

# PROMISE I UPDATE

## 2 Year Results



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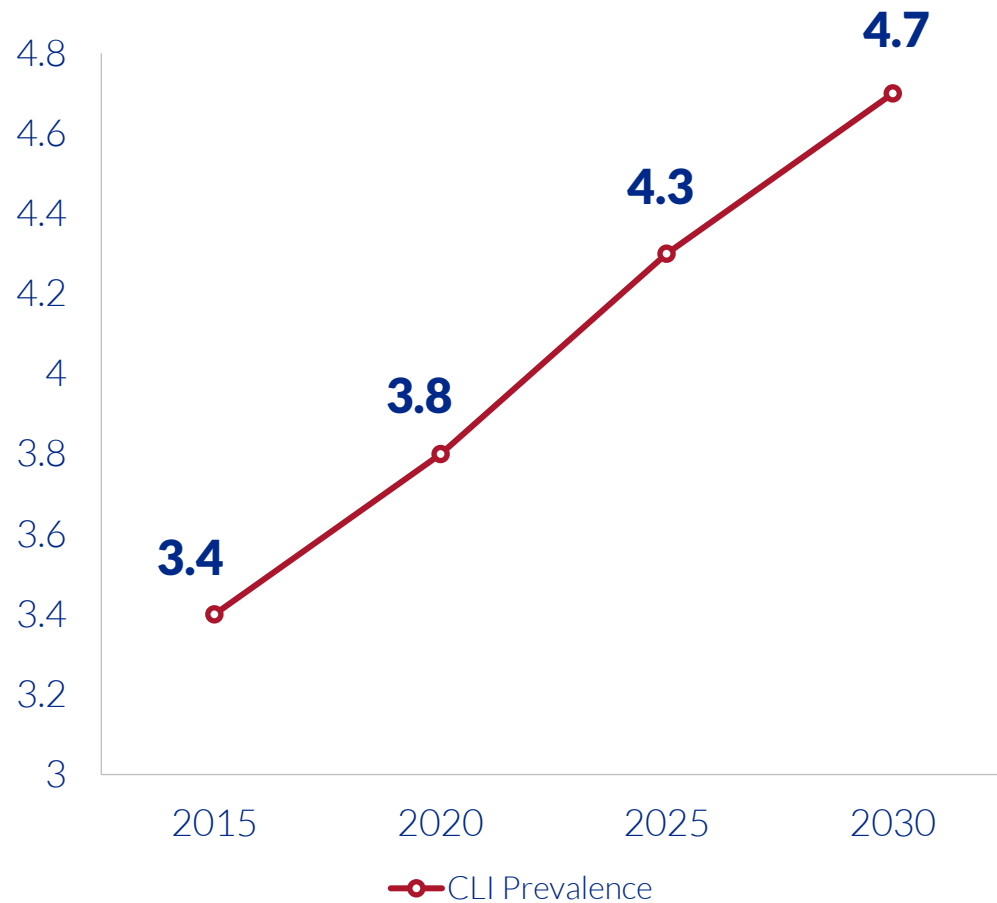
# Faculty Disclosure

**Daniel Clair, MD**

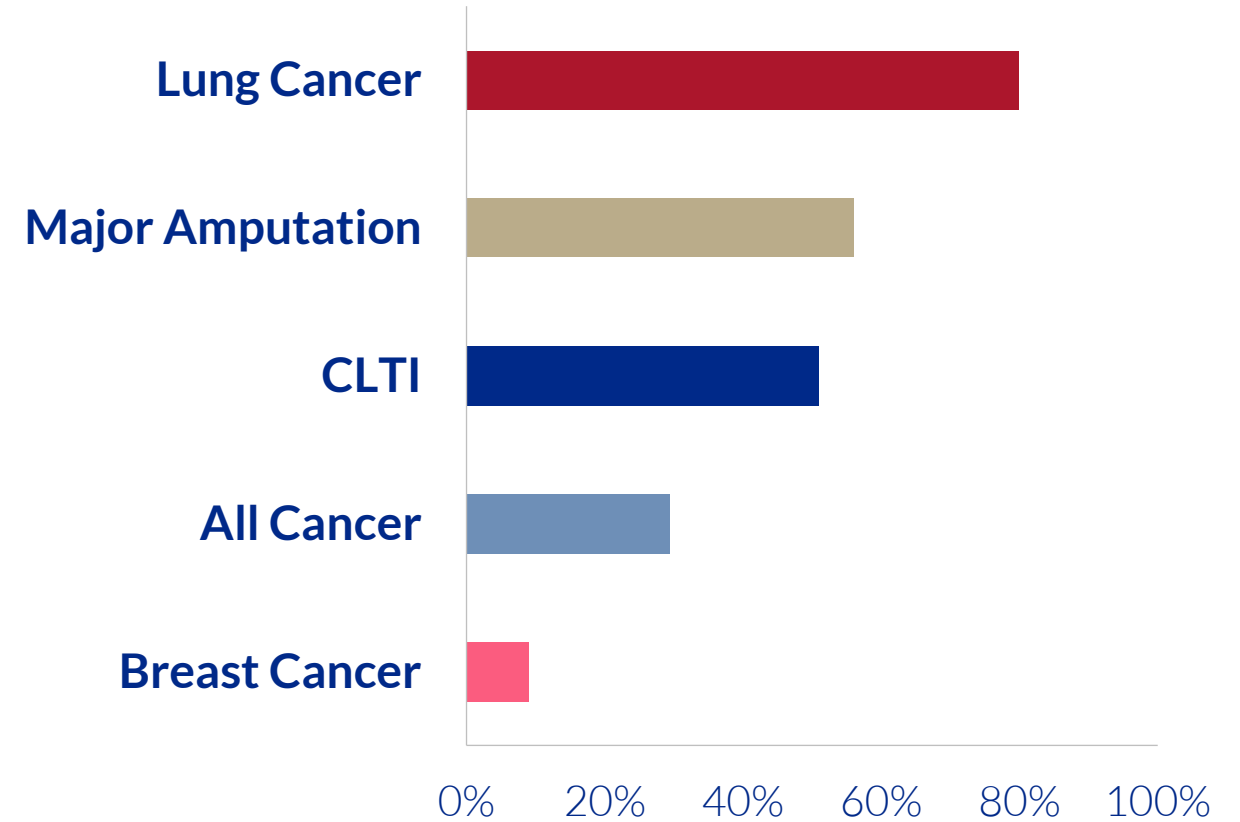
For the 12 months preceding this CME activity, I or my spouse/partner disclose the following types of financial relationships

