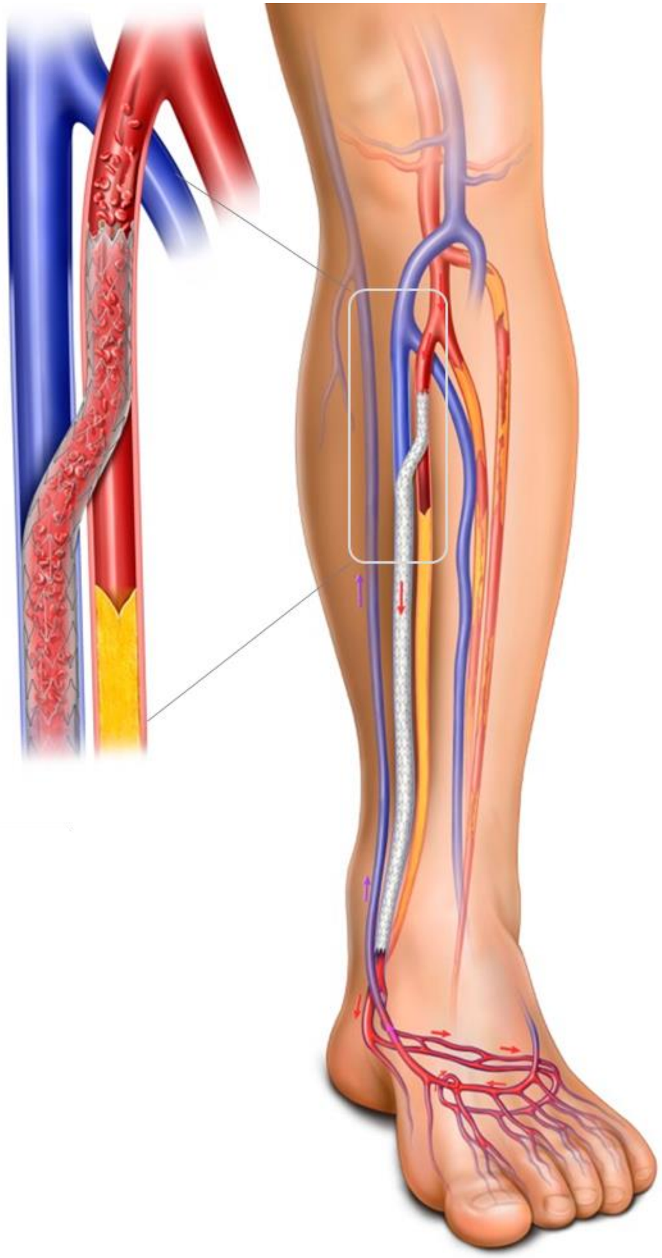
The "No-Option" Patient

Transcatheter Arterialization of Deep Veins (TADV)



Melanie Swoboda, NP-BC
Vascular Surgery
Henry Ford Health - West Bloomfield, Michigan

Disclosures

- No disclosures
- Some slides courtesy of LimFlow

Outline

- Critical limb threatening ischemia
- No option patient
- Transcatheter deep vein arterialization
    - Patient selection
    - Pre-operative imaging
    - Donor vessel anatomy
- Post operative considerations
- Evidence

CLTI: The Most Severe Form of Peripheral Arterial Disease

3.8M In the U.S. **affected by Chronic Limb-Threatening Ischemia** (CLTI) and the number continues to grow[1]

150K **Major lower extremity amputations** in the U.S. annually[2]

4X **More likely to face major amputation** if you are Black[3]

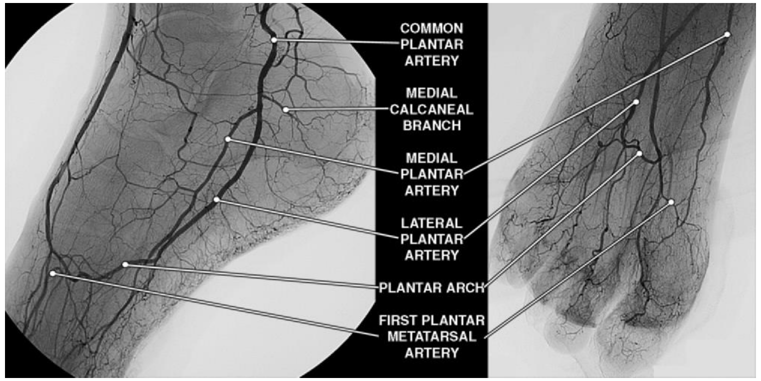
6th **Most expensive surgical procedure** in the U.S. = Major Amputation[4]

Driven by high complication rates, length of stay, readmissions, and hospitalizations[4]

20%
of CLTI patients
become “no-option”[6]

>50%
of no-option patients die or
require major amputation
within 6 months[7]

NORMAL FOOT



SEVERE ISCHEMIA

No acceptable **arteria**l target for standard revascularization

CHRONIC WOUNDS

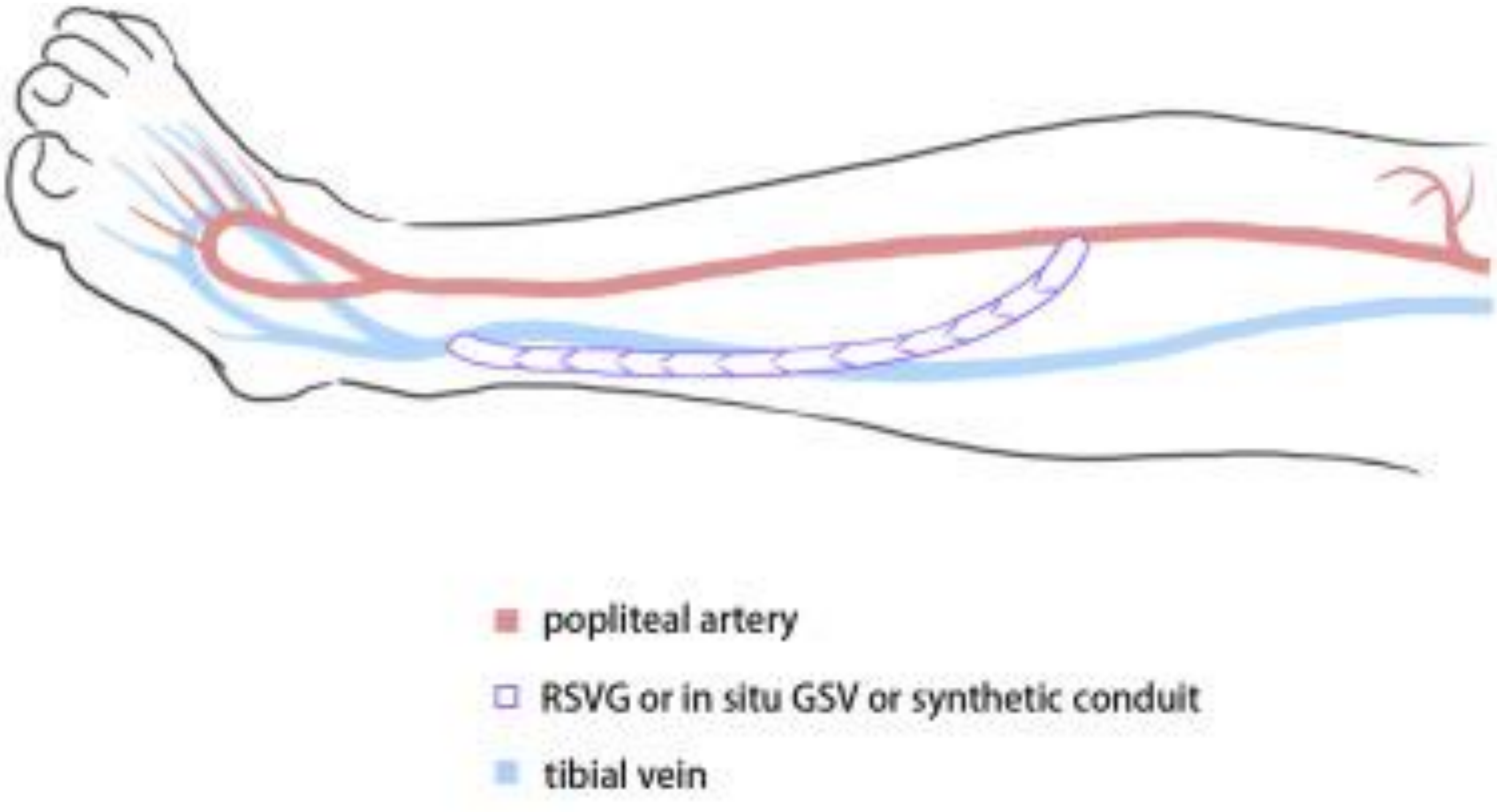
Typically do not heal without successful reperfusion

