

What Goes Around Comes Around: Fully Endovascular Femoropopliteal Bypass

With long-term durability of SFA interventions still a challenge, a new approach should be considered.

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Endovascular interventions are now reported to be more common than bypass surgery in the treatment of lower extremity peripheral artery disease.¹ From the patient's perspective, the possibility of avoiding potential complications, general anesthesia, and a prolonged hospital stay is compelling, as is the potential to treat multilevel disease in one session. A proliferation of endovascular techniques and approaches have improved outcomes, broadened the field of treatable patients, and enhanced our understanding of disease progression. But, notwithstanding ingenious technical and methodological innovation and improvements in imaging technology, certain patients' comorbidities and lesion architecture do not immediately lend themselves to safe, effective, minimally invasive solutions that provide durable patency.

The long-term results of infrainguinal interventions are still suboptimal; crossing a 20- to 30-cm segment of a totally occluded superficial femoral artery (SFA) has become possible, but the procedure can be time consuming and exhausting both for the operator and patient. Unfortunately, even with advanced technical skills, acute technical success does not translate into durable long-term patency. SFA interventions are plagued with redo procedures, generating a financial burden for the health system and frustration for the patient and treating physician.

The long-term results of percutaneous revascularization of long-segment disease are inferior to those of bypass surgery. One possible explanation is that, in open surgery, the conduit bypasses the calcified area with no physical interaction between the graft and the calcified artery. In contrast, after SFA stenting, the chronic radial force exerted by the stent, along with

torsion, compression, and flexion of the artery in the adductor canal all contribute to stent strut fractures, in-stent restenosis (ISR) and, eventually, occlusion.

Clearly, there is both an unmet need in endovascular approaches to long-segment SFA disease and an enduring trend towards endovascular-first approaches to revascularization in the peripheral vasculature. A growing number of patients cannot benefit from the durability of an open surgical bypass due to age and cardiovascular comorbidities.

The PQ DETOUR System (PQ Bypass) is designed to combine the benefits of surgical bypass with those of an endovascular approach. The recently completed 78-patient DETOUR I trial in Europe demonstrates the potential of endovascular bypass to treat long (mean, 29 cm; maximum, 44 cm), calcified occlusions of the SFA using two or three TORUS stent grafts (PQ Bypass) and the adjacent deep femoral vein as a conduit.² In the DETOUR procedure, the DETOUR Crossing Device is used to cross from the proximal 3 cm of the SFA into the deep femoral vein and then back into the popliteal artery, thereby avoiding interaction between the stent graft and the calcified SFA. The procedure is performed under local anesthesia, allowing for same-day or next-day discharge.

In the following case study of a patient in the DETOUR I trial, this fully endovascular femoropopliteal bypass procedure is described in detail.

CASE REPORT

A 67-year-old man with multiple comorbidities (atrial fibrillation, coronary artery disease, and chronic obstructive pulmonary disease) underwent coronary artery bypass grafting in 2010 and, subsequently, two percutaneous transluminal coronary angioplasty procedures. The patient was initially treated with stenting of



Figure 1. Long SFA occlusion before treatment.

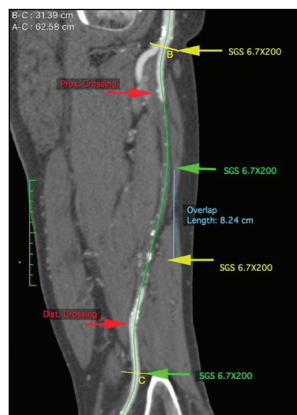


Figure 2. Preoperative planning showing coverage of the lesion with two TORUS stent grafts and overlap between two stents in the deep femoral vein.

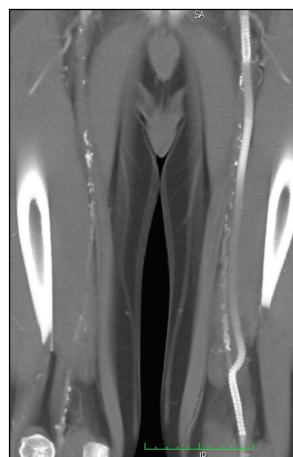


Figure 3. Two-dimensional reconstruction of the endovascular bypass.



Figure 4. CTA reconstruction of the stent graft reentering into the deep femoral vein the popliteal artery.



Figure 5. TORUS stent graft covering the proximal portion of the SFA and crossing into the deep femoral vein (uncovered stents of the bypass in the common femoral artery).

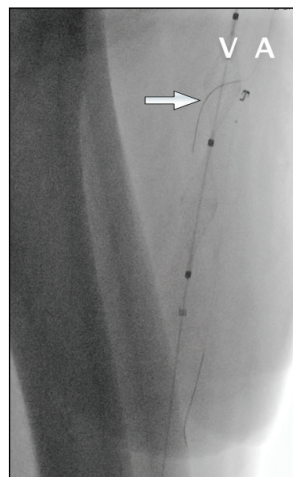


Figure 6. Crossing from the proximal stump of the SFA (A) into the deep vein (V).

his right common iliac artery and left SFA angioplasty in April 2016. In July 2016, he presented with pulmonary edema and non-ST-segment myocardial infarction and was treated with drug-eluting stent implantation into his left anterior descending coronary artery. After making a full recovery, he returned to the office complaining of right calf claudication. The culprit lesion was a > 23-cm occlusion of his right SFA (Figure 1).

