

Fixation Enhancements in EVAR

An overview of the mechanisms for EVAR graft fixation and where the technology stands today.

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The current era of endovascular aneurysm repair (EVAR) began in the United States in 1999 with FDA approval of the AneuRx (Medtronic) and Ancure (formerly Guidant Corporation) devices. EVAR held the promise of achieving aortic aneurysm repair through a minimally invasive approach. At that time, we understood very little about the needs for aortic fixation and the durability of EVAR, but we did know the 1-year safety and effectiveness data for these two devices, which had vastly different mechanisms for fixation.^{1,2}

The AneuRx device used stents on the outside of the fabric and had the theorized potential of tissue ingrowth, but it solely relied on radial force to hold the device in place. Although the 5-year data were positive, the limitations of radial force as a sole fixation method eventually became apparent.³⁻⁶ In dramatic contrast, the Ancure device used active fixation with hooks driven into the aortic wall for fixation but with almost no radial force in the stent itself. Ancure's design had problems in terms of hook fracture but also a very low late risk of device migration; it was eventually removed from the market for delivery system issues.^{7,8}

THE JOURNEY FORWARD

In the decades that followed, we saw the emergence of new devices and designs, including the incorporation of active and suprarenal fixation into most devices. Experimental data also support the idea of active fixation for improving resistance to migration.^{9,10} The suprarenal aorta tends to be less likely to dilate over time than the infrarenal neck and, therefore, makes a better potential place for lasting fixation.¹¹⁻¹⁵ We also know that the infrarenal neck of an aneurysm dilates over time, and the outward force exerted by a self-expanding aortic endograft promotes neck enlargement and migration.^{11,14,16-18} On the other hand, polymer sealing, similar to balloon-expandable stent grafts, does not place outward force on the aortic wall and is not associated with aortic neck enlargement.¹⁹⁻²¹

More recently, endovascular aneurysm sealing (EVAS) was proposed as a novel way to achieve fixation and sealing.^{22,23} However, newer data suggest that EVAS technology cannot achieve durable resistance to migration.^{24,25}

Active fixation has taken hold as a feasible and stable mechanism to resist migration in the infrarenal neck with the use of EndoAnchors (Medtronic).²⁶⁻²⁸ In fact, experimental data with cadaver aortas have suggested that the amount of force needed to displace an EVAR graft reinforced with six anchors is more than with a Dacron graft surgical aortic anastomosis.^{10,29} Data from the ANCHOR registry have proven the ability to treat migration of previously placed endografts.²⁸

CONCLUSION

Thus far, we have not seen the ideal fixation mechanism. We know that stability to the aortic bifurcation is helpful,³⁰ and we know that active fixation works better than passive fixation. Dilation of the aortic neck is more common in self-expanding designs and leads to an increased late risk of migration. The visceral aorta can dilate but does so much less commonly than the infrarenal or pararenal aorta. The biologic mechanism for aortic growth is still not fully understood; once that is defined, novel approaches will hopefully emerge. ■

1. Moore WS, Rutherford RB. Transfemoral endovascular repair of abdominal aortic aneurysm: results of the North American EVT phase 1 trial. *EVT Investigators. J Vasc Surg.* 1996;23:543-553.
2. Zarins CK, White RA, Schwartz D, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. *J Vasc Surg.* 1999;29:292-305; discussion 306-308.
3. Ouriel K, Clair DG, Greenberg RK, et al. Endovascular repair of abdominal aortic aneurysms: device-specific outcome. *J Vasc Surg.* 2003;37:991-998.
4. Zarins CK, for the AneuRx Clinical Investigators. The US AneuRx clinical trial: 6-year clinical update 2002. *J Vasc Surg.* 2003;37:904-908.
5. Sampaio SM, Panneton JM, Mozes G, et al. AneuRx device migration: incidence, risk factors, and consequences. *Ann Vasc Surg.* 2005;19:178-185.
6. Pintoux D, Chaillou P, Azema L, et al. Long-term influence of suprarenal or infrarenal fixation on proximal neck dilatation and stentgraft migration after EVAR. *Ann Vasc Surg.* 2011;25:1012-1019.
7. Broeders IAMJ, Blankensteijn JD, Wever JJ, Eikelboom BC. Mid-term fixation stability of the EndoVascular Technologies endograft. *Eur J Vasc Endovasc Surg.* 1999;18:300-307.
8. Matsumura JS, Chaikof EL. Continued expansion of aortic necks after endovascular repair of abdominal aortic aneurysms. *EVT Investigators. EndoVascular Technologies, Inc. J Vasc Surg.* 1998;28:422-430; discussion 422-430.

