

Percutaneous Deep Venous Arterialization

A brief technical overview of a new therapy for treating end-stage “no-option” critical limb ischemia.

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Critical limb ischemia (CLI) has far-reaching implications in terms of quality of life and survival, as well as socioeconomic consequences.

The patient’s desire for a minimally invasive approach and the presence of significant comorbidities continue to drive physicians toward a predominantly endovascular-first approach. With the advent of modern percutaneous techniques, including retrograde access, distal vessel angioplasty, and angiosome/wound-related arterial strategies, the ability to treat CLI has come a long way. However, patients arriving at the cath lab are increasingly older, have more severe complications of diabetes, and often have had previous interventions. In addition, soft tissue infection and tissue loss still present a challenge in some cases and truly hinder the final clinical outcome after an angiographic success.

It is common to see a presentation of a so-called desert foot without discernible targets for bypass or intervention. Many patients have already undergone multiple interventions. This is coined the “no-option” end-stage CLI patient. Stem cell therapy may offer some promise but is still in a relatively early phase of evaluation.

DEEP VENOUS ARTERIALIZATION

Deep venous arterialization (DVA) is not a new concept. It involves shunting arterial blood to the deep veins. Early surgical attempts and more recent surgical series reported good safety and clinical outcomes.¹⁻⁴ These

surgical approaches were plagued by valves, which are a hindrance to blood flow and would need to be made incompetent. In addition, numerous draining venous collaterals would “steal” the blood flow to the extremity.

We sought to implement this concept of DVA using a completely percutaneous approach (Figure 1), percutaneous deep venous arterialization (PDVA), and have achieved some initial angiographic and clinical success.

The Procedure

This proof-of-concept and safety study was carried out in Changi General Hospital in Singapore. This was a pilot, prospective, open-label, single-center, single-arm study under the auspices of our Institutional Review Board.

All patients were deemed “end stage” with no remaining conventional open or endovascular options as verified independently by another vascular surgeon or interventionist. Extensive bench, in vivo animal, and

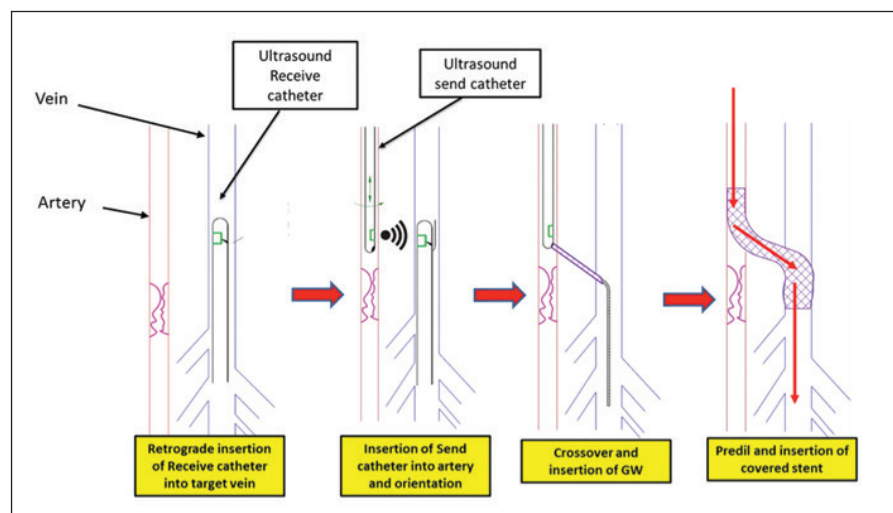


Figure 1. Overview of the LimFlow approach to percutaneous deep venous arterialization.

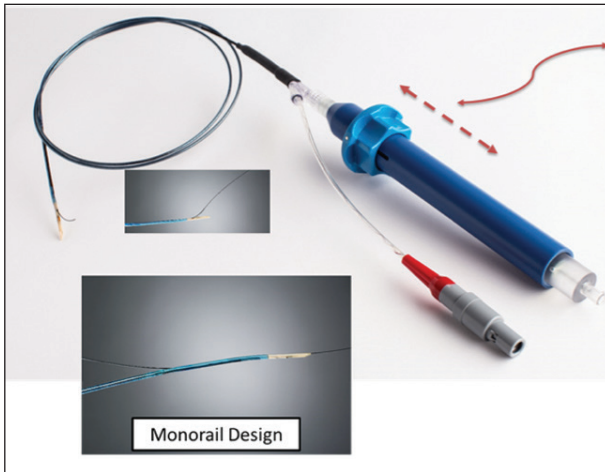


Figure 2. Arterial "send" catheter.

cadaver studies were successfully performed prior to the study.

