

Deep Vein Arterialization

Benjamin Jacobs, MD

Florida Vascular Society

April 29, 2022

Disclosures

- None

Background

- Critical limb ischemia is common and devastating, with dismal five year mortality.
- Especially challenging patients exist in whom conventional endovascular or open methods are precluded by absent outflow vessels in the foot.
 - Particularly common scenario in diabetics and end-stage renal disease patients.
- Deep Venous Arterialization utilizes reversal of flow in venous beds as alternative conduit for delivery of oxygenated blood to ischemic tissues.
- It is reserved for “no option” CLTI patients, in whom major amputation would be the next and only step.

**ARTERIOVENOUS ANASTOMOSIS—REVERSAL OF
THE CIRCULATION—AS A PREVENTIVE
OF GANGRENE OF THE EXTREMITIES.**

REVIEW OF THE LITERATURE AND REPORT OF SIX ADDITIONAL CASES.

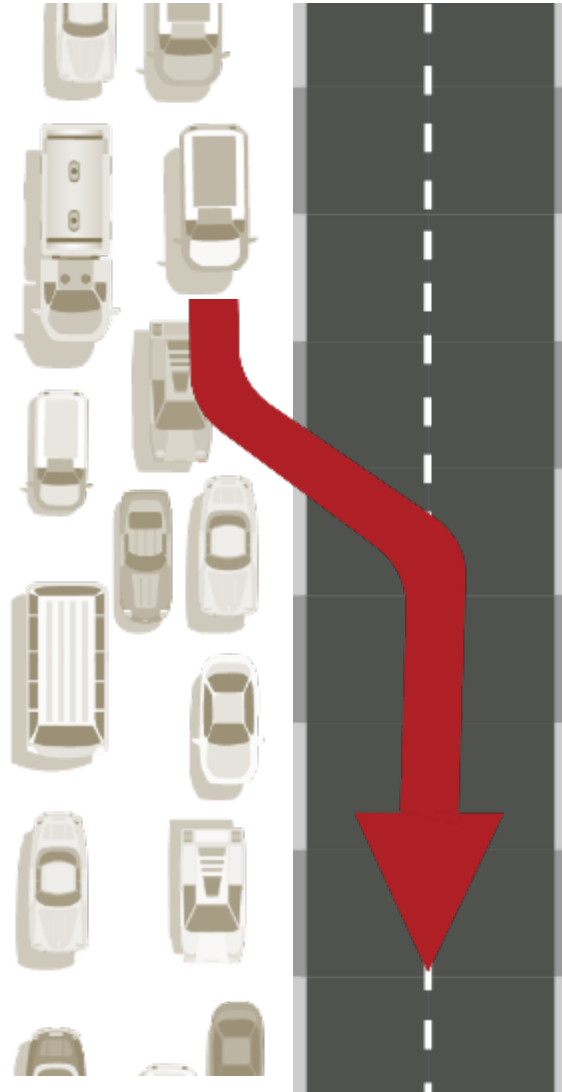
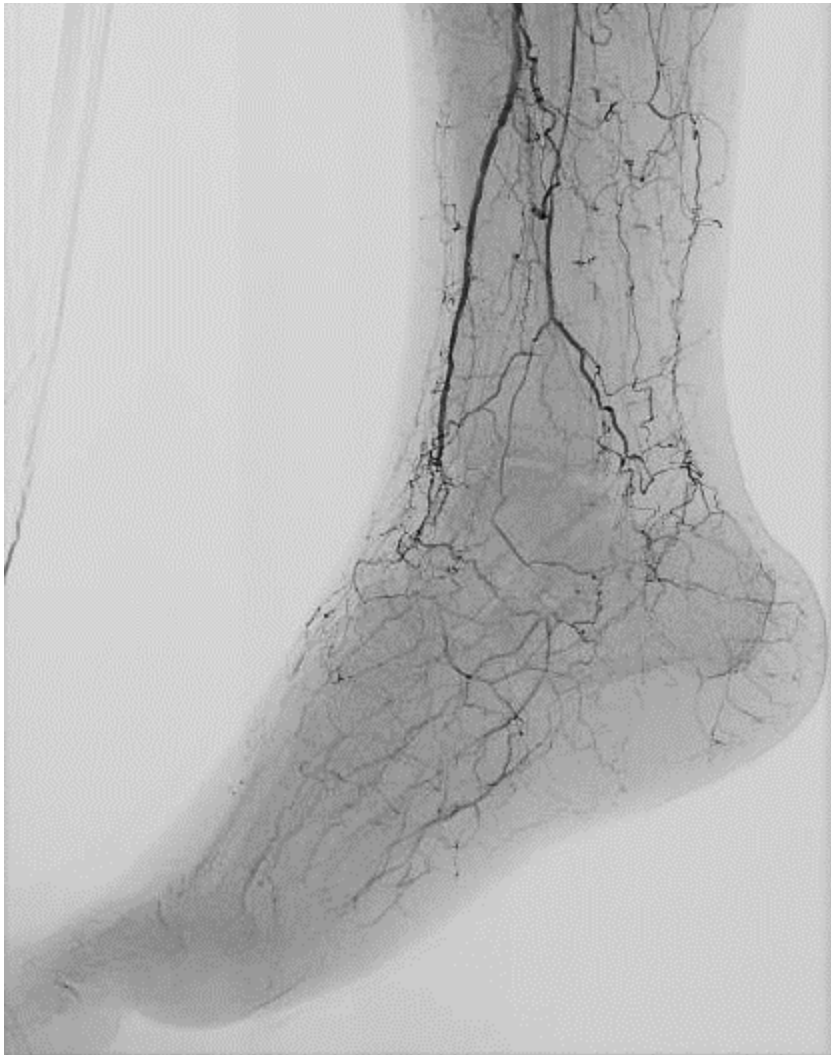
BY **BERTRAM M. BERNHEIM, M.D.**

