

# Transforming Open to Endo: Percutaneous Bypass as an Option for Long-Segment SFA Disease

A brief review of the Detour procedure technique, proposed advantages, and potential clinical applications.

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The field of endovascular medicine is evolving at a steady pace. Novel interventional devices continue to enter the market with the goal of safer procedures and more durable results. Many will recall the sometimes-painful coronary stent revolution, in which single-digit restenosis rates were finally achieved after 20 years. For many of those years, restenosis rates were an unacceptable 30% to 50%, and a considerable volume of our cases represented repeat interventions. Infrainguinal arterial interventions have been more of the same, and one could argue that the superficial femoral artery (SFA) is a more formidable foe—more reactive, calcified, prone to occlusion, and with proven resistance to many conventional endovascular strategies.

At the midway point of the endovascular revolution, several different approaches have safely demonstrated reasonable effectiveness in SFA lesions up to 15 cm in length. Naturally, we have tried to apply these same techniques to longer and more complex lesions. Unfortunately, the ability to achieve acceptable acute endovascular results in TransAtlantic Inter-Society Consensus C and D lesions has not been accompanied by satisfying rates of long-term patency. The reasons are many: amplified biologic reaction to treatment, suboptimal luminal gain with high residual resistance to

flow, profunda collateral competition, poor runoff, and distal embolization, to name a few. In the end, limited data support the use of current endovascular therapies for long, occlusive SFA disease (Table 1).<sup>1-8</sup>

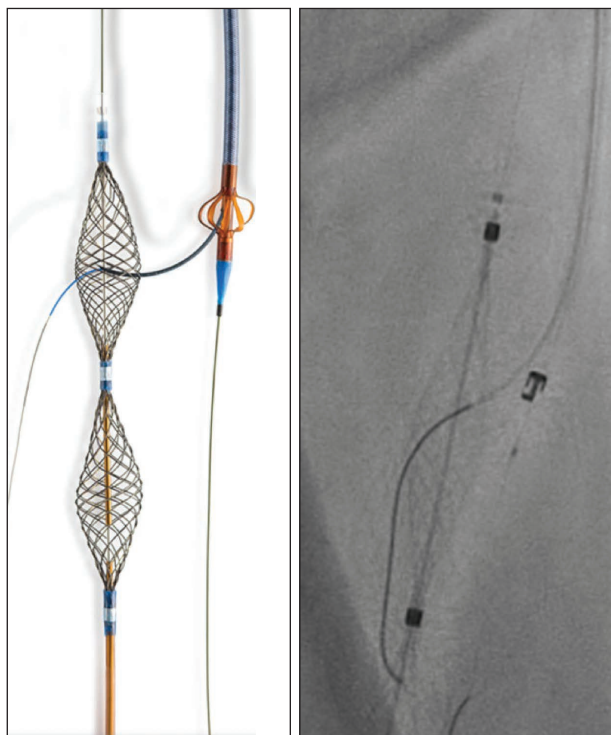
To date, surgical femoropopliteal bypass remains the gold standard for treatment of serious SFA disease. However, superior outcomes with surgical bypass do not come without a cost. Prolonged recovery time, wound infections, and lymphoceles are among the reasons that even those who perform bypass surgery increasingly choose an endovascular-first approach to SFA occlusions. There are several examples of major cardiac and vascular operations that have successfully evolved into minimally invasive procedures. In each instance, the goal has been to retain the superiority of the surgical outcome while reducing any negative impact on the patient. Coronary stents, endovascular stent grafts for abdominal aortic aneurysms, and percutaneous heart valves are among a growing list of technologies that have shifted the paradigm of how patients with advanced disease are managed. Percutaneous femoropopliteal bypass with the Detour system (PQ Bypass, Inc.) similarly seeks to mimic the durability of open surgical bypass via a percutaneous endovascular procedure that can be performed on an outpatient basis.