The inclusion criteria allowed for enrollment of adult patients at imminent risk of major amputation as a result of CLI. These included Rutherford class 5 or 6 patients with an absence of a reasonable target vessel for bypass or endovascular intervention or severely diseased plantar arch or digital vessels.

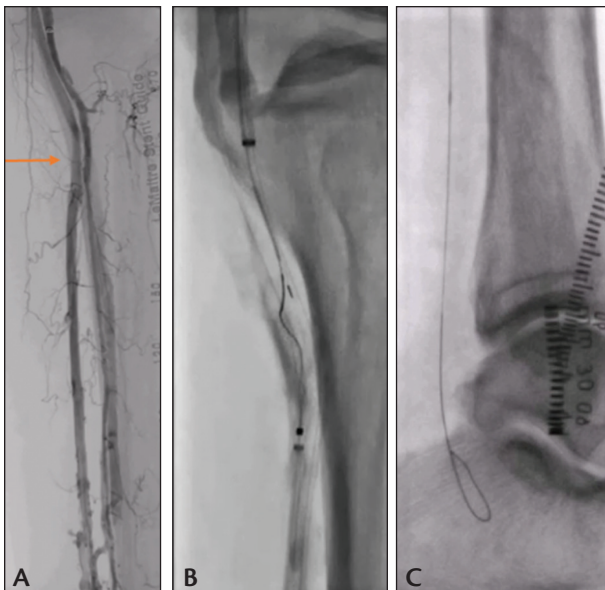


Figure 4. Simultaneous "double injection" through the 7-F arterial catheter and 5-F venous sheaths, showing the ideal crossover point (arrow), which is the area where the needle from the arterial catheter is anticipated to traverse into the vein (A). The crossover procedure. A 0.014-inch wire is driven into the vein from the artery after alignment of the catheters with ultrasound signals (B). Sending the guidewire past the valves (C).

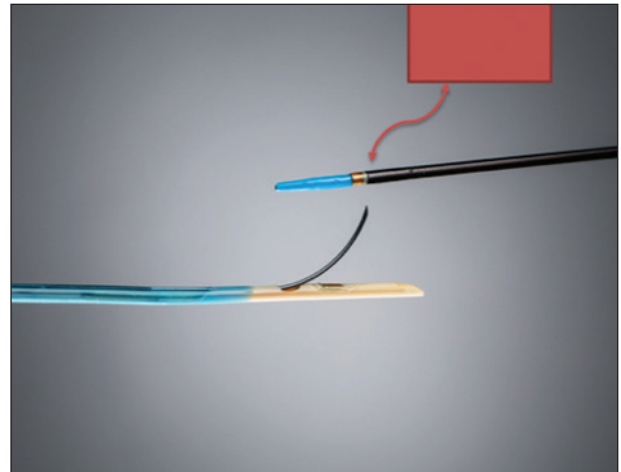


Figure 3. Venous "receive" catheter.

Seven patients were included in the study with the following conditions: five chronic nonhealing wounds/gangrene, one severe rest pain, and one severe rest pain and chronic nonhealing wound. All patients had diabetes and were between the age of 49 and 94 years. Five of the seven patients had PDVA with the LimFlow device (MD Start).

The primary objective of the investigation was to determine the safety of PDVA. Secondary objectives included