OF BALTIMORE, MD.,

Assistant in Surgery, the Johns Hopkins University.

A DISCUSSION has arisen of late between Coenen of Breslau and Wieting of Constantinople as to the efficacy of an arteriovenous anastomosis—reversal of the circulation—in preventing the spread of a real or threatened gangrene in the extremity of a human. Coenen claims that Carrel's statements and experiments in regard to the possibility of reversing the circulation in the limb of a dog are not conclusive. That, in fact, the valves of the veins do not give way as asserted and that as a result a true and complete reversal is never attained, the blood simply being shunted off to another vein and promptly returned to the heart without ever getting to the foot or hand. Furthermore, he asserts that the procedure is both anatomically and physiologically wrong, and he therefore warns against the indiscriminate performance of this operation.¹

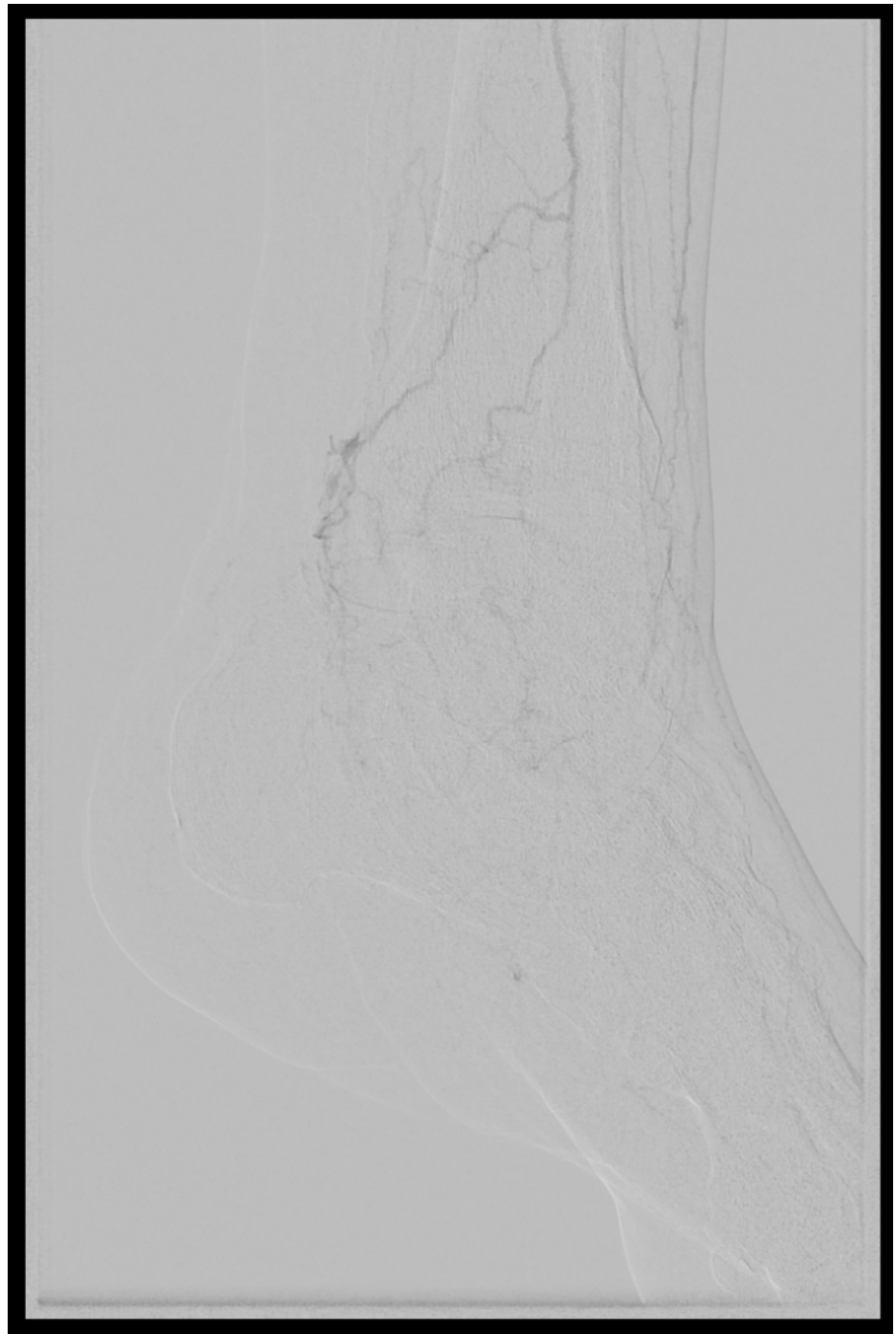
Permanently Bypass Unreconstructible Arteries