TABLE 1. DATA FROM PMA SUMMARY OF SAFETY AND EFFECTIVENESS DATA AND A VIVA META-ANALYSIS

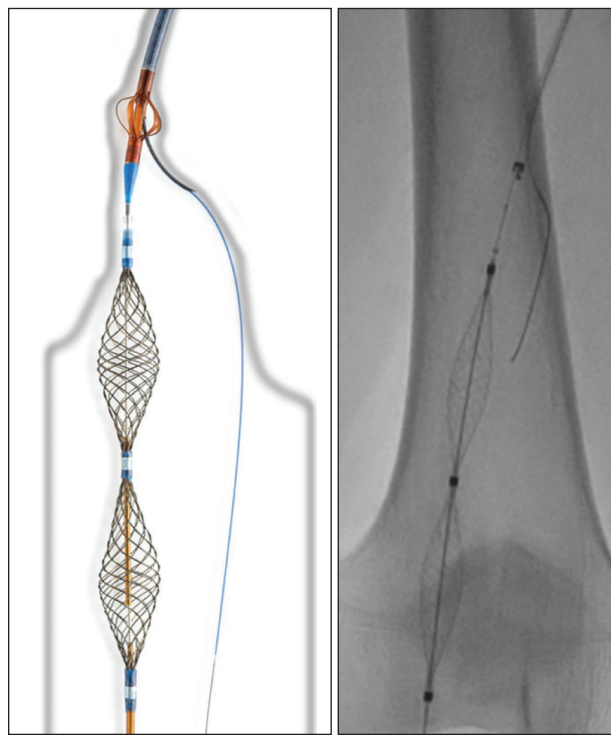
Stent Name	Manufacturer	PMA Number	Device Type	No. of Patients/ Lesions in Trial	No. of Patients With Lesions > 15 cm at 12-Month Follow-Up	12-Month Patency in Lesions > 15 cm
Supera <sup>1</sup>	Abbott Vascular	P120020	BMS	265	15	53.3%
LifeStent/LifeStent XL <sup>2</sup>	BD Interventional	P070014/S010	BMS	291	46	60.9%
Astron Pulsar/ Pulsar-18 <sup>3</sup>	Biotronik	P160025	BMS	302	33	54.5%
Innova <sup>4</sup>	Boston Scientific Corporation	P140028	BMS	299	36	47.2%
EverFlex <sup>5</sup>	Medtronic	P11023	BMS	287	24	33.3%
Lutonix <sup>6</sup>	BD Interventional	P130024	DCB	118	77	55.8%
Viabahn <sup>7</sup>	Gore & Associates	P240037	SG	144	16	54%
Viabahn 25 cm <sup>7</sup>	Gore & Associates	P040037	SG	71	54	67%
VIVA meta-analysis <sup>8</sup>	–	–	BMS	999	248	55.1%

Abbreviations: BMS, bare-metal stent; DCB, drug-coated balloon; PMA, premarket approval; SG, stent graft; VIVA, Vascular InterVenTional Advances.

Product image courtesy of PQ Bypass, Inc.

