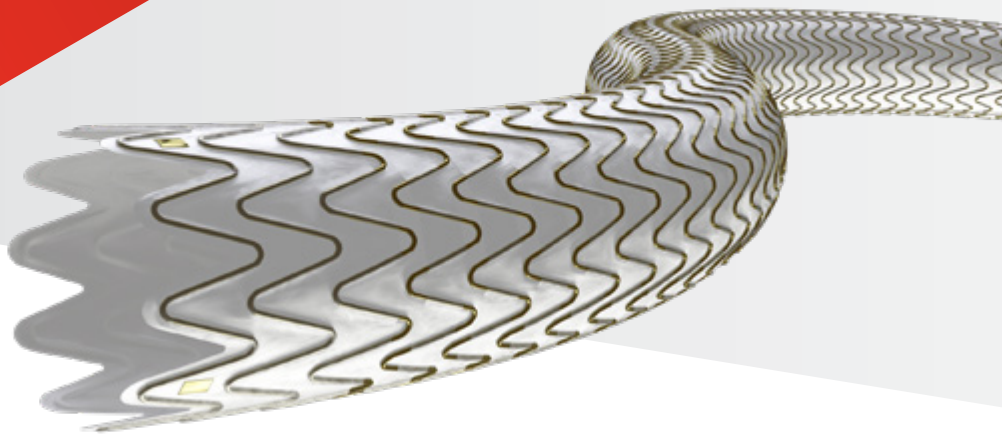
GORE® VIABAHN®
Endoprosthesis with PROPATEN
Bioactive Surface*

CASE STUDY



Management of vascular graft stenosis in a patient with recurrent thrombosis

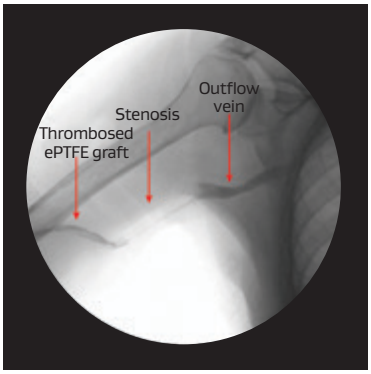
Case submitted by Daniel V. Patel, M.D.

Challenge

Treating a patient with a history of recurrent stenosis with thrombosis

Relevant patient history:

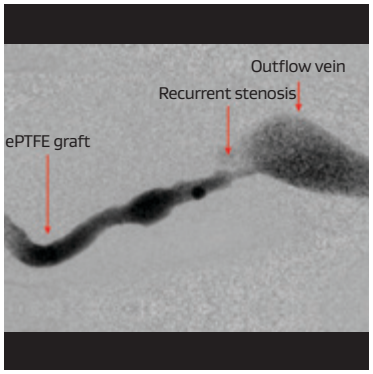
- An 84-year-old end-stage renal disease patient with a history of recurrent thrombosis and stenosis of ePTFE grafts.
- Previous access was a left-arm ePTFE graft that was dialyzed for 23 months before it was abandoned after three episodes in two months of recurrent thrombosis. This was attributed to venous anastomosis stenosis and was managed by balloon angioplasty.
- Right-arm access created with brachial artery to axillary vein ePTFE graft but developed a venous anastomosis stenosis with thrombosis of the graft at 13-months post-creation.



Procedure

Use of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in attempt to break the cycle of recurrent stenosis with thrombosis

- An endovascular thrombectomy of the right-arm graft was performed. Antegrade and retrograde access was obtained directly through the ePTFE graft.
- A pullback angiogram confirmed that the graft thrombosis was secondary to a stenosis at the venous anastomosis.
- Heparin was administered and angioplasty performed. Further maceration of the graft thrombus, EDWARDS FOGARTY® Catheter clearance of the arterial plug, and clot removal with thromboaspiration was performed.
- With flow restored to the graft, the graft remained pulsatile with a weak thrill.
- Stenosis was persistent and observed at the graft venous anastomosis.
- An 8 mm x 5 cm GORE® VIABAHN® Device was placed at the venous anastomosis resulting in restoration of brisk flow and strong thrill in access, with resolution of recoil.