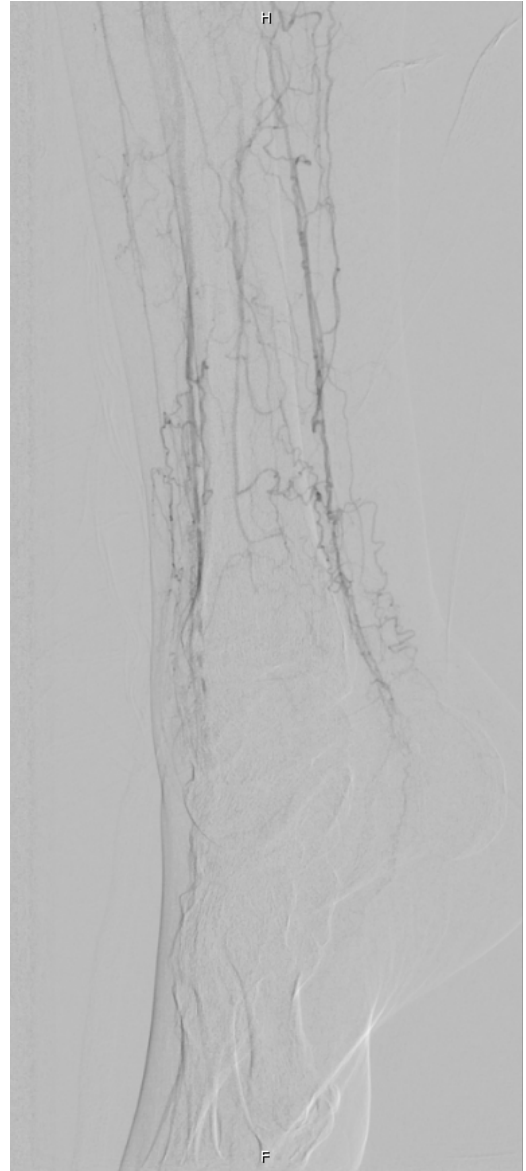
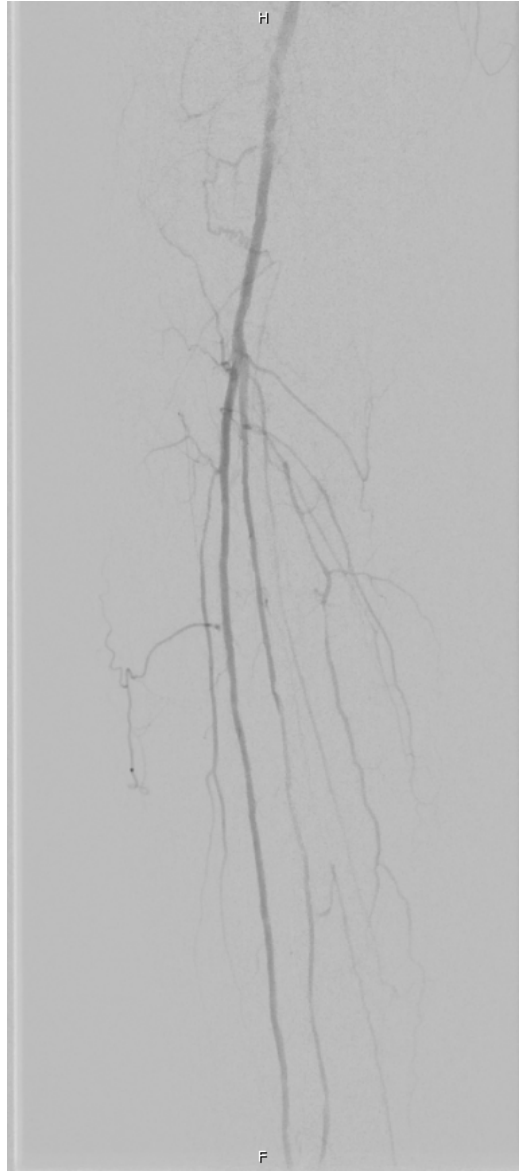
