Managing Patients With Long Complex Femoropopliteal Disease Using the DETOUR System

The *Journal of Critical Limb Ischemia* spoke with vascular surgeon Kyle B. Reynolds, MD, from MedStar Health in Washington, DC, about managing patients with long complex femoropopliteal disease with the DETOUR system, the first-ever fully percutaneous transmural arterial bypass (PTAB) therapy. Dr. Reynolds discusses how he uses it in his practice and how PTAB can improve patient outcomes.

For readers unfamiliar with DETOUR, what is it and how does it work?

The DETOUR system is a new FDA-approved percutaneous transmural arterial bypass (PTAB) procedure created to treat long complex femoropopliteal disease. It allows for the creation of a percutaneous femoropopliteal bypass, which is done by routing covered stent grafts through the femoral vein, typically going through the proximal superficial femoral artery (SFA). It has a purpose-built needle that allows us to cross from the proximal superficial artery into the femoral vein, and then back into the arterial system distally at the SFA or the above-the-knee popliteal artery. We then insert covered stent grafts so blood flow is redirected from the arterial system into the femoral vein and then back into the artery, bypassing the occlusion percutaneously in order to perfuse the lower extremity.

How has DETOUR expanded your options for complex femoropopliteal disease, particularly in long-segment occlusions?

DETOUR has helped in multiple ways as something to have in our endovascular armamentarium, both for interventionalists as well as vascular surgeons with the ability to do open surgery. I think it is very useful.

We know how well vein bypasses do in patient populations with long-segment diseases. However, there are patients who have already failed a vein bypass because, unfortunately, bypasses do not last forever, or sometimes patients are not necessarily good surgical candidates. They can be high risk, or they do not have adequate vein and you would need to use a prosthetic. In these scenarios, instead of creating a PTFE/prosthetic bypass down to the below-the-knee popliteal artery, if there is an adequate landing zone and you are not burning any bridges, this technology provides another option to treat complex, long-segment lesions. It is also useful for patients who have had failed multiple different endovascular options, giving an endovascular, minimally invasive ability to bypass the SFA and any occluded stents to get a more durable revascularization with better patency rates.

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You also have to weigh in a couple of other things. At a big tertiary care center where we get referrals, patients are transferred to us who have had multiple, previously failed interventions, so we start deeper in our revascularization bag. We also have patients who sometimes delay their care due to different social determinants of health. It could be a patient who is taking care of a loved one and is at risk of losing their leg and is concerned about a more extensive procedure, which can require an inpatient hospital stay or require rehab. It could be a patient who cannot take time off work, so they may have delayed their care. In these scenarios, PTAB is an early consideration since it gives us a revascularization option to restore blood flow while also getting the patient back home or back to work. The patient can leave the hospital the same day, avoiding rehab or a longer length of stay, with an improved quality of life by relieving their claudication or rest pain.

What types of patients do you believe are ideal candidates for DETOUR?

There are de novo lesions when DETOUR can be considered as your first treatment option. This tends to be with heavily calcified, long-segment, chronic total occlusions of the SFA. With this treatment option, you can revascularize the leg without burning any bridges as you save the patient's vein and avoid disrupting the below-the-knee popliteal artery bypass target. Using this strategy first avoids endovascular interventions that may be less effective in difficult, complex lesions that are known to have decreased patency rates and higher reintervention rates. This is also something to consider for patients who already have undergone bypasses. With failed above-the-knee popliteal artery bypasses, you can re-enter into the P1 segment and maintain your P3 segment for a future below-the-knee popliteal artery bypass. For patients with failed vein (or

prosthetic) below-the-knee popliteal bypasses, PTAB is a durable option with equivalent patency rates instead of a re-do bypass with prosthetic. We have also had patients who are not necessarily the healthiest and would be at extremely high risk for cardiovascular complications with general anesthesia for a bypass. PTAB has allowed us to be able to do an intervention under monitored anesthesia care or moderate sedation instead of general anesthesia, using a minimally invasive approach.

What is your decision-making process when choosing between traditional bypass, endo, or now DETOUR?

Unfortunately, not all patients are the same. Usually it is based off of the imaging, starting with an angiogram, as well as vein mapping to be able to see if the patient has an adequately sized healthy vein that could be used for a bypass. However, with patients who have already failed previous bypasses, and who do not necessarily have any adequate veins, I start thinking about PTAB sooner rather than later. If there are previous endovascular interventions that have failed, including the use of adjunctive devices to help open up occluded stents combined with specialty/drug-coated balloons to help maintain the patency—things that tend to fail when the patient gets interventions over and over again—I start thinking about using PTAB.

Have you used DETOUR in multilevel chronic limb-threatening ischemia (CLTI), and how did it complement other revascularization strategies? What results have you seen in patients with CLTI in terms of patency, wound healing, or symptom relief?

I have, as many of our patients with CLTI have significant disease in multiple segments. Usually, when you are thinking about CLTI, you are thinking about patients who have a lot of tibial disease. But when it is concomitant long-segment SFA disease, we have been able to get some good outcomes where SFA lesions have been treated; we have been able to bypass these lesions endovascularly and continue to treat the tibial lesions to increase perfusion to the wound and angiosome. From a technical standpoint, it has been easier than we expected to treat tibial lesions in one stage following the completion of the PTAB.

Just recently, I had a patient return to our clinic with a recurring wound after having a PTAB intervention over a year ago, and the PTAB was widely patent on duplex. We brought the patient to the OR, obtained contralateral access, and had no technical difficulty going through the stent grafts and then treating the recurring tibial artery lesion. Although this patient had a restenosis of the tibial artery lesion, the PTAB was widely patent and doing great as far as getting outflow out there.

Do you have any patient stories that highlight the kind of differences that DETOUR can make?

I had a patient whose wife had advanced dementia. He was her primary caretaker as well as the only person she recognized. Before getting an endovascular intervention, it was detrimental for him to coordinate care, having someone stay home to care for her as well as setting up his transportation to and from the hospital. He needed weeks in advance to plan, and it was very important to him to know what he was going to be able to do after his procedure. We performed an angiogram and saw that he had multiple stents in the SFA that were occluded. After the angiogram, we talked about doing a bypass, but bypass was not on the table for him, even though he had a significant wound that was getting worse, because he was worried about how he was going to be able to coordinate it with being away from his wife and his caregiving duties. He was going to delay his care, with the amputation risk, because he needed time to plan before a longer hospital stay. Once we did the appropriate imaging to assess his venous system, we decided he would be an ideal PTAB candidate. He was excited for this opportunity to be able to undergo the procedure and go home the same day and still be able to care for his wife. It was a joy that we were able to do this.

Other scenarios like this include patients who are still working and are the primary financial provider for their families and cannot afford to miss any time from work. Where delaying a bypass has an increased risk of amputation, the minimally invasive PTAB provides the ability to get back to work or carry out the activities of daily living. These are factors that I consider and have an open conversation with patients about all our options, weighing important social aspects to their risks and benefits. This technology in my toolbox adds another option to provide tailored, individualized care when treating our complex CLTI patients.

The DETOUR™ System and associated components, ENDOCROSS™ Device and TORUS™ Stent Graft System, are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to Instructions for Use for more information concerning Indications, Contraindications, Specific Anatomic Considerations, Warnings, Precautions, and Adverse Events. Rx only.