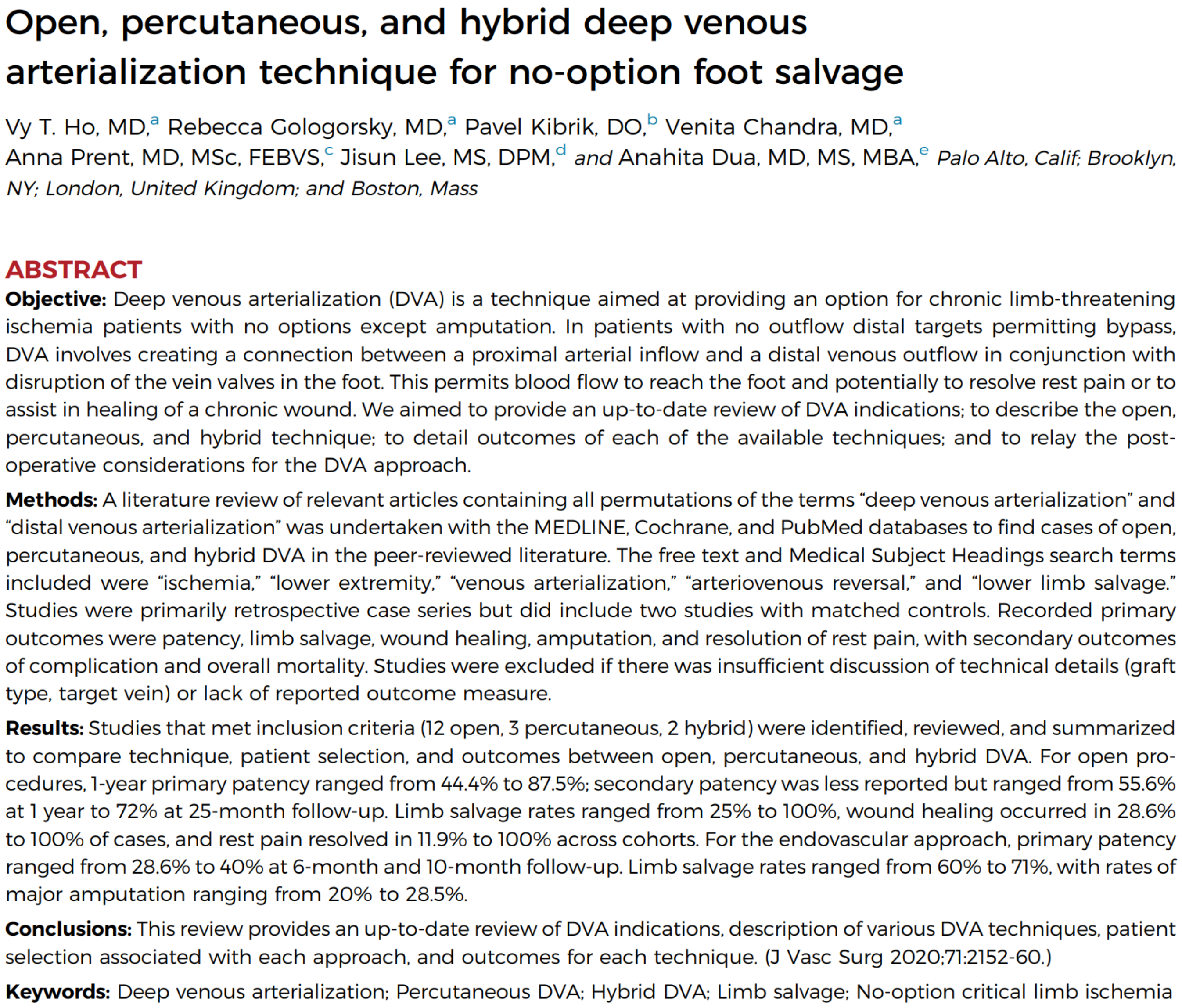
Maturation surveillance images courtesy of Dr. Roberto Ferraresi

No Good Option Patient

- "Palliative" wound care
- Repeated pedal interventions
- Futile control of rest pain or future infections
- Narcotic dependence
- Ultimately – BKA or AKA?
- Open deep vein arterialization

What is Deep Vein Arterialization?





Open, percutaneous, and hybrid deep venous arterialization technique for no-option foot salvage

Vy T. Ho, MD,[a] Rebecca Gologorsky, MD,[a] Pavel Kibrik, DO,[b] Venita Chandra, MD,[a] Anna Prent, MD, MSc, FEBVS,[c] Jisun Lee, MS, DPM,[d] *and* Anahita Dua, MD, MS, MBA,[e] *Palo Alto, Calif; Brooklyn, NY; London, United Kingdom; and Boston, Mass*

ABSTRACT

Objective: Deep venous arterialization (DVA) is a technique aimed at providing an option for chronic limb-threatening ischemia patients with no options except amputation. In patients with no outflow distal targets permitting bypass, DVA involves creating a connection between a proximal arterial inflow and a distal venous outflow in conjunction with disruption of the vein valves in the foot. This permits blood flow to reach the foot and potentially to resolve rest pain or to assist in healing of a chronic wound. We aimed to provide an up-to-date review of DVA indications; to describe the open, percutaneous, and hybrid technique; to detail outcomes of each of the available techniques; and to relay the post-operative considerations for the DVA approach.

Methods: A literature review of relevant articles containing all permutations of the terms “deep venous arterialization” and “distal venous arterialization” was undertaken with the MEDLINE, Cochrane, and PubMed databases to find cases of open, percutaneous, and hybrid DVA in the peer-reviewed literature. The free text and Medical Subject Headings search terms included were “ischemia,” “lower extremity,” “venous arterialization,” “arteriovenous reversal,” and “lower limb salvage.” Studies were primarily retrospective case series but did include two studies with matched controls. Recorded primary outcomes were patency, limb salvage, wound healing, amputation, and resolution of rest pain, with secondary outcomes of complication and overall mortality. Studies were excluded if there was insufficient discussion of technical details (graft type, target vein) or lack of reported outcome measure.

Results: Studies that met inclusion criteria (12 open, 3 percutaneous, 2 hybrid) were identified, reviewed, and summarized to compare technique, patient selection, and outcomes between open, percutaneous, and hybrid DVA. For open procedures, 1-year primary patency ranged from 44.4% to 87.5%; secondary patency was less reported but ranged from 55.6% at 1 year to 72% at 25-month follow-up. Limb salvage rates ranged from 25% to 100%, wound healing occurred in 28.6% to 100% of cases, and rest pain resolved in 11.9% to 100% across cohorts. For the endovascular approach, primary patency ranged from 28.6% to 40% at 6-month and 10-month follow-up. Limb salvage rates ranged from 60% to 71%, with rates of major amputation ranging from 20% to 28.5%.

Conclusions: This review provides an up-to-date review of DVA indications, description of various DVA techniques, patient selection associated with each approach, and outcomes for each technique. (J Vasc Surg 2020;71:2152-60.)

Keywords: Deep venous arterialization; Percutaneous DVA; Hybrid DVA; Limb salvage; No-option critical limb ischemia

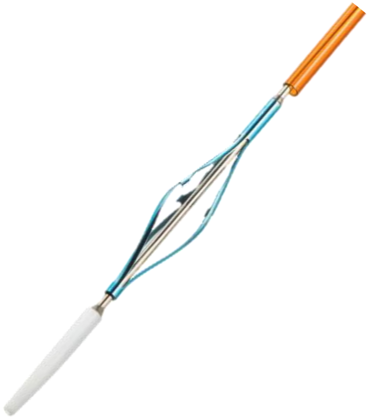
- Results varied with limb salvage "25-100%"
- Not reproducible
- Limited case-series
- Variability in techniques and patient selection

LimFlow TADV System

Transcatheter Arterialization of Deep Veins (TADV)

