Off-the-shelf percutaneous deep vein arterialization for no-option chronic limb-threatening ischemia related to Buerger disease

Justin A. Smith, MD,[a] Jagdesh Kandala, MD,[b] Jason Ty Turner, MD,[a]
Jae S. Cho, MD,[a] *and* Mehdi H. Shishehbor, DO, MPH, PhD,[b] *Cleveland, OH*

ABSTRACT

Percutaneous deep venous arterialization (pDVA) is an important technique in the pursuit of limb salvage for a certain high-risk subset of patients with chronic limb-threatening ischemia (CLTI) considered to have "no option" owing to the lack of tibial or pedal targets for revascularization. pDVA seeks to establish an arteriovenous connection at the level of the tibial vessels, in addition to tibial and/or pedal venoplasty, to provide a pathway for arterial perfusion via the tibial and/or plantar venous system. A commercial system for pDVA exists; however, it is not yet approved by the U.S. Food and Drug Administration. In the present report, we detail a method of pDVA that uses commercially available devices for a patient with no-option CLTI related to Buerger disease. (J Vasc Surg Cases Innov Tech 2023;9:101211.)

Keywords: CLTI; Deep venous arterialization; DVA; No-option

Despite the advances in open surgical and endovascular technologies, ≤20% of patients presenting with chronic limb-threatening ischemia (CLTI) fall into a high-risk subset with severe tibial and pedal disease, deemed as having "no option" for conventional revascularization techniques.[1] Deep vein arterialization (DVA) is a limb salvage technique that can be performed for such "no-option" patients with appropriate anatomy, in which perfusion to the foot is provided by creating an arteriovenous fistula at the level of the calf or distally, either by open surgical or endovascular methods.[2] Multiple small studies have described favorable limb salvage results (60%-75%) using percutaneous DVA (pDVA).[3-5] Although endovascular management of Buerger disease has been reported with favorable outcomes,[6] the application of pDVA to this patient cohort is not well characterized in the literature. To the best of our knowledge, only a single case of pDVA for a patient with Buerger disease or thromboangiitis obliterans has been reported.[7] We report a case of pDVA for a patient with no-option CLTI related to Buerger disease via a technique that uses commercially available devices. The patient provided written informed consent for the report of his case details and imaging studies.

CASE REPORT

A 55-year-old man presented with right foot rest pain and dry gangrenous second and third toes. His medical history was notable for hypertension, dyslipidemia, chronic active tobacco use (30 pack-years), and Buerger disease and his surgical history for left below-the-knee amputation for gangrene 15 years prior. His femoral and popliteal pulses were palpable, and only biphasic posterior tibial (PT) and dorsalis pedis signals were noted. The ankle brachial index was 0.62, with a toe brachial index of 0.0 and moderately dampened pulse volume recording waveforms (Fig 1).

Given the discrepancy between the clinical presentation and the noninvasive diagnostic test results, diagnostic arteriography was performed to define the extent and severity of the disease because the ankle brachial index has been shown to have limited correlation with the severity of below-the-knee disease.[8,9] Diagnostic arteriography demonstrated mildly diseased iliofemoral-popliteal segments. The anterior tibial artery was occluded at the distal calf, and the PT and peroneal arteries were occluded at their origins without distal reconstitution. The disease pattern was consistent with Buerger disease. No named arteries were visualized in the foot, consistent with "desert foot" (Fig 2). After discussion with our multidisciplinary limb salvage advisory council, pDVA was recommended. The patient was considered for the PROMISE II (percutaneous deep vein arterialization for the treatment of late-stage chronic limb-threatening ischemia) trial but was excluded because of the diagnosis of Buerger disease. It was then decided to perform

From the Division of Vascular Surgery and Endovascular Therapy,[a] and Division of Cardiovascular Medicine, Harrington Heart and Vascular Institute, Case Western Reserve University School of Medicine, University Hospitals Cleveland Medical Center.[b]

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M.H.S. and J.S.C. contributed equally to this article and share co-senior authorship.

Correspondence: Jae S. Cho, MD, Division of Vascular Surgery and Endovascular Therapy, Harrington Heart and Vascular Institute, Case Western Reserve University School of Medicine, University Hospitals Cleveland Medical Center, 11100 Euclid Ave, Cleveland, OH 44106 (e-mail: jsc163@case.edu).

