Results of the LimFlow System in the PROMISE I Trial

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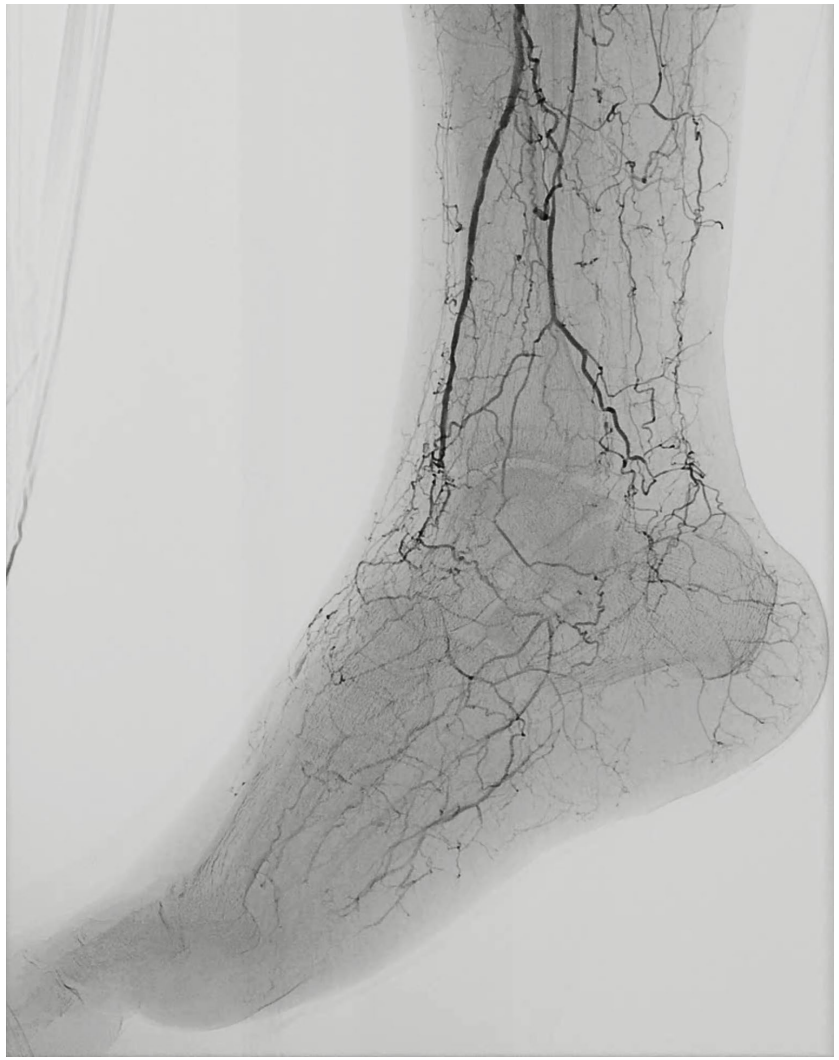
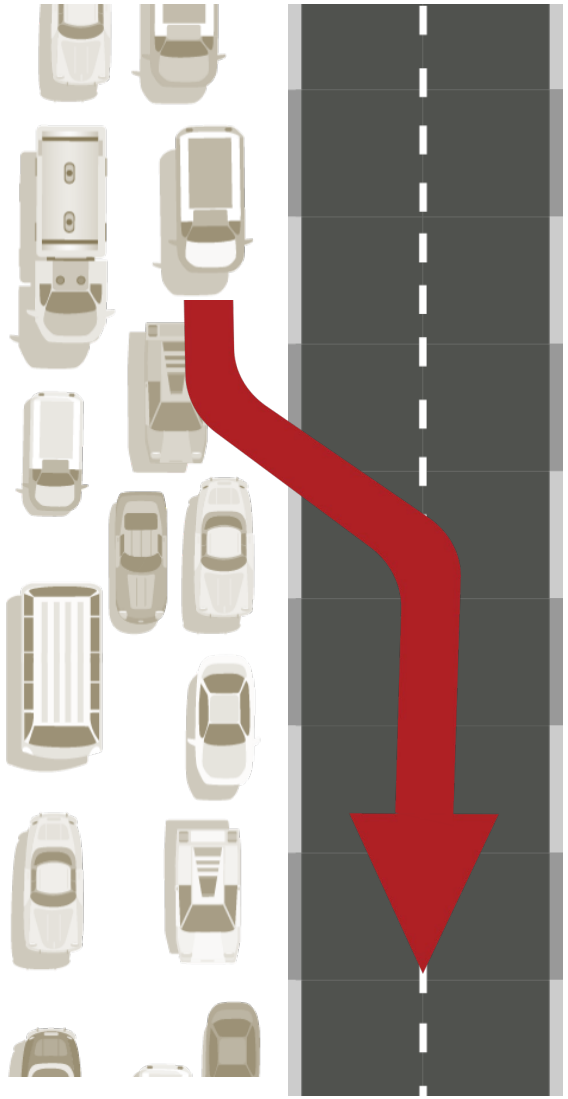
VIVA 19