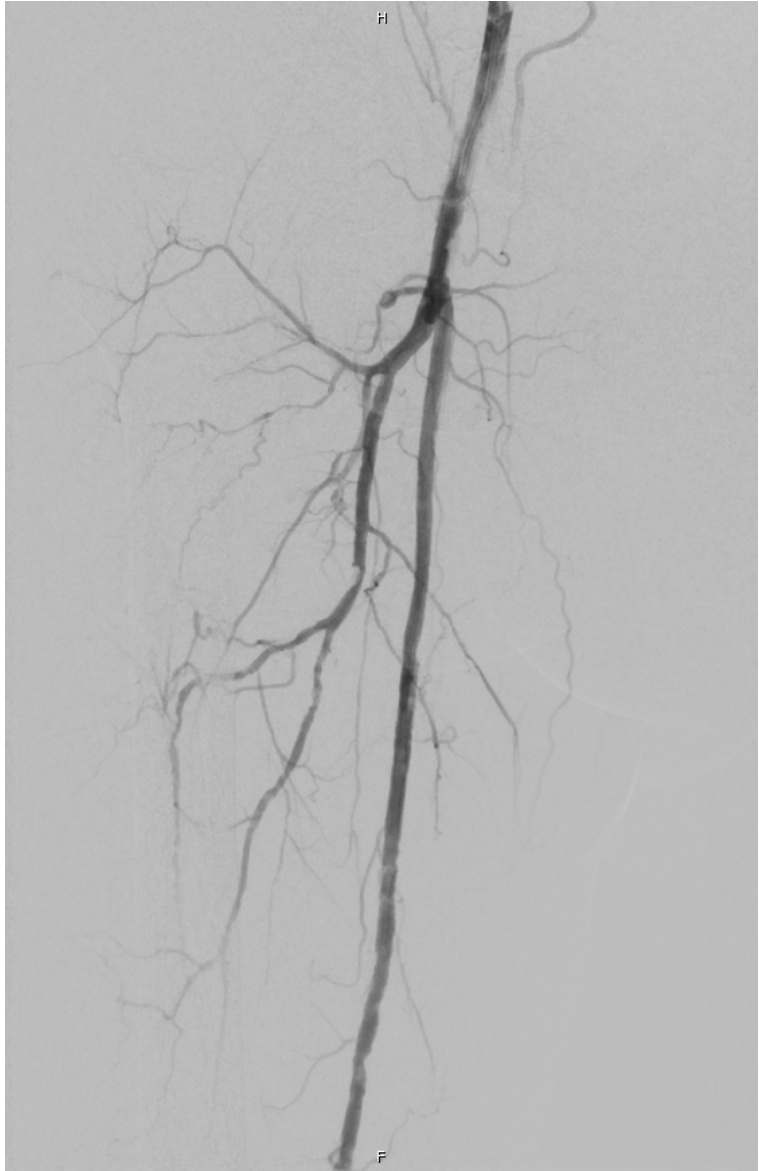


