GORE® VIABAHN®
Endoprosthesis
with Heparin Bioactive Surface*

MANAGING RECURRENT THROMBOSIS IN VASCULAR GRAFTS

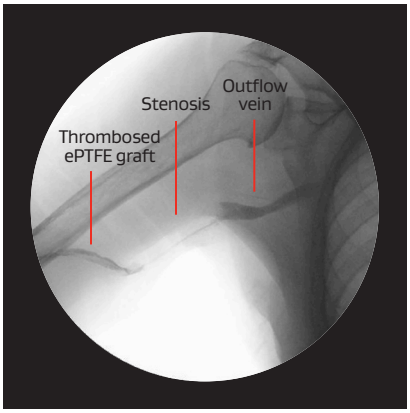
Case submitted by Daniel V. Patel, M.D.

Challenge

Treating a patient with a history of recurrent stenosis with thrombosis

Relevant patient history:

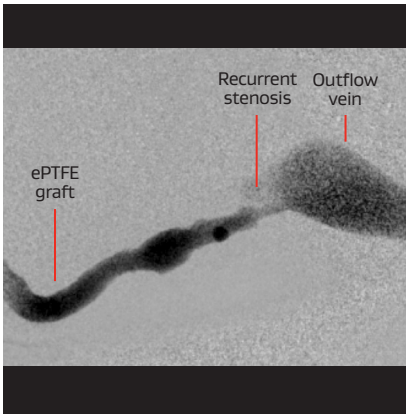
- An 84-year-old end-stage renal disease patient with a history of recurrent thrombosis and stenosis of ePTFE grafts.
- Previous access was a left arm ePTFE graft that was dialyzed for 23 months before it was abandoned after three episodes in two months of recurrent thrombosis. This was attributed to 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 VIABAHN® Device in attempt to break the cycle of recurrent stenosis with thrombosis

- An endovascular thrombectomy of the right arm graft was performed.
- A pullback angiogram confirmed that the graft thrombosis was secondary to a stenosis at the venous anastomosis.
- Heparin was administered, angioplasty was performed, and the clot was removed to restore flow. The graft remained pulsatile with a weak thrill.
- Stenosis was persistent and observed at the graft venous anastomosis.
- An 8 mm x 5 cm VIABAHN® Device was placed at the venous anastomosis resulting in restoration of brisk flow and strong thrill in access, with resolution of recoil.



Result

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

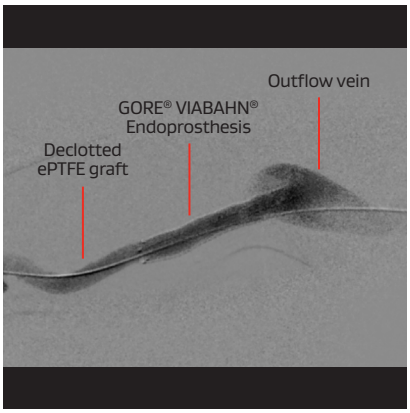
- Reduced the frequency of future percutaneous transluminal angioplasty (PTA) procedures (from one every three to five months to one every 10 months).
- Reduced the frequency of thrombotic events (zero within the 20 months since VIABAHN® Device implantation).

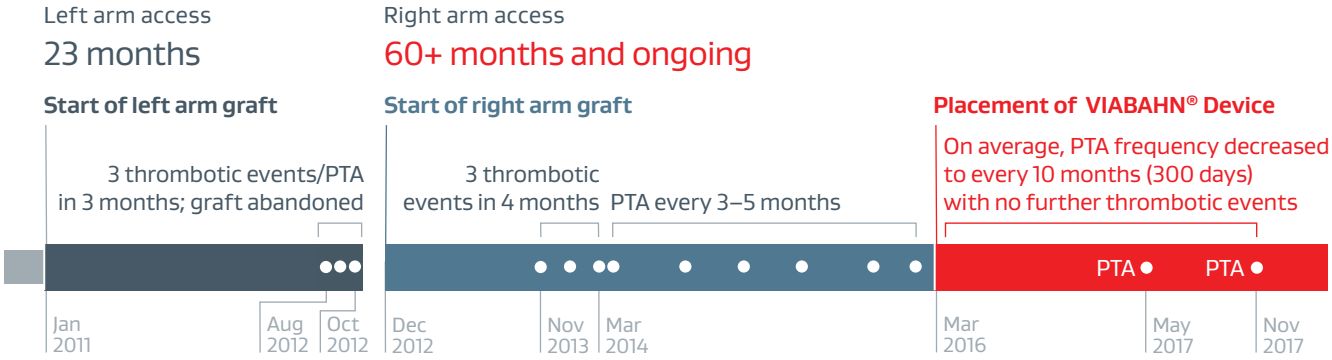
* As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS Heparin Surface.

Together, improving life

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 VIABAHN® Device at the venous anastomosis.
- The VIABAHN® Device is an excellent option for management of the venous anastomosis of arteriovenous grafts versus balloon angioplasty, as demonstrated in the Gore REVISE Clinical Study.[1,2]





Images courtesy of Daniel V. Patel, M.D. Used with permission.

1. Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. 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.
2. Mohr BA, Sheen AL, Roy-Chaudhury P, Schultz SR, Aruny JE; REVISE Investigators. 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 healthcare providers (HCP). HCP remain solely responsible for making decisions about patient care and the use of medical technologies.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm. The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm. The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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