LimFlow
Transforming CLI

What clinicians are saying about the LimFlow Percutaneous Deep Vein Arterialization (pDVA) System

Jihad A. Mustapha, MD
Interventional Cardiologist
Metro Health-University of Michigan Health
Grand Rapids, Michigan

"A new approach to treating CLI is needed today, more than ever. LimFlow can give patients at end stage, with no options, a second chance at treatment and potentially avoiding imminent amputation."

Desmond Bell, MD
Founder
Save A Leg, Save A Life Foundation (SALSAL)

"Unfortunately, more than half of the amputations in our country are still done without a prior noninvasive vascular test. The LimFlow procedure has the potential to be a game changer in our world."

Peter A. Schneider, MD
Vascular Surgeon
Hawaii Permanente
Honolulu, Hawaii

"CLI is the modern-day l eprosy, and, unfortunately, we can't always restore blood supply to the foot, especially in patients with end-stage disease. I think LimFlow has the potential to offer a solution for these patients."

New Hope for 'No Option' CLI Patients

Amputation previously was the only option for patients with end-stage Critical Limb Ischemia. LimFlow has developed the world's first fully percutaneous system designed to non-surgically restore flow to blood-starved limbs.

U.S. Feasibility Study Underway

LimFlow Receives FDA Approval for U.S. Feasibility Study of Minimally-Invasive Technology Designed to Restore Perfusion in "No Option" Critical Limb Ischemia Patients

April 26, 2017 08:00 AM Eastern Daylight Time

PARIS--(BUSINESS WIRE)--LimFlow SA, developer of minimally-invasive technology for the treatment of end-stage critical limb ischemia (CLI), a severe form of peripheral artery disease (PAD), announced today that the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption for a feasibility study of the LimFlow Percutaneous Deep Vein Arterialization (pDVA) System. When all other therapeutic options have been exhausted and a CLI patient is facing major amputation, the minimally-invasive LimFlow system is designed to bypass blocked arteries in the leg and rush oxygenated blood back into the foot. For many patients, restoring perfusion in the lower limbs resolves chronic pain, improves quality of life, promotes wound healing and prevents major amputation.

"By reinventing the peripheral anatomy to address this major clinical issue, we are providing an alternative for patients who have none today."

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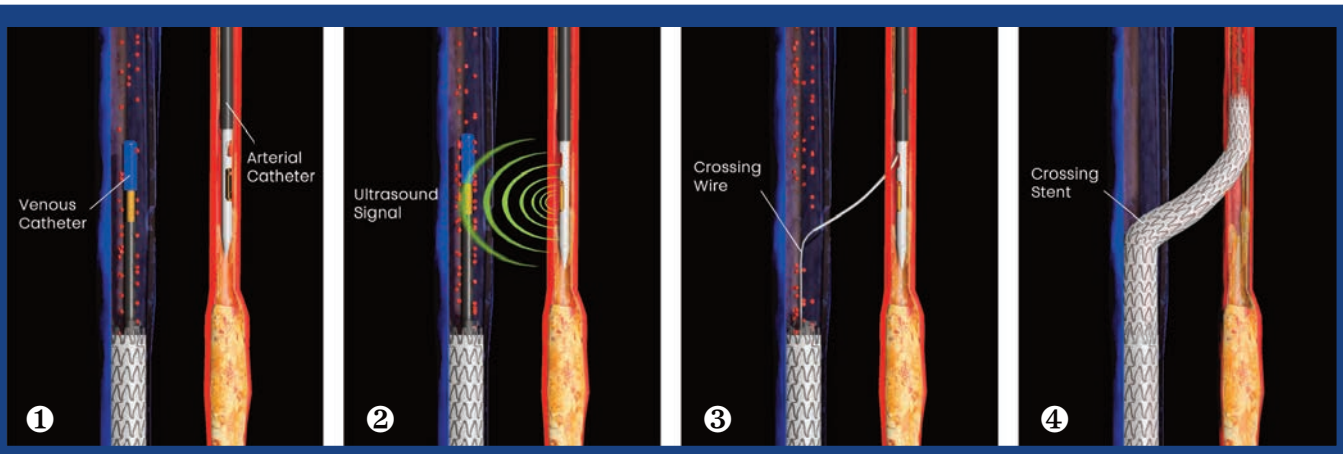
The feasibility study is a multi-center, prospective, single-arm study to be conducted at three U.S. centers encompassing 10 end-stage – or "no option" – CLI patients. Endpoints include amputation-free survival at one month, patency, limb salvage and wound healing, and the subjects will be followed out to two years. The primary investigator is Jihad Mustapha, MD, FACC, FSCAI, director of Cardiovascular Cath Labs, Endovascular Interventions and Cardiovascular Research at the University of Michigan Metro Health Hospital.