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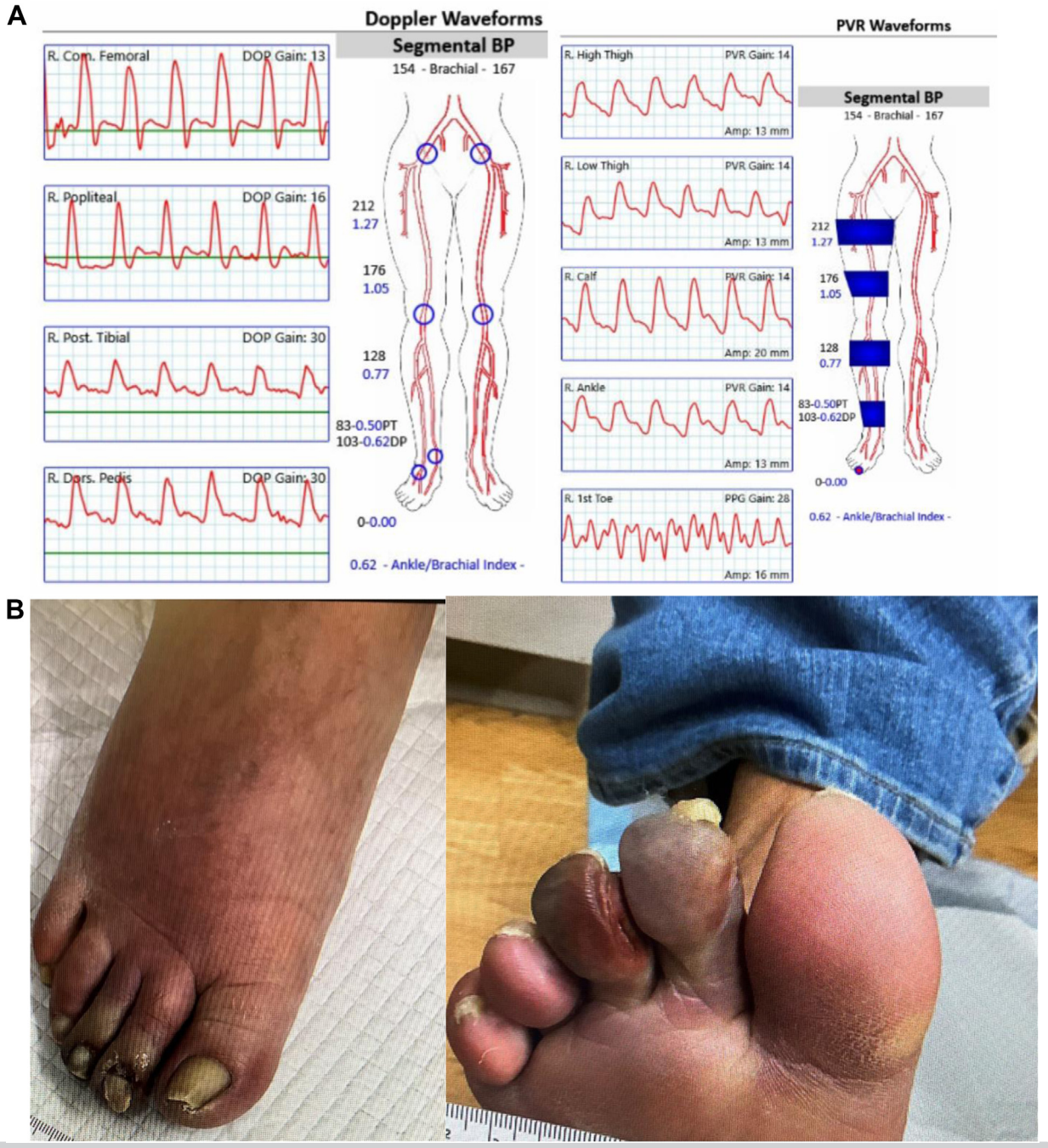

Fig 1. Noninvasive vascular testing and patient wound at presentation. **A,** Segmental pressures and pulse volume recording waveforms before intervention. **B,** Representative photographs of the extent of pedal gangrene at presentation. *Amp.,* Amplitude; *BP,* biphasic; *Com.,* common; *Dors.,* dorsalis; *DOP,* Doppler; *DP,* dorsalis pedis; *Post.,* posterior; *PPG,* photoplethysmography; *PT,* posterior tibial; *PVR,* pulse volume recording; *R.,* right.

off-the-shelf pDVA. Before the procedure, optimal medical therapy for CLTI was initiated, including a high-intensity statin, an antihypertensive regimen, clopidogrel, and smoking cessation.