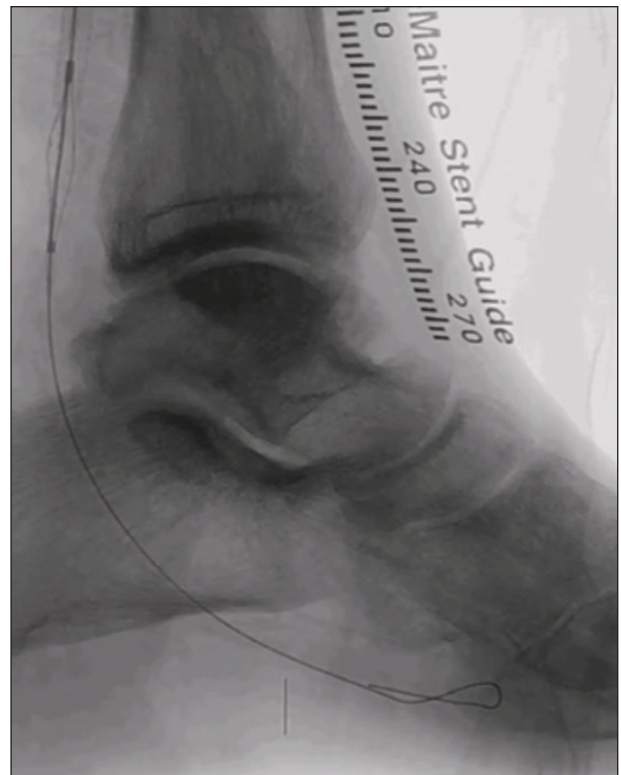


Figure 5. Angiogram of the foot showing placement of the reverse valvulotome.

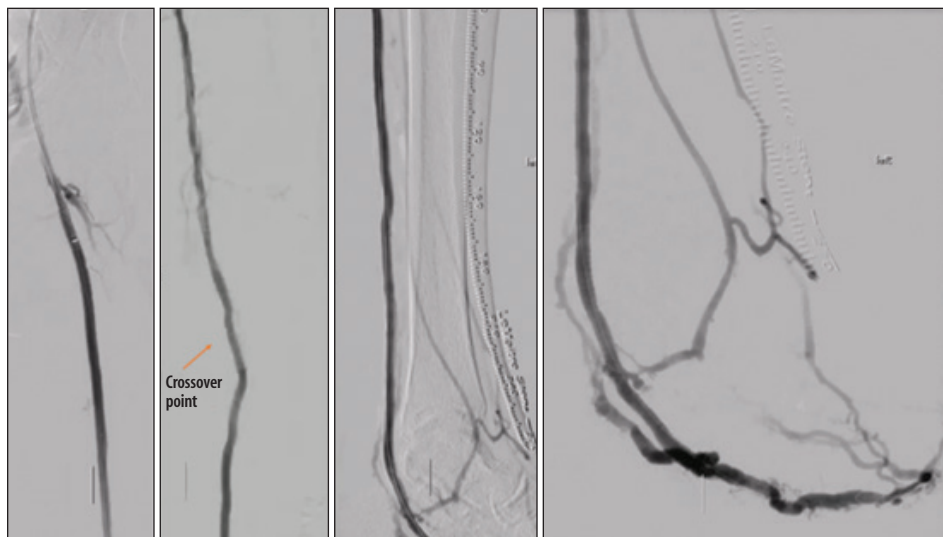


Figure 6. Angiogram showing the results immediately after the procedure was completed. The plantar venous arch is opacified.

A proprietary reversed valvulotome is used to disrupt the valves, in order to allow uninhibited proximal-to-distal blood flow (Figure 5).

The length of posterior tibial vein up to the patent posterior tibial artery is lined with a covered stent, which serves to cover the venous collaterals and also disrupt blood flow to the proximal valves. In addition, it guarantees a large conduit for blood flow by forcefully rupturing the proximal veins. The immediate angiographic result is shown in Figure 6.

clinical efficacy at 6 months with outcome measures such as thermal measurement, limb oxygenations, clinical observation, and wound healing during the 6-month follow-up period.

Subjective and objective markers of perfusion were evaluated with infrared thermography (FLIR, FLIR Systems), transcutaneous oximetry measurements, and wound healing time.

Device Overview and Technique

The LimFlow device consists of a 7-F arterial catheter, a 5-F venous catheter, and a console to facilitate the crossing procedure with a needle (Figure 2 and Figure 3). An antegrade arterial 7-F sheath and a retrograde posterior tibial vein 5-F sheath are both placed under ultrasound guidance.

Control angiography is performed to show the crossover point, the area where a needle from the arterial catheter is anticipated to traverse into the vein (Figure 4A). The arterial and venous catheters are aligned with a proprietary ultrasonic system. A 0.014-inch guidewire is then driven across the crossover point and into the retrograde sheath, supported by a 3- X 40-mm balloon, which is also used to predilate the arteriovenous fistula. The 0.014-inch guidewire is then exchanged for a 0.018-inch guidewire over a 0.018-inch support catheter and used to cross the valves (Figure 4B and Figure 4C).

