrombus-laden proximal seal zones. ■

Raghu L. Motaganahalli, MD, is with the Vascular Surgery Department at Indiana University Health Multi-Specialty Clinic in Indianapolis, Indiana. He has disclosed that he receives educational grant support from Endologix. Dr. Motaganahalli may be reached at rmotagan@iupui.edu.

Alok K. Gupta, MD, is with the Vascular Surgery Department at Indiana University Health Multi-Specialty Clinic in Indianapolis, Indiana. He has disclosed that he receives educational grant support from Endologix. Dr. Gupta may be reached at alokgupta@iupui.edu.

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ActiveSeal™ Endograft Technology and Aneurysm Sac Regression

New core lab analysis provides insight into clinical benefits.

BY KENNETH OURIEL, MD



The clinical practice of endovascular repair of abdominal aortic aneurysms (EVAR) has been evolving continuously since the inception of the technique by Juan Parodi more than 2 decades ago.¹ Advances have been driven by ever-improving endograft designs and the clinicians' growing comfort with the technical aspects of the procedure itself.² As designs improved, patient selection criteria were broadened, and EVAR supplanted open surgical repair as the most common technique for repair of infrarenal aortic aneurysms.³

Paradoxically, clinical outcomes did not improve in parallel with the transition to minimally invasive technology.⁴⁻⁷ Patients with increasingly more challenging aortic anatomy were treated with EVAR, in part explaining the decoupling of technological advances and clinical results. Endografts were implanted within vascular anatomy never envisioned by the device manufacturers—anatomy well outside the instructions for use.⁸ Furthermore, the advent of EVAR as a potentially less invasive treatment modality allowed clinicians to treat patients with medical comorbidities that, in the past, would have relegated them to observation alone (i.e., patients who would not have tolerated a major open surgical procedure).⁹ The inclusion of medically compromised patients accounts for differences in the study populations treated with EVAR versus open surgery. These differences may well increase the frequency of medical complications beyond what would have been observed in a healthier patient population suitable for open surgical repair.

TREATMENT DECISIONS

Clinical trials designed to gain premarket approval for an endograft are, by design, limited to highly selected patients with straightforward aortic anatomy and reasonably few medical comorbidities. These premarket device approval trials conducted under investigational

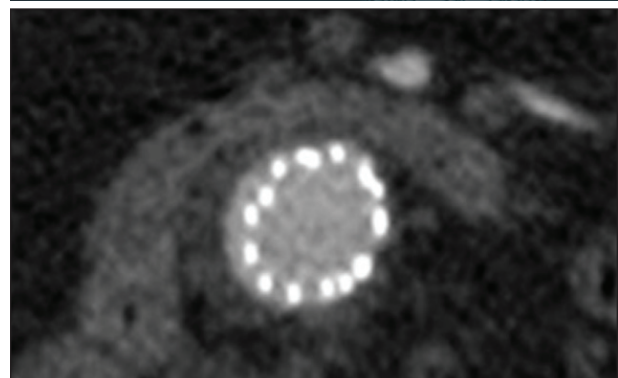
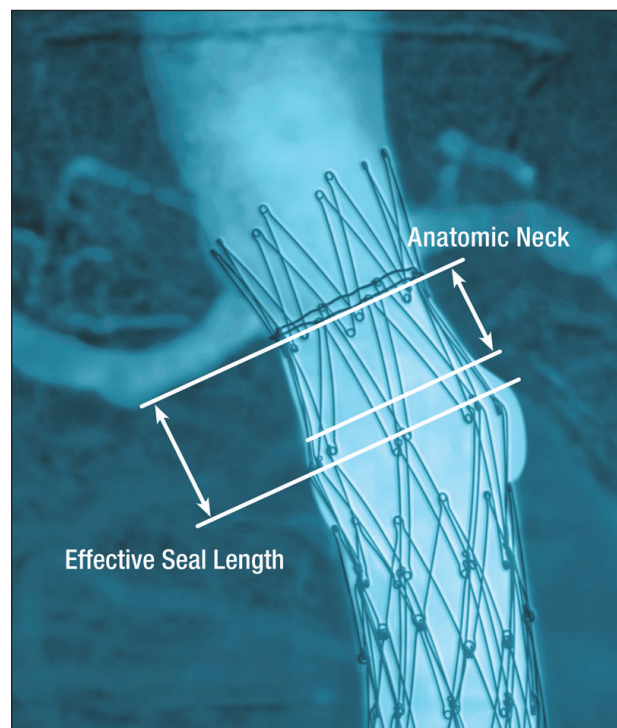


