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 leprosy, 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

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.
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%.

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.

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

Figure 2

Pre-LimFlow

Post-LimFlow

LimFlow
Transforming CLI