

EVAR in Thrombus-Laden Necks

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

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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-

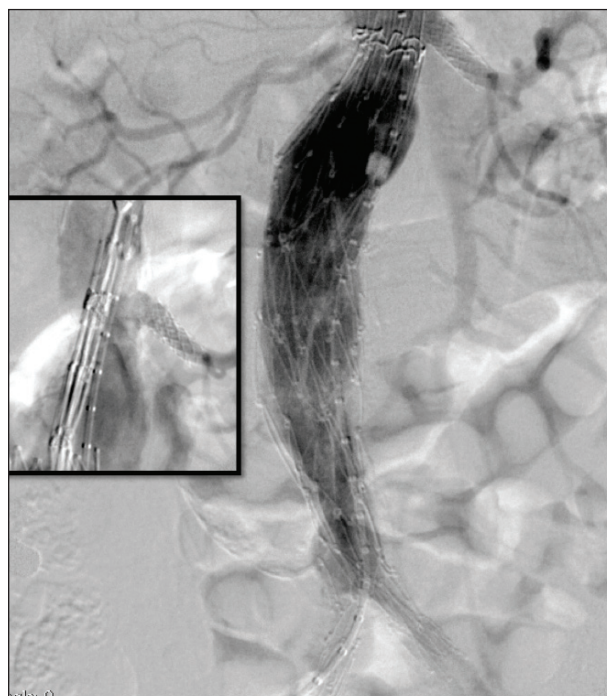


Figure 1. Deployment of the VELA Endograft in a reverse-tapered neck.

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

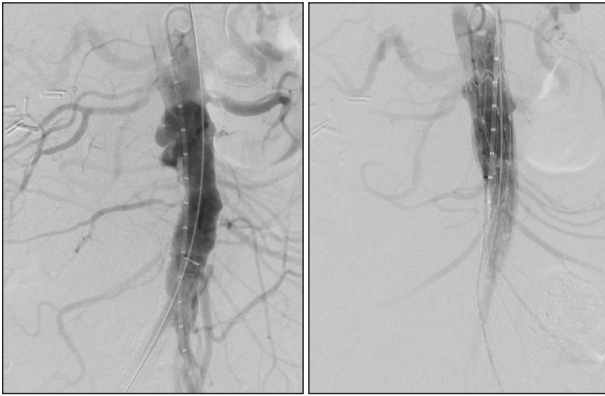


Figure 2. Deployment of the VELA Proximal Endograft in a severely calcified neck.

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-

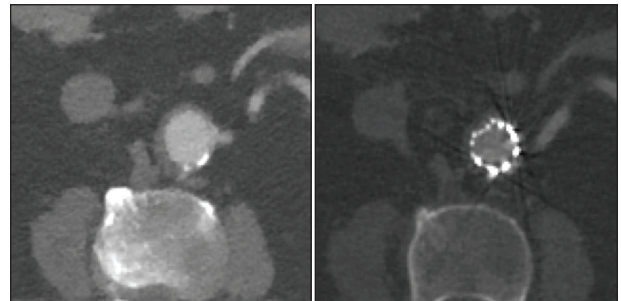


Figure 3. The VELA Endograft in a thrombus-laden neck, pre- and postprocedural axial CT scan.

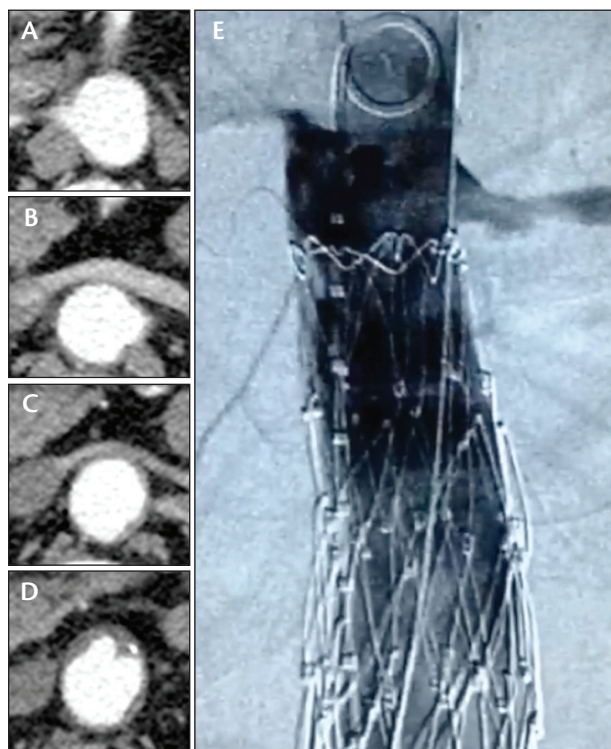


Figure 4. Progressive increase in aortic thrombus load and results of abdominal aortic aneurysm repair using the VELA infrarenal endograft. Suprarenal aorta (A), juxtarenal aorta (B), aorta on the level of lowest renal artery (C), aorta 10 mm below the level of lowest renal artery (D), and completion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

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