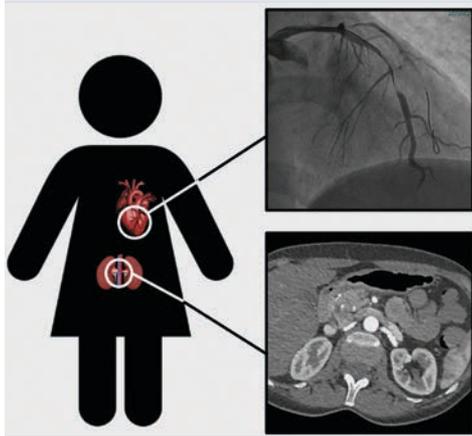


Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Unmasking Fibromuscular Dysplasia: When Spontaneous Coronary Artery Dissection Rings a Bell

Elena Sala, MD; Lorenzo Tua, MD; Alberto Cereda, MD; Gabriele Antonio Franchina, MD; Matteo Carlà, MD; Stefano Lucreziotti, MD

Case Report

A 47-year-old woman presented to the emergency department complaining of typical chest pain. She had a history of acute coronary syndrome (ACS) 8 years earlier, with no significant coronary artery disease reported at coronary angiography. At that time, assuming a vasospastic etiology, she was put on non-dihydropyridine calcium channel blockers, continuing to the present visit.

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Morton J. Kern, MD, MSCAI, FACC, FAHA

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Spoiler Alert: Finding the Right Cardiologist is Proving Difficult for All

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PAD GUIDELINES

What You Should Know About the 2024 AHA/ACC Guideline on the Management of Lower Extremity Peripheral Artery Disease

CLD talks with Guideline Committee Chair Heather L. Gornik, MD, FAHA, MSVM.

Can you share the main updates in the 2024 AHA/ACC Guideline on the Management of Lower Extremity Peripheral Artery Disease?'

The initial new element is a focus on the importance of evaluating peripheral artery disease (PAD) according to clinical subsets. We put an emphasis on determining which particular PAD subset the patient falls into.



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CASE REPORT

Transcatheter Arterialization of Deep Veins (TADV)

Mehdi H. Shishehbor, DO, MPH, PhD; Shilpkumar Arora, MD, MPH

Chronic limb-threatening ischemia (CLTI) represents the most advanced stage of peripheral artery disease (PAD), characterized by chronic ischemic rest pain, non-healing wounds, or gangrene in the lower extremities.¹ Despite advancements in surgical and endovascular treatments, up to 20% of CLTI patients are not candidates for revascularization due to the lack of suitable arterial targets or conduits for bypass surgery. These patients face a high risk of major amputations, with a 50% mortality rate within one year in patients over 65 years old.² The LimFlow system (Inari Medical) provides a new option by creating an arteriovenous fistula proximal to the diseased tibial arteries using a covered stent. This redirects oxygenated blood from the tibial arteries to the tibial veins, leveraging the venous system to deliver arterial blood to ischemic tissues, aiming to prevent major amputations and promote wound healing.³ The PROMISE II study has demonstrated the safety and efficacy of the LimFlow technique, showing high procedural success rates and significant improvements in amputation-free survival and wound healing among patients without conventional revascularization options.⁴



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Transcatheter Arterialization of Deep Veins (TADV)

Mehdi H. Shishehbor, DO, MPH, PhD; Shilpkumar Arora, MD, MPH

Case Report

A 76-year-old female with a past medical history of heart failure with reduced ejection fraction, diabetes mellitus, atrial fibrillation on coumadin, chronic obstructive pulmonary disease, and left lower extremity CLTI (wound image, Figure 1A) presented for a second opinion following multiple failed surgical and endovascular revascularization attempts by experienced operators. The initial ankle-brachial index and toe brachial index is shown in Figure 1B. Given the lack of further surgical or endovascular options for revascularization, we proceeded with transcatheter arterialization of the deep veins (TADV) using the LimFlow system.

In the cardiac catheterization lab, the patient was sedated and anticoagulation was maintained with heparin (activated clotting time [ACT] >300). Ultrasound guidance was employed for vascular

access. Access to the left lateral plantar vein was obtained using a micropuncture needle (Cook Medical) and a Command 14 wire (Abbott) was advanced cranially to the left popliteal vein. A 4-5 French 10 cm Glidesheath (Terumo) was placed in the left lateral plantar vein. Concurrently, left common femoral artery access was achieved under fluoroscopy, and a 7 French 55 cm Ansel sheath (Cook Medical) was advanced to the left popliteal artery from the left common femoral artery.