- **Honoraria received from BSCI, Bard Peripheral Vascular, Medtronic**
- **Consulted for Bard Peripheral Vascular, BSC, LimFlow**
- **Held common stock in: NONE**
- **Research, clinical trial, or drug study funds received from LimFlow**

## US CLTI Prevalence 2015-2030 (Millions)

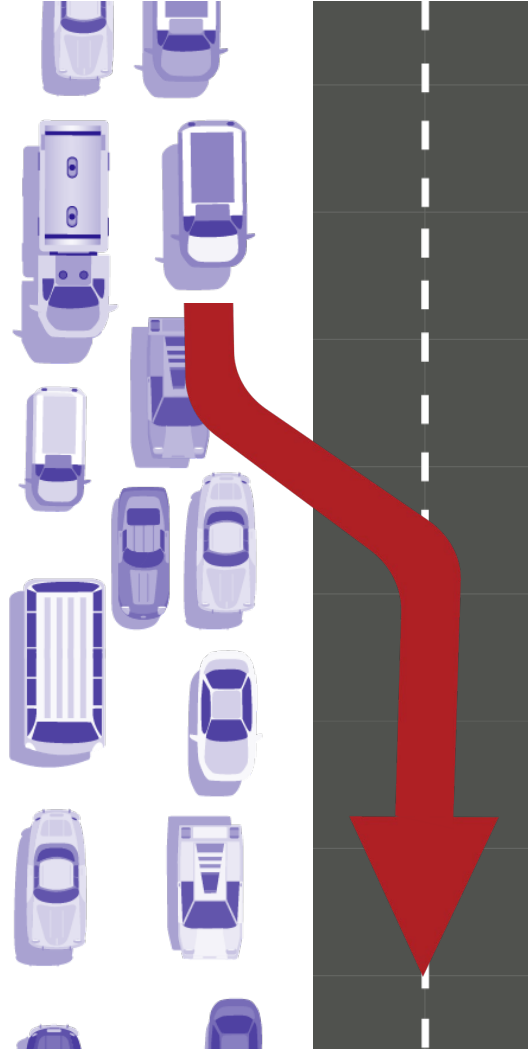


## 5 Year Mortality %



Armstrong DG, Five-year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer 2020. The Journal of Foot and Ankle Research

# Permanently Bypass Unreconstructible Arteries

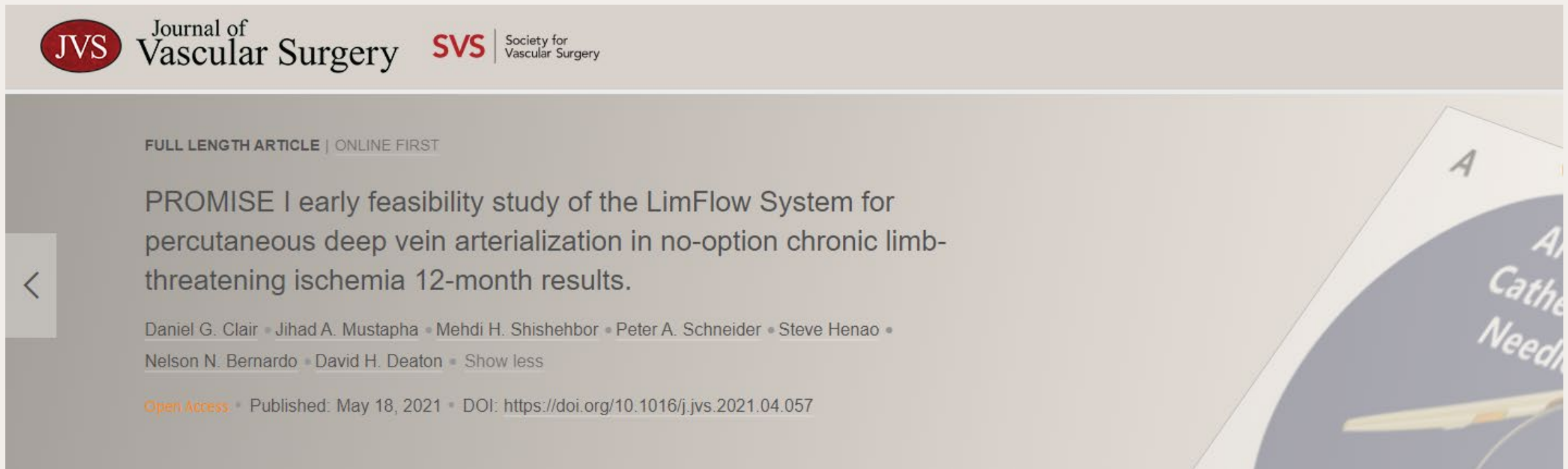


Courtesy of Roberto Ferraresi, MD

# PROMISE I 12 Month Data

## Published in the Journal of Vascular Surgery

Article is **Open Access** and available for download



**JVS** Journal of Vascular Surgery **SVS** Society for Vascular Surgery

FULL LENGTH ARTICLE | ONLINE FIRST

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 • Jihad A. Mustapha • Mehdi H. Shishehbor • Peter A. Schneider • Steve Henao • Nelson N. Bernardo • David H. Deaton • [Show less](#)

**Open Access** • Published: May 18, 2021 • DOI: <https://doi.org/10.1016/j.jvs.2021.04.057>




Partial view of a diagram on the right side of the page showing a catheter and needle, with text: "A", "Arterial Catheter", "Needle".

