A novel approach to deep venous arterialization using WavelinQ EndoAVF technology

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ABSTRACT

Deep venous arterialization is increasingly being considered for the management of patients with "no option chronic limb threatening ischemia" (CLTI) who would otherwise require a major limb amputation. WavelinQ (Becton Dickinson) is a new technology increasing in popularity for its role in the formation of endovascular arteriovenous fistulas but might well have applications in other areas of vascular surgery. We present a novel approach to deep venous arterialization using WavelinQ arteriovenous fistula technology for a patient with nonreconstructable chronic limb threatening ischemia experiencing both rest pain and forefoot gangrene. The patient's early tissue loss healed and he remained symptom free at 6 months after the intervention. (J Vasc Surg Cases Innov Tech 2024;10:101407.)

Keywords: Chronic limb threatening ischemia; Deep venous arterialization; Endovascular technique

The concept of deep venous arterialization (DVA) in vascular surgery has been considered for more than a decade, with strategies such as open surgical DVA and a hybrid open and endovascular approach predominating until recently. Owing to the success of the LimFlow system (LimFlow, Inc) and PiPeR (Pioneer Peschiera Revascularization) technique, DVA can now be performed using an endovascular-only approach to treat patients with "no option chronic limb threatening ischemia" (CLTI).[1] However, the commercially available technology for percutaneous DVA is not yet approved by the Therapeutic Goods Administration in Australia, and, as such, new techniques using adaptations of existing technology should be considered. We describe a case in which the WavelinQ EndoAVF device (Becton Dickinson) was adapted for use to facilitate DVA in a young patient with no option CLTI. The patient provided written informed consent for the report of his case details and imaging studies.

CASE REPORT

A 59-year-old man presented with a 3-month history of worsening right forefoot ischemic pain at rest. He was a former heavy tobacco and active marijuana smoker, leading to a presumed diagnosis of Buerger disease. His medications included aspirin 100 mg, atorvastatin 20 mg, tramadol sustained release 100 mg twice daily, and paracetamol 1g four times daily.

The patient underwent a diagnostic right lower limb angiogram, which demonstrated radiologic features consistent with Buerger disease with extensive below-knee disease and a "desert foot" appearance (Fig 1). After the procedure, an iloprost infusion was started at a rate of 10 mL/h, which was increased to ≤40 mL/h as tolerated by the patient for 6 hours for 5 consecutive days. Despite this, he developed early ulceration of the forefoot after 4 days of treatment. Given his nonreconstructable disease, he was provided information regarding DVA and consented to the procedure.

Due to our institutional experience with the WavelinQ EndoAVF system for creation of haemodialysis access, we believed it would be a suitable technology to facilitate DVA. The procedure was performed in an angiography suite. Under ultrasound guidance, 6F sheath access was obtained in the common femoral artery (CFA). The shorter working length of the WavelinQ arterial and venous catheters (50 and 42 cm, respectively) meant that a retrograde approach was required. Therefore, access to the posterior tibial artery (PTA) and posterior tibial vein (PTV) was secured with a 6F Terumo radial sheath (Terumo) in the distal calf with ultrasound guidance. Antegrade arterial access obtained in the ipsilateral CFA allowed for diagnostic imaging and stent placement to complete the DVA.

The WavelinQ catheters were inserted into the PTA and PTV. The proximal, patent segment of the PTA was chosen as the site of fistula creation. The arterial catheter, followed by the venous catheter, was advanced to the desired location under fluoroscopic guidance. Once coaptation of the catheters was confirmed, the venous catheter, containing the electrode, delivered a burst of radiofrequency energy to create the connection between the artery and vein.[2] Digital subtraction angiography confirmed formation of the fistula (Fig 2).

Initially, we hoped to avoid stenting across the anastomosis, with stenting only along the PTV to the pedal veins. However, significant collateral filling necessitated stenting. We used our