Plantar venography confirmed a complete plantar venous arch (Figure 3A). Angiography showed an ostial occlusion in the left posterior tibial artery. The ostial posterior tibial artery lesion was crossed with a Command 14 wire and CXI microcatheter (Cook Medical), and then dilated with a 3.0 mm x 120 mm peripheral balloon (Figure 3B). Repeat angiography indicated a potential crossover segment

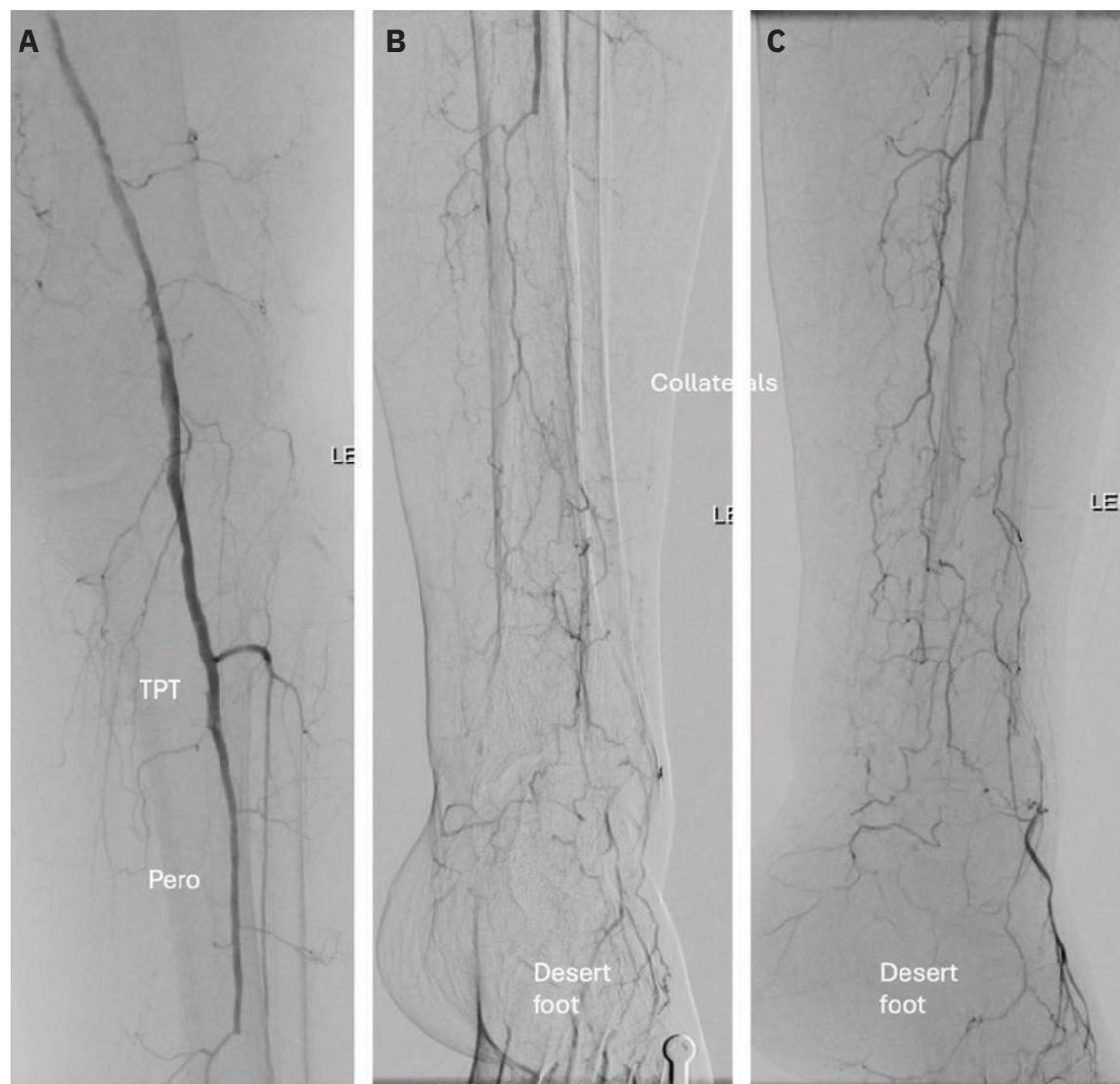


Figure 2. (A) Below-the-knee (BTK) angiography; (B-C) BTK and foot angiography. *TPT*, tibioperoneal trunk; *pero*, peroneal artery.

