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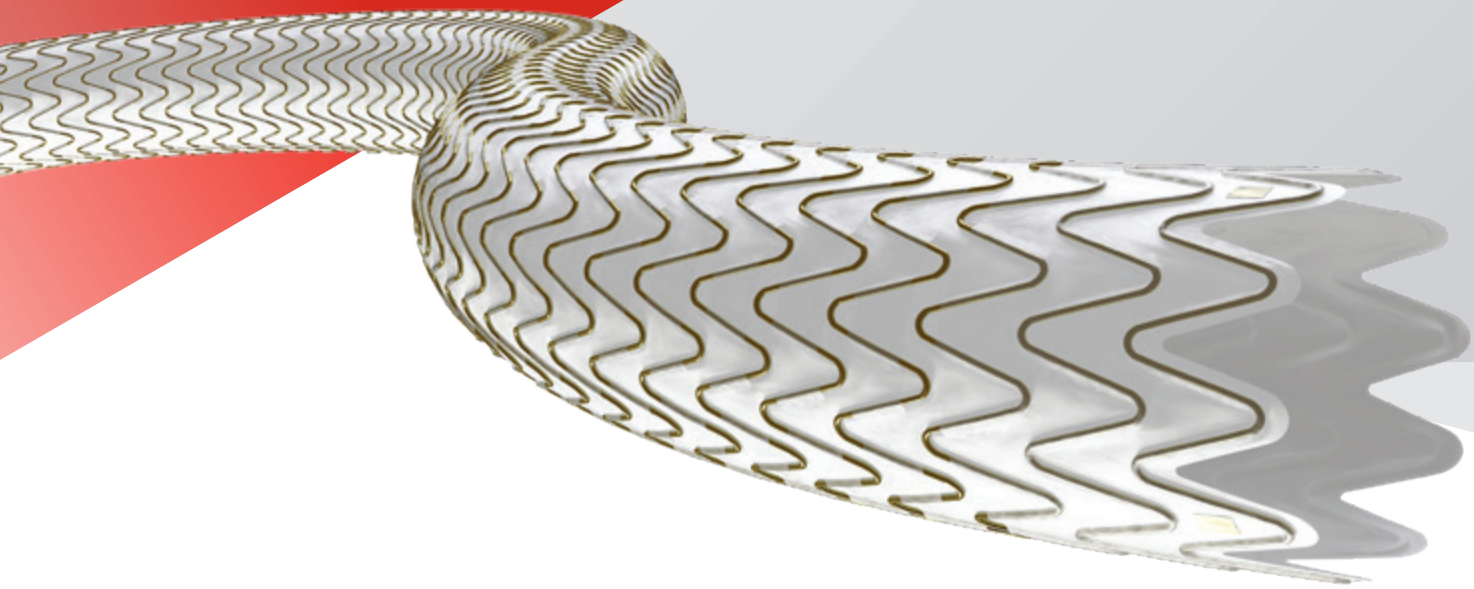
GORE **REVISE** CLINICAL STUDY



GORE® VIABAHN®
Endoprosthesis with PROPATEN
Bioactive Surface*

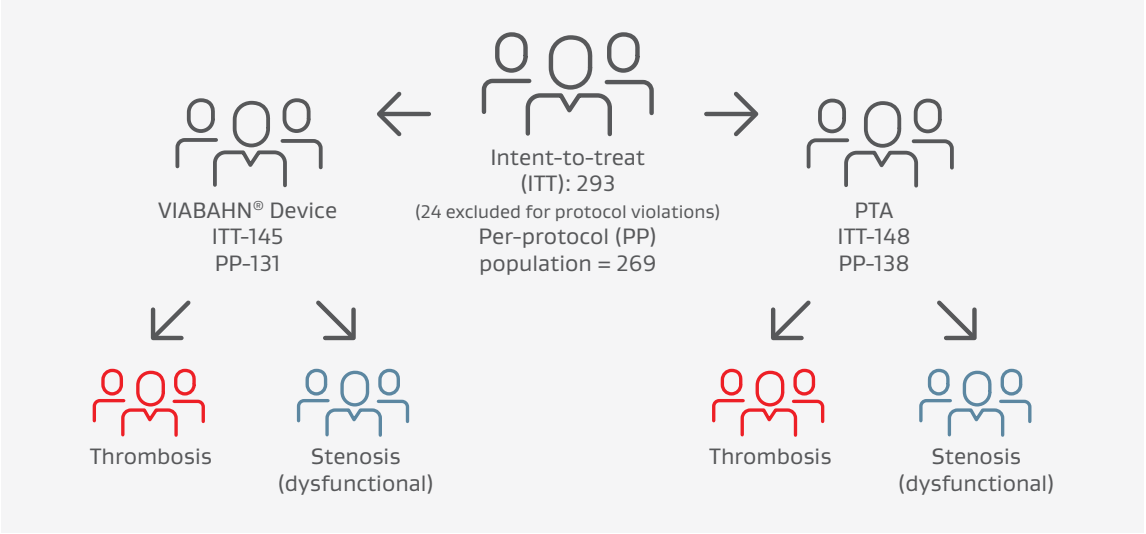
Gore clinical study receives **JVIR editor's award** for outstanding clinical research paper for 2019 from *Journal of Vascular and Interventional Radiology*

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

Gore REVISE Clinical Study

The REVISE Study is a multicenter, randomized, controlled trial that demonstrated the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface when used to revise arteriovenous access of prosthetic grafts at the venous anastomosis in thrombotic or stenotic (dysfunctional) vascular access for hemodialysis. The REVISE Study randomized against percutaneous transluminal angioplasty (PTA) and follow-ups tracked the natural course of vascular access and reinterventions as the subject underwent regular hemodialysis.