LimFlow TADV System - FDA Breakthrough Device Designation

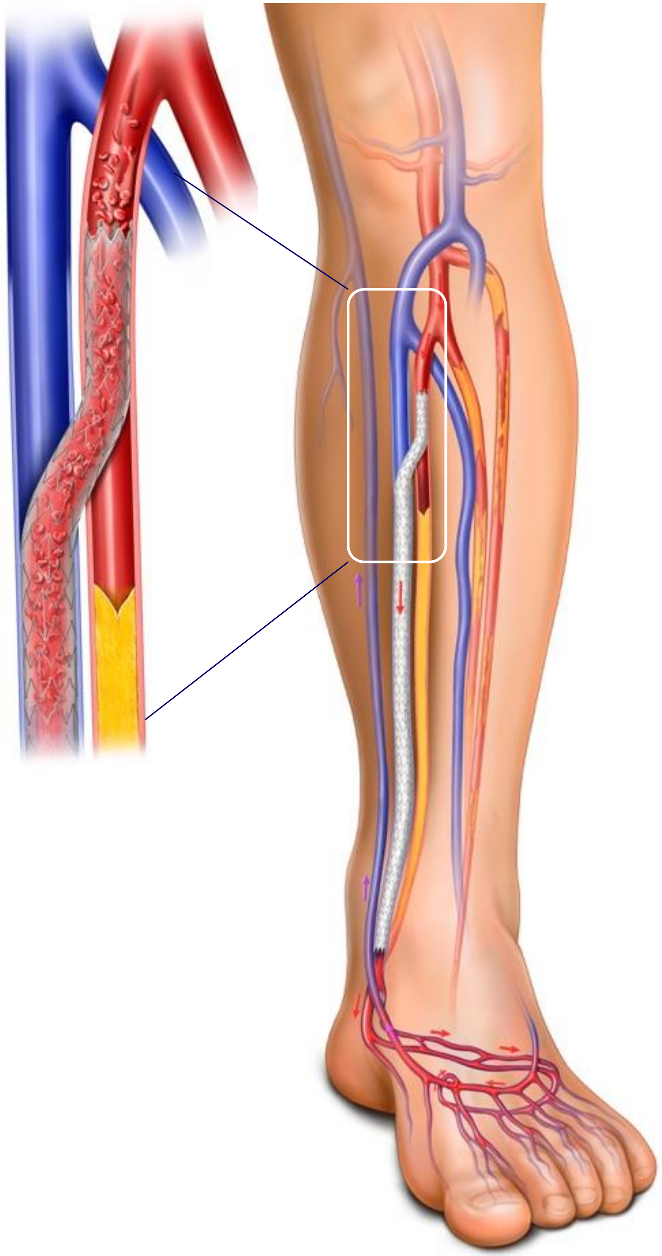
LimFlow Arterial & Venous Catheters



LimFlow Valvulotome

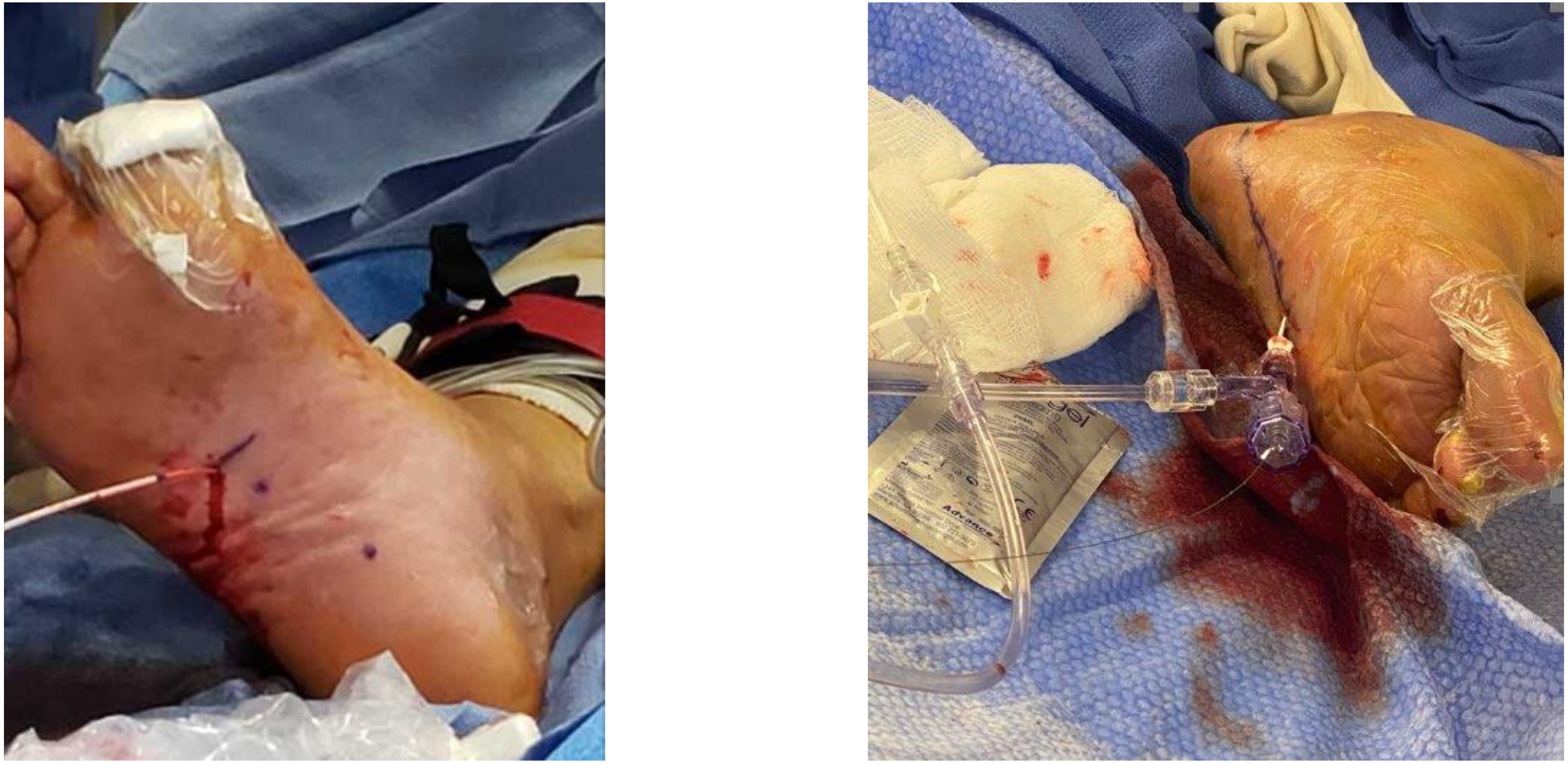
LimFlow Conical & Straight Stent Grafts

FDA Approved
October 2023,
Based on 132 patients.



HENRY FORD HEALTH

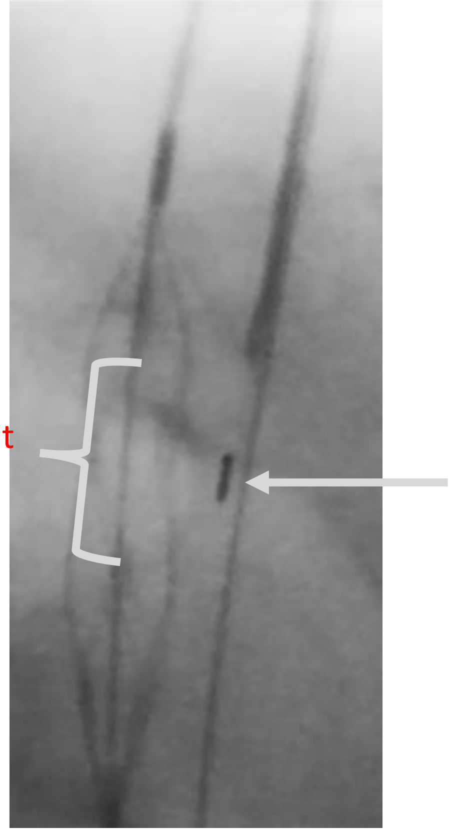
Pedal Access



Antegrade Femoral Access

- Common femoral access using antegrade approach
- Treat all inflow disease in the SFA and / or popliteal arteries prior to TADV procedure