Early Results

Pre- and postprocedure results of angiography using an iFlow postprocessing program (Siemens) are shown in Figure 7A and 7B. The postprocedure angiogram demonstrates rapid arrival of contrast from the time of acquisition of the DSA (coded yellow/red) (Figure 7B). This is compared to the preprocedure iFlow (Figure 7A). An angiographic “blush” is also seen at the edge of the wound, as well as multiple collateral vessels at the foot that serve as runoffs. Skin temperature also improved, as seen on FLIR thermography (Figure 8).

Clinical success was also seen in another patient, with wound healing after 115 days and the resolution of opioid-dependent rest pain immediately after the procedure (Figure 9). Increased transcutaneous oximetry levels were seen in four out of the five patients who underwent

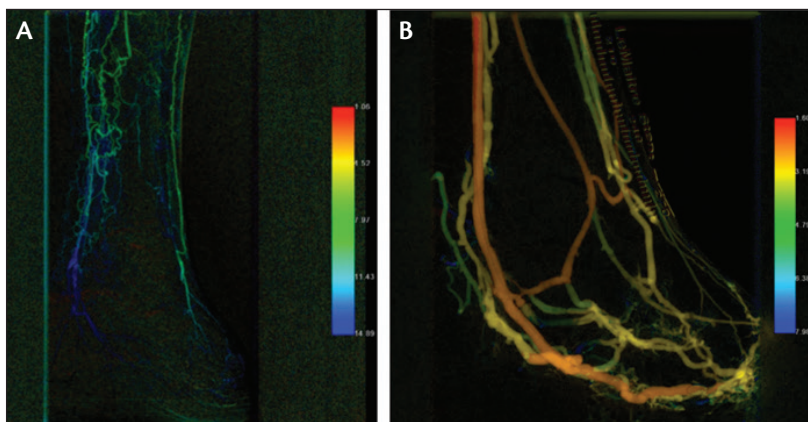


Figure 7. Preprocedure (A) and postprocedure (B) angiograms using iFlow. Note the angiographic blush at the wound on the extreme lower right.

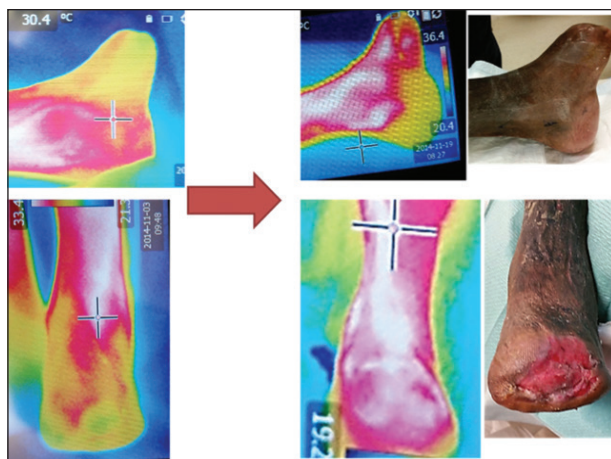


Figure 8. Preprocedure versus postprocedure FLIR thermography.

PDVA with LimFlow. Of the six patients with wounds, four healed, one is still healing, and one had to undergo amputation for systemic infection (the patient had heel gangrene with osteomyelitis but had evidence of good perfusion and granulation).

DISCUSSION AND SUMMARY

Percutaneous DVA represents a new concept in perfusing the foot by routing blood into the deep venous circulation. We were able to perform this safely, with no major adverse events observed within the first 30 days.

From our initial experience with LimFlow, the crossing was easily performed, and the valvulotome assisted in disrupting the valves and diverted blood to the wound bed, allowing us to achieve the goals of wound healing, resolution of rest pain, and a rise in transcutaneous oximetry. This technique represents a novel way to percutaneously treat the “no-option” end-stage CLI patient. It marries the advantage of surgical DVA with those of a minimally invasive procedure, aided by the LimFlow device.

Challenges clearly remain in the treatment of CLI. Wound healing still demands a multiprong approach with revascularization, control of infection, and meticulous wound care. The device is still undergoing improvements, and we continue to grow our experience of operating in the venous environment of the leg.

A CE Mark study is currently underway in Singapore, Germany, and Italy. A pre-investigational device exemption application has been submitted to the US Food and Drug Administration and accepted into an early feasibility study program. ■

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Figure 9. An example of wound healing in a patient who underwent percutaneous deep venous arterialization using LimFlow.

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