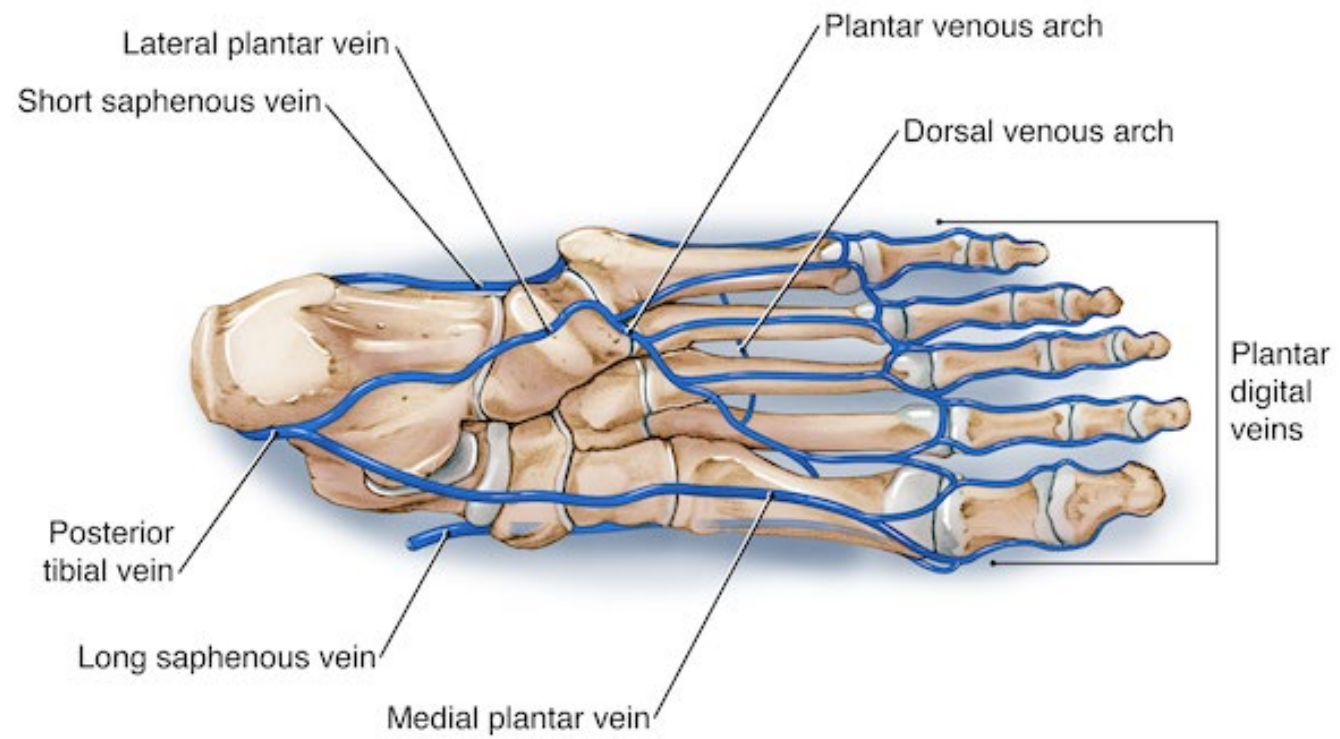
Courtesy of Roberto Ferraresi, MD

Who is a good candidate?

- Good (or fixable) Inflow
- Bad Outflow
- Desert Foot
- Rutherford Class 5 or 6
- Patent lateral plantar vein







Evaluate pre-operatively with Ultrasound or Venogram

Steps of the Procedure

- Pedal venous access at the Lateral Plantar Vein
- Select the posterior tibial vein
- Ascending phlebogram
- 5 French venous sheath
- Ipsilateral Antegrade Femoral Access, usual technique
 - Upsize to 7 French sheath
- Introduce snare via venous sheath
- Introduce crossing device via arterial sheath

Steps of Procedure

- Under fluoroscopic guidance, cross over into vein
 - 0.014 Thruway
- This “body floss” wire is now our working platform.
- Balloon crossover point.
- Valvulotomy
- Crossover stent
- Venous Stents

LimFlow Device

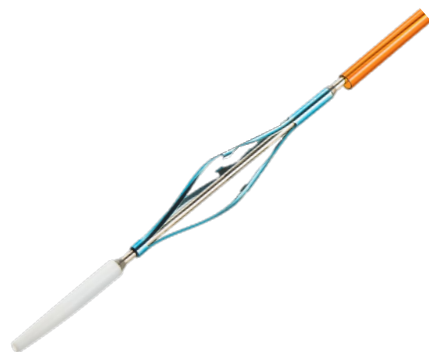
- Purpose built device for pDVA
- Currently in clinical trial.