# 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<sup>1</sup>*

### 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 Investigators



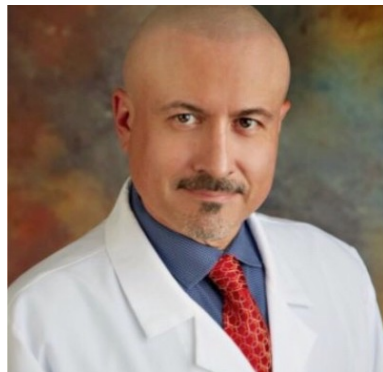
Dan Clair, MD



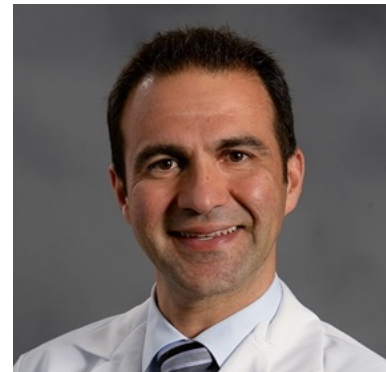
Peter Schneider, MD



Jihad Mustapha, MD



Steve Henao, MD



Mehdi Shishehbor, DO



Nelson Bernardo, MD



John Lantis, MD

# Patient and Procedural Characteristics

## Baseline Characteristics (=32)

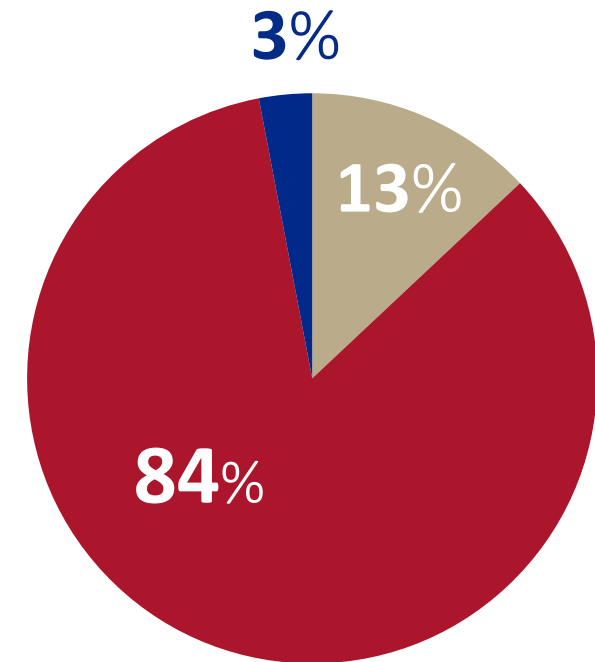
Age (Avg, years)	<b>71</b> (42-94)
Gender (% Male)	<b>66%</b>

## Comorbidities

Diabetes	<b>69%</b>
Type I	<b>13%</b>
Type II	<b>56%</b>
Hypertension	<b>88%</b>
Renal Insufficiency	<b>34%</b>

## TARGET VESSELS

	Anterior Tibial
	Posterior Tibial
	Peroneal



## Procedural Characteristics

Success Rate | **97%**

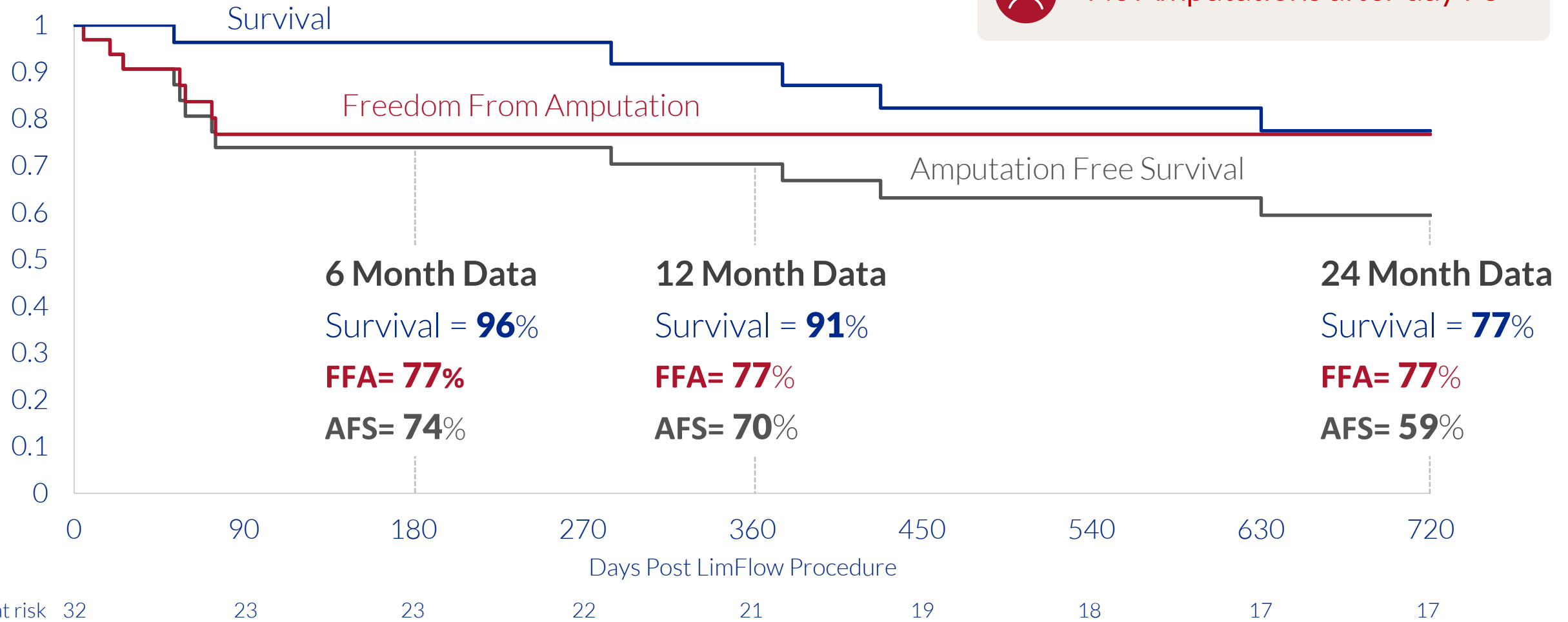
Data on File, LimFlow



## Primary Endpoint: AFS, Survival, FFA



No Amputations after day 75



Data on File, LimFlow



# Mortality Events

Patient	1	2	3	4	5
	<b>Day 53</b>  <b>Stroke</b>	<b>Day 285</b>  <b>Heart Failure</b>	<b>Day 375</b>  <b>Heart Failure</b>	<b>Day 428</b>  <b>Heart Disease</b>	<b>Day 630</b>  <b>Sepsis due to</b> gangrene and osteomyelitis in non-index foot