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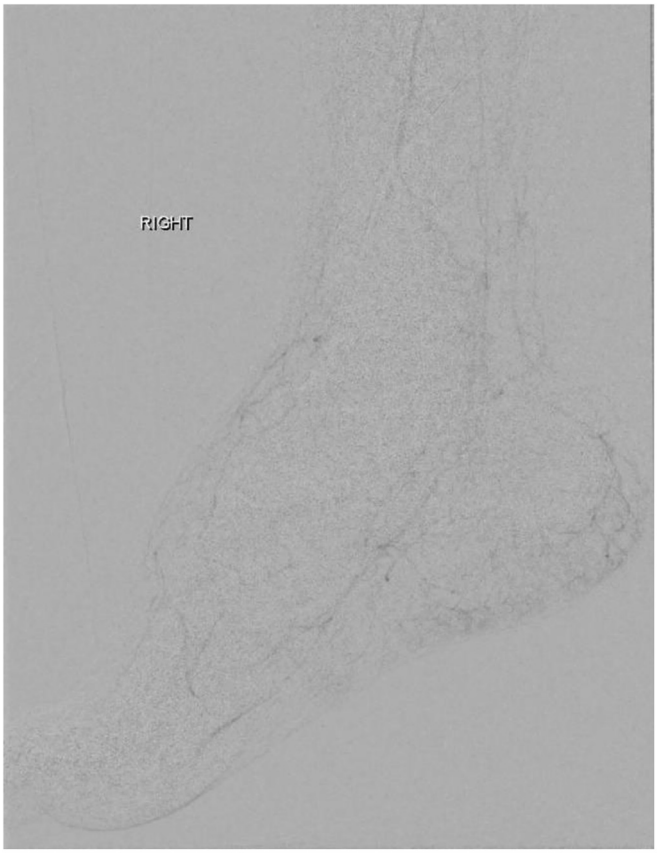

Fig 1. Digital subtraction angiogram of the right foot in the lateral view demonstrating reduced inframalleolar arterial contrast opacification.

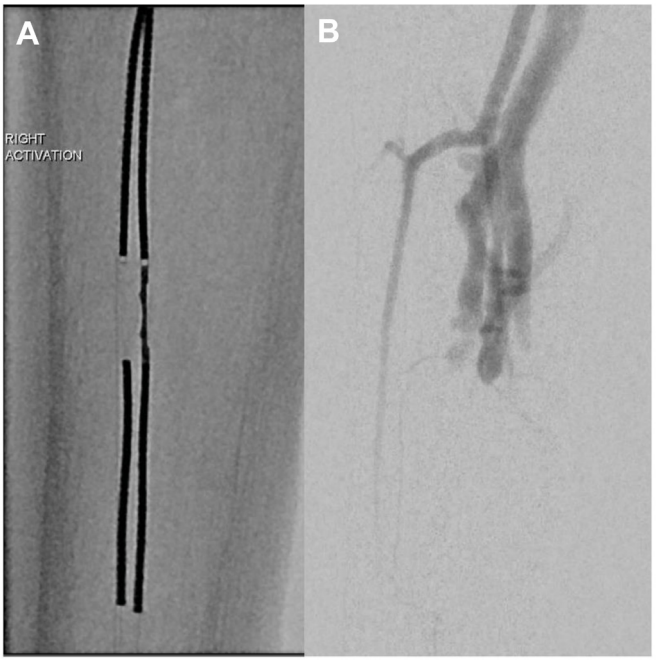

Fig 2. A, Fluoroscopic image demonstrating coaptation of the WavelinQ arterial and venous catheters with the radiofrequency electrode visible. **B,** Digital subtraction angiogram demonstrating the presence of a posterior tibial artery (PTA) and posterior tibial vein (PTV) fistula following activation of the WavelinQ catheters.

CFA access to cross the anastomosis. A 0.018-in. Command Wire (Abbot Cardiovascular) and a 2.6F CXI support catheter (Cook Medical) were tracked across the anastomosis, and a 4-mm balloon expandable covered stent (Papyrus stent; Biotronik) was placed to bridge the anastomosis, exclude the collateral vessels, and allow for safe tracking of further stents down the vein. The vein was prepared by passing the 0.018-in. wire down the PTV into the pedal venous arch. The 6F radial sheath access in the PTV was removed, and a 5-mm noncompliant Jade balloon (OrbusNeich) was inflated to high pressure (>16 atm) to achieve functional valve disruption. Similarly, the foot venous arch was treated with a 4-mm noncompliant Jade balloon with good effect. Next, 5-mm self-expanding covered Viabahn stents (W.L. Gore & Associates) were placed in the PTV to the inframalleolar level and postdilated with a 5-mm noncompliant Jade balloon (Fig 3).

A completion angiogram demonstrated flow through the venous arch of the foot (Fig 4). The PTA sheath was removed with a period of manual haemostasis, and the CFA puncture was closed with a Starclose closure device (Abbott Cardiovascular).