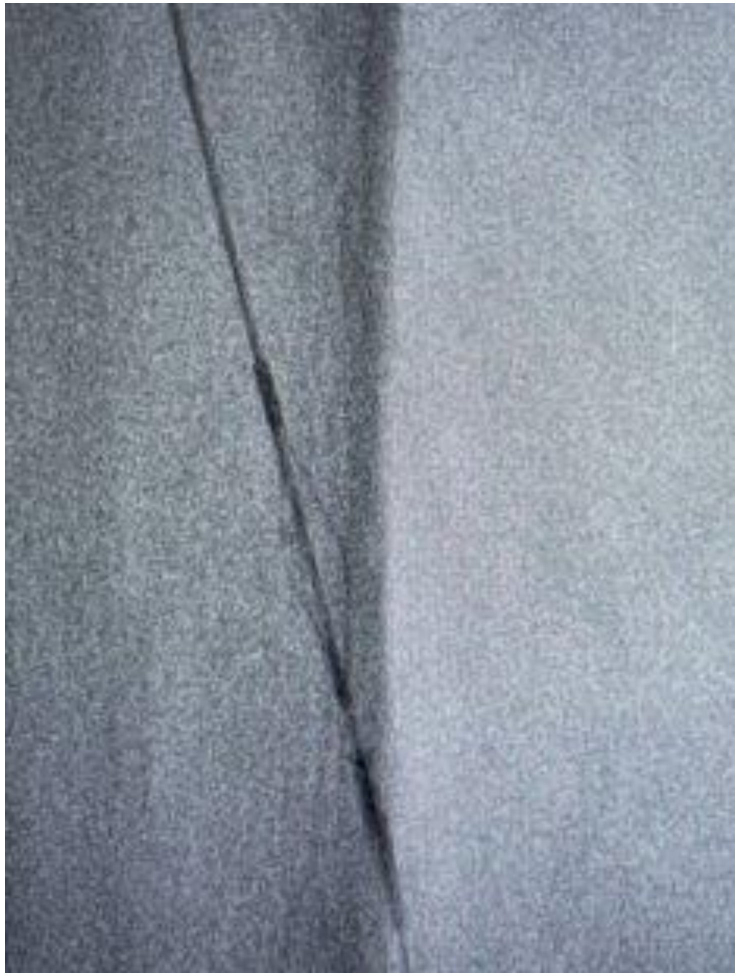
Crossing Wire



venous alignment zone

arterial alignment zone

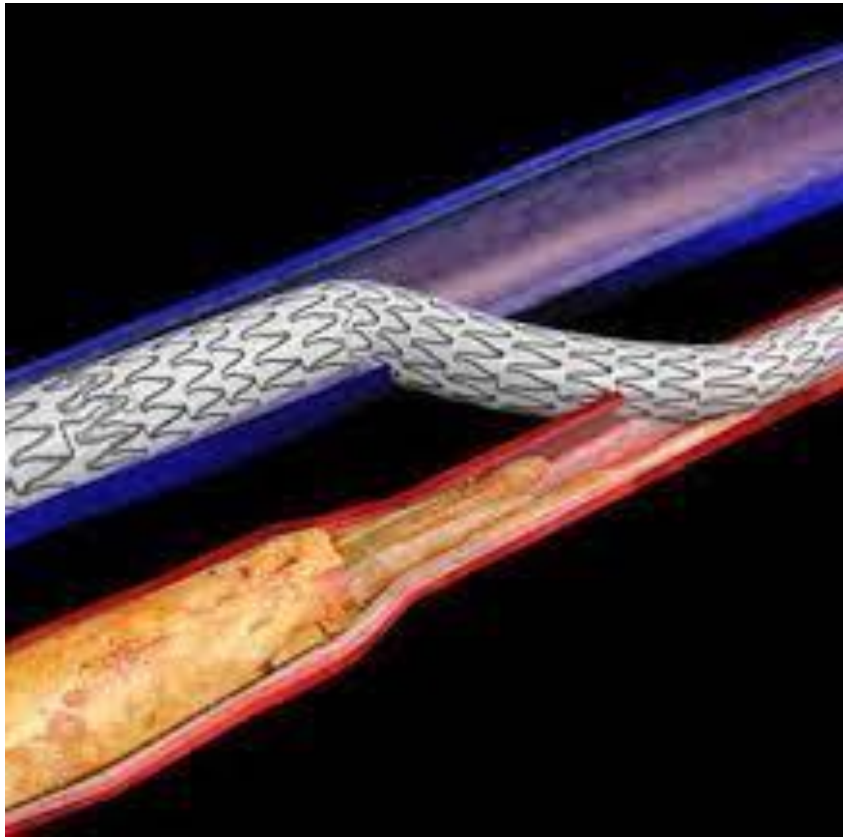
Valvulotome

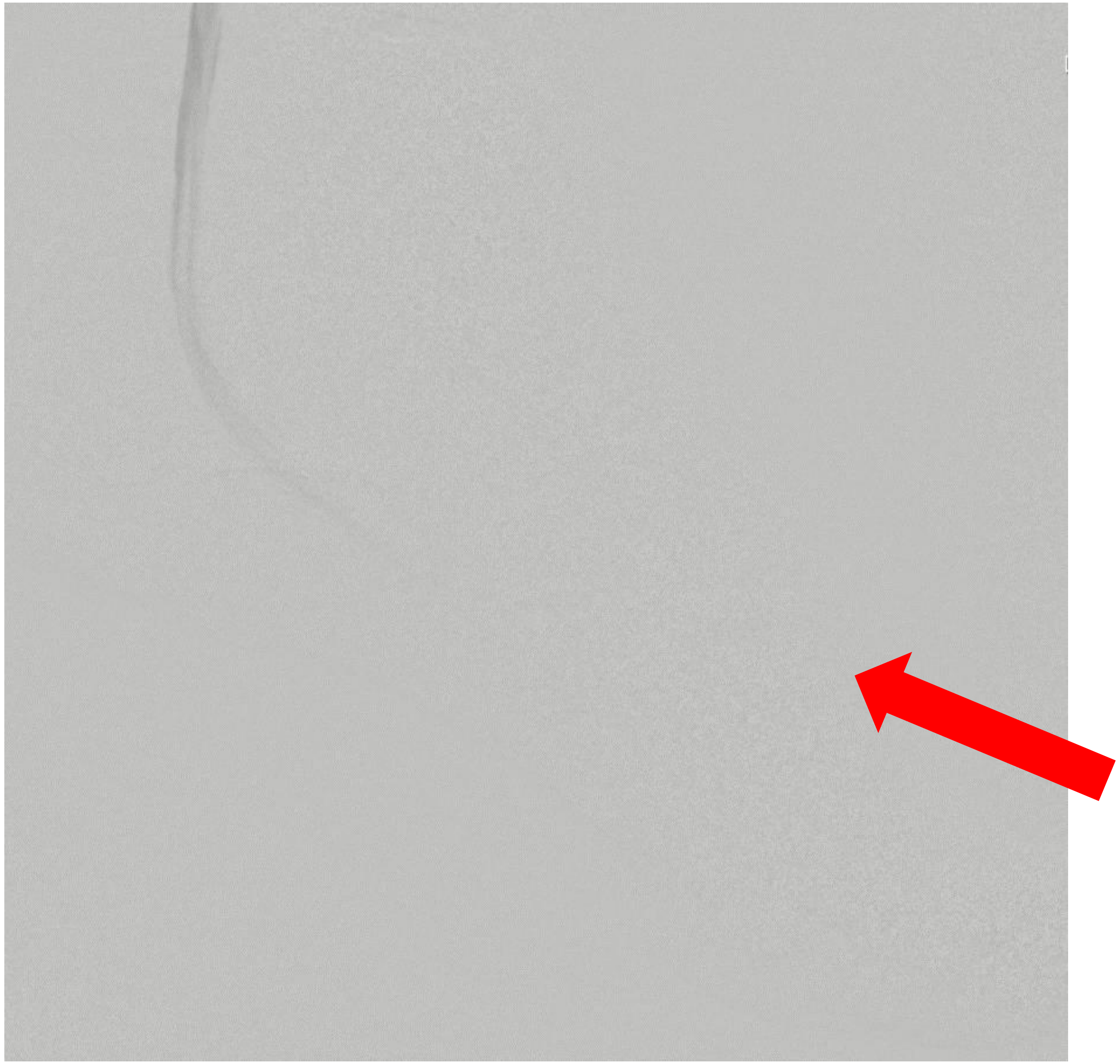


Valvulotome

Post Valvulotome
angioplasty of tibial vein

Stenting & Post Dilation





TADV Patient Selection

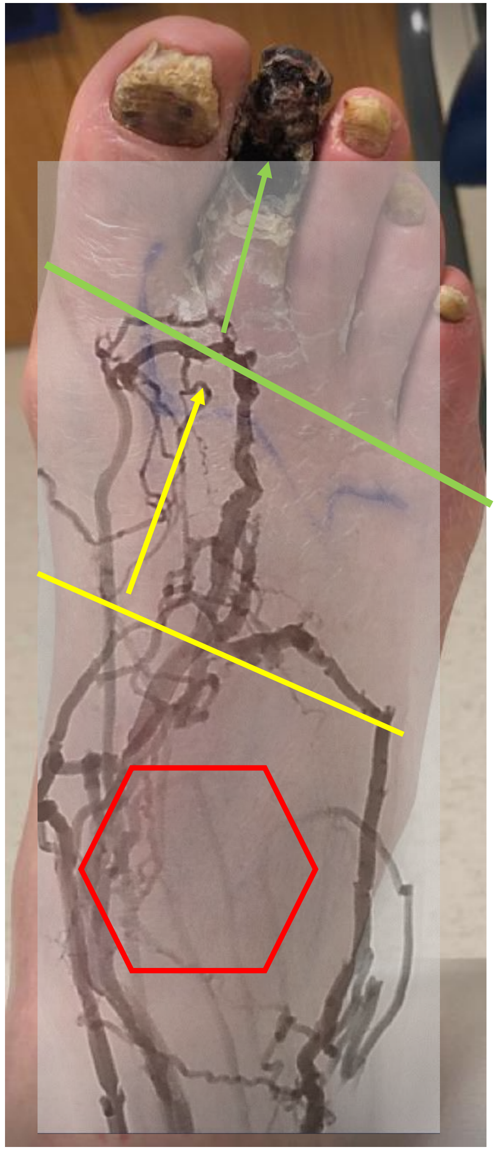
Wound Characteristics

Arterial Anatomy

Venous Anatomy

HENRY FORD HEALTH

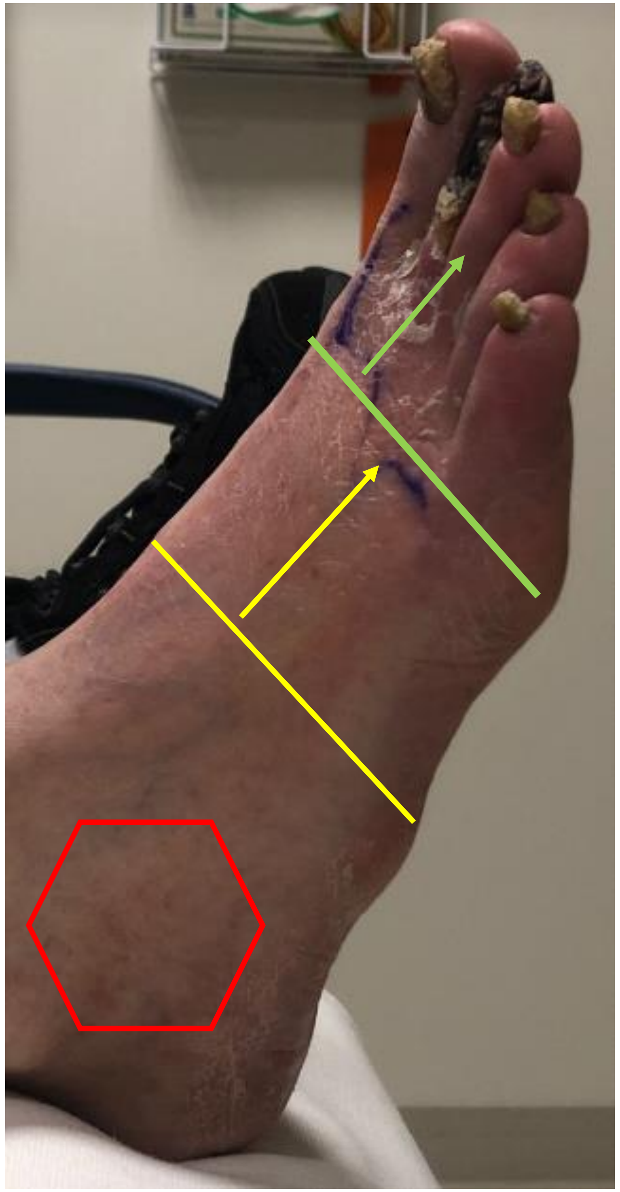
SCREENING: WOUND ASSESSMENT



Green - Involving the forefoot and little to no overlap to the metatarsal region

Yellow - Metatarsal Region - assess how much tissue is salvageable

Red – - Heel and/ or ankle wound involvement. Assess patient’s ambulatory future



Characteristics of an ideal TADV wound:

- Forefoot wound/tissue loss
- Stable wound – could wait a few weeks for surgical intervention
- Dry gangrene
- No clinical signs of infection

Characteristics of a marginal TADV wound:

- Wound extending to mid-metatarsal area
- Infection-easily managed/mitigated with antibiotics and/or bedside temporization
- Closed wound site

Characteristics of a poor TADV wound:

- Extensive tissue loss encompassing majority of the ambulatory surface of the foot
- Infection extending to the level of bone

Ideal Venous Vessel Description

- Minimal tortuosity (Figure 1)
- ≥3 mm in diameter (Figure 2)
- Continuous from metatarsal to Posterior Tibial Vein
- Compressible (no thrombus or mural thickening) (Figure 3)