# Wound Core Lab Results–Wound Size

## AVERAGE WOUND AREA

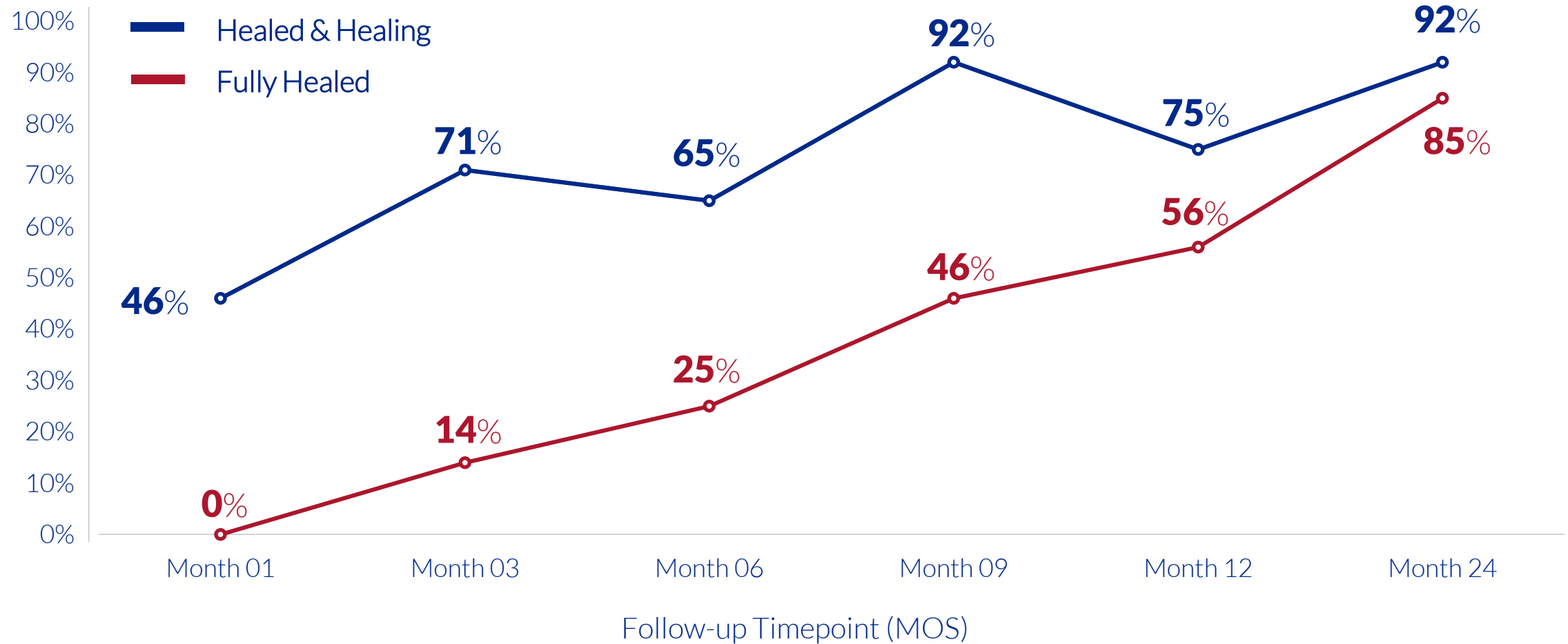


**\*Two patients**  
experienced TMA of  
treated foot **between**  
**3 and 6 months**



# Wound Core Lab Results–Healing Status

## WOUND STATUS OVER TIME



Data on File, LimFlow