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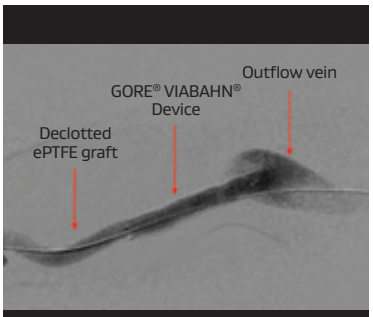
* As used by Gore, PROPATEN Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

Result

In this case, the use of the GORE® VIABAHN® Device to treat the stenosis at the venous anastomosis:

- Reduced the frequency of future percutaneous transluminal angioplasty (PTA) procedures (from one every 3-5 months to one every 10 months).
- Reduced the frequency of thrombotic events (zero since placement of the GORE® VIABAHN® Device).



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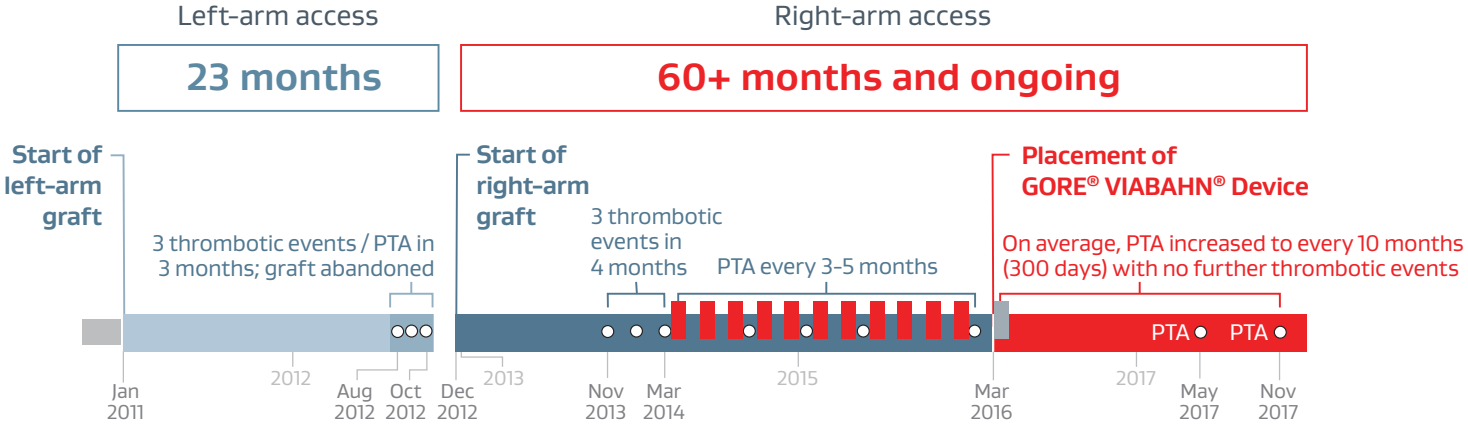
Case takeaways

- In this case, balloon angioplasty management of the previous left-arm graft ultimately resulted in graft failure and recurrent thrombosis at just under two years.
- At five years the right arm graft has maintained significantly longer secondary patency than the original left-arm graft, with no further episodes of graft thrombosis after placement of the GORE® VIABAHN® Device at the venous anastomosis.
- The GORE® VIABAHN® Device is an excellent option for management of the venous anastomosis of AV grafts versus balloon angioplasty, as demonstrated in the Gore REVISE Clinical Study.[1,2]



1. Vesely T, DaVanzo W, Behrend T, *et al.* Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. *Journal of Vascular Surgery* 2016; 64(5):1400-1410.e1. http://www.sciencedirect.com/science/article/pii/S0741521416301756

2. Mohr BA, Sheen AL, Roy-Chaudhury P, *et al.* Clinical and economic benefits of stent grafts in dysfunctional and thrombosed hemodialysis access graft circuits in the REVISE Randomized Trial. *Journal of Vascular & Interventional Radiology* 2018;30(2):203-211.e4.

The outcomes and observations reported are based on individual case experience and the patients treated. The steps described here may not be complete, and are not intended to be a replacement for the *Instructions for Use* or the education, training and professional judgment of Health Care Providers. Health Care Providers remain solely responsible for making decisions about patient care and the use of medical technologies.

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