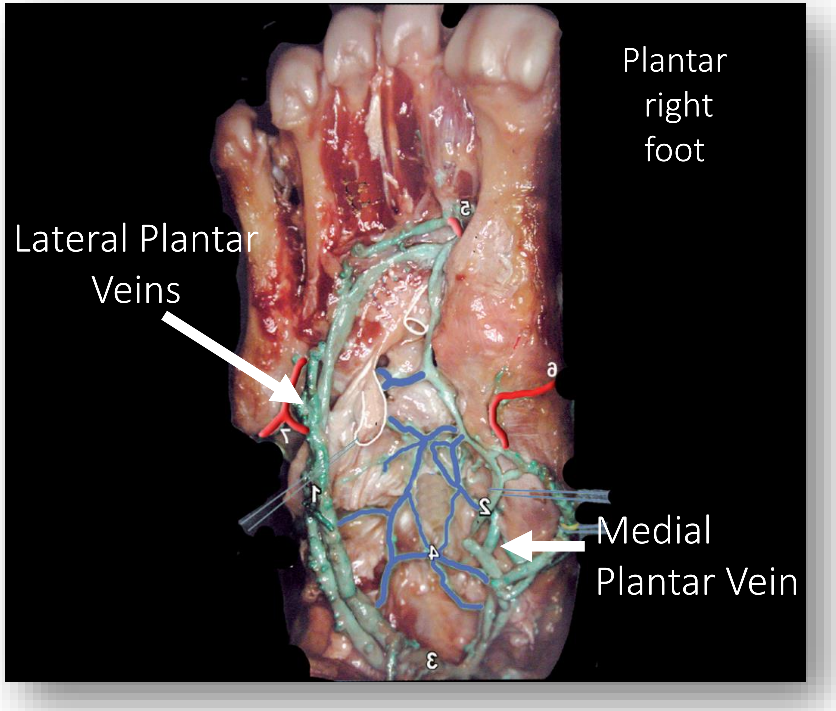


Figure 1

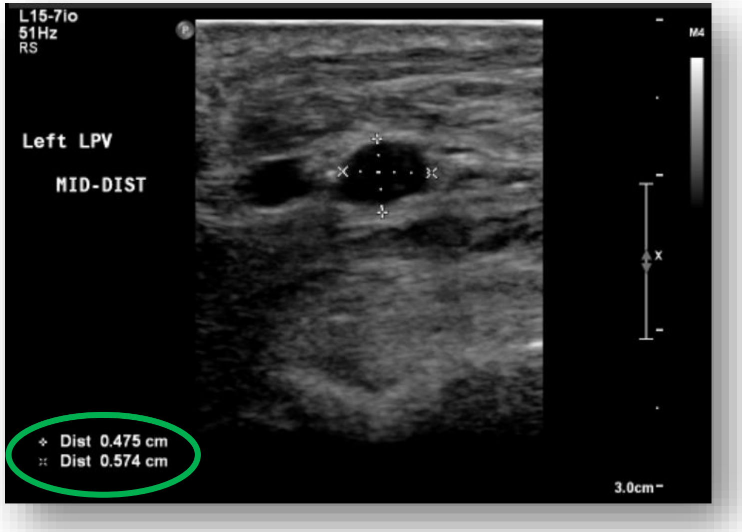


Figure 2

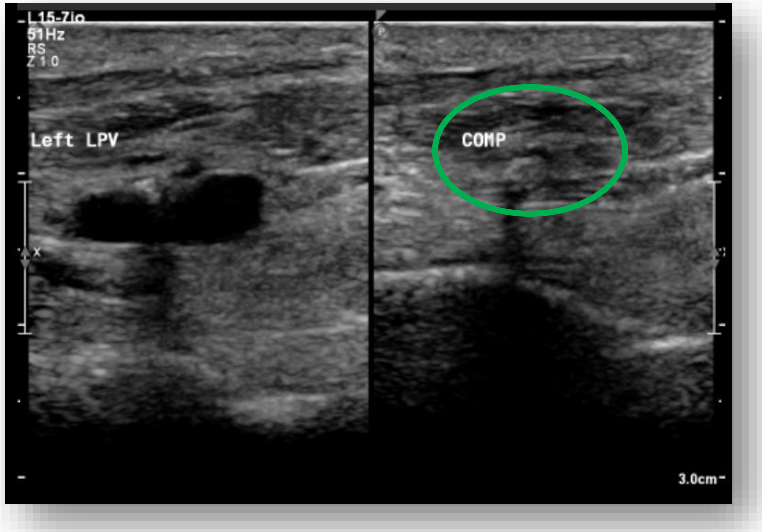
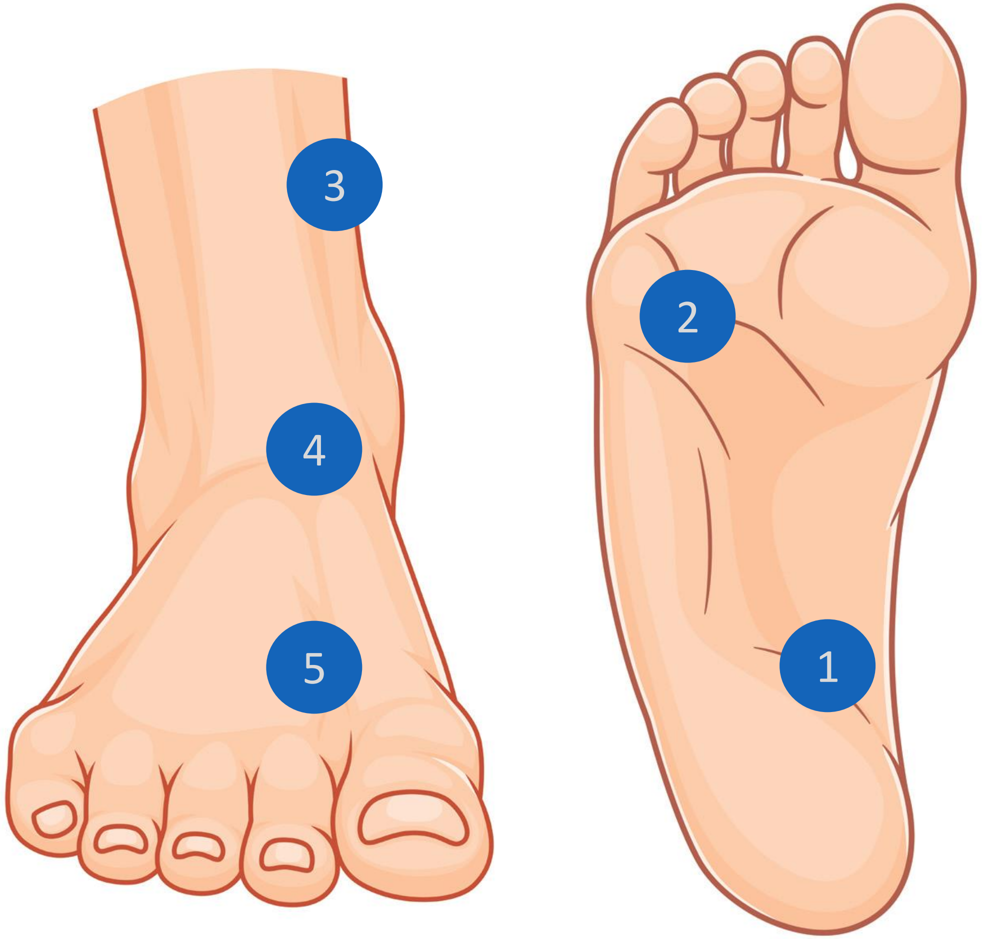


Figure 3

Assess compressibility and obtain Anterior-Posterior Diameter Measurements of:

1. Lateral Plantar Vein (LPV) Proximal Foot
2. LPV Mid-Distal Foot
3. Greater Saphenous Vein (GSV) at Ankle
4. Medial Marginal Vein (MMV) Mid Foot
5. MMV Distal Foot/Metatarsal Perforator

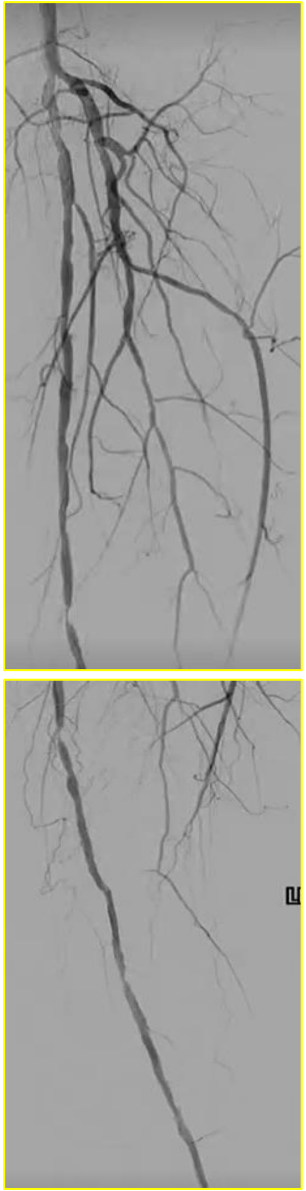


Ideal LPV size for access is >3mm

Inflow Disease

- Evaluate and treat all inflow disease in the SFA and / or popliteal arteries prior to TADV procedure
    - If stenting is required, recommend deployment after TADV is complete