## PROMISE I Case Example



### PATIENT HISTORY

79-year-old male

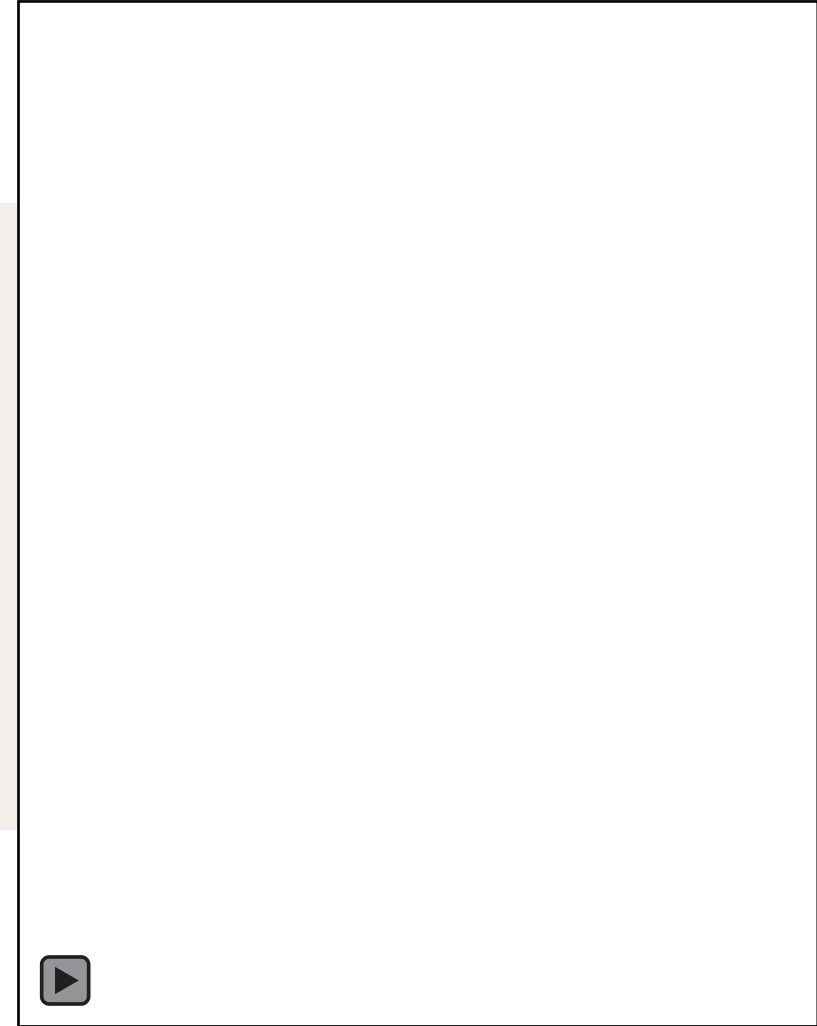
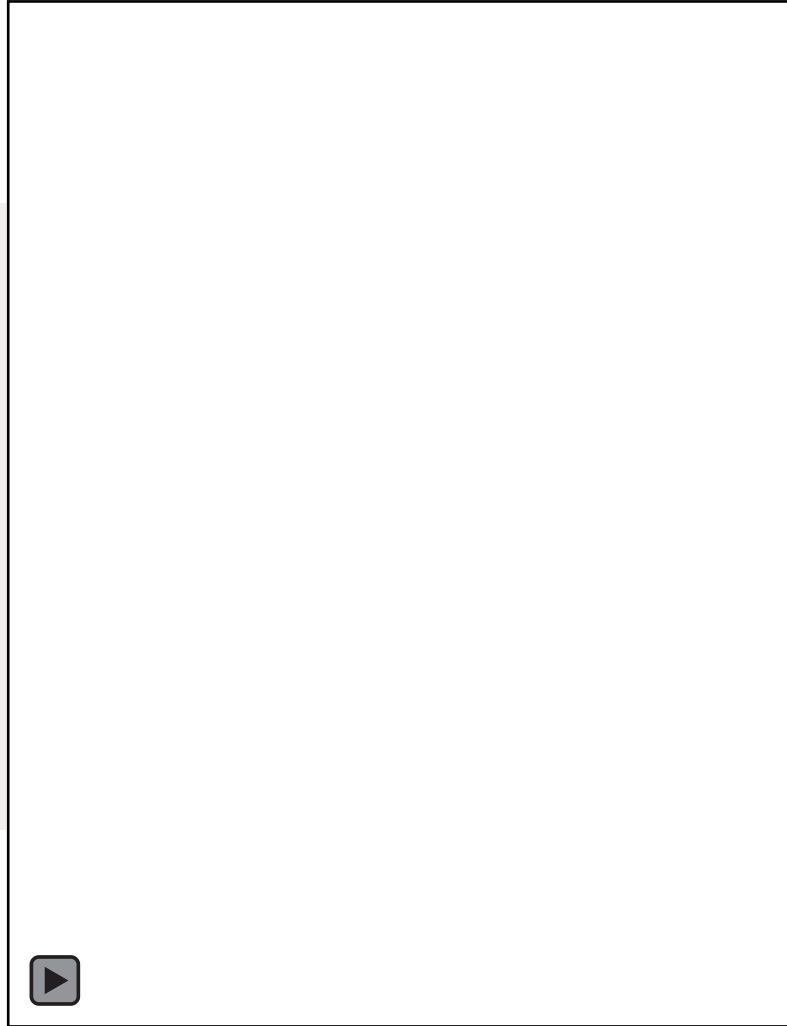
**Type II diabetes, hypertension, hyperlipidemia, PVD and intermittent claudication, and asthma**

