**POTENTIAL OFF- LABEL USE STATEMENT**

The authors report no conflicts of interest.

**REFERENCES**


**KEY WORDS:** peripheral vascular disease, critical limb ischemia, endovascular therapy.
have extensive calcification and long-segment arterial obstructions preventing successful intraluminal wire passage despite best attempts. This difficulty is compounded by the dense fibrocalcific nature of the proximal occlusive cap and the presence of numerous marginal collaterals at the occlusion margin through which wires preferentially direct. Due to the absence of dedicated distal tibial re-entry devices, if a subintimal path is created, spontaneous reentry into distal targets is required for interventional success. In our experience, this can be challenging, with inline flow restored to the foot in approximately 60% of subintimal cases; success rates are even lower when recanalizing an occluded posterior tibial artery due to difficulty advancing wires around the medial malleolus. In these instances, angiographically demonstrated patent distal calf or pedal arteries may be accessed directly with the goal of performing retrograde tibial recanalization.

Primary transpedal revascularization represents a novel interventional strategy for patients with unfavorable anatomy and an anticipated low likelihood of success using traditional techniques. In addition, a primary transpedal route may have benefit in allowing intraluminal revascularization if this is desired, such as when planning the use of drug-eluting balloons for treatment: due to the absence of marginal collaterals and a fibrous cap when passing wires cranially, maintaining a wire position within the true lumen may be facilitated.

More recently, an intentional first-line transpedal approach has been advocated by Mustapha, citing an able-
ty to easily access the pedal vessels with ultrasound guidance, and describing treatment of both the anterior tibial and posterior tibial branches via a dorsalis pedis puncture. The rapid adoption of dissemination of these techniques will be enabled by the development of dedicated devices and training pathways, similar to what has evolved for transradial catheterization.26

TOOLS

Transpedal revascularization is complex and time consuming. There are several key tools that interventionists must be familiar with and have available in order to achieve successful revascularization. Prior to embarking on this journey one must allot the appropriate amount of time for the procedure; often, a second interventionalist may be needed for portions of the procedure.

Transpedal access generally requires a handheld duplex ultrasound in order to visualize the tibiopedal vessels. Vascular access can be achieved by using a dedicated Micropuncture Pedal Access Set (Cook Medical). This kit comes with a 21-gauge, 4-cm echogenic needle, a 7-cm Micropuncture introducer, an 0.018˝ stainless steel mandril wire, and a hemostasis valve. The Check-Flo hemostasis valve (Cook Medical) can be attached to the 4 Fr introducer once access is achieved, allowing it to be used as an interventional introducer with a 2.9 Fr inner diameter. If a larger diameter introducer sheath is required, 4 Fr sheaths (and greater) are readily available. Vessel spasm can be prevented through the use of nitroglycerin and heparin.

Catheter, microcatheter, and wire choices are generally operator dependent (Table 1); however, in our lab we usually start with 2.6 Fr CXI Support Catheter or 4 Fr Kumpe Catheter (both from Cook Medical) to be our go-to catheters. The 2.6 Fr CXI Support Catheter (Cook Medical) fits nicely within the 4 Fr introducer/dilator from the Pedal Access Set and can be used as the main working catheter. Up-sizing to a traditional 4 Fr sheath (e.g. in order to utilize atherectomy or other devices) requires placement of a 0.035˝ wire, which can be inserted through the 4 Fr micro access dilator.

In the setting of chronic total occlusion (CTO), initial wire choice is often focused on either hydrophilic or CTO-type wires. Our experience with

Figure 2A. Ultrasound image depicting the expected location of the tibial artery flanked on either side by its corresponding vein.

Figure 2B. Fluoroscopic guided localization of a posterior tibial artery using calcification for target.