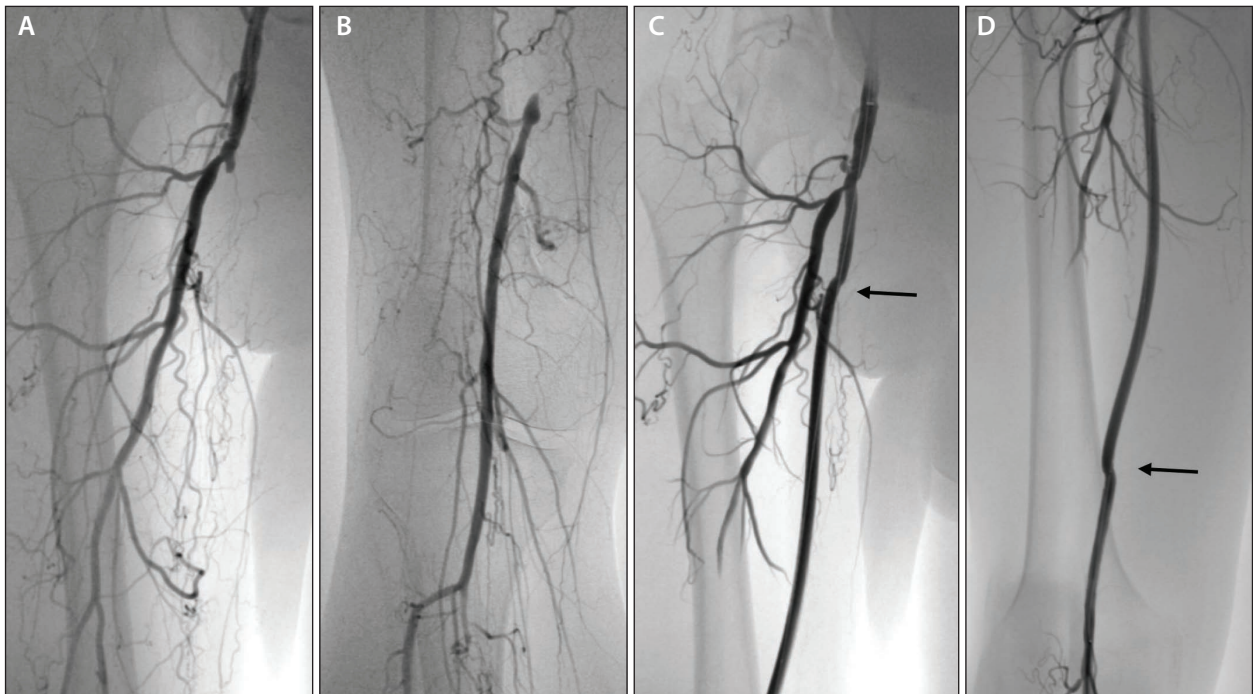


**Figure 1.** Snare and crossing device in parallel at the proximal aspect of the long lesion/occlusion. The needle was fired through the SFA into the femoral vein, and the wire passed safely into the venous compartment.



**Figure 2.** The snare and crossing device are interlocked in series in the femoral vein, and the needle of the crossing device has been safely fired into the popliteal artery (note the wire being advanced distally).

Product image courtesy of PQ Bypass, Inc.



**Figure 3.** Baseline angiogram depicting long chronic total occlusion of the right SFA with a short stump (A). Baseline angiogram showing collateral reconstitution of the P1 segment of the popliteal artery beyond the adductor canal (B). Final angiogram after successful percutaneous bypass. Note the proximal anastomosis as the graft enters the adjacent femoral vein (arrow) (C). Final angiogram after the Detour procedure with a smooth transition into the popliteal artery. Note the distal anastomosis as the graft enters the popliteal artery (arrow) (D).

## THE DETOUR PROCEDURE

### Technique

The Detour procedure is performed through a contralateral arterial puncture and an ipsilateral venous puncture to create a stent graft bypass that circumvents long-segment SFA disease using the adjacent femoral vein (FV) as a conduit. As is standard in lower extremity procedures, the first step is ultrasound-guided, contralateral femoral arterial access with placement of a crossover sheath. An ipsilateral sheath is placed in the posterior tibial vein in similar fashion. Angiography and venography are performed, and parallel access to the SFA and adjacent FV are secured. A proprietary snare is advanced retrograde through the venous sheath under fluoroscopy to a position adjacent to where the SFA disease originates, and at that level, the snare is deployed. Through the arterial sheath, a specialized crossing device is advanced to the proximal SFA and is positioned parallel to the snare. The deployed snare provides a highly visible target for the crossing device and holds the FV in a fully expanded and receptive position. Using fluoroscopic markings on the distal end of the crossing device, it is oriented directly at the snare, and a spring-loaded hypotube needle is fired

into the snare through the sidewalls of the SFA and FV. A standard 0.014-inch wire is then advanced through the crossing device and into the snare (Figure 1). The snare is collapsed and resheathed, and the wire is captured and withdrawn until it is safely externalized through the venous sheath.

