The GORE® VIABAHN® Endoprosthesis for In-Stent Restenosis in the Superficial Femoral Artery

BY ROBERT L. MINOR, JR, MD, AND JEFFREY R. COOK, MD

A 59-year-old African American woman was initially evaluated for limiting right calf claudication. Lower extremity Doppler exam revealed a resting ABI of 0.75 in the right leg. Her past medical history was notable for diabetes, hypertension, hyperlipidemia, and prior cigarette smoking. Medications included metformin, lisinopril, lovastatin, and aspirin. Initial peripheral angiography demonstrated a chronic total occlusion (CTO) spanning 10 cm of the middle segment of the right superficial femoral artery (SFA) (Figure 1A). Interventions at that time involved implantation of three bare-nitinol SFA stents measuring 5.5 X 100 mm, 5.5 X 60 mm, and 6 X 60 mm in the distal, mid, and proximal SFA, respectively (Figure 1B). The patient was initiated on clopidogrel. However, 6 months after her index procedure, she developed severe recurrent symptoms. Repeat right lower extremity Doppler exam revealed a resting ABI of 0.54, and an exercise ABI of 0.28. Repeat angiography demonstrated severe and diffuse in-stent restenosis throughout the entire stented segment of the right SFA (Figure 2A). Regarding the run-off vessels, there was a distal occlusion of the posterior tibial artery, but patent anterior tibial and peroneal arteries (Figure 2B).

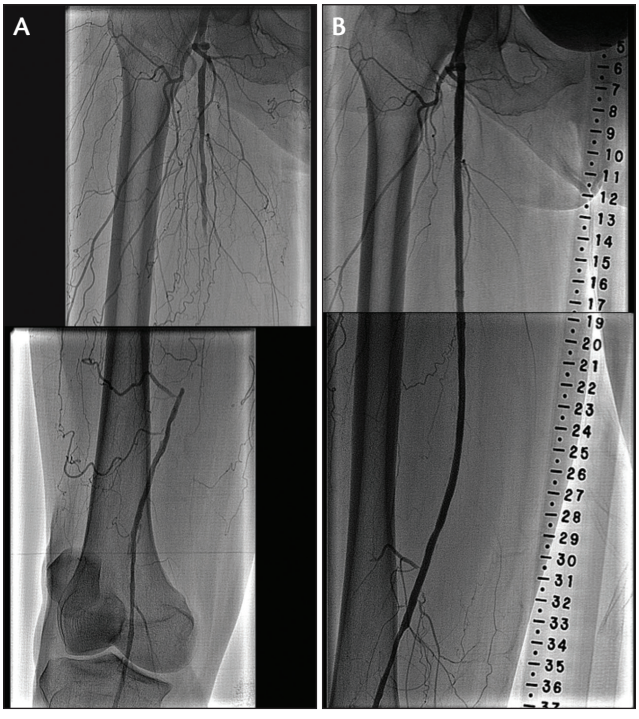

Figure 1. CTO in the right SFA (A). Initial procedural completion angiogram after treatment with bare-nitinol stents (B).

PROCEDURAL DESCRIPTION

The patient underwent repeat endovascular intervention using the left common femoral approach. A 7-F sheath (Cook Medical) was advanced in a contralateral fashion to the right common femoral artery. A steerable 0.035-inch Versacore guidewire (Abbott Vascular) was used to traverse the right SFA. A Quick-Cross catheter (Spectranetics Corporation) was advanced over this wire into the right popliteal artery, and the wire was exchanged for a 5-mm-diameter SpiderFX distal embolic protection filter (Medtronic). The entire segment of the right SFA with in-stent restenosis was then treated using rotational

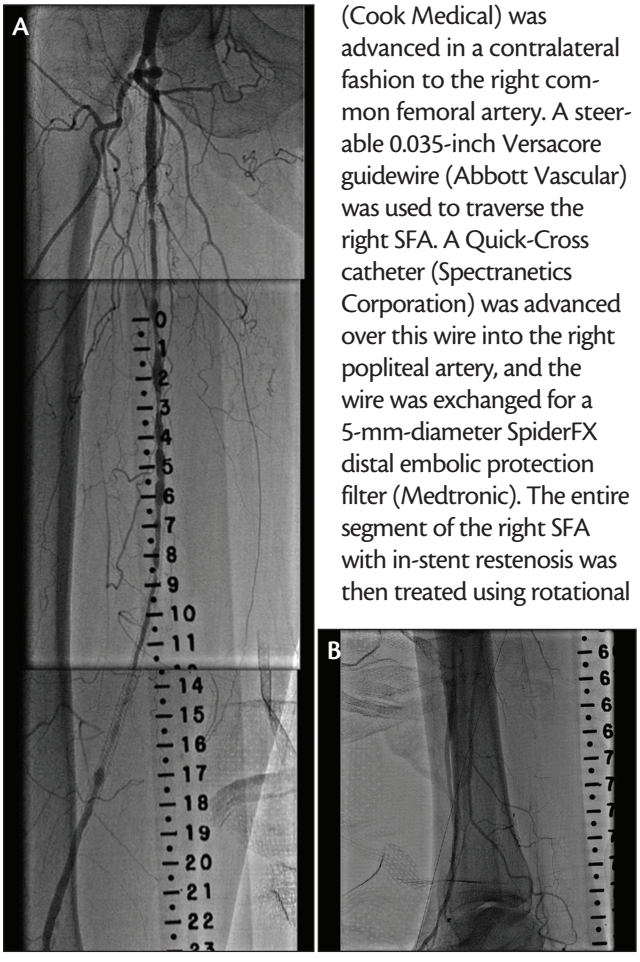

Figure 2. Diffuse in-stent restenosis of the SFA 6 months after implantation (A). Two-vessel tibial runoff (B).