The patient underwent endovascular bypass with the DETOUR System in October 2016 under local anesthesia (Figure 2). The long SFA occlusion was bypassed

(Figure 3) using two overlapping 6- X 200-mm TORUS stent grafts utilizing the adjacent deep femoral vein as a conduit (Figures 4–6). He was discharged the following day. The endovascular bypass remains patent at 6 months and the patient is symptom free. The follow-up duplex Doppler scan confirmed the patency of the bypass (Figure 7). No deep venous thrombosis (DVT) was detected, and his ankle-brachial index was 1.

TECHNIQUE

The aim of this novel technology is to offer a viable alternative to the traditional open surgical femoropopliteal bypass. Calcified occlusions of the SFA can be treated. The only study requirement was a short proximal SFA stump and a good-quality P1 segment of the popliteal artery, which is needed as a landing zone for the distal stent graft. The adjacent deep femoral vein is used as a conduit for the bypass. To avoid interaction and compression of the stent graft within the calcified SFA, crossing into the deep venous system is performed from the proximal first 3 to 4 cm of the SFA. Later, the reentry from vein to popliteal artery is

created above the upper margin of the patella.

The procedure starts by accessing the posterior tibial vein using ultrasound. After placing a sheath and performing venography to confirm the patency and diameter of the deep venous system, a contralateral arterial access with an 8-F Flexor Balkin sheath (Cook Medical) is performed. A through-and-through access is established for extra support, which is needed for crossing into and out of the venous system. After performing the crossing from the proximal SFA into the deep vein and back into the popliteal artery with the

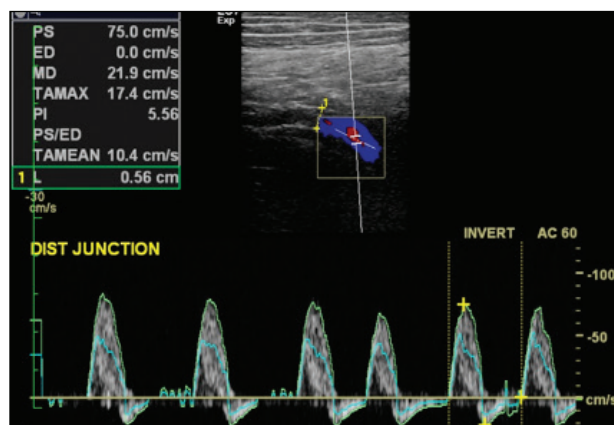


Figure 7. Six-month follow-up duplex Doppler demonstrating gentle curve and unimpaired flow through the junction.

DETOUR Crossing Device and DETOUR Snare, two or three overlapping TORUS stent grafts are implanted, creating an endovascular bypass.

Approximately 3 cm of the graft is placed in the popliteal artery to ensure adequate anchoring. A larger overlap between stent grafts in the deep femoral vein is required to prevent the stent grafts from decoupling. According to the study protocol, crossing of the knee joint level is discouraged.

USE OF THE FEMORAL VEIN

Use of the deep femoral vein as a conduit for endovascular bypass is both novel and controversial. Potential patients for the DETOUR endovascular bypass procedure are carefully screened. History of DVT, thrombophilia, and femoral vein diameter < 10 mm are all contraindications unless the patient has a duplicate femoral vein. A thorough duplex Doppler scan is performed in the upright position. If the vein diameter is ≥ 10 mm or if the patient has a duplicate femoral vein, the patient qualifies for the procedure. Even with the graft inside the vein, it is estimated that the lumen is reduced by $\leq 50\%$, thus preserving adequate venous return.

DISCUSSION

The DETOUR procedure is a novel approach to filling the gap in endovascular approaches to long-segment SFA disease by combining the advantages of bypass with the benefits of a percutaneous approach, which shows promise in both patency and safety. The DETOUR I study's 6-month data were presented by Prof. Dierk Scheinert at the 2017 Leipzig Interventional Course.² During this initial study interval, no cases of DVT were detected. Primary patency was 84.7% and all patients reported improvement in claudication, defined as a shift from Rutherford class 3 or 4 to either Rutherford class 0

or class 1. These data reflect a unique and innovative approach toward the treatment of long (> 15 cm) SFA occlusions.

The future of primary stenting for long SFA lesions is unclear. There is no evidence so far that drug-eluting stents will solve the conundrum of ISR and reinterventions in this territory; long-term data are also lacking with regard to the use of atherectomy in combination with drug delivery to the vessel wall. Not to mention the fact that lesion length in most endovascular trials does not come close to 20 cm.

We have demonstrated that fully endovascular bypass is technically possible, compares favorably with current available techniques, and can be performed as a day-case surgery. Due to favorable results of the European DETOUR I trial, a United States study (DETOUR II) is scheduled to begin this fall. An important endpoint is the impact of partial occupancy of the deep venous system on potential morbidity defined as DVT and postthrombotic syndrome.

SUMMARY

After half a century of endovascular innovation, long-segment lesions in the SFA remain refractory to percutaneous revascularization modalities. Despite endovascular advancements, we cannot assure our patients that their arteries will stay open for 10 or 15 years, an outcome not unusual for open vascular surgery.

Maybe it is time to take a detour from attempts at long intraluminal crossing, especially in the most calcified lesions. If endovascular bypass is proven to be durable, it can become one of the options in the treatment of long-segment SFA lesions, especially for those patients who cannot be treated with open surgery under general anesthesia. ■

1. Goodney PP, Beck AW, Nagle J, et al. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. *J Vasc Surg.* 2009;50:54-60.
2. Scheinert D. Novel percutaneous bypass treatment for patients with long, complex (TASC II D) SFA occlusions: the DETOUR I trial. Presented at: Leipzig Interventional Course (LINC); January 24, 2017; Leipzig, Germany.

The PQ Bypass technology platform has CE Mark approval but is not yet approved by the US Food and Drug Administration.

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