Arterio-Venous Crossing



Arterial and Venous Catheters

Vein Preparation

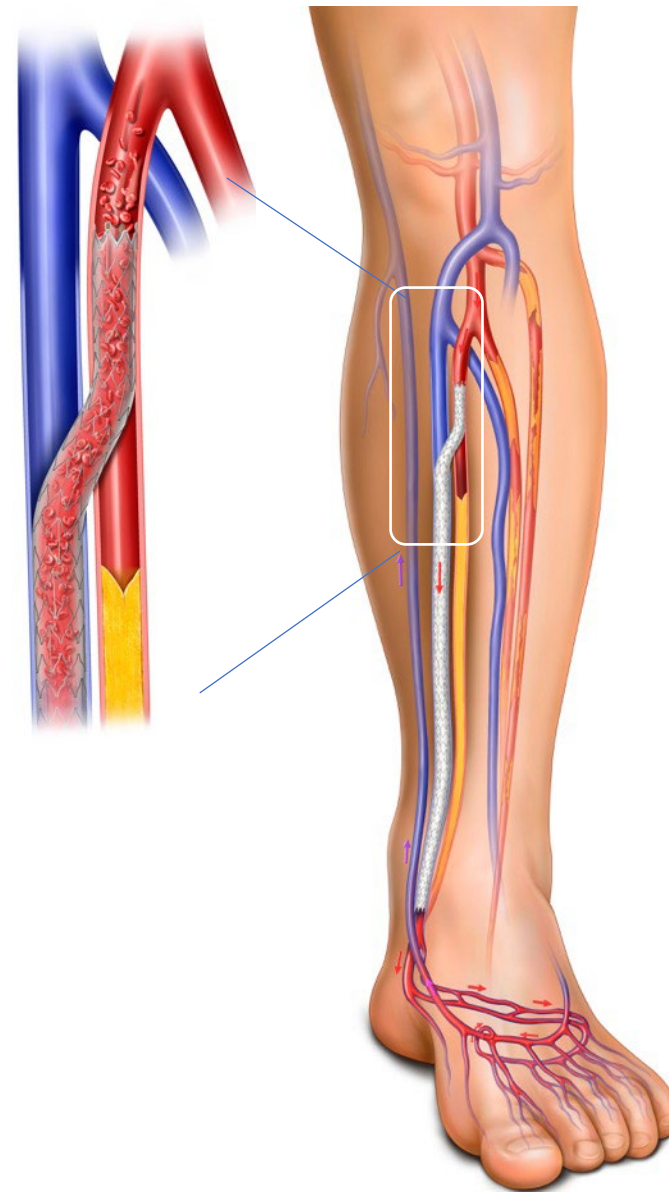


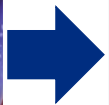
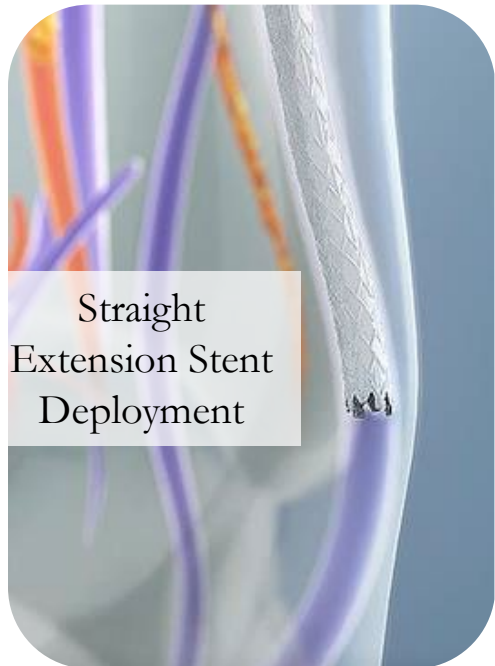
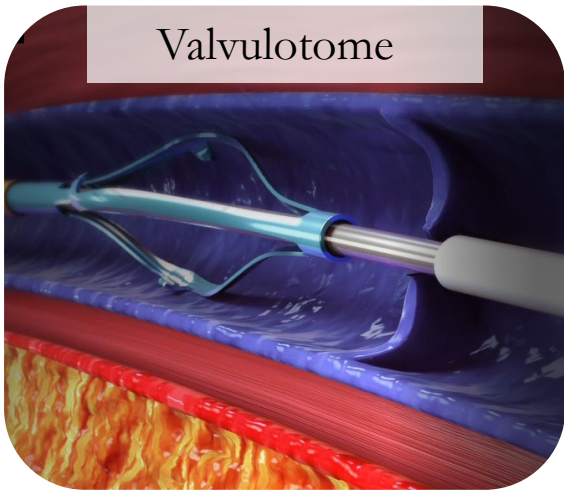
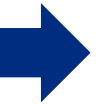
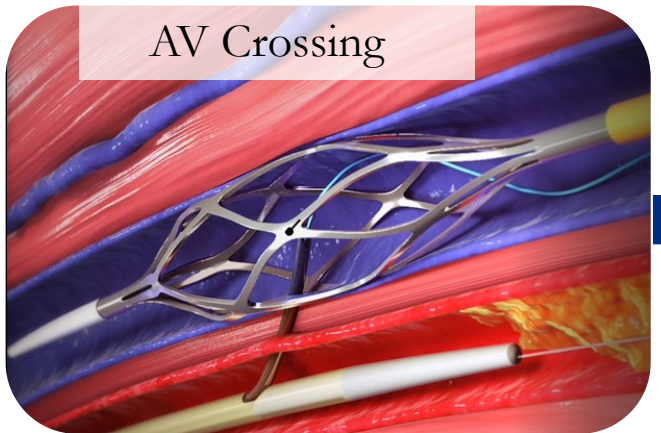
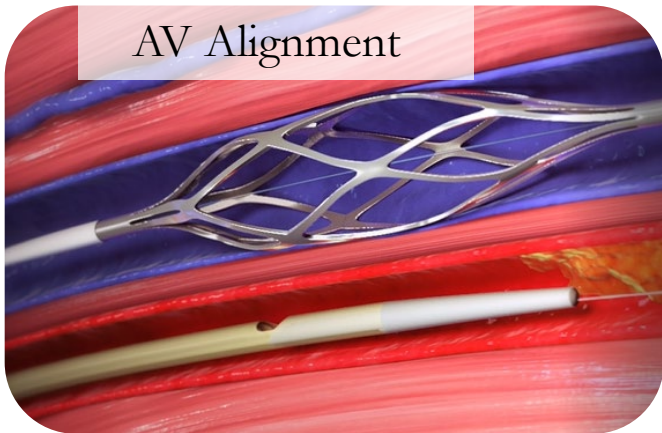
Push Valvulotome