Figure 1. ActiveSeal apposition positively correlates with sac regression.

TABLE 1. PREDICTORS OF EARLY SAC REGRESSION

Variable	Median	Effect on Sac Regression
Age	76 y	Younger: no effect
Sex	70%	Male: no effect
AAA diameter	47 mm	Smaller: no effect
Suprarenal neck angulation	9°	Less: no effect
Infrarenal neck angulation	16°	Less: no effect
Proximal neck diameter	22 mm	Smaller: no effect
Anatomic aortic neck length	18 mm	Longer length: increased regression ($P = .019$)
Conical neck	27%	Conical: no effect
Apposition length	24 mm	Longer: no effect
Apposition surface area	18 cm ²	Greater area: increased regression ($P = .039$)

device exemptions typically exclude patients with anatomic and medical risk factors commonly encountered in routine clinical practice.^{10,11} Although it is easy to decry the off-label use of endografts in real-world, postmarket use, there remains no consensus on precise guidelines for when EVAR is appropriate.

Retrospective analyses of patients with “hostile” versus “friendly” aortic neck anatomy have not consistently identified predictive thresholds for anatomic variables such as neck length, neck diameter, angulation, reverse-tapered configuration, and mural thrombus or calcification.¹²⁻¹⁴ Absent specific guidance beyond the manufacturers’ instructions for use, endovascular specialists must rely on their individual experience with the specific endograft systems to guide patient selection and the choice of therapy.

AFX ANALYSIS DATA

The AFX® Endovascular AAA System (Endologix) was designed to address some of the limitations of previous endografts. AFX has high-conformability multilayer expanded polytetrafluoroethylene graft material built external to the stent frame. The material is attached to the frame only at its proximal and distal margins, allowing independent movement of the graft material during the cardiac cycle. This ActiveSeal™ technology has the potential to enhance graft-to-aortic wall apposition from the pressure gradient between the endograft lumen and aortic sac.

In a recent article published in the *Journal of Vascular Surgery*, Welborn et al reported a real-world retrospective observational analysis of 108 sequential patients implanted with the AFX System at two United States centers.¹⁵ Independent core laboratory analysis was performed in 87 patients with follow-up CT images at 9 ± 6 months

The main takeaway of the analysis is that in a diverse, contemporary, real-world cohort of patients treated with the AFX System, the ActiveSeal effect augments the effective seal length.

(mean \pm SD) after EVAR. Furthermore, precise aortic neck anatomic characteristics were assessed in an imaging cohort of 37 patients with adequate high-resolution baseline and early (5 ± 2 month) follow-up CT images suitable for an in-depth analysis of ActiveSeal geometry in the proximal aortic neck. A slice-by-slice analysis of graft-to-aortic wall apposition was performed to determine the effective seal length (aortic length with consecutive 360° graft apposition) and apposition surface area (the product of aortic circumference and slice thickness, summed for each slice over the effective seal length).

Although the indications for the AFX device are limited to patients with proximal neck length ≥ 15 mm, 40% of the patients in the Welborn et al series presented with neck lengths < 15 mm, and 26% presented with neck lengths < 10 mm. Proximal neck mural thrombus and calcium were present in 36% and 40% of patients and exceeded 50% of the circumference in 7.9% and 2.4% of patients, respectively. This distribution of the neck length is concordant with other recently published real-world series.^{8,16,17} As such, the AFX study likely reflects patient selection in the contemporary practice of EVAR.

