

Endoluminal Bypass of the SFA



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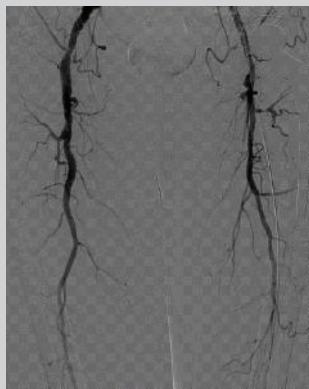


Figure 1a

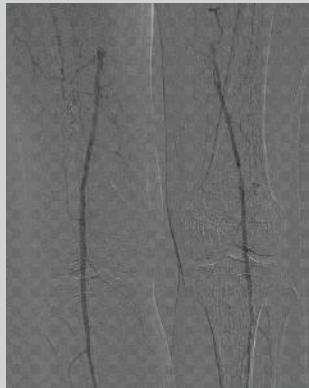


Figure 1b

Figure 1a and 1b:
Preoperative angiography showing patent common and deep femoral arteries. The SFA is occluded while the above-knee popliteal artery is patent with outflow in three crural vessels.

CLINICAL CHALLENGE

A 76-year-old patient presented with disabling claudication of his left leg. He had a medical history of nephrectomy, left hemiarthroplasty and right femoropopliteal bypass and he is a former smoker. The patient had an ankle-brachial index of 0.60 and duplex ultrasound scanning showed an occluded superficial femoral artery (SFA). The patient was treated with exercise therapy for three months without any effect on absolute and pain-free claudication distance. It was decided to plan an arterial reconstruction. Pre-operative arterial subtraction angiography confirmed the diagnosis of an occluded left SFA with outflow in three crural vessels (Fig. 1a and 1b).

PROCEDURE

The operation was performed under regional anesthesia. The patient received 5000 I.U. of heparin and 1 g cefazolin intravenously. The left common femoral artery was punctured percutaneously to position a 7 Fr sheath into the common femoral artery. A 0.035" hydrophilic GLIDEWIRE® (Terumo Medical Corporation) was placed in the left SFA, the occlusion was crossed in a subintimal plane, and a re-entry into the true lumen of the distal SFA artery was created. The occluded segment was predilated with a 5 mm non-compliant balloon and an endoluminal bypass was created using three (6 mm x 150 mm) GORE® VIABAHN® Endoprostheses with Heparin Bioactive Surface. The bypass was post-dilated with a 6 mm non-compliant balloon and the entry site was closed using an ANGIO-SEAL closure device (St. Jude Medical, Inc.).



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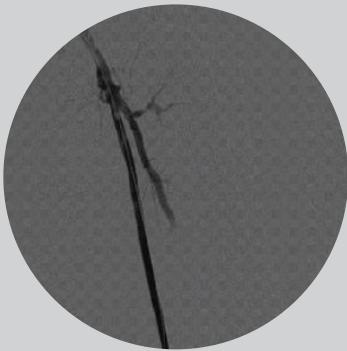


Figure 2a

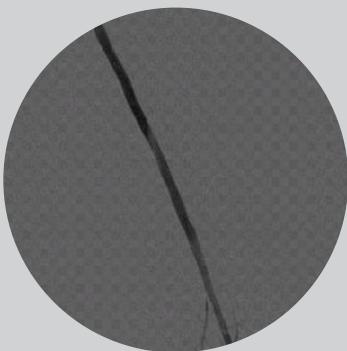


Figure 2b

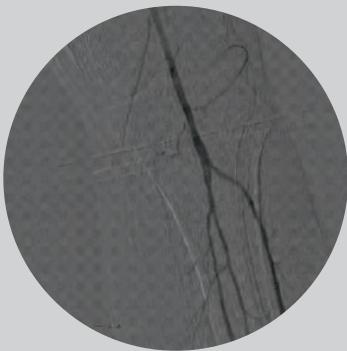


Figure 2c

Figure 2a, 2b and 2c:
Completion angiography showing adequate endoluminal bypass of the left SFA with good outflow in three crural vessels.

RESULTS

Completion angiography showed satisfactory deployment of the stent-grafts with good outflow in three crural vessels (Fig. 2a - 2c). There were no postoperative complications and the patient was discharged on the first postoperative day. The postoperative ankle-brachial index was 0.98. He was treated with clopidogrel 75 mg, acetylsalicylic acid 80 mg and simvastatin 20 mg. The patient remained free of symptoms, and after a follow-up of seven months, a duplex ultrasound scan showed a patent bypass without stenosis. The repeat ankle-brachial index was 0.95.

PHYSICIAN COMMENTS

The SFA is exposed to rotational, compressive and bending movements. A stent-graft used in this artery has to be very flexible and resistant to kinking and fracture. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface offers a unique combination of flexibility, covered stent and heparin-bonded technologies, which makes it an excellent endoprosthesis for an endoluminal femoropopliteal bypass. By reducing infolding in case of oversizing, the contoured proximal edge of the device may improve flow dynamics and vessel wall apposition.



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INDICATIONS FOR USE: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions 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 iliac artery lesions with reference vessel diameters ranging from 4.0 – 12 mm. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis 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 incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. Rx Only

Products listed may not be available in all markets.

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