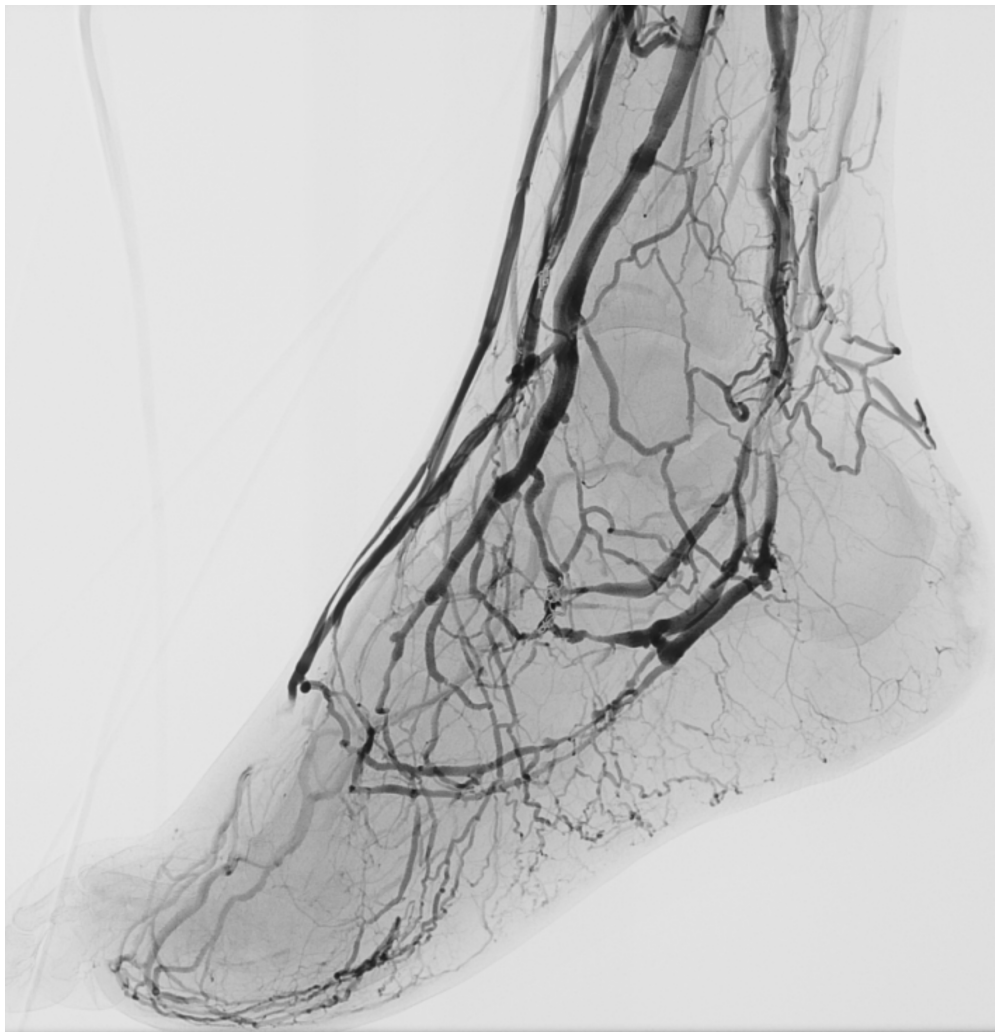
Disclosures

- Consultant: BD-Bard, BSC, Elastimed, LimFlow, Medtronic, Venture Medical.
- Funds paid to medical group.

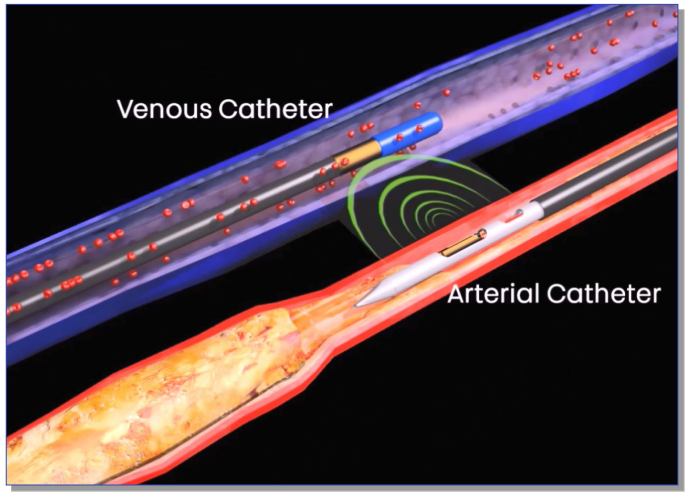
Permanently Bypass Unreconstructible Arteries