After dilating the proximal anastomosis, the crossing device and snare are reintroduced on the same wire and advanced distally to a position where collaterals reconstitute the proximal popliteal artery. Here, the two devices are aligned in series by docking their distal tips together. The snare is deployed to provide a stable platform, and the crossing device is again oriented under fluoroscopic guidance and directed toward the popliteal artery. The hypotube needle is then fired through the walls of the FV and popliteal artery, and a wire is advanced safely into the arterial lumen and distally to the tibial branches (Figure 2). The devices are then removed, and the distal anastomosis is dilated in preparation for stent graft placement. Two or three Torus stent grafts (PQ Bypass, Inc.) are then delivered and deployed in overlapping fashion from the proximal popliteal artery, to and through the FV, and back into the proximal SFA. After postdilation, images are

obtained, and the sheaths are removed, thus completing a fully percutaneous bypass (Figure 3).

### Benefits and Potential Applications

There are several proposed benefits of percutaneous bypass aside from avoiding the obvious clinical brunt of open surgery and general anesthesia. In existing long-segment SFA interventions, operators are ultimately trying to resuscitate an end-stage vessel that is no longer capable of normal function. This often requires excessive traffic through the SFA with multiple devices that, in the end, runs the risk of exchanging infrainguinal occlusive disease for infrageniculate distal embolization. Operators work long and hard to gain an acceptable acute result, but this approach cannot rival the volumetric flow attributed to a bypass conduit. The combination of residual plaque, extrinsic compression, inflammation, and competitive collateral flow are all factors that influence the procedural result.

In the Detour procedure, there is a short segment of stent graft that resides intraluminally at either end of the bypass, thus limiting the amount of device-to-artery interaction, and most of the percutaneous bypass resides in the adjacent FV, where the stent grafts can expand to their full diameter, resulting in a greater flow capacity. By navigating around the diseased segment of the SFA, the intervening plaque is left in place and embolization to the tibial arteries may be minimized. Because the Detour procedure uses the FV as a conduit, it is best to avoid this approach in patients with a previous deep vein thrombosis or small FV diameter (< 10 mm). Favorably, the Detour procedure does not limit future endovascular intervention or preclude open surgical (bypass) options.

The Detour procedure is designed to be a frontline therapy for long-segment SFA disease. Most patients with extensive disease of the SFA fall into one of five general categories: (1) those with lesions treated with existing endovascular devices, with knowledge that long-term patency will be less than ideal and repeat procedures may be necessary; (2) those with lesions that are conservatively managed because their disease is too advanced for an endovascular approach but not critical enough for open surgical bypass; (3) those with occlusions who are sent for open bypass but an

alternative may be desired due to comorbid conditions or an anticipated complication; (4) those with lesions treated endovascularly that reocclude; and (5) those who undergo open bypass but it subsequently fails. Whether used as a minimally invasive alternative for surgical bypass or applied as a primary endovascular strategy, the Detour procedure is designed to manage occlusions, diffuse stenoses, densely calcified lesions, and restenotic long-segment SFA disease.

### SUMMARY

Percutaneous bypass of the SFA has been studied in a prospective, multinational trial (DETOUR I), which led to CE Mark approval of the Detour system in 2017. Publication of the study results are anticipated soon. In the United States, the procedure and investigational devices are being researched in DETOUR II, which began enrolling patients earlier this year. The burden of proof now lies in the data, and we look forward to sharing results as they evolve. ■

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*Disclosures: Co-founder and Chief Medical Officer of PQ Bypass, Inc.*