With a tourniquet applied at the ankle to distend the foot veins, the lateral plantar vein was accessed under ultrasound guidance and confirmed by venography. An Outback reentry catheter (Cordis) from the femoral artery was advanced into the tibioperoneal trunk. A 7-mm balloon was advanced retrograde via the venous sheath into the adjacent tibioperoneal vein and inflated to serve as a target for arteriovenous creation (Fig 3, *A*). Under fluoroscopic guidance, the reentry device was aligned to direct the needle toward the balloon, puncturing it on deployment of the needle to indicate entry into the venous system, and an 0.018-in. wire was advanced into the venous

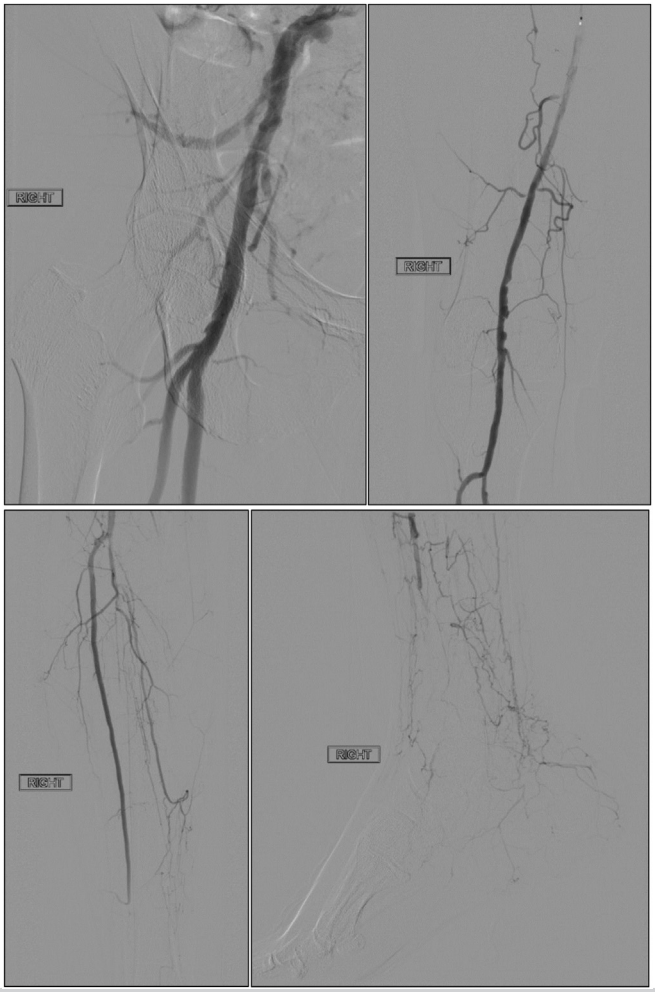

Fig 2. Images from initial diagnostic arteriogram.

system. The arteriovenous wire was snared and externalized to establish through-and-through access (Fig 3, *B* and *C*). Venoplasty and valvulotomy of the arteriovenous connection and PT vein into the plantar venous system were performed to 5 to 7 mm in antegrade fashion via the arterial sheath over the through-and-through wire (Fig 3, *D*). Two Viabahn stents (W.L. Gore & Associates; 5 × 25 mm and 5 × 15 mm) were then deployed from the tibioperoneal trunk into the PT vein and plantar venous system past the ankle and postdilated (Fig 3, *E*).

Venography of the plantar segment revealed an incomplete pedal venous arch, across which a wire could not be advanced. Thus, optimization of the outflow for the arteriovenous supply to the foot was performed via venoplasty of a secondary venous plexus that appeared to supply the plantar arch (Fig 3, *E*). Completion arteriography demonstrated a patent arteriovenous connection into the foot and brisk filling of the plantar venous arch (Fig 3, *F*).

After the procedure, the patient was discharged with a regimen of dual antiplatelet and therapeutic apixaban. Surveillance duplex ultrasound 2 weeks after the procedure showed two significant venous tributaries providing early drainage away from the foot, explaining the patient's persistent rest pain and interval progression of gangrene of the other toes. These tributaries were coil embolized to improve perfusion to the foot (Fig 4). Follow-up duplex ultrasound at 2.5 months showed a patent DVA with antegrade flow into the foot (Fig 5, *A*). Ultimately, he underwent transmetatarsal amputation at 2.5 months after the procedure with complete healing (Fig 5, *B*). At the last follow-up visit at 13 months after the procedure, he was well without leg edema and was ambulating independently.