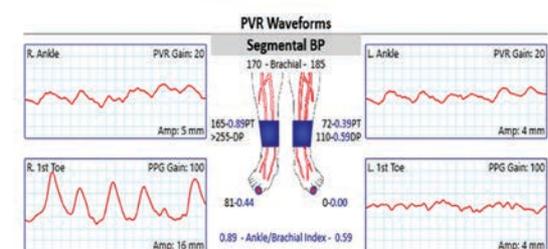


Figure 1A-B. Wound (top) and pulse volume recording (PVR) (bottom) prior to TADV.

at the proximal posterior tibial artery. A 5 mm x 100 mm peripheral balloon was advanced from the left lateral plantar vein to the left cranial posterior tibial vein to cross over the segment, and was dilated to mark the posterior tibial vein. Using the ARC device (LimFlow), the Nitrex wire (Medtronic) was crossed from the posterior tibial artery to the posterior tibial vein under fluoroscopy guidance (Figure 3C). The posterior tibial artery-posterior tibial vein crossover site was dilated with a 3.5 mm x 120 mm balloon (Figure 3D). Vector valvulotome (forward-cutting) (LimFlow) was used to destroy the valves of the posterior tibial vein. The posterior tibial vein-lateral plantar vein was stented with 5.5 mm x 150 mm (LimFlow) covered stents (two stents were placed) (Figure 4A). The posterior tibial artery-posterior tibial vein crossover site was stented with a 3.5 mm x 60 mm tapered covered stent (LimFlow) (Figure 4A). The stents were dilated with a 5.0 mm x 150 mm peripheral balloon in the venous segment and a 3.5 mm x 120 mm peripheral balloon in the arterial segment (Figures 4B-C).

The Nitrex wire was removed, and the plantar venous arch was crossed with a Command 14 wire and CXI microcatheter. The arch was dilated with a 3.0 mm x 80 mm peripheral balloon, and the lateral plantar vein sheath was removed, achieving hemostasis simultaneously (Figure 4D). The final angiogram demonstrated brisk flow through the TADV covered stent graft to the plantar venous arch without any flow-limiting residual stenosis, dissection, or perforation (Figure 5). Complete wound