Mild

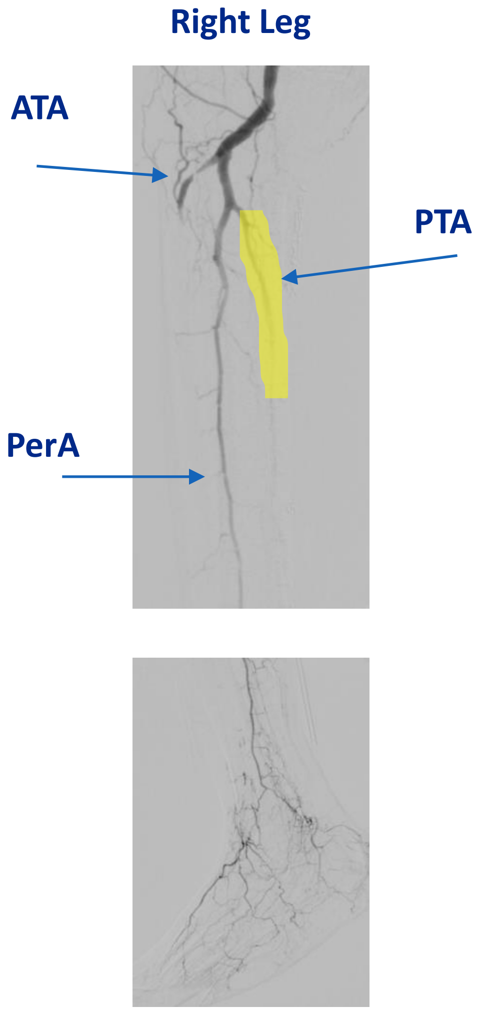


Moderate

Chronic Total Occlusion

Severe

Examples of Donor Tibial Artery Anatomy



- Ideal Situation – Donor Posterior Tibial Artery

- Preserving peroneal artery for perfusion to foot

Post-TADV Best Practices

HENRY FORD HEALTH

Pain

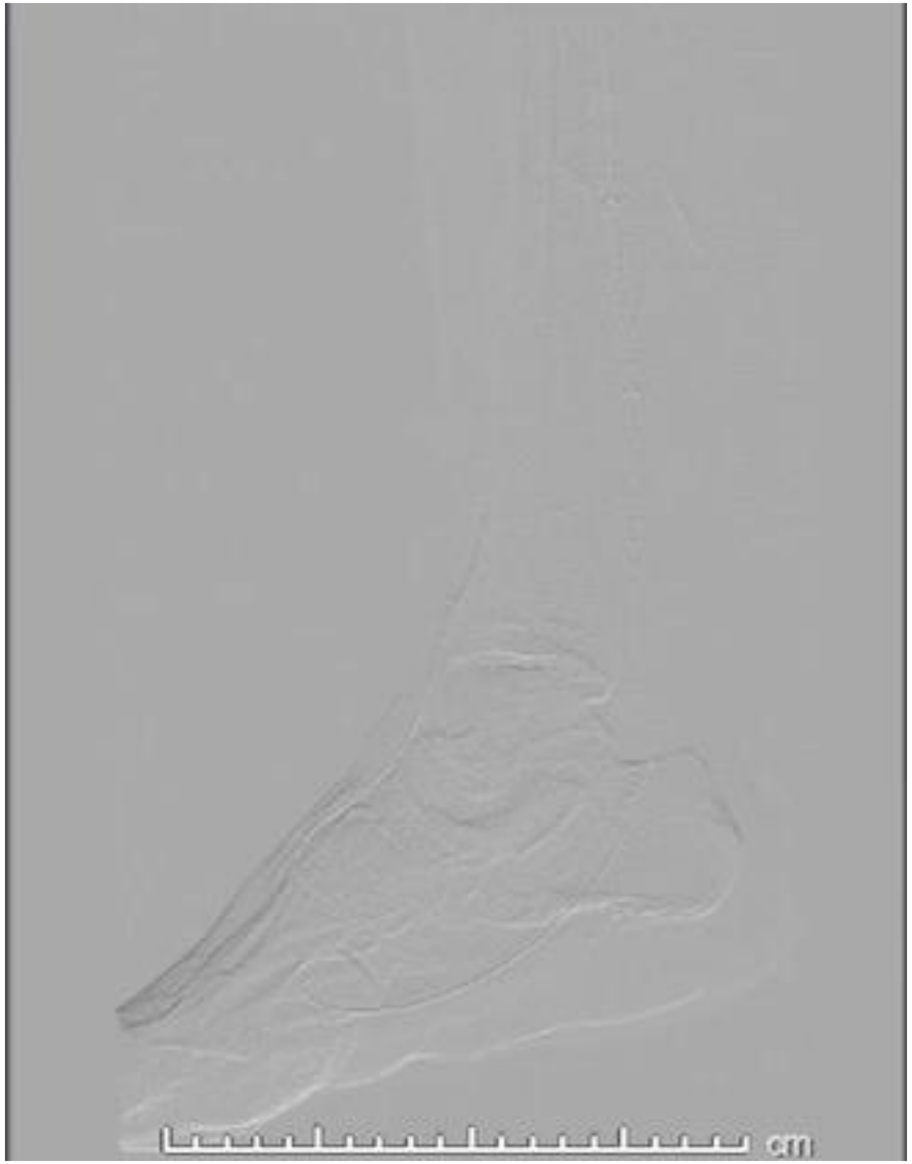
- Potential sources to consider:
  - Periprocedural
  - Edema
  - Ischemia
- Practitioner choice for pain control should include the following:
  - Regional anesthetic
  - PO/IV systemic medication
- Severe pain and/or pain unresolved within 24 – 48 hours should raise concern for new ischemia and should be investigated for arterial steal

Swelling

- Common for 3 – 4 weeks post-procedure
- Sign of blood flow to foot in treated limb
- Untreated edema may inhibit wound healing
- Treatment considerations:
  - Elevate affected limb
  - May use light (≤ 20mmHg) compression with a wrap/bandage

Flow Optimization

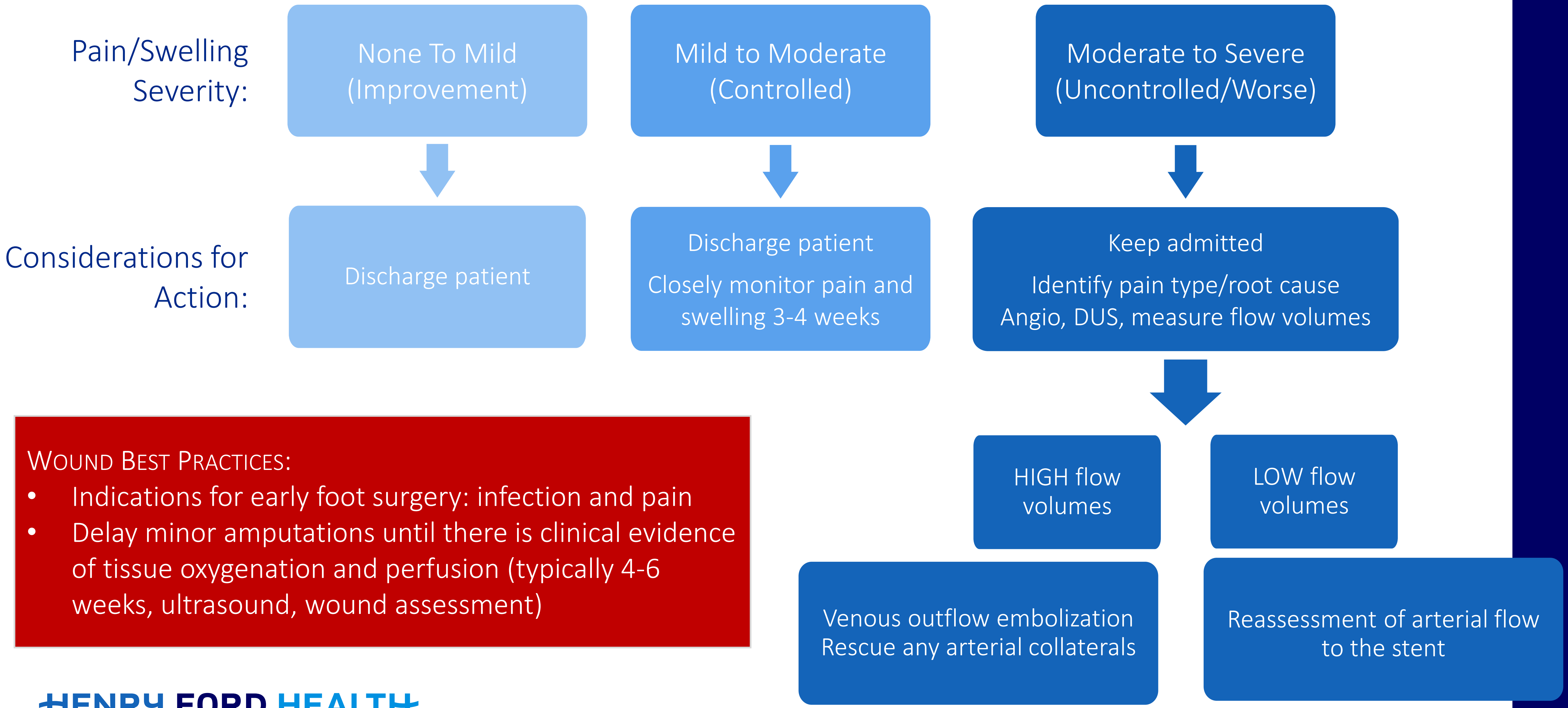
- Blood diverted proximally through a perforator or branch before reaching the distal part of the foot may inhibit wound healing and fistula maturation
- May require embolization of stealing vessels to focalize flow distally
- Diminished or stagnant flow in the lateral plantar vein may result in pain or worsening wounds



Things to Consider in the TADV Patient

- Early debridement (less than 4 – 6 weeks post-TADV) must be performed cautiously; debride only necrotic/infected tissue
- **AVOID** primary wound closure in early TADV patients
  - Utilize low-pressure (60 – 80mmHg) NPWT when appropriate
- Multidisciplinary communication and coordination among teams; including podiatry and wound care
- 1/3 of patient’s require an open transmetatarsal amputation due to progressive tissue loss and/or pain
- VAC placement or skin graft is preferred over any primary closure

Actions after arterialization



Pain/Swelling Severity:

None To Mild (Improvement) → Discharge patient

Mild to Moderate (Controlled) → Discharge patient
Closely monitor pain and swelling 3-4 weeks

Moderate to Severe (Uncontrolled/Worse) → Keep admitted
Identify pain type/root cause
Angio, DUS, measure flow volumes

Considerations for Action:

- HIGH flow volumes: Venous outflow embolization
Rescue any arterial collaterals
- LOW flow volumes: Reassessment of arterial flow to the stent

WOUND BEST PRACTICES:

- Indications for early foot surgery: infection and pain
- Delay minor amputations until there is clinical evidence of tissue oxygenation and perfusion (typically 4-6 weeks, ultrasound, wound assessment)

Recommended Physician Follow Up Schedule

Treatment plan at physicians' discretion. Recommendations based on protocol and learnings from PROMISE II study

	Post Procedure	Discharge /48hrs	1 Week	2 Week	3 Week	1 Month	6 Weeks*	2 Month	3 Month	6 Month	9 Month	1 Year	2 Year
Angiogram	X												
MD Hand-Held/Blind Doppler	X	X	X	X	X	X	X	X	X				
Duplex		X		X		X	X	X	X	X	X	X	X
Pain	X	X	X	X	X	X	X	X	X	X	X		
Swelling	X	X	X	X	X	X	X	X	X	X	X		
Wound Status	X	X	X	X	X	X	X	X	X	X	X		

**DUS recommended if patient has new or increased pain and/or wound deterioration*

If no increased pain and/or wound deterioration noted after year 1, yearly Duplex surveillance is recommended.