No history of smoking

**Non-healing gangrenous wound** on the first toe

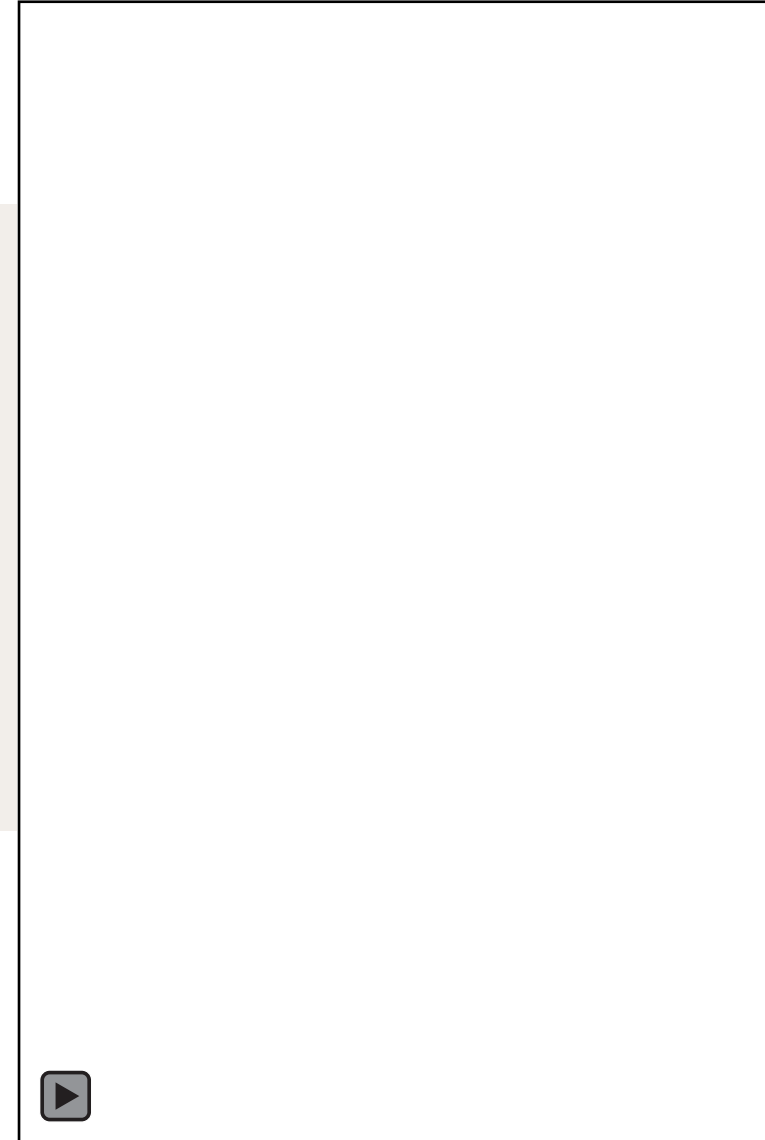
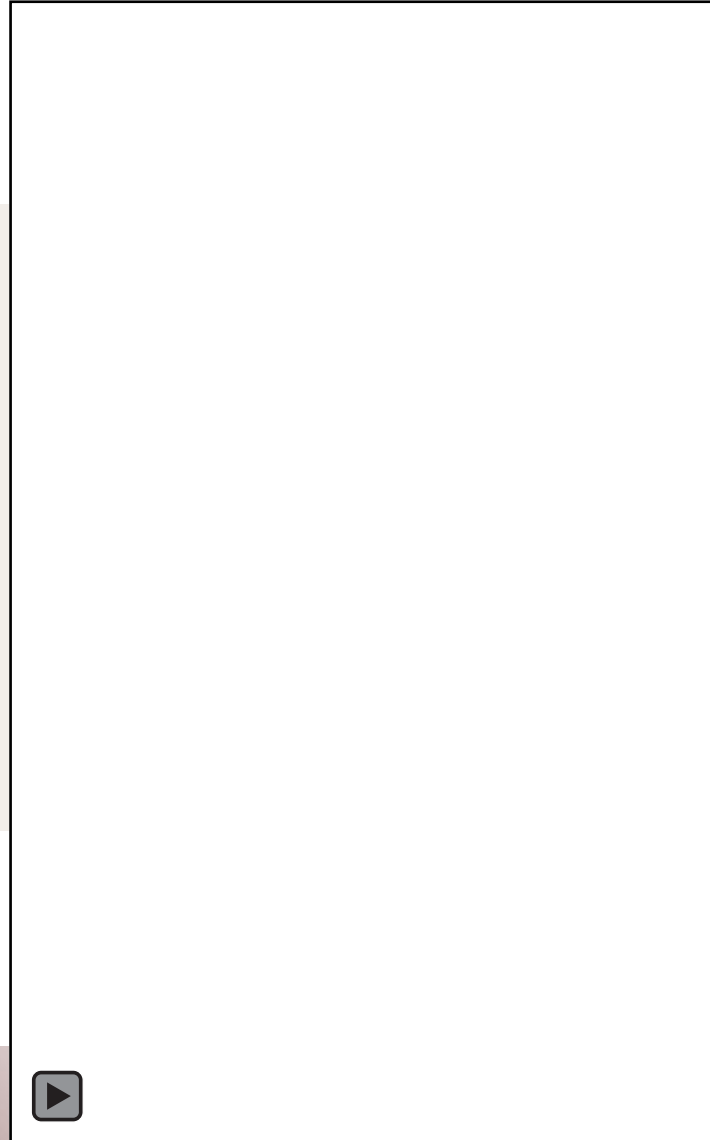