Figure 2C. Utilizing angiographic image to localize the pedal vessel for puncture.
the 0.014” Command wire (Abbott Vascular) and 0.014” Approach CTO wire (Cook Medical) have been favorable, however, there are many hydrophilic and total occlusion wires available on the market today. It may be worthwhile to stock several wires with shorter working lengths such as 130 cm for transpedal access cases. We have also used the 0.018” 70-degree Glide-wire (Terumo Interventional Systems) with good result, particularly when retrograde recanalization results in sub-intimal wire passage, with the intent of achieving rendezvous in the subintimal space with an antegrade catheter to complete the case. Additionally, if a 4 Fr sheath and 4 Fr catheter are used, one can use a 0.035” glidewire for intraluminal or subintimal crossing (Terumo Interventional Systems).

When utilizing the SAFARI technique (subintimal antegrade flossing using antegrade and retrograde intervention), initial attempts are made to pass the retrograde wire directly into the lumen of the antegrade catheter. If this cannot be achieved, a re-entry device and snare may be needed.

We typically use the Outback LTD Re-entry catheter (Cordis Corporation) in combination with either an 0.035” Expro Elite snare (Vascular Solutions) or 0.014” Micro Elite snare (Vascular Solutions). The re-entry catheter is typically used as the antegrade device, with the snared re-entry wire then pulled out through the pedal access for through-and-through control.

**TECHNIQUE**

**Pedal puncture**

Transpedal access can be performed under direct ultrasound, fluoroscopic, and angiographic or roadmap guidance (Figure 2). A handheld duplex ultrasound can generally identify the desired pedal vessel for puncture.

It is important to recognize the vessel in both long- and short-axis views to avoid venous puncture. Compression sonography helps identify the pulsatile artery from the adjacent vein, although Doppler interrogation may be used when arterial pressure is markedly diminished to ascertain which structure represents the pedal artery. When viewed in short axis, the artery is usually flanked by the accompanying vein on both sides (Figure 2A). In general, if wire passage is free and smooth, one should inject a small amount of contrast to confirm arterial vs venous access. In a heavily calcified pedal vessel one can perform the pedal puncture under direct fluoroscopic guidance (Figure 2B).

For noncalcified puncture sites, roadmapping from the antegrade catheter may be performed to identify the artery. When patient motion is a problem, repeated angiographic injections during access can also be helpful to guide puncture (Figure 2C). To reduce radiation exposure to the operator’s hand during fluoroscopic or roadmap guided punctures, a remote needle access tool is distributed by Spectranetics, or surgical clamps can be used to guide the insertion needle.

**Pedal access**

If the micropuncture set 0.018” mandril wire freely passes into the artery, then the nested 3 Fr and 4 Fr dilators are inserted directly. However, if wire movement is restricted, or if the wire cannot be passed into the artery past the point of the solder connection between the coil tip and wire mandril, then the inner 3 Fr dilator may be inserted alone to allow contrast injection and assurance of successful arterial positioning. Dense-ly calcified puncture sites pose a unique problem in which it may be difficult to advance even the 3 Fr inner dilator into the artery. This is particularly true if the puncture has been too vertical, with kinking of the wire during attempted dilator advancement. In these cases, a reinforced rigid 3 Fr dilator (Cook) may be tried, or the access needle itself may need to be carefully advanced in a rotary position to gain more purchase into the artery. The mandril wire can then be advanced until its soldered portion is within the artery, or a wire without a soldered transition (i.e. Roadrunner wire; Cook) may be tried.

Once a secure position in the desired artery is confirmed, choose the appropriate working access. We will either use the 4 Fr introducer with Check-flo valve accompanied with the 2.6 Fr CXI support catheter as described above or choose a standard 4 Fr vascular sheath and 4 Fr catheter. If dense calcification or the absence of sufficient patent distal artery for wire exchange prevents the introduction of the initial 3 Fr or 4 Fr micropuncture dilator, a different or more distal arterial puncture may be necessary.

**Antegrade crossing and catheter/wire positioning**

After failed recanalization of occluded tibial segments (using standard and advanced techniques), the antegrade wire or catheter should be left in place as a target for re-entry from the retrograde access. One may position the antegrade catheter or wire in the most distal aspect
of the true lumen or in a distal subintimal space that would be a good location for re-entry via rendezvous technique (Figure 3).