DISCUSSION

DVA for CLTI is not new. First described in 1881 by Francois-Frank[10] in dogs and later in humans in 1894, open surgical DVA resulted in morbidity related to lower extremity swelling, congestive heart failure, and poor wound healing.[11] Interest in this procedure was revived in 1977 when Sheil[12] reported the resolution of rest pain and healing of wounds in six patients who underwent femoral artery to dorsal venous arch bypass with the great saphenous vein. Multiple series have reported successful outcomes since.[2,3,13] In parallel, successful outcomes have been reported for endovascular approaches, and a specific system (LimFlow) is commercially available in Europe.[1] This system uses its proprietary arterial and venous catheters and ultrasound guidance to determine proper alignment for arteriovenous fistula creation, an over-the-wire valvulotome, and proprietary stent grafts.[1] Data from the PROMISE I study investigating the LimFlow system for pDVA showed a 77% amputation-free survival rate for ≤24 months, with a 97% procedural success rate for the 32 enrolled patients.[1] The prospective, multicenter PROMISE II investigational device exemption trial recently reported its findings, with a 6-month amputation-free survival rate of 66% and a limb salvage rate of 76% compared with a preset performance goal of 54%.[5]

Before undertaking pDVA, establishment of a patient's anatomic and clinical candidacy is critical. Patients should be evaluated for their ability to adhere to the necessary risk factor modifications (eg, smoking cessation, medication adherence), wound care regimens, and close clinical and imaging surveillance. Tobacco cessation is of particular importance for patients with Buerger disease, because it is the crux of the disease process. Anatomically, patients must have a patent arterial tree down to the proximal tibial level (or a diseased vessel that can be revascularized to provide this inflow pathway) and a patent pedal venous arch. The present report, however, is unique in demonstrating that satisfactory results can be accomplished in the absence of a complete pedal arch via directed venoplasty into alternate available outflow pathways that drain the pedal arch.

The key procedural aspects of pDVA include the use of commercially available reentry devices for establishment