# Screening Angiogram

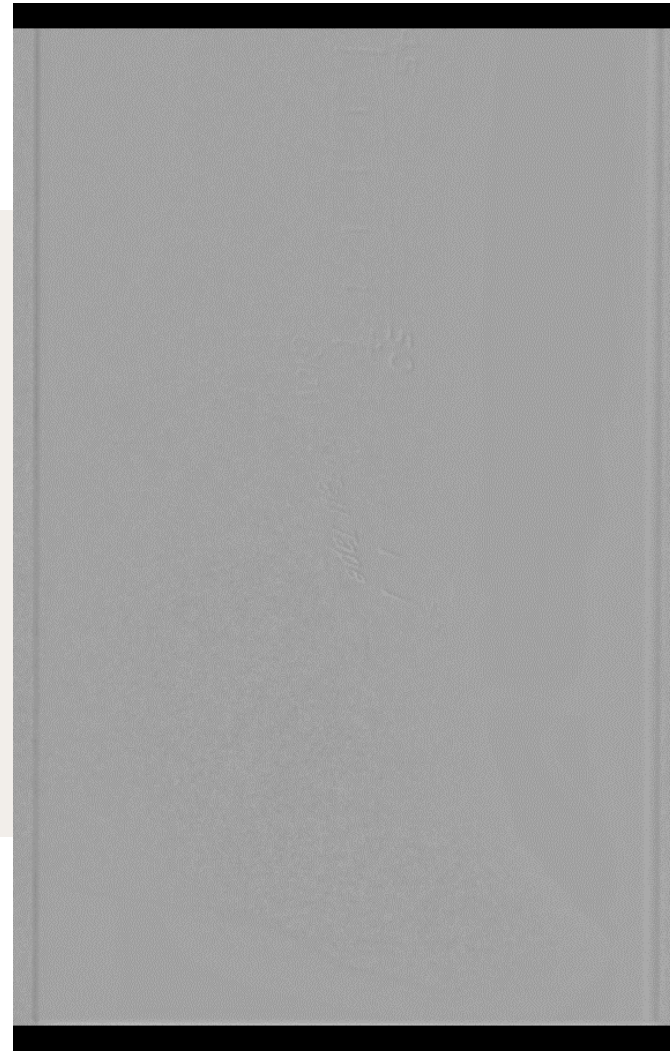




# LimFlow Procedure

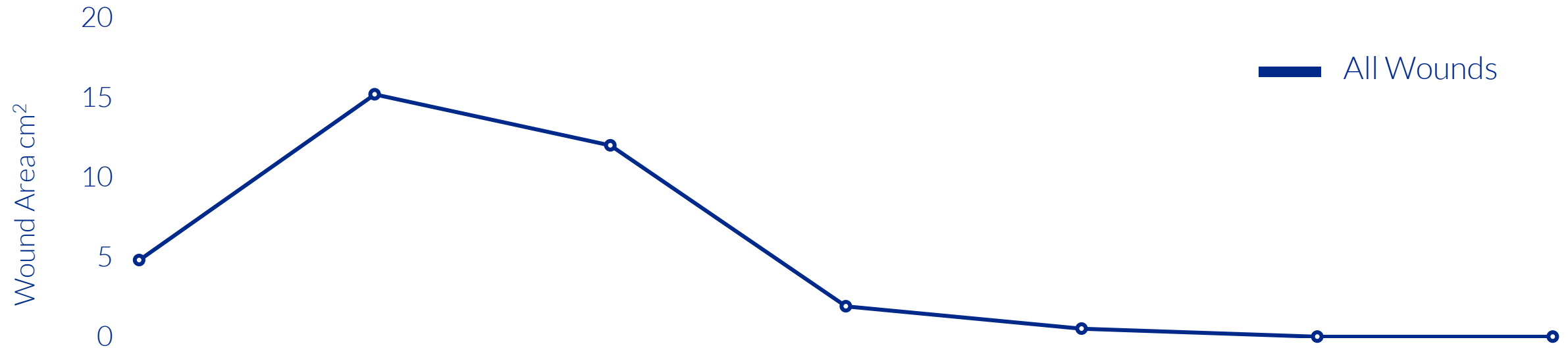


# Final Angiogram



# Case Example, Wound Healing

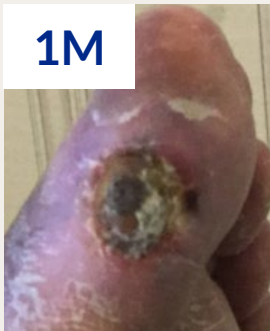
## WOUND HEALING OVER TIME



BL



1M



3M



6M



9M



12M



24M



Follow-up  
Timepoint

# PROMISE I Reintervention Data



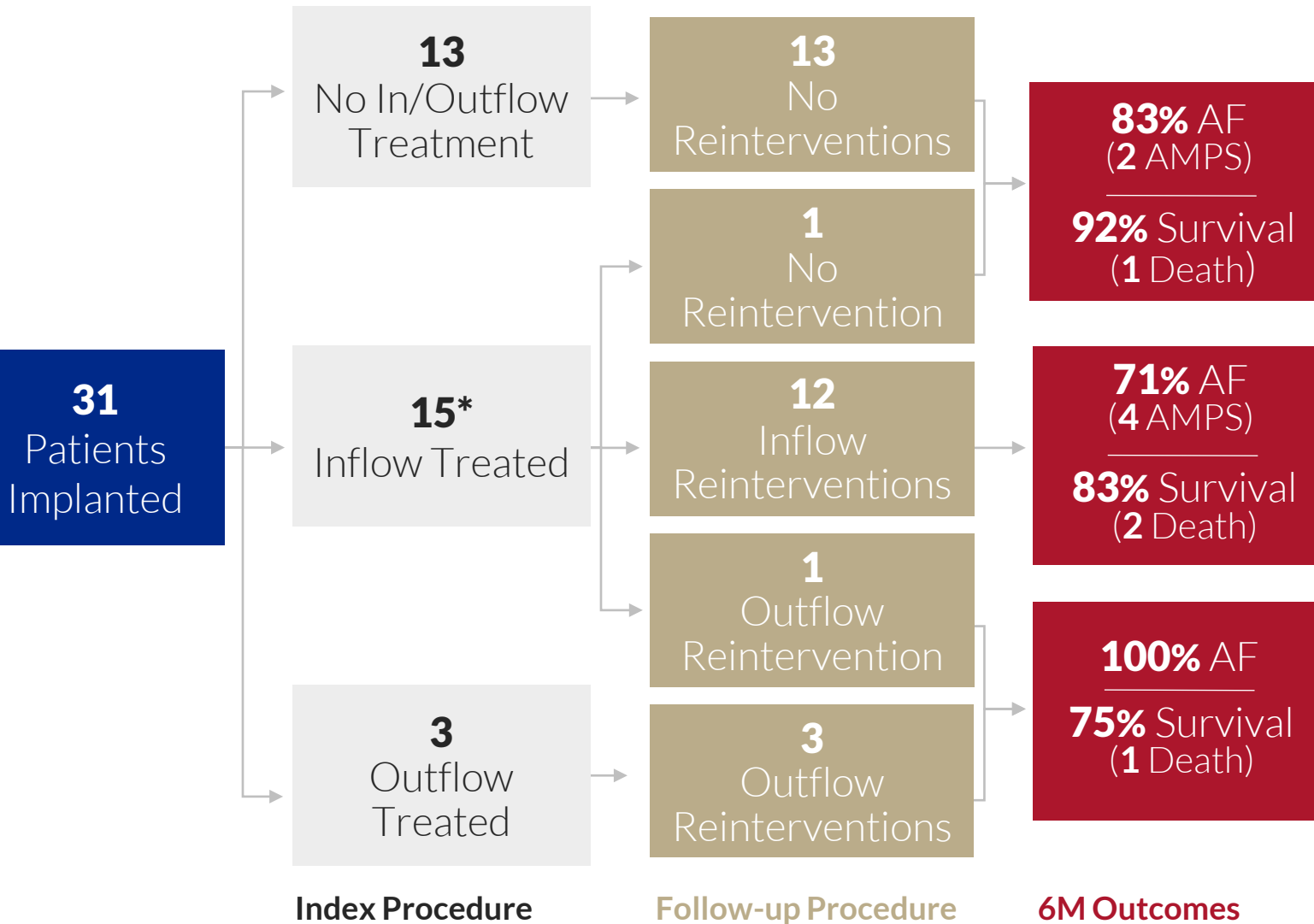
## Summary

**Outcomes** do not appear different across groups  
 13/13 **required no intervention**  
 14/15 & 3/3 **required reintervention**

## Considerations for revascularization

**Patients who require** inflow/outflow interventions intraoperatively should be managed more closely to maintain DVA circuit patency

