GORE REVISE CLINICAL STUDY

Together, improving life

Gore REVISE Clinical Study

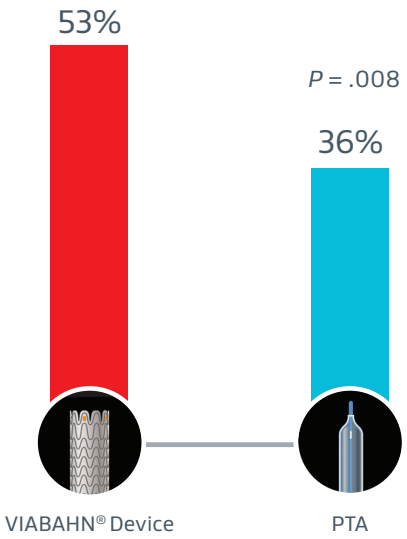
Multicenter, prospective, randomized evaluation of the GORE® VIABAHN® Endoprosthesis at the venous anastomosis of arteriovenous (AV) grafts versus percutaneous transluminal angioplasty (PTA).

The REVISE Study is the only study to include an endoprosthesis across the elbow and the only randomized control trial to include thrombosed grafts.[1–4]

Results and key takeaways: Patency

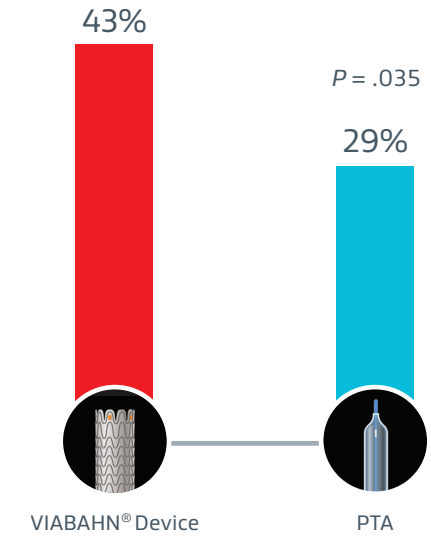
The VIABAHN® Device had nearly 50% higher primary patency at six months than PTA alone.[5]

Target lesion[5]



47% relative improvement over PTA

Circuit[5]



48% relative improvement over PTA

Increased primary patency of both the target lesion and the circuit by ~ 50% when compared to PTA at six months.[5]

The VIABAHN® Device demonstrated secondary patency across the elbow at two years of 83% with zero reported fractures.[6]

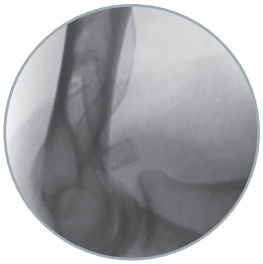


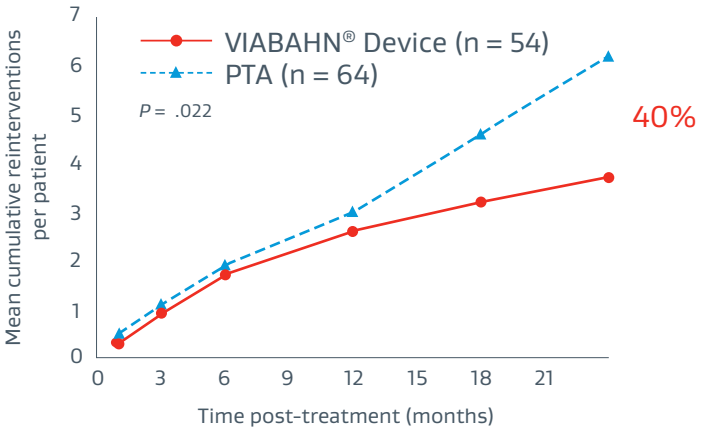
Image courtesy of William DaVanzo, M.D.

Results and key takeaways: Thrombosed grafts

Thrombosed graft lesions treated with the VIABAHN® Device required fewer reinterventions and drove lower costs versus PTA at two years.[7]

40% fewer reinterventions[7]

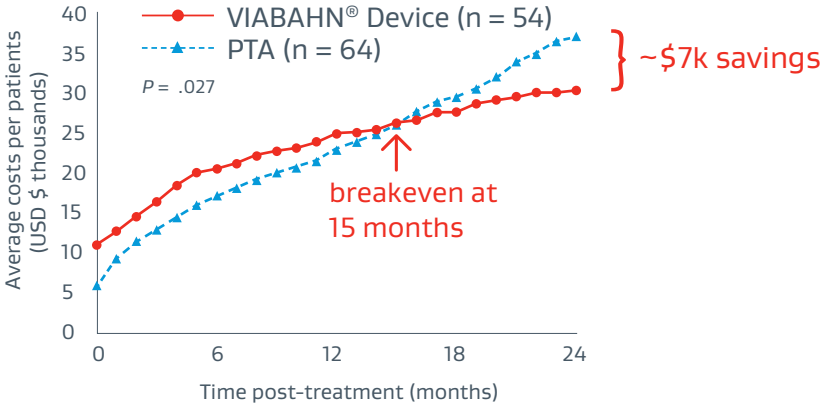
Reinterventions[7]



Fewer reinterventions resulted in $11,943 savings (on average) in reintervention costs per patient: $19,322 vs. $31,265 ($P < .001$)

18% reduction in total lesion treatment costs[7]

Total costs[7]



Compared to total two-year treatment costs with PTA only ($37,206), treatment with the VIABAHN® Device ($30,329) becomes more cost-effective at 15 months post-placement, generating $6,877 in total cost savings per patient.

References

1. W. L. Gore & Associates, Inc. GORE VIABAHN Endoprosthesis Versus Percutaneous Transluminal Angioplasty (PTA) to Revise AV Grafts in Hemodialysis (REVISE). ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2014. https://clinicaltrials.gov/ct2/show/NCT00737672. Published August 15, 2008. Updated October 14, 2014. September 11, 2019. NLM Identifier: NCT00737672.
2. Flair® Endovascular Stent Graft [Instructions for Use]. Tempe, AZ: C. R. Bard, Inc; 2014. B05659 Rev.3/08-14.
3. Covera® Vascular Covered Stent [Instructions for Use]. Tempe, AZ: C. R. Bard Peripheral Vascular; 2018. B05872. Rev4/ 08-18.
4. Haskal ZJ, Trerotola S, Dolmatch B, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. *New England Journal of Medicine* 2010;362(6):494-503.
5. 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. https://www.sciencedirect.com/science/article/pii/S0741521416301756
6. W. L. Gore & Associates, Inc. GORE® VIABAHN® Endoprosthesis versus Percutaneous Transluminal Angioplasty (PTA) to Revise Arteriovenous Grafts at the Venous Anastomosis in Hemodialysis Patients. (GORE REVISE Study, AVR 06-01). Flagstaff, AZ: W. L. Gore & Associates, Inc; 2012. [IDE Final Clinical Study Report]. G070069.
7. 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* 2019;30(2):203-211.e4.

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, 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, and 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 noncompliant 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 incidence of Heparin-Induced Thrombocytopenia (HIT) type II. *Refer to Instructions for Use* at eifu.goremedical.com for a complete description of all warnings, precautions and adverse events. $\mathrm{R}_{\mathrm{x\ Only}}$

Products listed may not be available in all markets.

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