Based on evidence suggesting benefit from dual antiplatelet therapy for patients after Viabahn stent implantation and our unit's protocol, the patient began lifelong dual antiplatelet therapy with aspirin 100 mg and clopidogrel 75 mg.[3] The patient experienced significant improvement in his symptoms after the procedure with a palpable pulse in the inframalleolar segment of the PTV. He was discharged home on day 4 postoperatively with no analgesia requirement and was reviewed in the clinic 3 weeks later with complete symptom resolution. On review 3 months later, the patient's wounds had completely healed, he had no rest pain, and an ultrasound scan demonstrated patent stents with arterial waveform flow down PTV and into the pedal veins (Fig 5).

DISCUSSION

We have demonstrated the novel application of technology currently marketed for use for haemodialysis access. WavelinQ provides an alternative option for endovascular-only DVA for centers that might not have access to the LimFlow system or Pioneer Plus device.

DVA to treat patients with Buerger disease has been gaining academic interest in recent years. There have been three case studies and one invited commentary since 2020 on percutaneous DVA for patients diagnosed with Buerger disease, all of whom had successful outcomes.[4-7] In 2017, Modaghegh and Hafezi[8] reported a limb salvage rate of 92% in patients with Buerger disease who developed CLTI and were treated endovascularly. More recent data have reinforced the benefits of

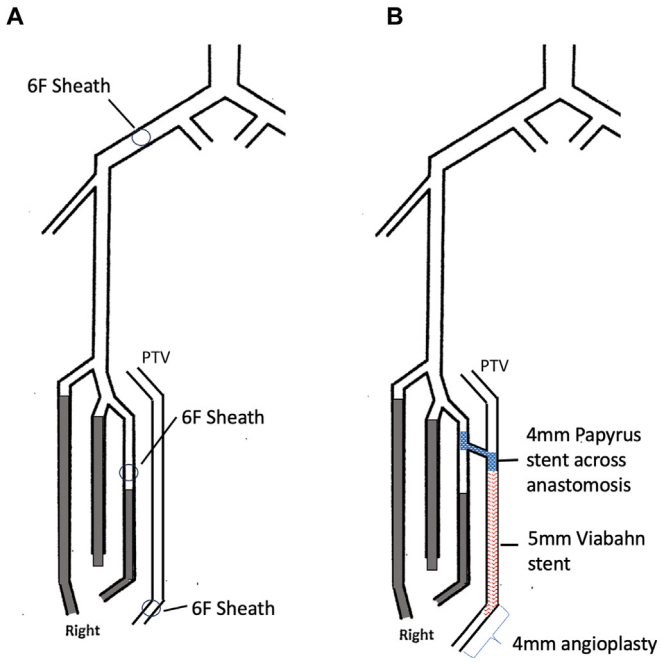

Fig 3. A, Diagrammatic representation of right lower limb arteries and posterior tibial vein. Diseased tibial arteries represented and percutaneous access sites marked. **B,** Postprocedural worksheet demonstrating posterior tibial artery (PTA) to posterior tibial vein (PTV) anastomosis, with stenting across the anastomosis with a 4-mm Papyrus stent, stenting along the PTV with a 5-mm Viabahn stent, and angioplasty of pedal veins.