Despite the frequency of challenging aortic neck anatomy, only two type Ia (2.3%) endoleaks were observed on the 87 follow-up CT scans assessed by the core laboratory. Each occurred in patients with neck lengths < 10 mm, and one had severe neck angulation and significant mural thrombus. The rate of type II endoleaks on CT performed more than 30 days after EVAR was 6.7%, which is appreciably lower than that of other series. In the imaging cohort, the mean effective seal length was 25 ± 17 mm, exceeding the average length of the anatomic neck by 5 ± 13 mm. The apposition surface area was 19 ± 13 cm². In a univariate analysis, the apposition surface area was found to be a statistically significant predictor of early sac regression (mean, 0.4 ± 0.7 mm diameter reduction per month; Table 1 and Figure 1).

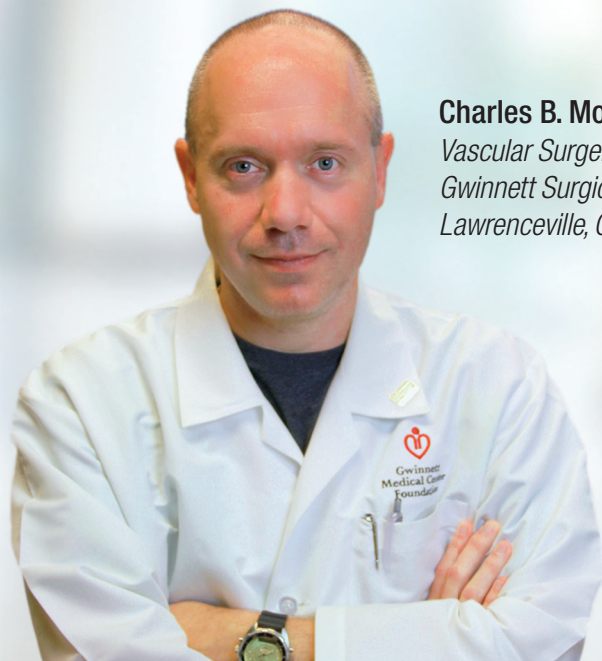
SUMMARY

The main takeaway of the analysis is that in a diverse, contemporary, real-world cohort of patients treated with the AFX System, the ActiveSeal effect augments the effective seal length. Effective seal length augmentation appears to be clinically significant and correlated with early sac regression. Intuitively, effective seal length is an amalgamation of multiple anatomic characteristics of the proximal neck that interact with the specific endograft design. As such, it is an index that may be used to better understand hostile and friendly neck anatomies. Additional research is required to confirm the clinical significance of the effective seal length on long-term clinical outcomes and to establish prospective algorithms to relate effective seal length to anatomic variables and endograft design. ■

Kenneth Ouriel, MD, is President and CEO, Syntactx in New York, NY. He has disclosed that his employer, Syntactx, receives funding from the manufacturer of the AFX device, Endologix. Dr. Ouriel may be reached at kouriel@syntactx.com.

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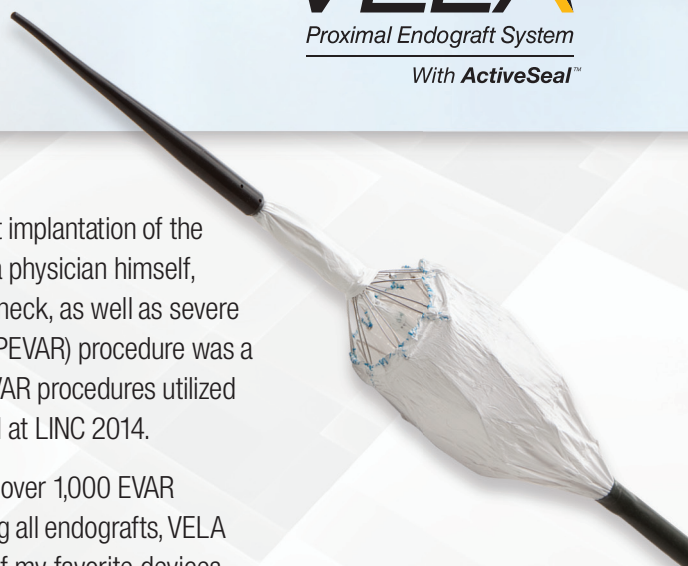
“VELA™ has become one of my favorite devices.”