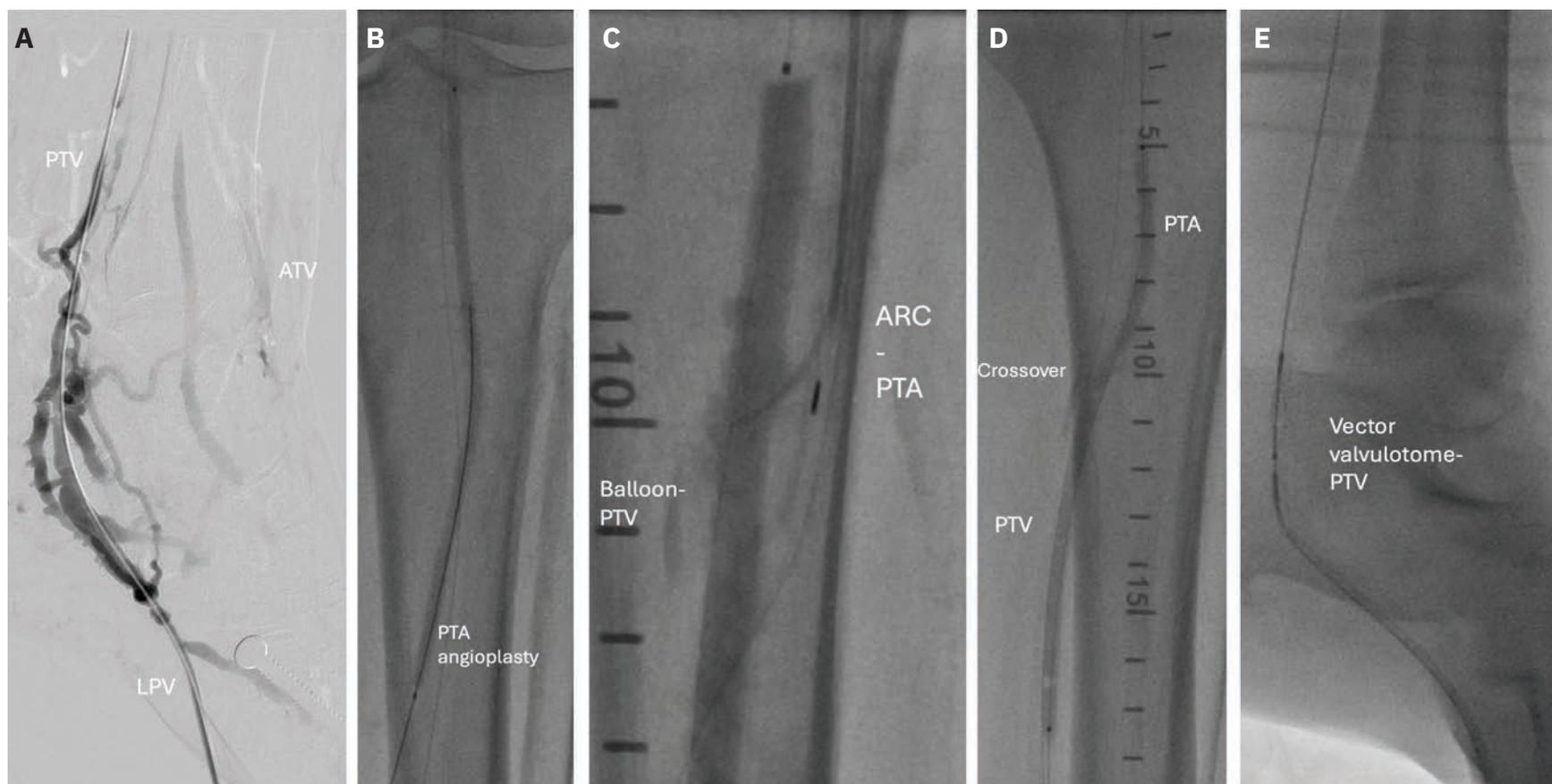


Figure 3. Transcatheter arterialization of the deep veins (TADV) procedural steps. (A) Plantar venogram; (B) Angioplasty of the PTA; (C) Crossover from PTA to PTV; (D) Crossover angioplasty; (E) PTV valvulotomy for destroying valves. PTV, posterior tibial vein; PTA, posterior tibial artery; ATV, anterior tibial vein; ARC: ARC device from LimFlow (Inari Medical).

healing occurred over six months with extensive podiatry care (Figure 6).

Discussion

The treatment of chronic limb-threatening ischemia (CLTI) remains a significant challenge, particularly for patients who have exhausted conventional revascularization options. In these “no-option” patients, the risk of major limb amputation is high, with substantial associated morbidity and mortality. Recent advancements, including transcatheter arterialization of deep veins (TADV), have shown promise in addressing this critical need.

Midterm outcomes from the ALPS study⁵ support the effectiveness of TADV using the LimFlow device. This study included 32 patients with no-option CLTI and reported amputation-free survival rates of 83.9% at six months, 71.0% at 12 months, and 67.2% at 24 months. Limb salvage rates were similarly high, with 86.8% at six months, and 79.8% at 12 and 24 months. These outcomes were achieved despite the complexity of the patient population, which included a high prevalence of diabetes, renal insufficiency, and immunosuppression.⁵

The PROMISE II study further evaluated the safety and efficacy of the LimFlow system in a larger, multicenter cohort of 105 patients with no-option CLTI. The results showed a high technical success rate of 99%, with amputation-free survival rates of 66.1% at six months, significantly exceeding the performance goal of 54%. The study also reported substantial improvements in limb salvage and wound