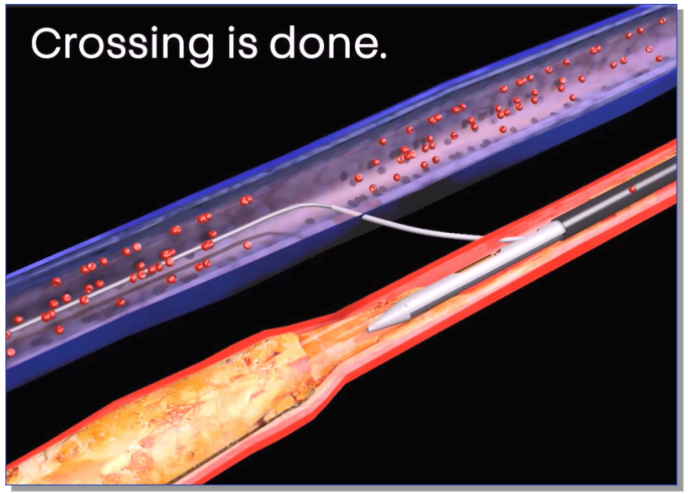


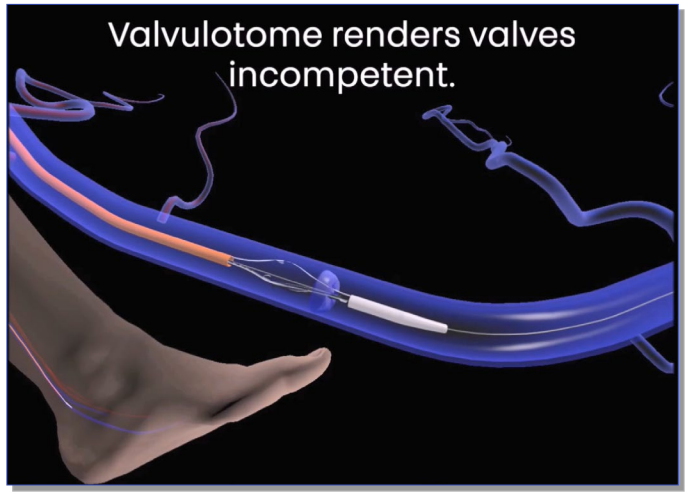


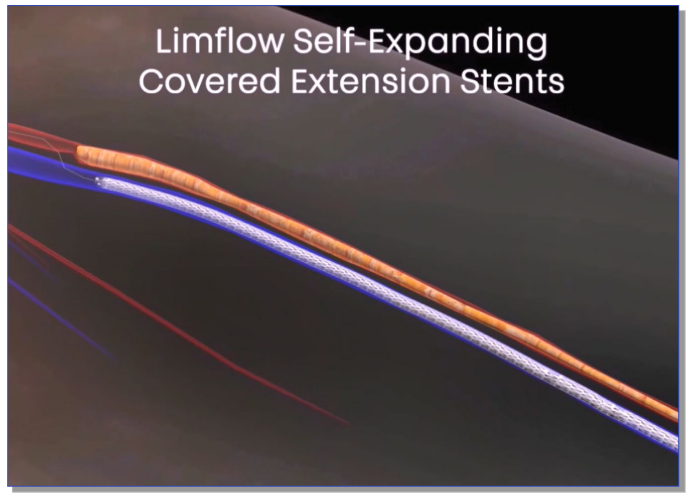


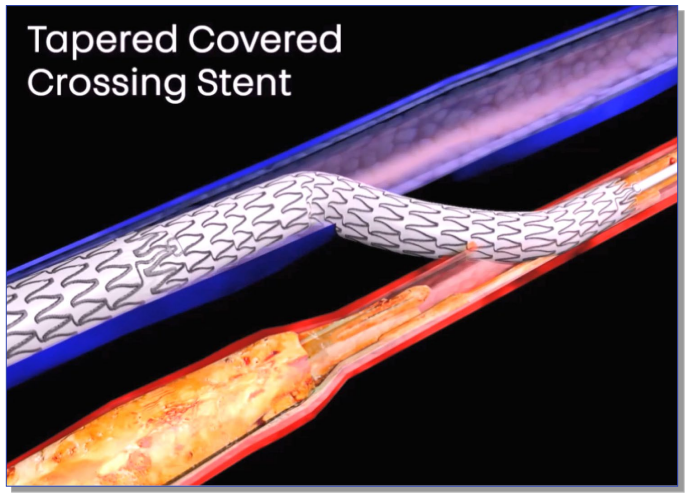
LimFlow Procedure Overview

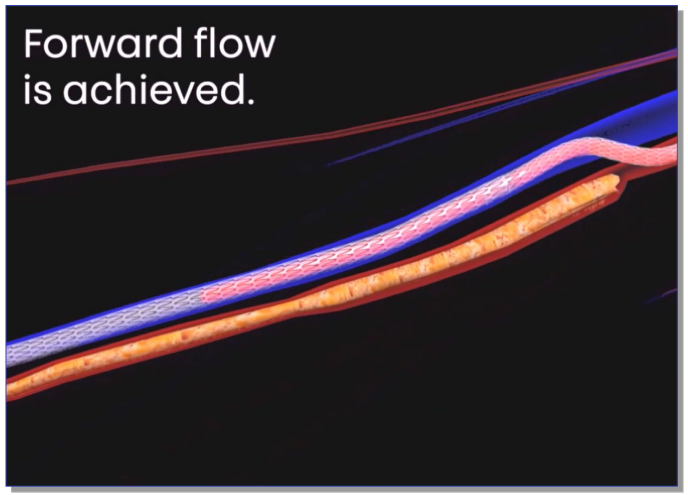












CAUTION: Investigational device. Limited by Federal law to investigational use.

PROMISE I Study Purpose

- PROMISE I is an Early Feasibility Study (EFS)[1], launched mid-2017
- The clinical study was conducted to:
  - Establish clinical safety to move into a pivotal study
  - Identify and address operator challenges
  - Determine patient characteristics and therapeutic parameters that impact performance
- EFS experience allows us to:
  - Optimize operator technique
  - Develop subsequent protocols and refine:
    - Patient screening
    - Wound analysis
    - Patient follow-up

1) FDA Guidance, issued 0ctober 1, 2013. Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

PROMISE I Study Design

Key Endpoints

Primary safety endpoint

- Amputation Free Survival (AFS) at 30d

Secondary endpoints

- AFS at 6M
- Procedure & Technical Success
- Wound Healing
- Patency

Key Inclusion/Exclusion Criteria

Inclusion:

- Rutherford 5/6
- No-Option CLTI
- Approval by independent review committee

Exclusion:

- Life expectancy <12 months
- Dialysis
- Severe heart failure

Follow-Up Schedule

	BL	1M	3M	6M	9M	1Y	2Y
Wound Assessment	✓	✓	✓	✓	✓	✓	✓
TcPO2	✓	✓	✓	✓	✓	✓	
Doppler		✓	✓	✓	✓	✓	✓

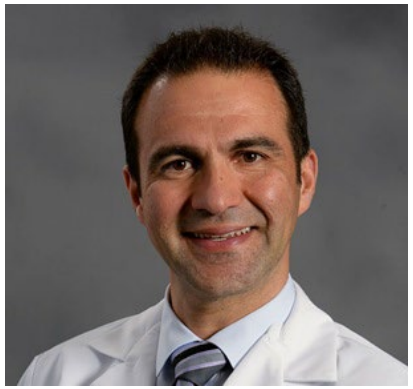
Investigators

Jihad Mustapha, MD

Dan Clair, MD

Peter Schneider, MD

Steve Henao, MD



Mehdi Shishehbor, DO

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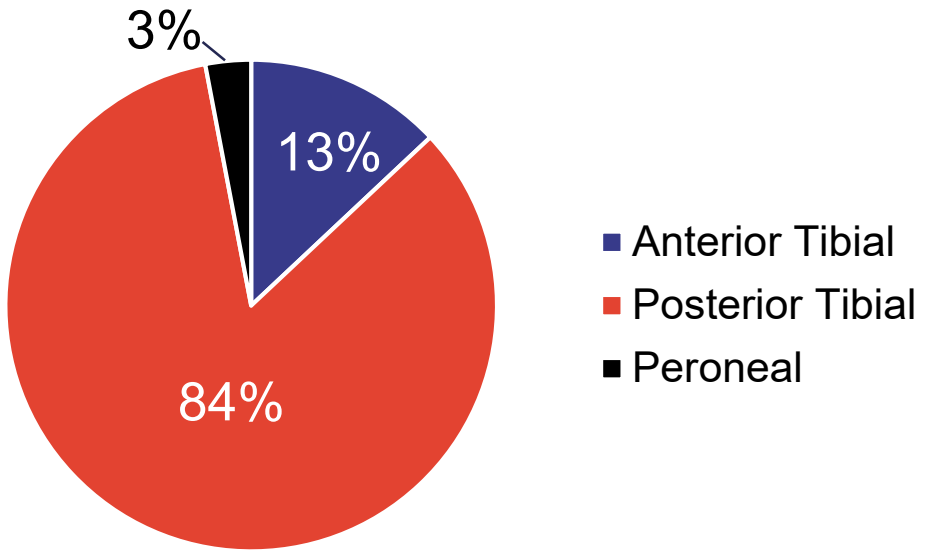
John Lantis, MD

Patient and Procedural Characteristics (N=32)

Baseline Characteristics	
Age (Avg, years)	71 (42-94)
Gender (% Male)	66%

Comorbidities	
Diabetes	69%
Type I	13%
Type II	56%
Hypertension	88%
Renal insufficiency	34%