Flow Focalization



Conical & Straight Stent Grafts





PROMISE I: Early feasibility study of the LimFlow System for percutaneous deep vein arterialization in no-option chronic limb-threatening ischemia: 12-month results

Daniel G. Clair, MD,^a Jihad A. Mustapha, MD,^b Mehdi H. Shishehbor, MD,^c Peter A. Schneider, MD,^d Steve Henao, MD,^e Nelson N. Bernardo, MD,^f and David H. Deaton, MD,^g *Columbia, SC; Grand Rapids, Mich; Cleveland, Ohio; San Francisco, Calif; Albuquerque, NM; Washington, DC; and Philadelphia, Pa*

ABSTRACT

Objective: We report the 6- and 12-month outcomes of the PROMISE I early feasibility study after treatment of no-option chronic limb-threatening ischemia (CLTI) with percutaneous deep vein arterialization (pDVA) using the LimFlow System.

Methods: Thirty-two patients with no-option CLTI, previously offered major amputation, were enrolled in this single-arm early feasibility study of the LimFlow pDVA System. No-option CLTI was defined as being ineligible for surgical or endovascular arterial revascularization. Patients were assessed for clinical status, pain, wound healing, and duplex ultrasound at 30 days, 6 months, and 12 months post-treatment. Primary endpoint analysis was amputation-free survival (AFS) at 30 days and 6 and 12 months. AFS was defined as freedom from above-ankle amputation of the index limb and freedom from all-cause mortality. Secondary endpoints evaluated included technical success of the procedure, and wound healing at 6 and 12 months.

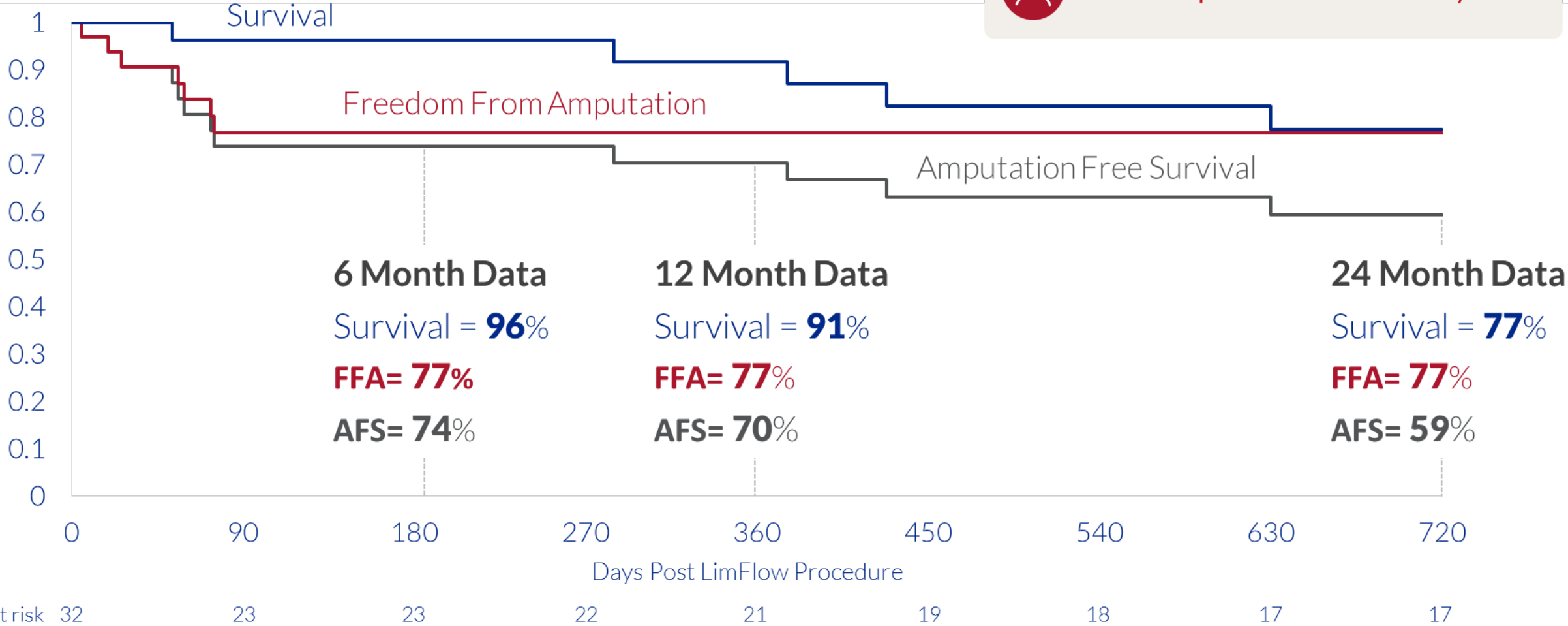
Results: Of 32 enrolled patients, 31 (97%) were successfully treated with the LimFlow System at the time of the procedure, and two (6.3%) were lost to follow-up. The 30-day, 6-month, and 12-month AFS rates were 91%, 74%, and 70% respectively. The wound healing status of fully healed or healing was 67% at 6 months, and 75% at 12 months. Reintervention was performed in 16 patients (52%) with 14 (88%) of the maintenance reinterventions occurring within the first 3 months. The majority of reinterventions (n = 12; 75%), involved the arterial inflow tract proximal to the stented LimFlow circuit, and no in-stent stenoses were determined to have been the cause of reintervention.