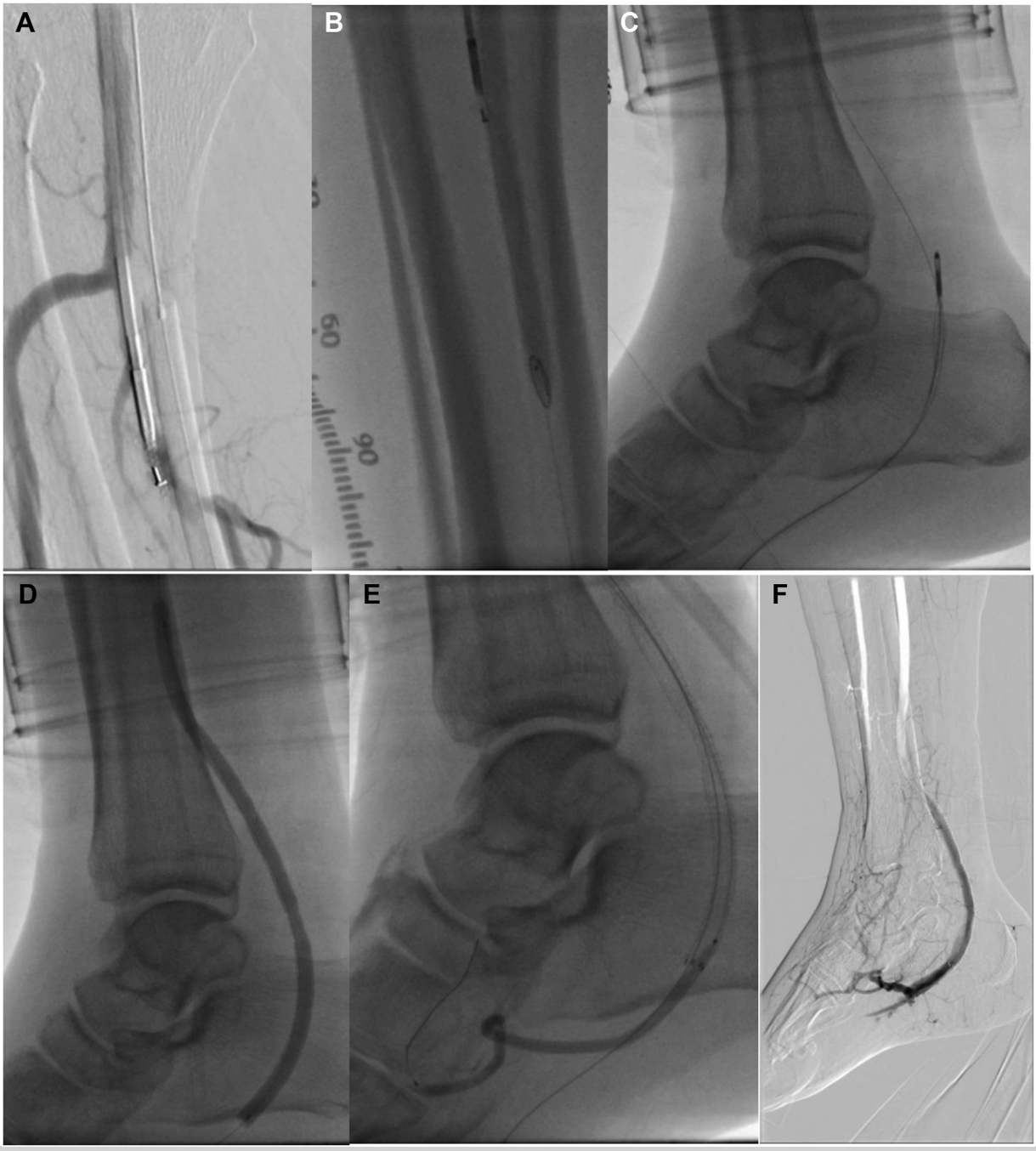

Fig 3. Percutaneous deep venous arterialization (pDVA) intervention steps. **A,** Reentry device positioned adjacent and oriented for needle throw into the target venous balloon. **B** and **C,** Passage of 0.018-in. wire into the venous system, with snaring and externalization via the plantar venous sheath. **D,** Balloon venoplasty for valve lysis. **E,** Deployment of covered self-expanding stents to line the arteriovenous fistula and venous outflow with additional plantar venoplasty. **F,** Completion angiogram of arterialized plantar venous system.

of the arteriovenous fistula, balloon venoplasty for valvulotomy, and the use of covered self-expanding stents to line the fistula and outflow venous pathway. Although alternative methods have been described for arteriovenous fistula creation (eg, double snare technique, bull's eye technique, spear technique), the use of reentry devices under fluoroscopic or intravascular ultrasound guidance remains the most prevalent technique.[14-17]

Close attention to wound healing and routine duplex ultrasound surveillance are paramount after DVA. Minor amputations can be required to remove gangrenous or infected tissue, as observed in 47% of patients in the

