GORE® VIABAHN®
Endoprosthesis
with PROPATEN Bioactive Surface*

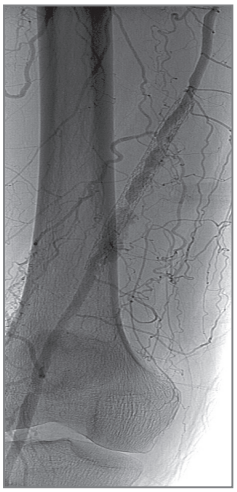
RELINE USING THE VIABAHN® DEVICE AS FIRST LINE THERAPY WHEN TREATING COMPLEX IN-STENT RESTENOSIS

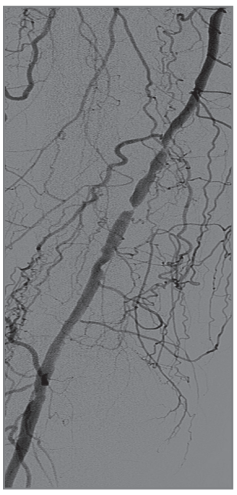
Case submitted by Benjamin J. Pearce, M.D.

Challenge

Treatment of a patient with recurrent in-stent restenosis (ISR)

- In 2007 the patient (age 72) presented with claudication requiring superficial femoral artery (SFA) cryoplasty
- Over an 11-year period the patient received multiple reinterventions
  - Less than three months after initial treatment — symptoms returned. Patient was treated with laser atherectomy at adductor hiatus and a 7 x 100 mm self-expanding bare metal nitinol stent was placed.
  - 2011 — Recurrent symptoms due to ISR treated with laser atherectomy and balloon angioplasty.
  - 2012 — Repeat laser atherectomy and balloon angioplasty.
  - 2015 — Debilitating dyspnea and return of distal disease based on drop of ankle-brachial index and elevated duplex velocity with ratio > 2; No peripheral intervention undertaken as limb ischemia was less symptomatic than coronary disease.
  - 2018 (age 83) — Successful transcatheter aortic valve replacement and alleviation of dyspnea. Patient re-presented with significant short distance claudication with inability to complete cardiac rehab; ISR with peak systolic velocity > 400 cm/s.





Procedure

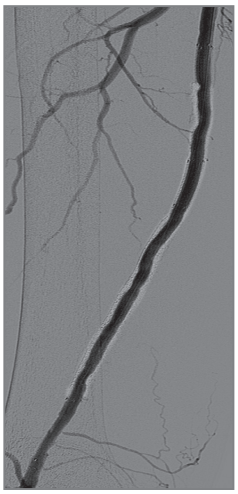
The VIABAHN® Device performed as an endoluminal bypass that covered and sealed off neointimal hyperplasia

- Due to multiple attempts at prior atherectomy and balloon angioplasty, procedure entered with intent to reline the bare metal stents (BMS) with the VIABAHN® Device.
- Contralateral access gained to perform aortogram and rule out inflow/outflow disease.
- 6 Fr TERUMO® DESTINATION® Guiding Sheath placed after anticoagulation.

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

Together, improving life

- Angiography confirmed ISR with two vessel runoff via large anterior tibial and peroneal arteries and some proximal progression of SFA disease.
- Crossed with 0.035" SPECTRANETICS QUICK-CROSS® Support Catheter and TERUMO® GLIDEWIRE® Guidewire.
- 7 mm MEDTRONIC SPIDERFX Embolic Protection Device placed through SPECTRANETICS QUICK-CROSS® Support Catheter.
- Pre-treated with a 5 x 100 mm balloon angioplasty including new disease proximal to old stent.
- First deployed a 6 mm x 15 cm VIABAHN® Device and then overlapped with a 6 mm x 10 cm VIABAHN® Device.



Result

Relining with the VIABAHN® Device delivered durable results for complex ISR

- Completion with no significant residual stenosis and no embolization of runoff.
- Due to age and travel, the patient was kept overnight and discharged the next morning with palpable dorsalis pedis pulse.

Case Takeaway

For any complex SFA ISR, relining with covered stent grafts has become a "go to" procedure as first line therapy. The Gore RELINE Clinical Study with the VIABAHN® Device showed high primary patency even in the most challenging disease: 75% one-year primary patency with an average lesion length of over 17 cm.[1] In this ISR disease case, relining the BMS with a VIABAHN® Device produced a favorable outcome and successfully excluded the neointimal hyperplasia associated with ISR of the BMS.

Images courtesy of Benjamin J. Pearce, M.D. Used with permission.

1. Bosiers M, Deloose K, Callaert J, *et al.* Superiority of stent-grafts for in-stent restenosis in the superficial femoral artery: twelve-month results from a multicenter randomized trial. *Journal of Endovascular Therapy* 2015;22(1):1-10.

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