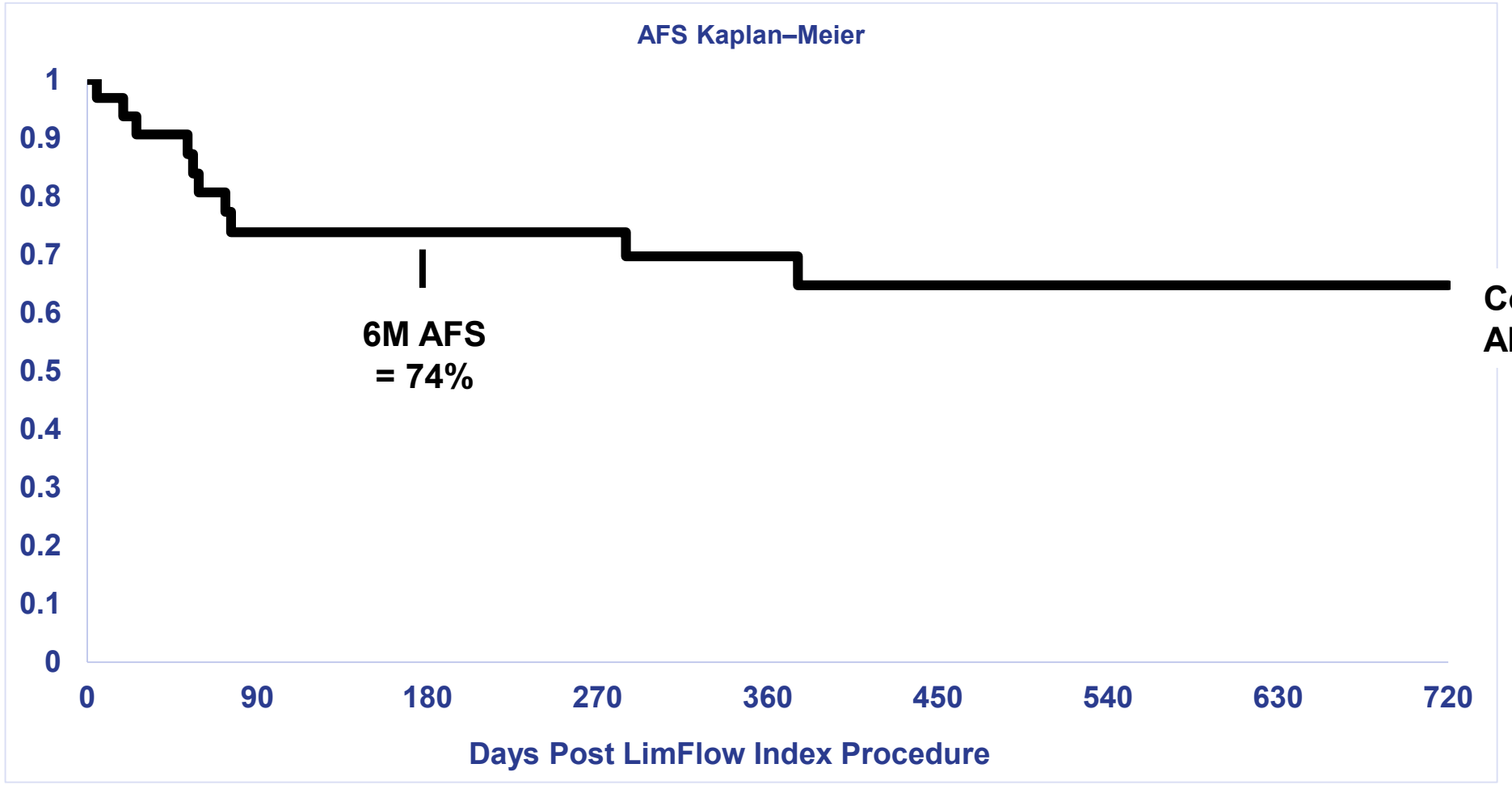
Target Vessels



Procedural Characteristics	
Success Rate	97%

Data on File, LimFlow

Primary Endpoint: Amputation Free Survival (N=32)