Examples of Wound Care Follow Up Best Practices

Gangrenous, necrotic toes due to forefoot ischemia

gTMA

Primary gTMA with coverage +/-NPWT

After wound surface is clean

- Can proceed to skin substitute application to act as a scaffold to bridge to a granular wound base followed by application of split thickness skin graft (STSG)

Images on file from PROMISE II Study

Wound Care Case Study #2

04/03/2023
One day before TADV

04/21/2023

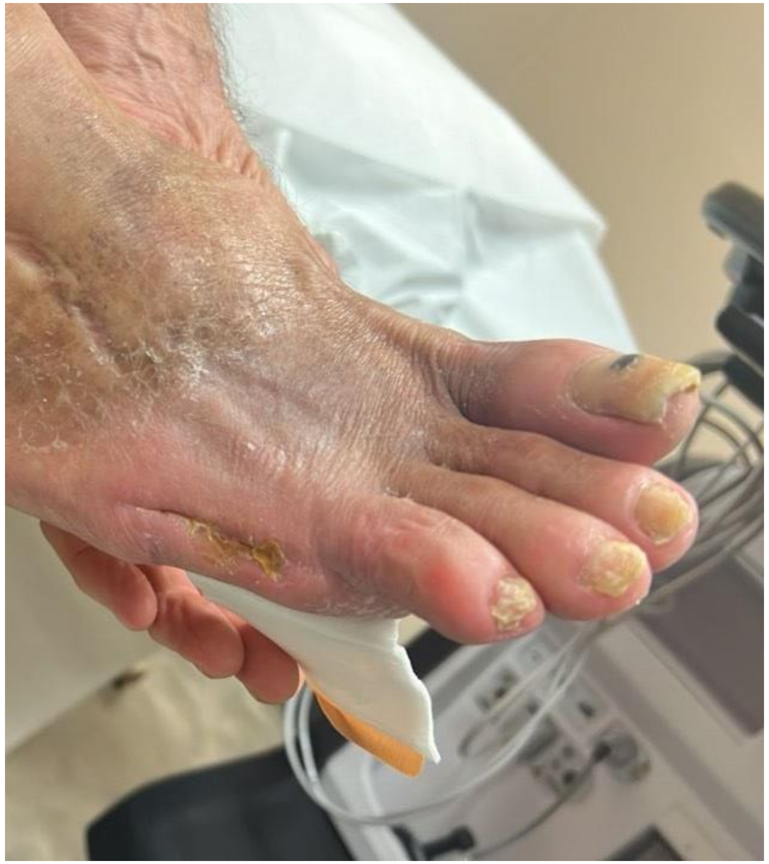
05/17/2023

Images on file from PROMISE II Study

Wound Care Case Study #2 continued…

06/16/2023

07/14/2023



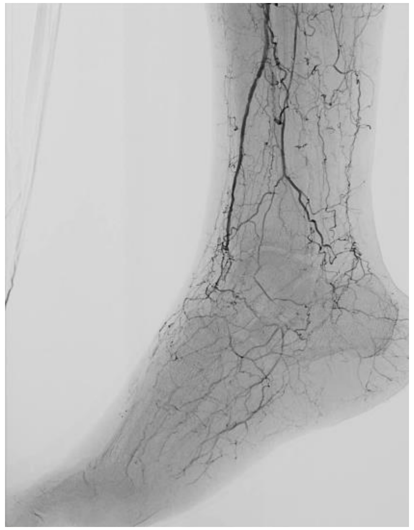
09/21/2023
Healed

Images on file from PROMISE II Study

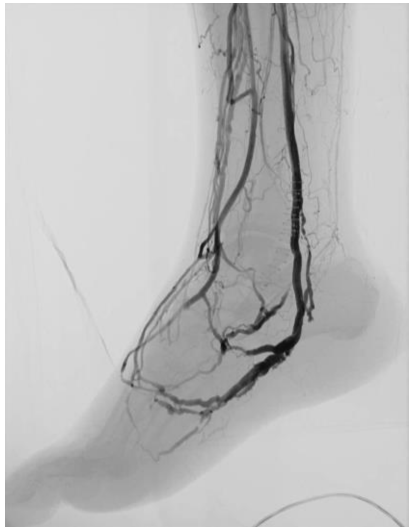
Before and After TADV

Circuit Maturation After TADV

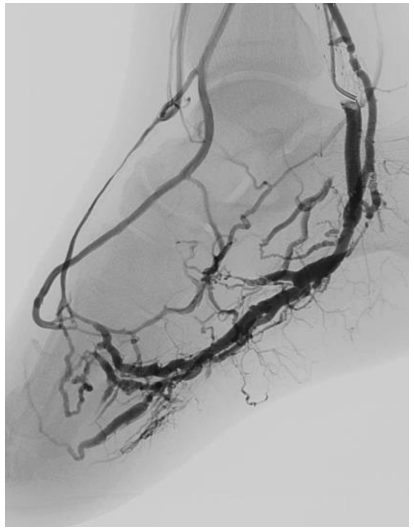
Healthy Foot



Baseline



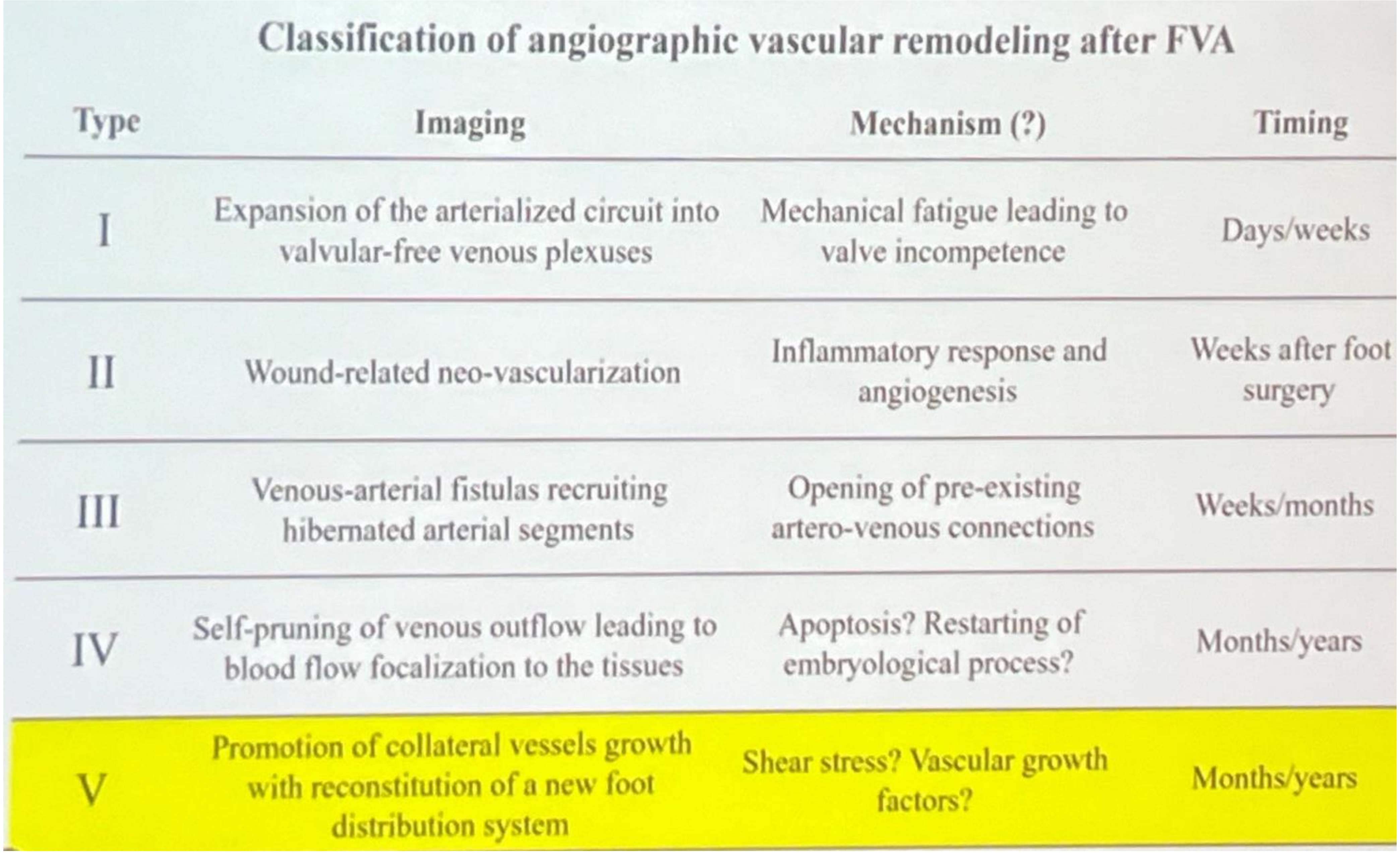
Acute Result



45 Days

90 Days

Maturation surveillance images courtesy of Dr. Roberto Ferraresi



Classification of angiographic vascular remodeling after FVA

Type	Imaging	Mechanism (?)	Timing
I	Expansion of the arterialized circuit into valvular-free venous plexuses	Mechanical fatigue leading to valve incompetence	Days/weeks
II	Wound-related neo-vascularization	Inflammatory response and angiogenesis	Weeks after foot surgery
III	Venous-arterial fistulas recruiting hibernated arterial segments	Opening of pre-existing artero-venous connections	Weeks/months
IV	Self-pruning of venous outflow leading to blood flow focalization to the tissues	Apoptosis? Restarting of embryological process?	Months/years
V	Promotion of collateral vessels growth with reconstitution of a new foot distribution system	Shear stress? Vascular growth factors?	Months/years