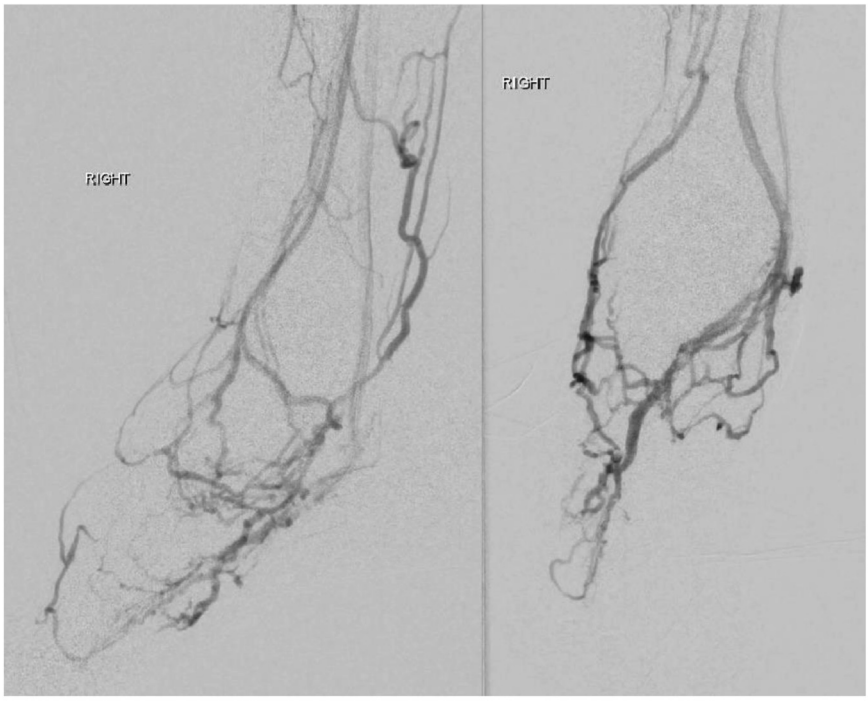

Fig 4. Digital subtraction angiogram of the right foot in the lateral and oblique views demonstrating arterialized venous blood flow on completion of deep venous arterialization.

endovascular-only DVA, with limb salvage rates of 86.8%, 79.8%, and 79.8% at 6, 12 and 24 months, respectively, in the Limflow Promise II trial of patients who would otherwise require a major limb amputation.[9] In addition, endovascular-only approaches to peripheral arterial disease are known to reduce the length of hospital stay and the incidence of systemic complications compared with open alternatives.[10]

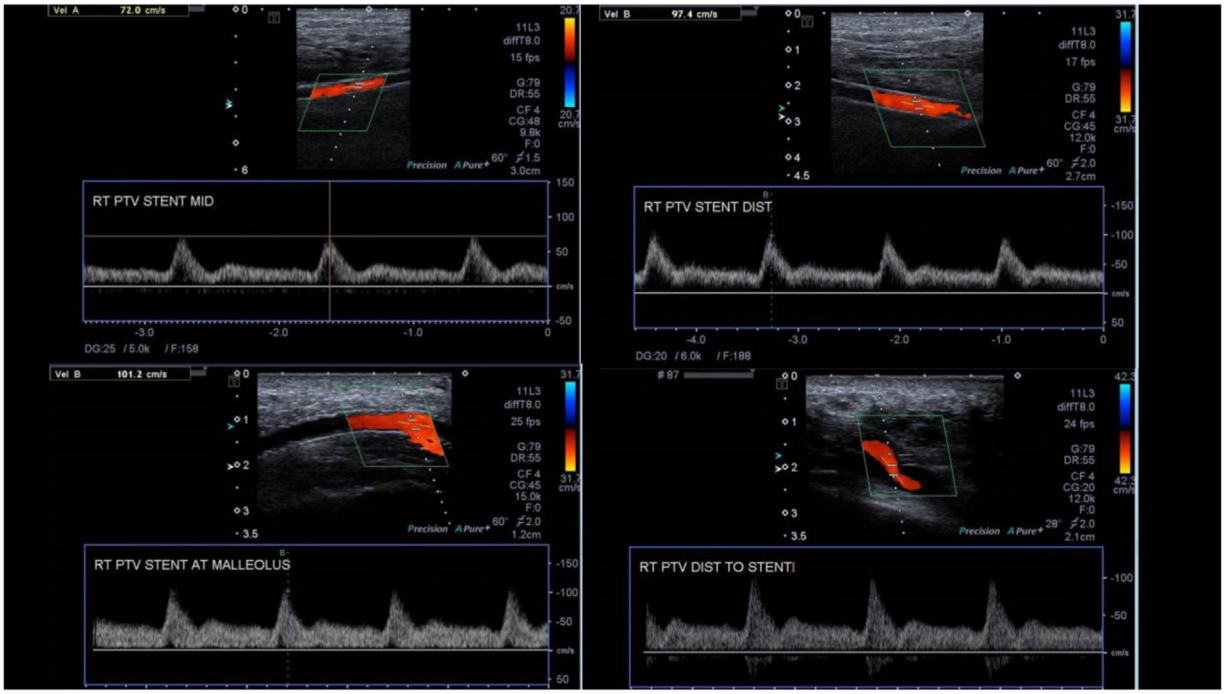

Fig 5. Four Doppler ultrasound images of waveform and velocities at 3-month follow-up. **A,** Duplex ultrasound image of mid-posterior tibial vein (PTV) stent. **B,** Duplex ultrasound image of distal PTV stent. **C,** Duplex ultrasound image of PTV stent at the malleolus. **D,** Duplex ultrasound image of PTV distal to the stent.