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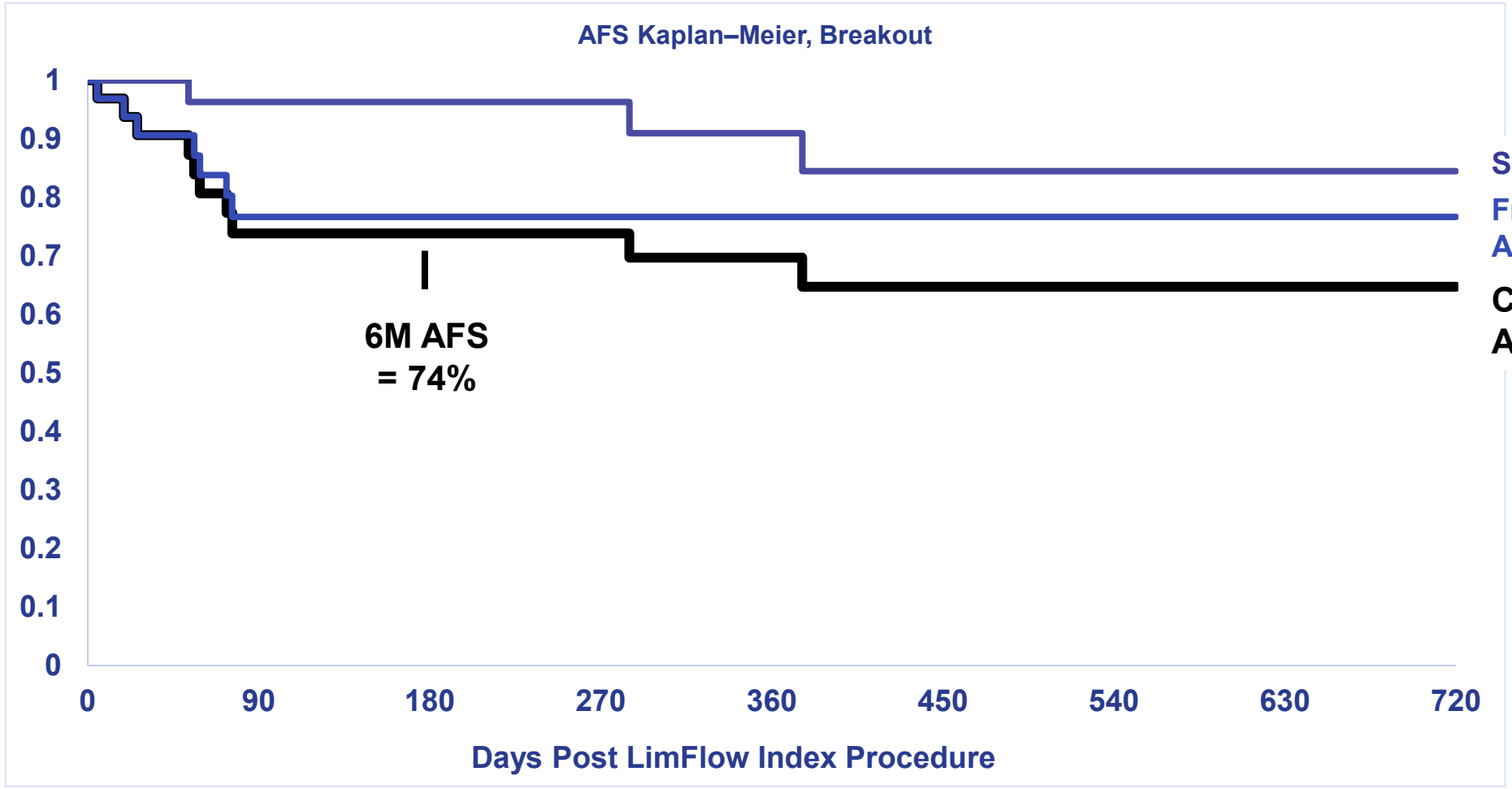
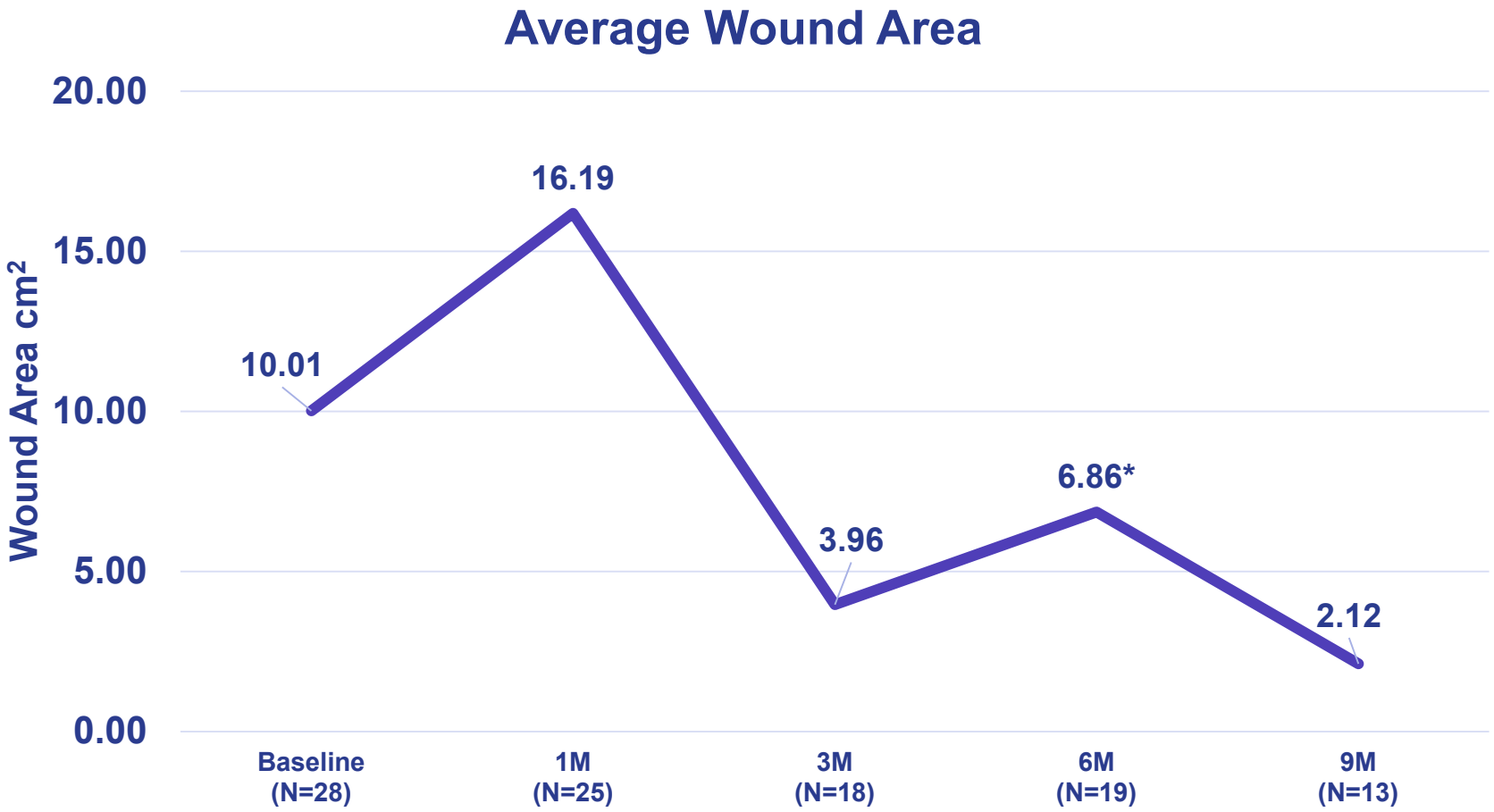