Charles B. Moomey, M.D.

*Vascular Surgery and Endovascular Therapy
Gwinnett Surgical Associates, Gwinnett Health Systems
Lawrenceville, Georgia*

VELA™
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“No other system enhances the tactile relationship between the interventionalist and the aorta like VELA.”

Having performed over 1,000 EVAR procedures utilizing all endografts, VELA has become one of my favorite devices. It allows for precise radiographic positioning using the circumferential radiographic marker and the ePTFE

release sleeve. Operators are able to create a unique, custom deployment that closely matches each patient’s individual anatomy and physiology. With this complete control, VELA allows for construction of optimal seal in each patient. No other system enhances the tactile relationship between the interventionalist and the aorta like VELA, which I believe will be the foundation for its future success.”

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PEVAR in a Single Vascular Surgery Practice

Physician perspectives on the evolving standard of care.

PARTICIPANTS



Stuart Harlin, MD, is with the Coastal Vascular and Interventional Center in Pensacola, Florida. He stated that he has no financial interests related to this article.



Christopher LeCroy, MD, is with the Coastal Vascular and Interventional Center in Pensacola, Florida. He has disclosed that he is on the speakers bureau and is a trainer for Endologix.



Fernando Kafie, MD, is with the Coastal Vascular and Interventional Center in Pensacola, Florida. He stated that he has no financial interests related to this article.



Huey McDaniel, MD, FACS, is with the Coastal Vascular and Interventional Center in Pensacola, Florida. He disclosed that he has received consulting, received speaking honoraria, and has proctored for Avinger, Bard, Endologix, W.L. Gore, Medtronic, NMTC, and Terumo. He has also disclosed that he does not own stock in any of the previously mentioned companies and does not own a health care business.

Centrally located in Pensacola, Florida, Coastal Vascular and Interventional Center serves 11 diverse communities along the Gulf Coast of Florida and Alabama. The group is composed of eight board-certified vascular surgeons and interventional radiologists and offers a broad range of treatments from vein radiofrequency ablation to complex endovascular treatment for aortic disorders.

The practice's physicians participate in major clinical trials, train vascular specialists regionally and nationally, and are committed to clinical research. Yet, when it comes to their

adoption of percutaneous endovascular aneurysm repair (PEVAR), the individual trajectories of these physicians are as diverse as their backgrounds. We spoke with them about their practice, PEVAR, and the future of this minimally invasive treatment for abdominal aortic aneurysms (AAAs).

Coastal Vascular is a pretty unusual practice. Can you tell us more about who you are and what you do differently?

Dr. Kafie: When I was coming out of training at UCLA, there were no private practice groups that were 100% vascular surgery; it was simply not available. Either you created it, or it was not available. This is what we did in Pensacola. We started it with some great doctors from all over the country. It took us 15 years to build this community of eight board-certified minimally invasive vascular specialists. Another unique aspect of our practice is that we do not have academic centers here to refer a patient.

Dr. Harlin: We are the academic center.

Tell us more about your introduction to PEVAR. When did it happen, and how did it occur?

Dr. Harlin: I did my first PEVAR procedure in 2000, jumping on that bandwagon pretty early. During the next several years, I did some cases percutaneously with largely favorable results. Over the years, I started to do more PEVAR cases, to the point that now it is the majority of what I do.

Dr. McDaniel: Endovascular repair of AAAs was a great advancement for vascular surgery, and going percutaneously was an even greater leap. In the state where I was practicing, many patients are fairly obese, making an incision in the groin a large undertaking. We started going percutaneous in the early 2000s, but when the folks from the University of Florida started doing it, they were excluding those obese patients. I then had an opportunity to participate in Endologix's PEVAR trial and to proctor their PEVAR training courses.