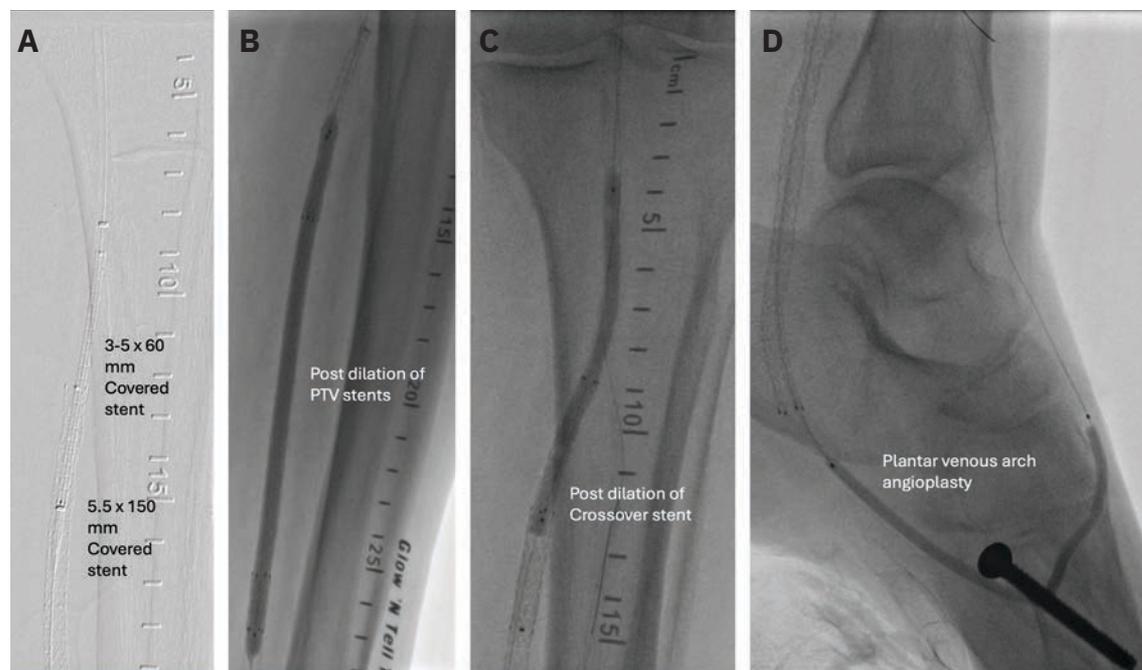


Figure 4. TADV procedural steps (continued). (A) Covered stent to PTV and across PTA-PTV crossover; (B) Post dilation of PTV covered stent; (C) Post dilation of PTA-PTV covered stent; (D) Angioplasty of plantar venous arch. PTA, posterior tibial artery; PTV, posterior tibial vein

CLTI patients face a high risk of major amputations, with a 50% mortality rate within one year in patients over 65 years old.² The LimFlow system (Inari Medical) provides a new option by creating an arteriovenous fistula proximal to the diseased tibial arteries using a covered stent.

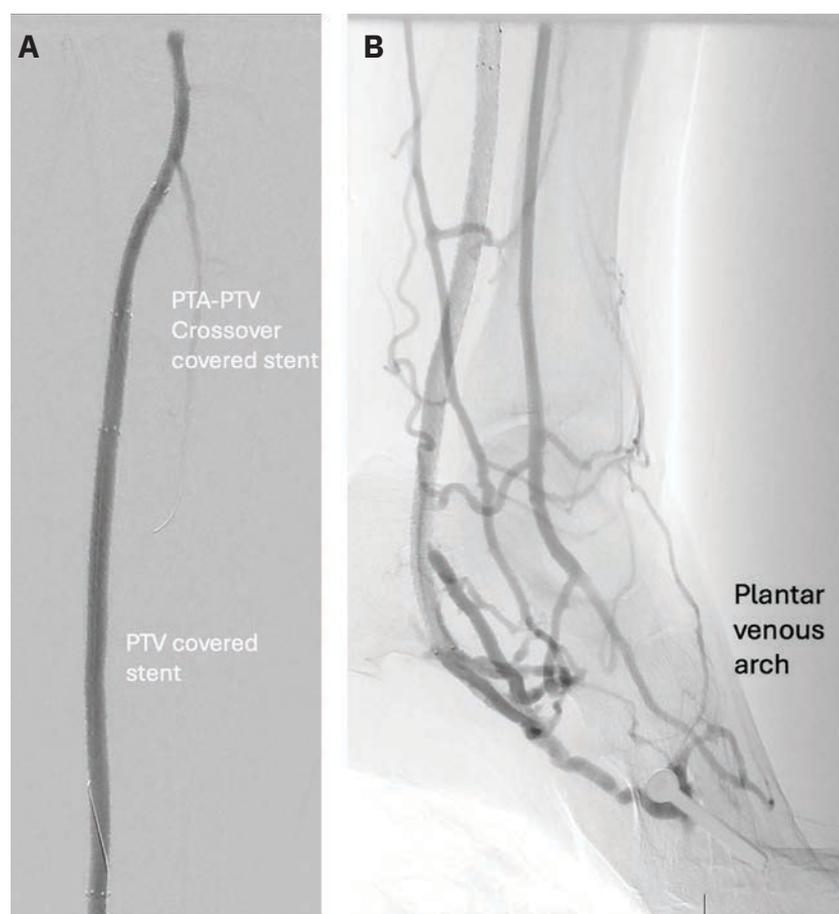


Figure 5. Final angiogram of TADV graft and plantar venous arch.