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]

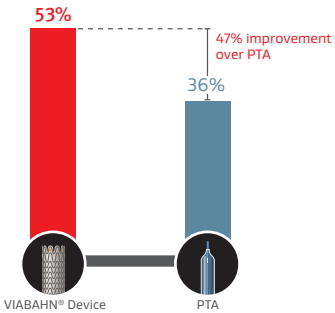


Results and key takeaways

Target lesion primary patency in the VIABAHN® Device group was significantly higher than the PTA group ($P = .008$)[5]

This was true at every time point through the 24-month analysis period. At 6 months, target lesion primary patency was 52.9% in the VIABAHN® Device group and 35.5% in the PTA group.[1,5]

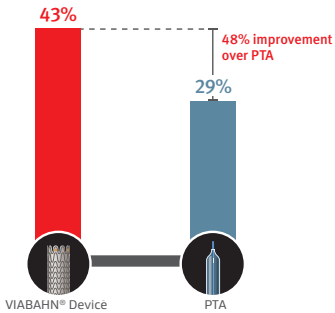
6-month target lesion primary patency



Circuit primary patency of the VIABAHN® Device showed a nearly 50% relative increase compared to PTA[5]

This was true at every time point from the 6-month to the 24-month analysis period.[5]

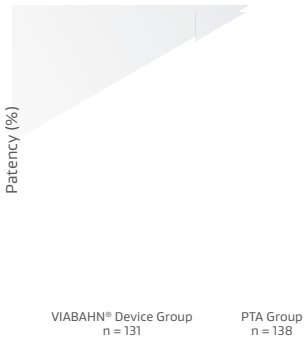
Six-month circuit primary patency



The VIABAHN® Device provided consistent patency independent of number of times a lesion had previously been treated[5]

The REVISE Study shows that the patency of the VIABAHN® Device will not decrease due to multiple previous interventions while the PTA treated graft will decrease.[5]

6-month target lesion patency with intervention history



Secondary patency across the elbow at 2 years is 83% with zero reported fractures.[6]
The VIABAHN® Device is shown to re-establish flow to stenosed (dysfunctional) grafts in points of flexion.[5,6]

The VIABAHN® Device demonstrated a reduction in the number of repeat interventions per patient with thrombosed grafts as compared to PTA, by reducing the mean number of future interventions over 2 years by 40% (3.7 for the VIABAHN® Device versus 6.2 for PTA),[7] *Figure 1*.

The VIABAHN® Device has strong clinical and health economic data to support the treatment of a thrombosed prosthetic graft. The reduction of interventions over a two year period by 40% reduces cost by ~$12K per patient,[7] *Figures 2–3*.

Figure 1. All reintervention types: Thrombosed circuits

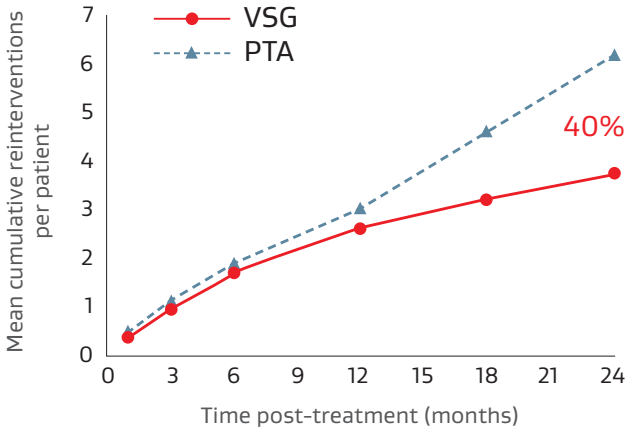


Figure 2. Average total costs: Thrombosed circuits

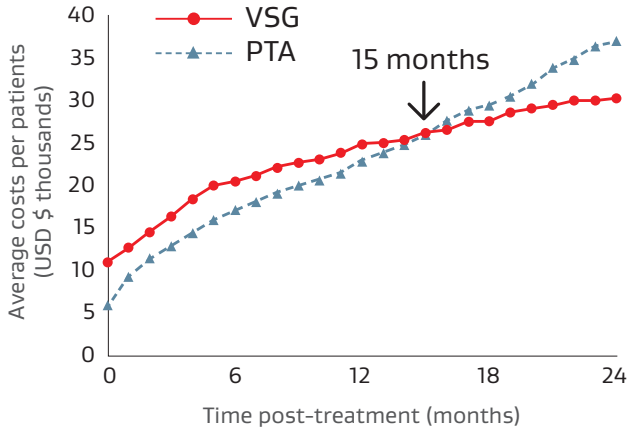


Figure 3. Reintervention costs: Thrombosed circuits