The Evidence

HENRY FORD HEALTH®

PROMISE I Study

Objectives

- Establish safety for pivotal study
- Identify/address operator challenges
- Determine patient and therapeutic considerations that impact performance

Use early experience to

- Optimize operator technique
- Develop subsequent protocols
- Refine

  Patient screening

  Wound analysis

  Patient follow-up

Prospective, single-arm early feasibility study

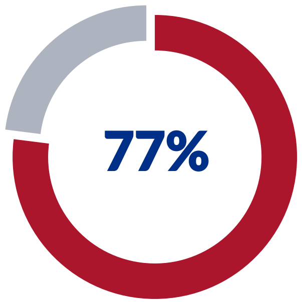
Population	**Patients with no-option** chronic limb-threatening ischemia (CLTI)
Enrollment	**32** patients at **7** sites (2017-2019)
Primary Endpoints	**Amputation-free** survival **Survival** **Freedom** from amputation
Observational Endpoints	Wound **size** Wound **healing**

PROMISE I

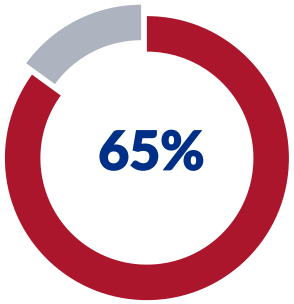
32 No-Option Patients

6 Month Outcomes[6]

Limb Salvage



Wounds Healed or Healing

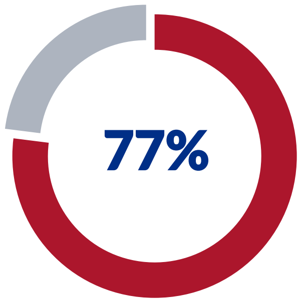


Demographics

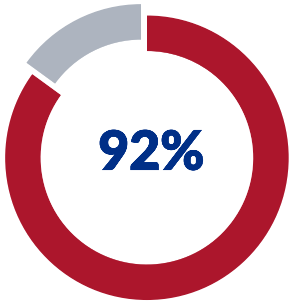
87%	Rutherford 5
13%	Rutherford 6
69%	Diabetes
34%	Renal insufficiency

24 Month Outcomes[6]

Limb Salvage



Wounds Healed or Healing



HENRY FORD HEALTH

PROMISE II

NATIONAL PIs

Dr. Dan Clair
Vanderbilt University

Dr. Mehdi Shishehbor
University Hosp. Cleveland

ENROLLMENT

105
patients

20
sites in US

KEY CRITERIA

Inclusion

- No-Option CLTI
- Rutherford 5/6
- Stable Dialysis allowed

Exclusion

- Life expectancy <12M
- Severe heart failure
- Hepatic Insufficiency

US Pivotal Trial

Multicenter, prospective pivotal study
of the LimFlow System

PRIMARY ENDPOINT
Bayesian

Amputation Free Survival (AFS) at 6M

Pre-specified literature-based PG of 54%

SECONDARY ENDPOINTS

Technical Success

Wound Healing

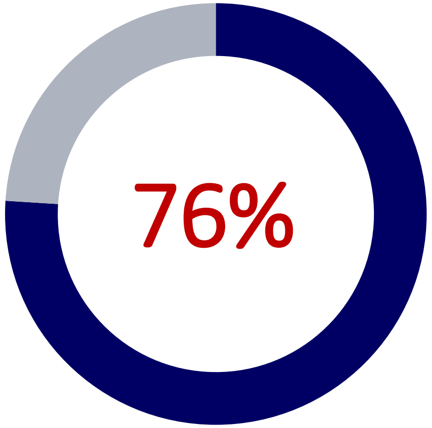
Rutherford Class

Pain

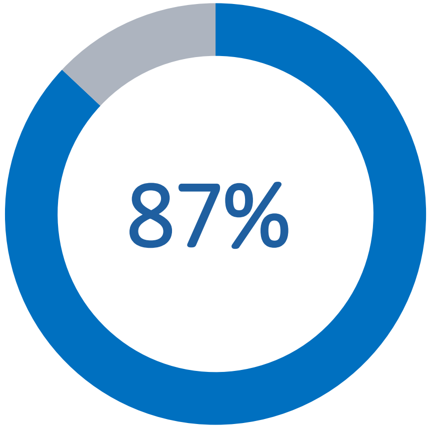
Primary Endpoint[7]

6 Month AFS, Limb Salvage, Survival (KM Estimates)

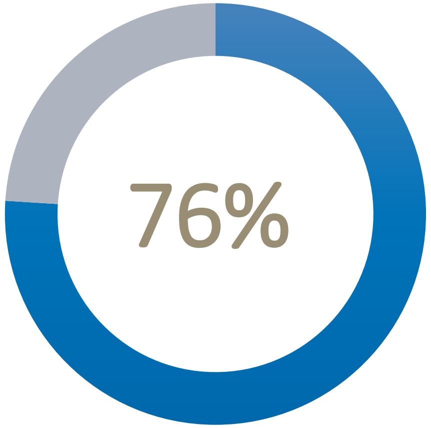
Limb Salvage



Survival



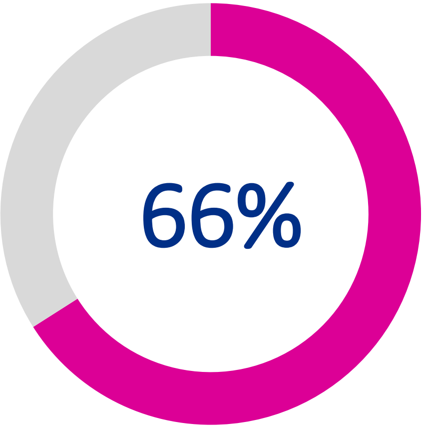
Wounds Healed or Healing



Primary Endpoint
6 Month AFS, Limb Salvage, Survival (KM Estimates)

The NEW ENGLAND JOURNAL of MEDICINE

Amputation Free Survival (AFS)*



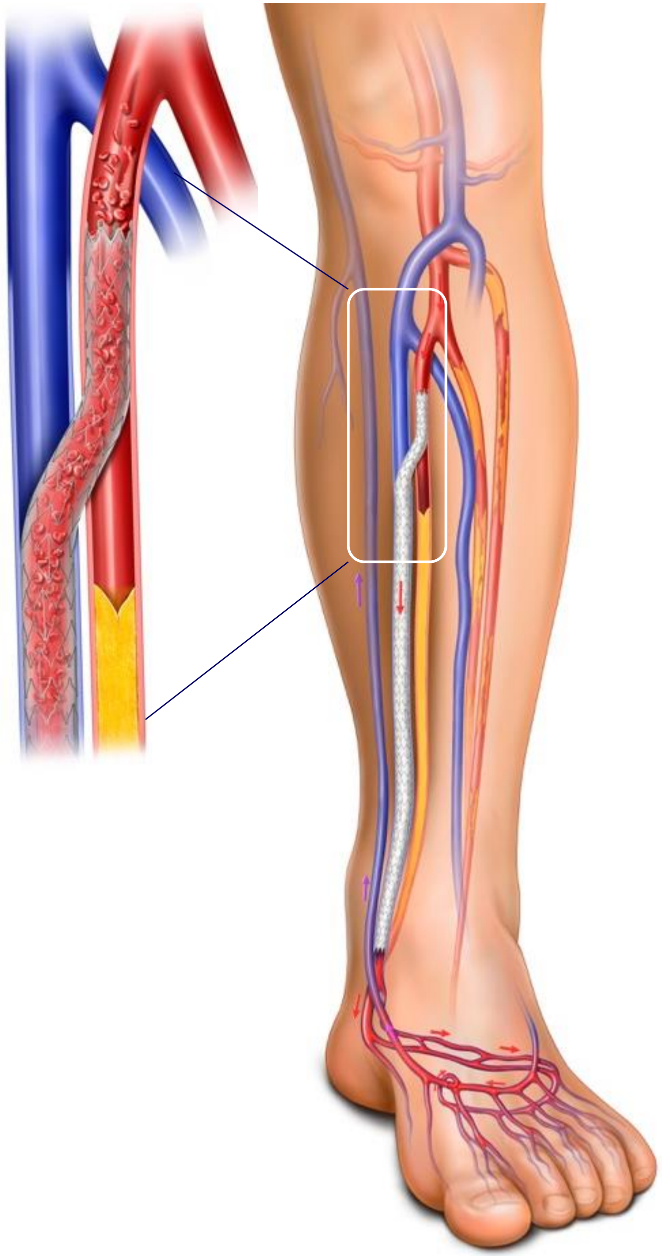
p=.005
(z-test using greenwood estimate)

*Includes 3 COVID Deaths

AFS defined as freedom from above-ankle amputation or all-cause mortality

Conclusion

- Viable option for the 'no option patient'
- Keys to success
  - Patient selection
  - Arterial/Venous anatomy
- Close surveillance
  - Multidisciplinary approach
  - Serial Duplex




INARI MEDICAL
Henry Ford Hospital
West Bloomfield
First Commercial LimFlow TADV
in Michigan
LimFlow

Thank you