Dr. LeCroy: I came out of a very conservative training program that favored open femoral exposure almost

exclusively. They did PEVAR, but only in a select group of patients. I was not really percutaneously oriented when I started to practice, and I stayed that way for a good while. But I had seen enough lymphocele from groin incisions and enough overweight patients with wound breakdown. So, as technology improved with smaller sheaths and Prolene sutures, and the clinical data started to emerge, I started to go percutaneous, and it took off like wildfire. You obviously need to consider patient selection, but it is applicable to a very large percentage of our aneurysm patients. Since I switched, I see almost no groin complications from percutaneous access, and when my patients come back, we can hardly see the access site, and there have been very few complications. My patients are happy.

Dr. Kafie: I have to admit, I was very leery of starting PEVAR. I also came from a very conservative program and liked to close the artery with an interrupted suture and made sure there was absolutely no bleeding. In fact, with one of the percutaneous cases I did with Dr. McDaniel, even though the artery was not bleeding, I had to open it to make sure it was not bleeding; I saw two beautiful sutures doing exactly what they are supposed to do. I was extremely impressed.

What was the biggest barrier to switching to the percutaneous approach: the idea of losing control of the vessel or the reputation of devices failing?

Dr. Kafie: Both. Opening a large hole in the artery, then getting used to closing it with an uninterrupted suture without narrowing the vessel and ensuring that there is no bleeding, as well as the history of closure device failures, made it a challenge. The two most painful procedures that we perform are AAA open repair and fixing somebody else's failed closure. That's personally painful because you are dealing with uncontrolled bleeding.

Dr. Kafie, what pushed you over that edge toward a percutaneous approach?

Dr. Kafie: Peer pressure. When a patient came in and said, "Dr. Harlin does it percutaneously, why can't you?" I said, "... time for me to learn."

How do the patients know about this approach?

Dr. Kafie: The Internet. And veterans will go to their Lions Club or Rotary Club meetings and compare their incisions. Here's Kafie's, here's Dr. LeCroy's—bigger is not always better.

How do you go about training and introducing the percutaneous technique in your practice?

Dr. McDaniel: My observation is that you have to commit to minimally invasive procedures as a part of what

you do. You have to do iliac stents, endarterectomies of the lower extremities, you need to use preclosure in other settings and arteriography of the legs. Once you become comfortable with these procedures, you should go to the Endologix PEVAR training program and get hands-on experience with the device.

Dr. LeCroy: For those who do a lot of percutaneous interventions, it is not a great leap, but you need the right skill set. We have years of experience of feeling, clamping, and working on femoral vessels, so we can usually tell by looking at the preoperative CT if it is going to clamp and if the anterior wall of the vessel will take a closure device. There are plenty of people who use closure devices and do not have a tactile experience working with vessels, and they are great endovascular doctors, but they do not have the other side of it, that open experience, correlating the image on CT to what it actually feels like. This is what we have to do every day—triage patients if we can safely perform percutaneous access, or someone will have to open them up.

Dr. McDaniel: In my experience, problems with the percutaneous approach always happen with smaller sheaths. It is a different closure technology, and I think people sort of take it for granted. I am a huge fan of the Endologix device because it is uniquely designed for a totally percutaneous approach. I think Endologix got it right when they went with an anatomically fixated endograft, simply because you still have the option of working below the inguinal ligament from the contralateral groin, and if you have a problem, you can go back over the bifurcation and treat it. If you have stenosis, which happens once out of every 20 times, you can employ angioplasty, and hopefully resolve it without stenting most of the time. If you have a high stick, you can introduce a covered stent if you do not want to cut down on the groin. With an anatomic fixation endograft, you have options that you might not otherwise have when using a traditional main body, long leg/short leg endograft.