As is the case for all new technology and adaptations of existing technology, there are limitations, in particular, the learning curve. In our institution, our experience with the WavelinQ device and lack of access to LimFlow meant that the WavelinQ device was an appropriate option. Specific to the WavelinQ catheter, the working length was designed for upper limb fistula formation and, in the case of DVA, necessitates distal, retrograde access in the lower limb to reach the desired position of anastomosis in the vessel. The development of longer catheter working lengths is necessary if the WavelinQ is to become a long-term option in the field of DVA.

Balloon angioplasty for valvular disruption is associated with vessel barotrauma, possibly increasing the risk of restenosis. Use of a valvulotome would be desirable to avoid this; however, as stated, a push valvulotome such as that used in LimFlow is not currently available in our institution.

Heavy calcification is a limitation for all reentry devices, including the WavelinQ system.[11] The cost of the WavelinQ is another factor. Although it is unclear how the cost will compare to that of the LimFlow system once it becomes commercially available in Australia, it is currently more expensive than most standard reentry devices on the market. Despite this, the technology represents another tool in the armamentarium of limb salvage specialists. Also, compared with the costs involved with major limb amputation, the opportunity to achieve limb salvage likely represents an economic benefit.

CONCLUSIONS

We expect further experience with the WavelinQ device in both upper and lower limbs will continue to reveal more options for its future use and methods to reduce the cost of the procedure. With the boundaries of limb salvage continuing to be challenged by proceduralists unsatisfied with settling for "no option CLTI," there is a need for new technologies and/or adaptations of current technology. In the present case, adaptation of the technology designed for haemodialysis access allowed for limb salvage in a young patient who otherwise would have required a major limb amputation.

DISCLOSURES

C.L.D. has a consulting role with Becton Dickinson. O.K.P., T.K.R., and R.M. have no conflicts of interest.

REFERENCES

1. Schmidt A, Schreve MA, Huizing E, et al. Midterm outcomes of percutaneous deep venous arterialization with a dedicated system for patients with no-option chronic limb-threatening ischemia: the ALPS multicenter study. *J Endovasc Ther.* 2020;27:658–665.
2. WavelinQ [Internet]. WavelinQTM EndoAVF system - rethink fistula creation. Available at:. Accessed January 3, 2023. https://wavelinq.bd.com/#:~:text=WavelinQ™%20EndoAVF%20System%20is,traditionally%20used%20during%20open%20surgery.

3. Soukas P, Becker M, Stark K, Tepe G, RELINE MAX Investigators. Three-year results of the GORE VIABAHN endoprosthesis in the superficial femoral artery for in-stent restenosis. *Catheter Cardiovasc Interv*. 2023;2:100598.
4. Myers SI. The use of "off the shelf" percutaneous deep venous arterialization technology for a patient with severe chronic limb ischemia with no other options for limb salvage. *J Vasc Surg Cases Innov Tech*. 2023;9:101212.
5. Moriarty KT, Rundback JH, Shackles C. Percutaneous deep venous arterialization for the treatment of Buerger's disease. *J Vasc Surg Cases*. 2023;103:2—4.
6. Smith JA, Kandala J, Turner JT, Cho JS, Shishehbor MH. Off-the-shelf percutaneous deep vein arterialization for no-option chronic limb-threatening ischemia related to Buerger disease. *J Vasc Surg Cases Innov Tech*. 2023;9:101211.
7. Ryu SW, Tan GW, Pua U. Percutaneous deep vein arterialization in buerger's disease. *J Vasc Interv Radiol*. 2020;31:1897—1900.
8. Modaghegh MH, Hafezi S. Endovascular treatment of thromboangiitis obliterans (Buerger's disease). *Vasc Endovasc Surg*. 2018;52:124—130.
9. Shishehbor MH, Powell RJ, Montero-Baker MF, et al. Transcatheter arterialization of deep veins in chronic limb-threatening ischemia. *N Engl J Med*. 2023;388:1171—1180.
10. Tang QH, Chen J, Hu CF, Zhang XL. Comparison between endovascular and open surgery for the treatment of peripheral artery diseases: a meta-analysis. *Ann Vasc Surg*. 2020;62:484—495.
11. Pescatori LC, Tacher V, Kobeiter H. The use of re-entry devices in aortoiliac occlusive disease. *Front Cardiovasc Med*. 2020;7:144.

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