

Fully Percutaneous Femoropopliteal Bypass: First-of-its-Kind Procedure for Patients With Peripheral Artery Disease

Interview by Lauren LeBano

Lower-extremity peripheral artery disease (PAD) is the third-leading cause of atherosclerotic cardiovascular morbidity, following coronary artery disease and stroke. PAD affects more than 200 million people worldwide, and the prevalence of PAD is increasing as baby boomers enter high-risk age groups. With estimates of more than 20% of the population projected to age into the 65-and-over cohort by the year 2050, PAD is a growing epidemic with staggering social and economic costs.

PAD of the femoropopliteal arterial segment is the most common cause of intermittent claudication (pain that interferes with a patient's ability to function). Once PAD progresses to lifestyle-limiting claudication or, even further, to critical limb ischemia, physicians will consider performing a procedure to increase blood flow to the lower extremities. Endovascular interventions are now reported to be even more common than bypass surgery in the treatment of lower-extremity PAD. From the patient's perspective, the possibility of avoiding general anesthesia, prolonged hospital stays, and complications such as wound infection, hemorrhage, or nerve injury is compelling. But while a proliferation of endovascular techniques and approaches have improved outcomes, broadened the field of treatable patients, and enhanced our understanding of disease progression, 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 20–30 cm segment of a totally occluded superficial femoral artery (SFA) has become possible, but it can be extraordinarily time consuming and frequently requires the use of many different devices. Even with advanced technical skills, acute technical success does not translate into durable, long-term patency. The long-term results of percutaneous revascularization of complex, long-segment PAD are inferior to those of bypass surgery, with many patients returning multiple times over the course of their lives to have the same lesion re-treated. Clearly, there is an unmet need in endovascular approaches to the treatment of long-segment SFA disease, as an ever-growing number of patients are not able to benefit from the durability of an open surgical bypass due to age and cardiovascular comorbidities.

Percutaneous femoropopliteal bypass (the DETOUR procedure) is an entirely new procedure and may be the solution to this unmet need and undertreated population. Enabled by PQ Bypass' proprietary DETOUR System – comprised of the TORUS Stent Graft, DETOUR Crossing Device, and DETOUR Snare – the DETOUR procedure creates a pathway



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that originates in the SFA, crosses into and travels through the femoral vein, and then ends by returning into the popliteal artery, completely bypassing the diseased part of the artery. This includes diffuse calcification and stubborn chronic total occlusions that would normally exacerbate the difficulty of therapy and potential patient hardship. This pathway allows Torus stent grafts to be placed in a continuous line and consistently redirect oxygen-rich blood around the blockage, restoring blood flow to the lower leg and foot of the patient. Unlike existing technologies such as stents and drug-coated balloons, and specialty crossing devices, which merely create a channel through the disease and are not designed for extremely long blockages, the DETOUR procedure is a unique solution designed to provide the durability and patency of open bypass surgery through a minimally-invasive approach.

The evolution of treatment from open surgical procedures to minimally invasive and low-trauma therapies is a pattern that can be observed in several other highly prominent disease states. This includes events such as abdominal aortic aneurysms and transcatheter aortic valve replacement/transcatheter aortic valve implantation. Even further back in vascular medicine's history, the very creation of devices such as stents, balloons, and crossing devices demonstrated a desire on both sides of the operating table for minimally invasive image-guided procedures. By drawing the principles of this pattern into the treatment of lower-extremity PAD through the DETOUR I and recently FDA-approved investigational device exemption DETOUR II studies, PQ Bypass is merely extending the body of evidence that minimally invasive procedures can and will be used to treat conditions that historically required open surgical intervention.

In the age of value-based, patient-centered care, the DETOUR System and procedure may offer a new, minimally invasive, high-quality, cost-effective revascularization option. ■

Dr Mustapha discloses the following: Consultant for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cardiovascular Systems Inc, Cook Medical, Medtronic, Spectranetics, and Terumo.

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