Dr. LeCroy: If you have a bleeding failure, you can add another closure device, typically in a different plane, and if that does not work, do the cutdown, and repair the artery. It adds 10 minutes to the procedure, there is almost no blood loss, and by one of those means, we leave an operating room with hemostasis every time.

Dr. Harlin: The percutaneous certification courses offered by Endologix are certainly very good. Dr. LeCroy and I went to one just to be able to say that we have gone through the formal training. We had performed

quite a number of cases percutaneously prior to the course, but we certainly saw other things and came up with other ideas that we had missed before, so that was kind of cool.

What specifically did you come up with that you had not seen?

Dr. Harlin: Just little differences in technique about the angulations, the overlaps, and specifically the third suture stuff. You also learn how others had made mistakes before. As you talk to the faculty and other physicians in the course, you hear, “Remember how we did X, Y, Z?”—a complication you had not previously thought about.

As you look at yourself as a practice, with all of your experience, what percentage of patients are accessed percutaneously versus with cutdown?

Group: 80% percutaneous, higher for Dr. McDaniel.

How do hospitals react to the idea of PEVAR?

Dr. Harlin: The devices in percutaneous cases cost more, no doubt about that. The hospitals would certainly prefer if we did cutdowns. But, we have myriad marketing strategies: TV shows, a website, testimonials. We, as a practice, are dedicated to demonstrating the value of PEVAR and educating the patients and administration that we have superior outcomes compared to others who do the same procedures. Our group is one of the only private practices in this part of the world that is part of the Society for Vascular Surgery’s Vascular Quality Initiative. We did this simply to demonstrate our superior outcomes and commitment to transparency of how our patients do in comparison, not only regionally but also nationally.

What components of the Vascular Quality Initiative specifically reflect your preference for the percutaneous approach?

Dr. Harlin: The immediate factor is the length of stay. Everyone goes home the next day. When you’re averaging a length of stay between 1 and 2 days and observe a 50% decrease, it is an immediate, easily demonstrable thing. The patient satisfaction score is usually higher, plus readmission for infection and the rate of other complications are also better.

Where do you see your practice and the entire movement of minimally invasive EVAR going in the coming years?

Dr. Harlin: Is it going to be 100% percutaneous? The answer is no, for several reasons. There will always be patients with challenging arteries or other reasons that you cannot achieve access via their groins. However, percutaneous access will be a progressive majority. I know it is hugely controversial, but in our opinion, the next step is outpatient EVAR. There have been three peer-reviewed articles on same-day discharge in the inpatient setting. We did a small study through the institutional review board on EVAR in the office-based lab with surgical backup.

Patients are going to demand it, and insurers are going to demand it for cost containment. There are patients whom you will always have to treat in hospitals, especially for snorkels, renals, etc.; technology manifests itself that way. When I was a general surgery resident, every hernia repair was inpatient, and now there is no inpatient code for hernia repair. In our study, we were trying to mitigate every contingency as far as, “If this happens, what are you going to do in order to have enough safeguards?” Robust data from other trials will be required to predict who is likely to fail based on body mass index, skin height to arterial depth, etc., and the answer is nowhere close to being known. It will take a long time to become accepted by the majority.

Would anyone like to share any parting thoughts?

Dr. LeCroy: It has long been accepted that EVAR is a treatment of choice for AAA repair. We are now living in an era when percutaneous access is going to be accepted as a standard approach, understanding that there are some open cases out there that will require femoral exposures and open repairs. In a zeal to do everything percutaneously, we should not lose sight of the reasons that we are successful at it, as a group practice and as a larger community of vascular surgery. All of the baseline experience with arterial surgery and all of the endovascular techniques we have learned is what makes a vascular surgeon uniquely qualified for PEVAR. The next frontier is outpatient EVAR.

Dr. Harlin: We have been implanting Endologix endografts for 6 years now. The quality of the relationship we have established, the flexibility, competency, and resources that company has extended to us have been absolutely central to what we have been able to accomplish and has made a fundamental difference in our practice. ■

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