9. Melas N, Saratzis A, Saratzis N, et al. Aortic and iliac fixation of seven endografts for abdominal-aortic aneurysm repair in an experimental model using human cadaveric aortas. *Eur J Vasc Endovasc Surg.* 2010;40:429-435.
10. Melas N, Perdikides T, Saratzis A, et al. Helical EndoStaples enhance endograft fixation in an experimental model using human cadaveric aortas. *J Vasc Surg.* 2012;55:1726-1733.
11. Iezzi R, Santoro M, Di Natale G, et al. Aortic-neck dilation after endovascular abdominal aortic aneurysm repair (EVAR): can it be predicted? *Radiol Med.* 2012;117:804-814.
12. Sampaio SM, Panneton JM, Mozes G, et al. Aortic neck dilation after endovascular abdominal aortic aneurysm repair: should oversizing be blamed? *Ann Vasc Surg.* 2006;20:338-345.
13. Dillavou ED, Muluk S, Makaroun MS. Is neck dilatation after endovascular aneurysm repair graft dependent? Results of 4 US phase II trials. *Vasc Endovascular Surg.* 2005;39:47-54.
14. Sternbergh WC III, Money SR, Greenberg RK, Chuter TA; for the Zenith Investigators. Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: results from the Zenith multicenter trial. *J Vasc Surg.* 2004;39:20-26.
15. Sun Z. Transrenal fixation of aortic stent-grafts: current status and future directions. *J Endovasc Ther.* 2004;11:539-549.
16. Tonnesen BH, Sternbergh WC III, Money SR. Late problems at the proximal aortic neck: migration and dilation. *Semin Vasc Surg.* 2004;17:288-293.
17. Litwinski RA, Donayre CE, Chow SL, et al. The role of aortic neck dilation and elongation in the etiology of stent graft migration after endovascular abdominal aortic aneurysm repair with a passive fixation device. *J Vasc Surg.* 2006;44:1176-1181.
18. Cao P, Verzini F, Parlani G, et al. Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts. *J Vasc Surg.* 2003;37:1200-1205.
19. de Donato G, Setacci F, Bresadola L, et al. Aortic neck evolution after endovascular repair with TriVascular Ovation stent graft. *J Vasc Surg.* 2016;63:8-15.
20. Swerdlow NJ, Lyden SP, Verhagen HJM, Schermerhorn ML. Five-year results of endovascular abdominal aortic aneurysm repair with the Ovation abdominal stent graft [published online September 9, 2019]. *J Vasc Surg.*
21. Kolvenbach R, Pinter L, Cagiannos C, Veith FJ. Remodeling of the aortic neck with a balloon-expandable stent graft in patients with complicated neck morphology. *Vascular.* 2008;16:183-188.
22. Carpenter JP, Cuff R, Buckley C, et al. One-year pivotal trial outcomes of the Nellix system for endovascular aneurysm sealing. *J Vasc Surg.* 2017;65:330-336.e4.
23. Batagini NC, Hardy D, Clair DG, Kirksey L. Nellix endovascular aneurysm sealing system: device description, technique of implantation, and literature review. *Semin Vasc Surg.* 2016;29:55-60.
24. Stenson KM, de Bruin JL, Loftus IM, Holt PJE. Migration and sac expansion as modes of midterm therapeutic failure after endovascular aneurysm sealing. *J Vasc Surg.* 2020;71:457-469.e1.
25. Hing JJX, Ch'ng JK, Tay KH, Chong TT. Limb stent occlusion from intraoperative Nellix stent migration and prolapse. *Ann Vasc Surg.* 2019;54:144.e149-144.e12.
26. Avci M, Vos JA, Kolvenbach RR, et al. The use of endoanchors in repair EVAR cases to improve proximal endograft fixation. *J Cardiovasc Surg (Torino).* 2012;53:419-426.
27. Deaton DH. Improving proximal fixation and seal with the Helifx Aortic EndoAnchor. *Semin Vasc Surg.* 2012;25:187-192.
28. Jordan WD Jr, Mehta M, Varnagy D, et al. Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy. *J Vasc Surg.* 2014;60:885-892.e2.
29. Goudekettig SR, Vermeulen JJM, van Noort K, et al. Effect of different EndoAnchor configurations on aortic endograft displacement resistance: an experimental study. *J Endovasc Ther.* 2019;26:704-713.
30. Coppi G, Silingardi R, Tasselli S, et al. Endovascular treatment of abdominal aortic aneurysms with the Powerlink endograft system: influence of placement on the bifurcation and use of a proximal extension on early and late outcomes. *J Vasc Surg.* 2008;48:795-801.

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