CASE REPORT

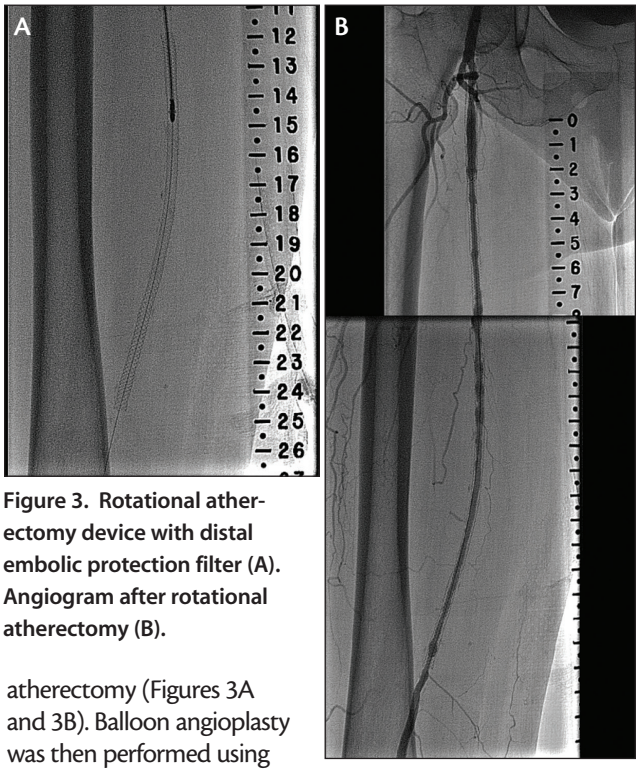

Figure 3. Rotational atherectomy device with distal embolic protection filter (A). Angiogram after rotational atherectomy (B).

atherectomy (Figures 3A and 3B). Balloon angioplasty was then performed using a Fox sv 5- X 100-mm angioplasty balloon (Abbott Vascular). Subsequently, a 5- X 250-mm GORE VIABAHN Device with Heparin Bioactive Surface was implanted in the distal and midsegment of the region of in-stent restenosis in the right SFA, followed by a second 6- X 50-mm GORE VIABAHN Device in the proximal segment. Postdilatation was performed with the FOX sv 5- X 100-mm balloon in the distal and midsegments, followed with a FOX sv 6- X 100-mm balloon in the proximal segment, maintaining balloon inflations within the edges of the GORE VIABAHN Devices. Nevertheless, a distal edge dissection was discovered, and a third 5- X 50-mm GORE VIABAHN Device was placed. The embolic protection filter was retrieved and inspected, revealing successful capture of tissue consistent with intimal hyperplasia.

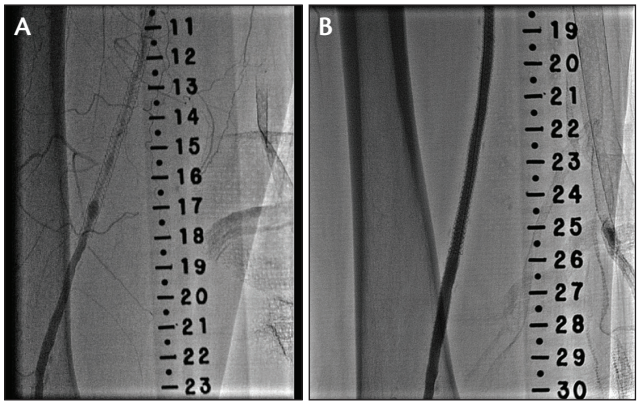

Figure 5. Magnified image of severe in-stent restenosis of the stent in the distal SFA (A). Magnified image after treatment with the GORE VIABAHN Device (B).

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RESULTS

Completion angiography revealed a widely patent right SFA with brisk flow and no residual stenosis (Figure 4). There was also excellent distal flow into the pedal arch vasculature, with no evidence of distal tissue embolization. The patient was continued on clopidogrel and low-dose aspirin. She has remained asymptomatic, and follow-up Doppler exam performed 9 months after placement of the GORE VIABAHN Devices for in-stent restenosis confirmed improvement in the right leg resting ABI from 0.54 to 1.0.

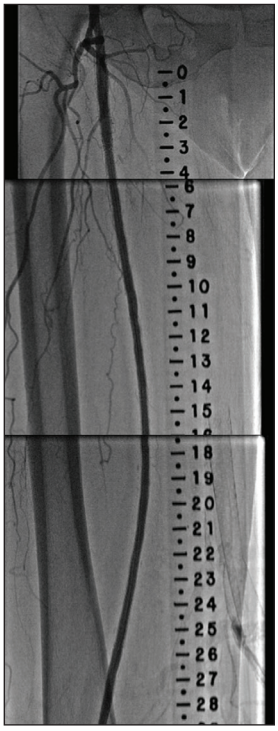

Figure 4. Completion angiogram after placement of the GORE VIABAHN Device for in-stent restenosis in the SFA.

DISCUSSION

The use of the GORE VIABAHN Device with Heparin Bioactive Surface provides an excellent treatment option for in-stent restenosis in the SFA, particularly when it involves a long stented segment. In this case, rotational atherectomy with embolic filter protection was used to initially debulk the restenotic tissue. With the subsequent use of both balloon pre- and postdilatation, placement of GORE VIABAHN Devices resulted in an angiographic result suggesting optimal expansion throughout the SFA containing the previously implanted stents (Figures 5A and 5B). ■

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