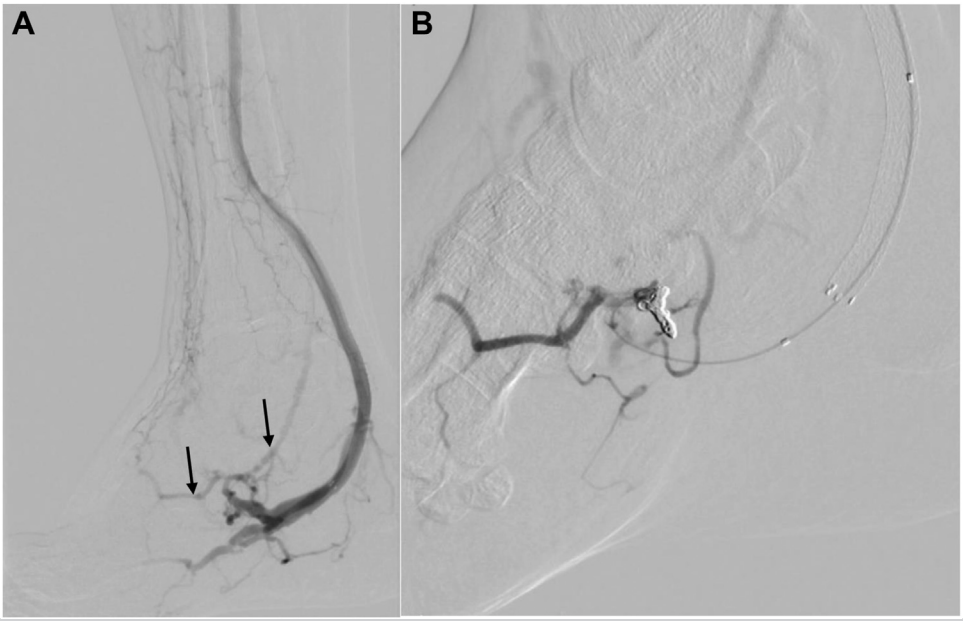

Fig 4. Secondary intervention for coiling of stealing venous tributaries. **A,** Initial angiogram demonstrating patent deep vein arterialization (DVA) filling the pedal venous system, with two venous tributaries providing early drainage away from foot (*arrows*). **B,** Angiogram after coil embolization demonstrating successful occlusion of the common branch of stealing tributaries and preferential flow into the pedal venous arch.

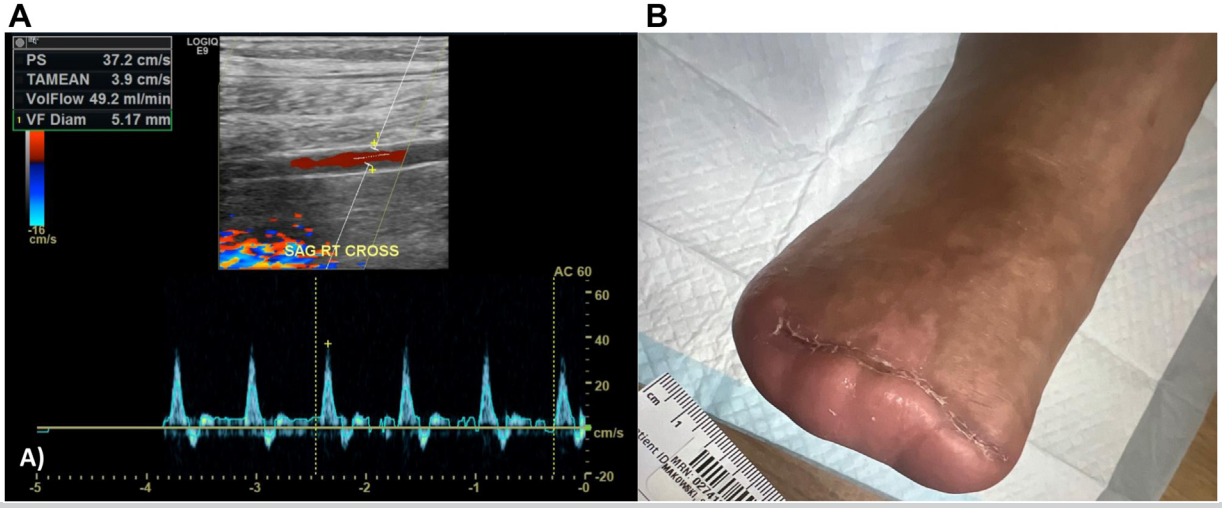

Fig 5. Postintervention outcomes. **A,** Follow-up duplex ultrasound demonstrating triphasic signal and flow in the cross-over percutaneous deep venous arterialization (pDVA) stent at 2.5 months after the procedure. **B,** Healed right transmetatarsal amputation site at 4.5 months.

LimFlow feasibility trial (PROMISE I).[1] Vigilant monitoring for DVA patency, the detection of inflow and outflow lesions, and prepedal drainage pathways that steal blood flow from the foot and timely intervention are key to success, as shown in the present report. Delayed and/or stalled wound healing should prompt clinical assessment of the wound care regimen, adherence to medical therapy, and imaging assessment of the pDVA. Angiography after pDVA was commonly performed to address proximal or distal steal syndrome in the PROMISE II study. Secondary procedures are common, with 52% of patients in the PROMISE I trial requiring some sort of repeat intervention.[1]

It is important to note that this technique constitutes off-label use of these devices. Until a device approved by the Food and Drug Administration is available for pDVA, this should only be undertaken after proper patient selection and full disclosure to the patient. The

efficacy of this technology for patients with Buerger disease remains to be elucidated. A multidisciplinary approach is also essential to maximize the expertise of interventionalists, surgeons, podiatrists, and nursing and wound care specialists and achieve optimal outcomes.

CONCLUSIONS

pDVA is feasible for properly selected patients with no-option CLTI using devices currently available commercially in an off-label manner. Vigilant surveillance and multidisciplinary care are essential to achieve limb salvage after pDVA.

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