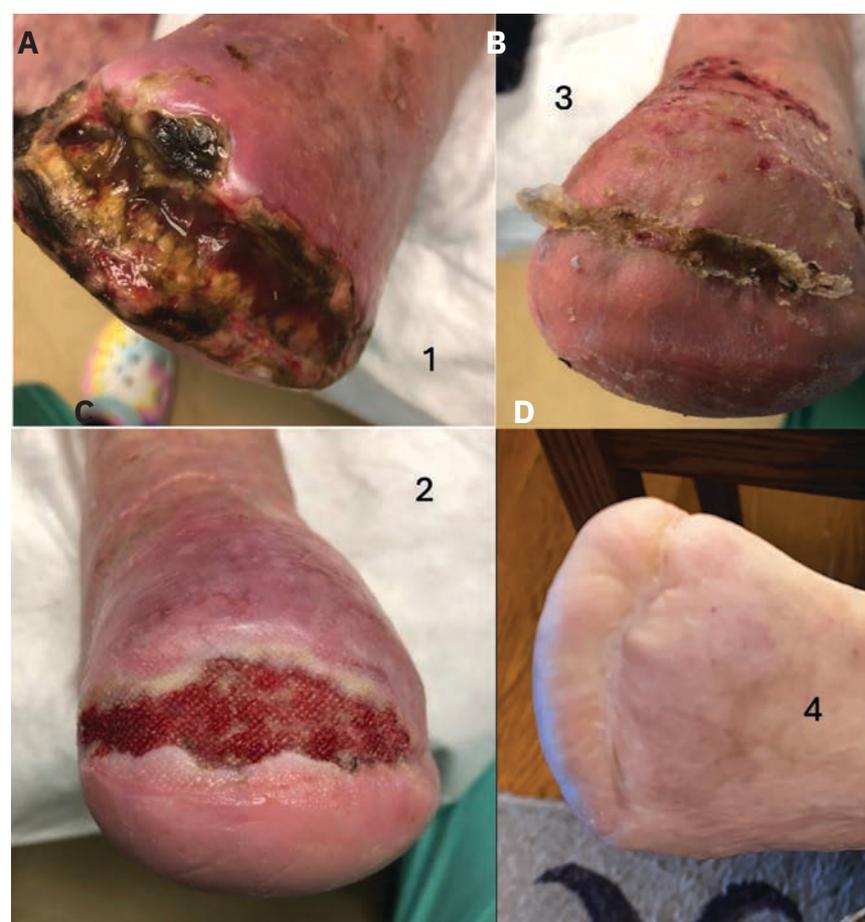


Figure 6. Wound healing over six months.

healing, with complete wound healing observed in 25% of patients and partial healing in 51%.⁴

Data from multiple centers further underscore the technical success and potential durability of the LimFlow procedure. High rates of limb salvage and wound healing were observed, with significant improvement in clinical outcomes. However, reintervention for circuit occlusion was relatively common, highlighting the need for ongoing monitoring and potential additional procedures to maintain patency.⁴

The current body of evidence underscores the potential of TADV to significantly improve outcomes in no-option CLTI patients. Existing studies highlight the importance of patient selection, procedural expertise, and comprehensive post-procedure care, including wound management, and monitoring for potential complications such as graft occlusion and venous hypertension.

Conclusion

The LimFlow procedure provides a promising alternative for patients with no-option CLI, potentially reducing the need for major amputations. This case demonstrates the potential of TADV in

achieving limb salvage and highlights the importance of patient selection and procedural expertise. Future research should focus on long-term outcomes and optimization of this innovative technique. ■

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Disclosures: Dr. Mehdi Shishehbor reports he is a member of the global advisory board for Medtronic, Abbott Vascular, Boston Scientific, Inari Medical, ANT, and Inquis Medical. Dr. Shilpkumar Arora reports no conflicts of interest regarding the content herein.

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