Conclusions: The LimFlow pDVA System was utilized in treating patients with no-option CLTI. A high technical success rate was observed, with a significant percentage of patients surviving free of major amputation at 12 months. These results suggest early safety and provide an initial assessment of the efficacy of the LimFlow pDVA System that supports the expansion of carefully executed studies to determine whether this is a viable option that can be used in this critically disadvantaged and growing patient population. (*J Vasc Surg* 2021;74:1626-35.)

Keywords: Amputation; Chronic limb-threatening ischemia; Critical limb ischemia; No-option chronic limb-threatening ischemia; Percutaneous deep vein arterialization

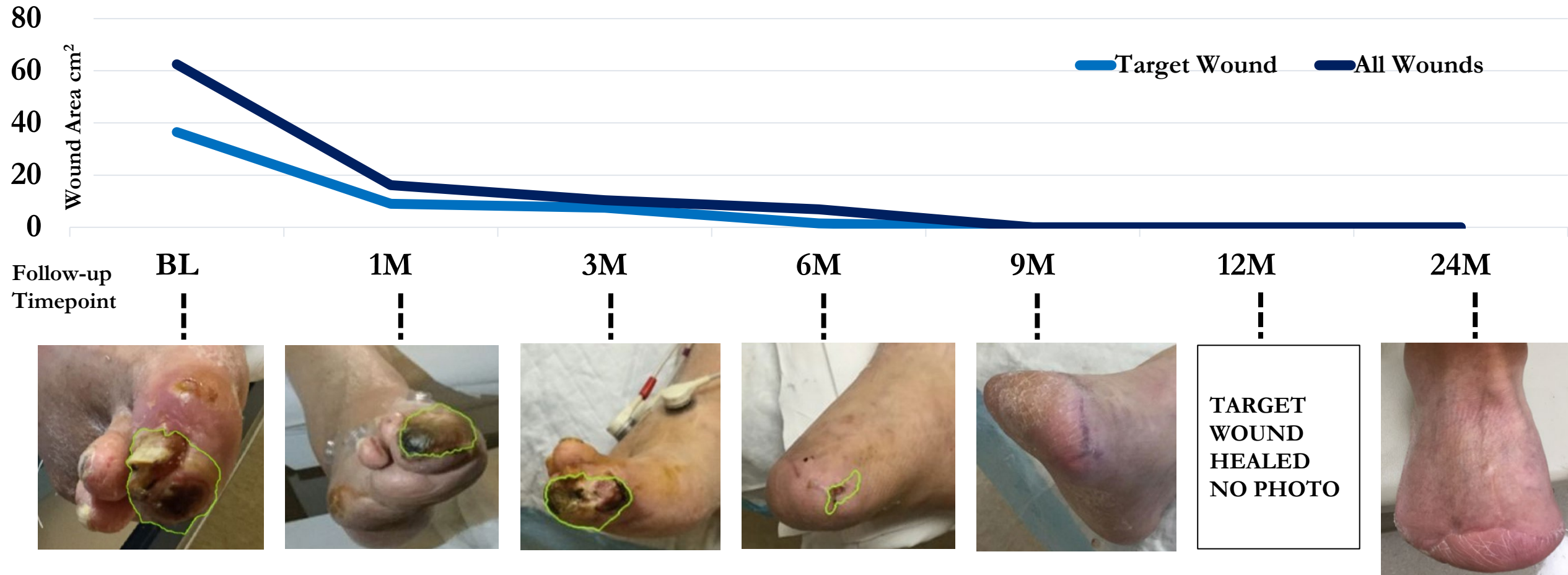


No Amputations after day 75



Case example: Promise I

Wound Healing Over Time



Wound Healing Progression

Index
September – '20



October – '20



December – '20



March – '21



June – '21



Questions

UF | UNIVERSITY *of* FLORIDA

Benjamin Jacobs, MD
benjamin.Jacobs@surgery.ufl.edu
734-657-9037