Amputation is the last resort treatment for CLI. The goal is pain relief, removal of diseased, necrotic, or infected tissue, and construction of a stump suitable for a prosthesis. However, 5%-10% of patients who undergo a below-the-knee amputation will die before being discharged from the hospital, and there is a 20% to 37% major complication rate that can lead to re-amputation further up the limb. LimFlow is a minimally invasive technology designed to divert blood around diseased arteries in the leg and into the tibial veins without the disadvantages associated with invasive open surgical techniques, bringing blood and oxygen to starved tissues in the foot. An abundance of oxygen in the tissue can immediately relieve pain and promote healing of chronic wounds for many patients, improving their quality of life.

(more)

Percutaneous Deep Vein Arterialization (pDVA): How It Works

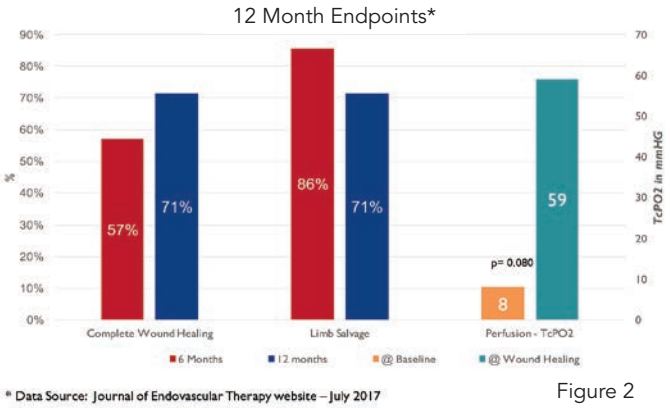


1. In a minimally invasive manner, an ultrasound catheter is inserted into a vein at the ankle, while another ultrasound catheter is inserted into an artery in the groin.
2. The catheters are advanced until they arrive at the location of the blockage in the artery. An ultrasound signal confirms the best location to create a channel from the artery into the vein.
3. A connection is then made by sending a needle from the ultrasound catheter into the vein, which is slightly enlarged using a low-profile balloon to facilitate passage of other devices. A device known as a "Push Valvulotome" travels through the vein down to the foot, disabling the valves so oxygenated blood can flow down to the foot instead of upward to the heart, as usually happens with veins.
4. A crossing stent is deployed from the artery to the vein, and additional stents are installed moving downward to the foot, an approach designed to create a new channel for high and continuous blood flow to rush into the foot. The vein may now begin to play the same role blocked arteries used to play. This may all be achieved without open surgery.

Promising Clinical Data

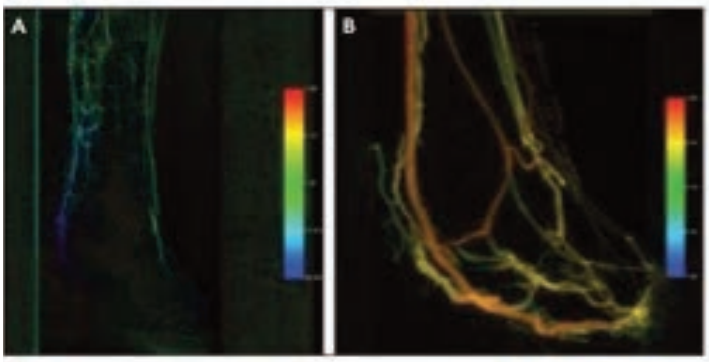
A prospective, open-label, single-arm pilot study was led by primary investigator Steven Kum, MD, of Changi General Hospital, Singapore, and encompassed seven no-option CLI patients with an average age of 85. All patients had diabetes and were Rutherford Class 5 or 6, with 86% (6/7) also classified as WIfI (Wound Ischemia foot Infection) "high risk."

All primary safety endpoints were met in 100% of patients, with no deaths, above-the-ankle amputations or major reinterventions at 30 days. The technical success rate was 100%.



* Data Source: Journal of Endovascular Therapy website – July 2017

Figure 2



Pre-LimFlow Post-LimFlow

At six months, 86% of patients (6/7) had avoided major amputation, and at 12 months 71% of patients (5/7) had done so. Complete wound healing was achieved in 57% of patients (4/7) at six months and in 71% of patients (5/7) at 12 months. The median healing time was 4.6 months.

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