Data on File, LimFlow

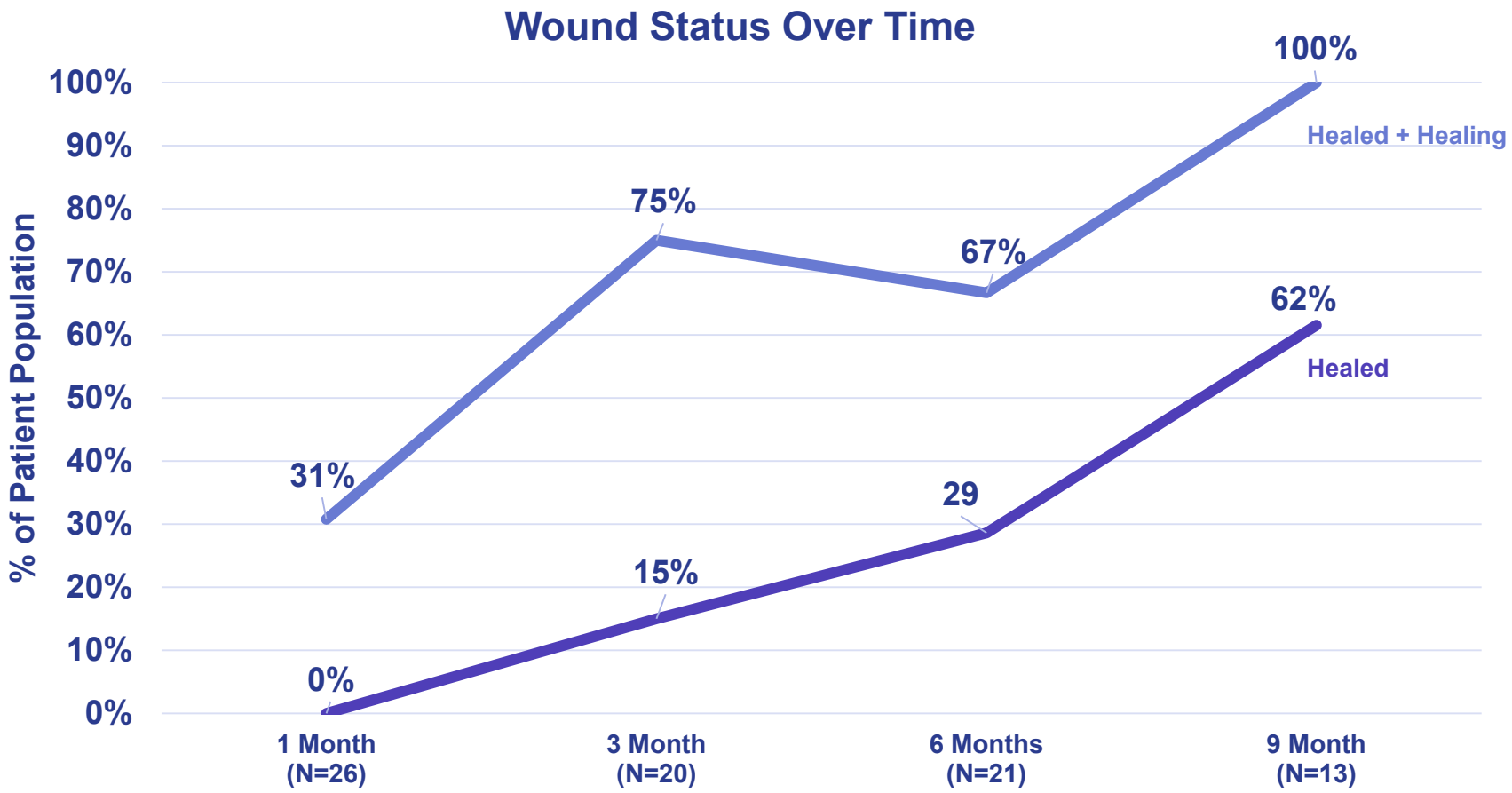
Wound Core Lab Results– Wound Size



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

Data on File, LimFlow

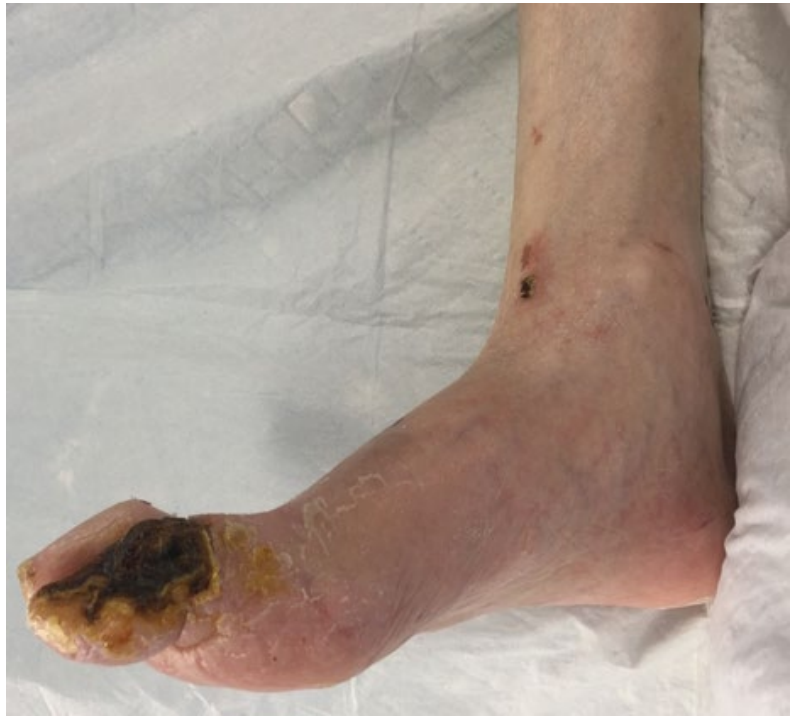
Wound Core Lab Results– Healing Status

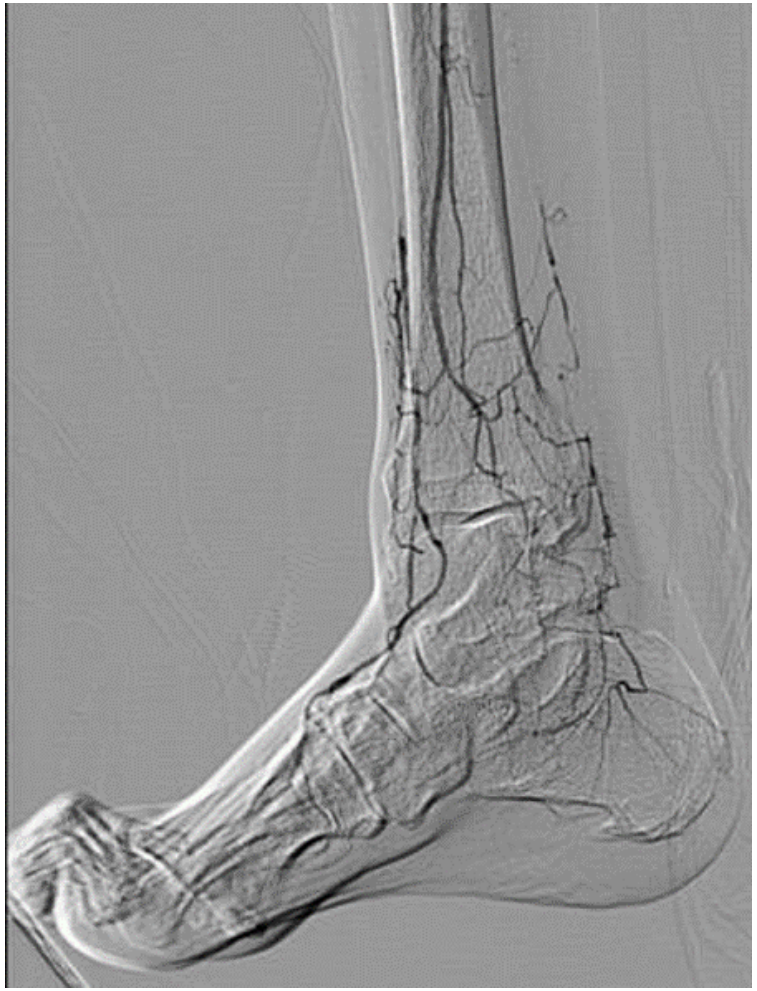


Data on File, LimFlow

Case Example: Patient Info

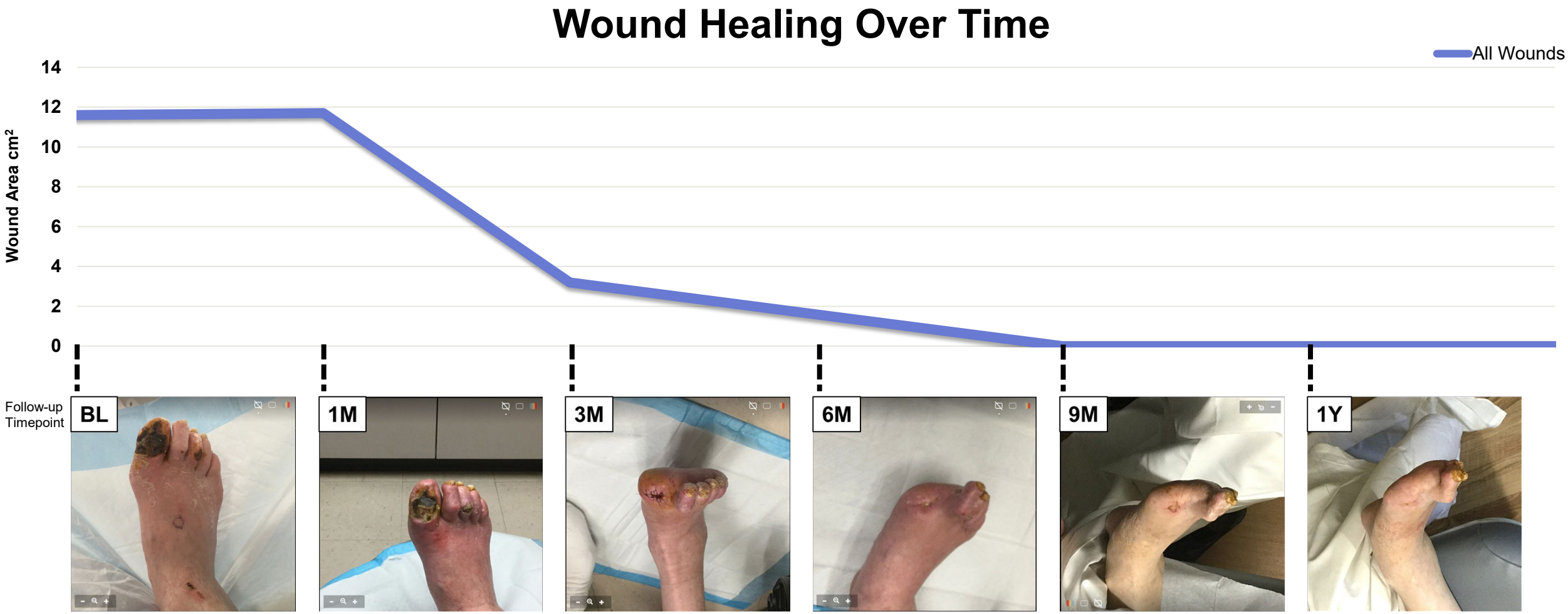
- 80 y/o, R5 male
- Type II diabetes
- Hx of smoking and MI
- Hyperlipidemia
- 2 failed prior interventions
- Nonhealing hallux gangrene





Data on File, LimFlow

Case Example, Wound Progression



Lessons Learned

- Patient selection
  - Not appropriate for *all* limbs, requires salvageable tissue
- Wound care
  - Multidisciplinary collaboration
  - Minor amputation management, debridement, timing
- Fistula maturation
  - Close monitoring
- Interventions

Conclusions

- The LimFlow System is a *novel, safe, and reproduceable* approach for treating patients with no-option CLI
- It may *improve wound healing rates and reduce amputation rates* in a population for whom amputation would otherwise be considered inevitable
- Initial findings from this early feasibility trial are very promising
- Approval was recently granted to start US pivotal