**\*1 Patient expired prior follow-up**



# Lessons

## Inflow Treatment

**Treat inflow arterial lesions** effectively and monitor after procedure



## Pedal Venous Access

**Access pedal venous anatomy** as distal as possible

**Care during** access, vein easily injured or sent into spasm

**May need** dorsal venous access



## AV Crossing Considerations

**Maintain** pre-existing arterial flow

**Cross-over** below areas of critical collaterals



## Post Procedure

**Directed flow** to areas needed

**Venous arterialization** takes time to “mature”

**Frequent** multidisciplinary care

**Rapid response** to clinical symptoms



## Patient Selection

**Need** salvageable tissue and stable wounds

**Ultrasound interrogation** of foot veins

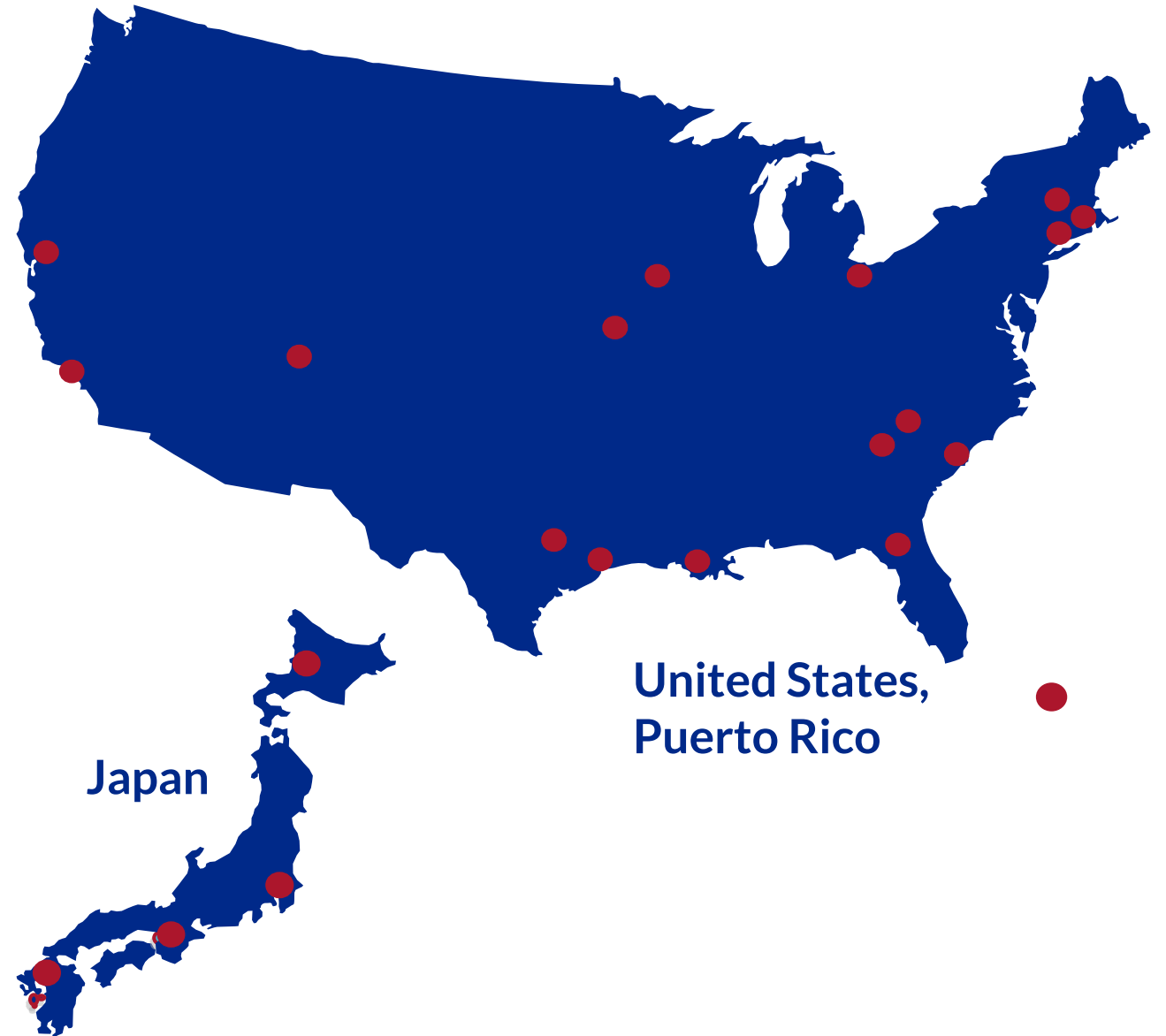


## PROMISE II

**22** sites (**18** US, **4** Japan)

>**75%** enrolled

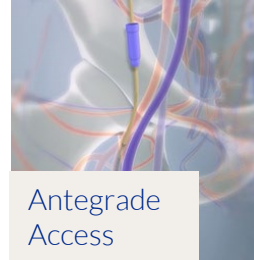
**Enrollment and  
follow-up** underway



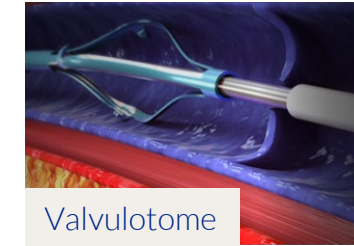


## PROMISE II: Refined Product and Procedure

ARTERIAL ACCESS



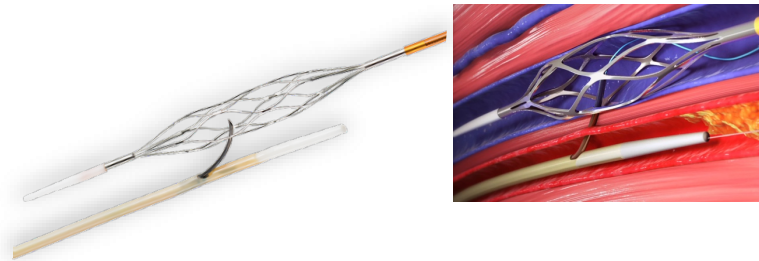
VALVULOTOME



VENOUS ACCESS



CROSSING UNDER FLUOROSCOPY



STENT DEPLOYMENT



**Obviated the need for** ultrasound when crossing with improved arterial and venous catheters



**Introduced new stent graft delivery system**

### **Deep vein arterialization**

is safe and  
technically feasible



### **Lessons from this initial trial**

will be  
incredibly valuable  
moving forward



### **Limb salvage for patients**

with “no-option”  
revascularization  
achievable  
in **77%** of patients



### **We continue to gain insights**

into technical  
issues and methods to  
improve outcomes for  
these patients