**Retrograde vessel crossing and catheter positioning**

From the tibial access, using a wire and catheter retrograde crossing of the desired tibial vessel is performed using a standard technique. One should be careful to maintain intraluminal passage through the vessel in order to re-enter more proximally. If one is able to secure intraluminal passage through the proximal occluded segment, it is possible to either directly cannulate the antegrade catheter or sheath or use a snare to pull the wire from the retrograde sheath through the antegrade sheath. Dedicated catheters are now available to ease the direct cannulation technique (Quick-Cross Capture Guidewire Retriever; Spectranetics).

**Re-entry device, snare positioning, deployment and “flossing”**

If re-entry from the retrograde sheath fails, the re-entry and snare technique is useful to gain “through and through” luminal access. From the antegrade sheath, position the Outback catheter as distally as possible in the subintimal plane (usually at the point of failed re-entry) (Figure 4A). From the retrograde sheath, advance a catheter and snare as proximally as possible. Deploy the Outback needle and advance the wire from the Outback catheter into the snare and pull the snare through the retrograde sheath (Figure 4B). Fluoroscopy in multiple planes helps to align the puncture towards the snare and reduce the number of passes needed for success. If there is particularly dense calcification at the initially selected re-entry site, then a more proximal or distal position should be tried.

Once the wire is pulled through the retrograde sheath, clamp the wire and remove the Outback from the antegrade sheath. The wire is now “flossed” and one may proceed in the usual manner to revascularize the disease segments. Angioplasty and stenting as needed ensues in the normal manner using this wire as your working wire.

**Hemostasis**

After the completion of intervention, hemostasis is generally achieved by manual compression with a hemostatic pad; we often use the TipStop bandage (Gambro) for this purpose. Balloon-assisted hemostasis may also
be achieved by inflating an angioplasty balloon at low pressure across the puncture site for 3 to 5 minutes. Finally, for peroneal punctures, inflation of an external blood pressure cuff over the calf can be performed for several minutes.

**CLINICAL DATA**

The reported clinical experience with transpedal tibial intervention involves predominantly case reports and small series. In the original series by Spinosa et al, procedural success was accomplished with the SAFARI technique in 12 patients using anterior tibial-dorsalis pedis or posterior tibial access. One-year patency in this series (including transfemoral SAFARI procedures for femoropopliteal occlusions) occurred in 58%. Gandini et al reported their experience using the SAFARI technique in four patients with nonhealing wounds and femoropopliteal occlusions. Antegrade access was obtained via the ipsilateral common femoral artery, and retrograde puncture through either the distal anterior tibial or posterior tibial artery, with subintimal wire snaring at the popliteal level and retrieval through the femoral access to allow subsequent procedure completion. All patients had wound healing by 3 months, and there were no pedal puncture site complications. Paleno and Manzo described direct puncture of the first dorsal metatarsal artery or pedal loop for retrograde catheter insertion in patients in whom the distal anterior tibial, dorsalis pedis, or posterior tibial arteries were not accessible. In this report, recanalization and intervention via the distal access was successfully achieved in 24 of 28 patients (86%). Restoration of straight line flow after intervention resulted in a 71% 6-month limb salvage rate; amputation avoidance was not achieved in any of the cases in which transpedal puncture could not be performed. Similar success rates have been described by Rogers et al, with 85% of 13 patients undergoing favorable revascularization using combined antegrade and pedal approaches. More recently, direct retrograde atherectomy techniques have been applied as a primary treatment strategy.

**CONCLUSION**

Transpedal interventions represent a unique and potentially limb preserving recanalization and revascularization technique in patients with CLI and advanced tibial occlusive disease. There will potentially be an increasing prevalence of patients with complex patterns of infrapopliteal atherosclerotic disease, and familiarity with the SAFARI technique will be of growing importance for interventionalists treating CLI patients.

**Editor’s Note:** Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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