LimFlow Clinical Update: PROMISE I US Study & ALPS Study

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Disclosures

Consulted for:

Boston Scientific, Surmodics, Cagent, CSI, Philips, Medtronic, Intervene, Limflow, Silk Road, Cagent, Devoro

PROMISE I Study & ALPS Overview

PROMISE I

- PROMISE I was an Early Feasibility Study (EFS) of the LimFlow System in no-option CLTI patients in the US
- Launched mid-2017, enrollment completed 2019, enrolled 32 no-option patients
- 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

Dan Clair, Jihad Mustapha, Peter Schneider, Mehdi Shishebor, Nelson Bernardo, John Lantis, Steve Henao

ALPS

- ALPS was a retrospective analysis conducted to evaluate results of no-option CLTI patients treated with LimFlow
- Sites in Alkmaar, Leipzig, Paris and Singapore
- Analysis of 32 consecutive patients treated with LimFlow
- From July 2014 to June 2018

Andrej Schmidt, Costantino Del Giudice, Michiel Schreve, Steven Kum, Daniela Branzan, Eline Huizing, Cagdas Unlu.

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		✓	✓	✓	✓	✓	✓

The ALPS Multi Centre Study Design

Key Endpoints

Primary Endpoint

- **Amputation Free Survival (AFS) at 6 Months**

Secondary Endpoints

- **Wound Healing**
- **Limb Salvage**
- **Survival**
- **At 6, 12, 24 Months**

Key Inclusion/Exclusion Criteria

Inclusion:

- **Rutherford 5/6**
- **No-Option CLTI**

Exclusion:

- **Acute limb ischemia**
- **Extensive tissue loss or infection which precluded limb salvage**
- **Known deep vein thrombosis**

Patient Characteristics

PROMISE I

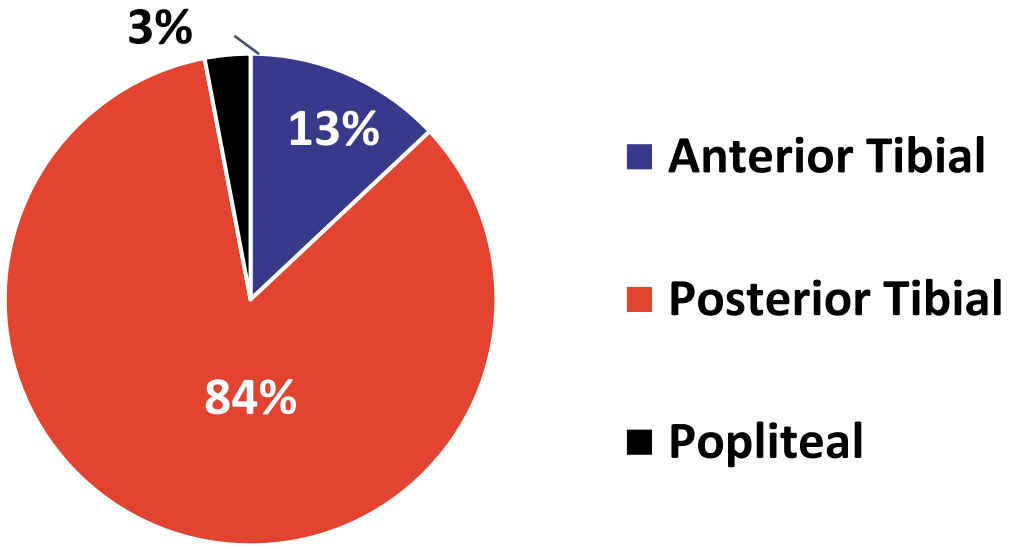
Baseline Characteristics (n=32)	
Age (Avg, years)	71 (42-94)
Gender (% Male)	66%
Comorbidities	
Diabetes	69%
Hypertension	88%
Renal insufficiency	34%

ALPS

Baseline Characteristics (n=32)	
Age (Avg, years)	67 (53-81)
Gender (% Male)	63%
Comorbidities	
Diabetes	66%
Hypertension	84%
Renal insufficiency	53%
Dialysis Dependent	16%

PROMISE I & ALPS Procedural Characteristics

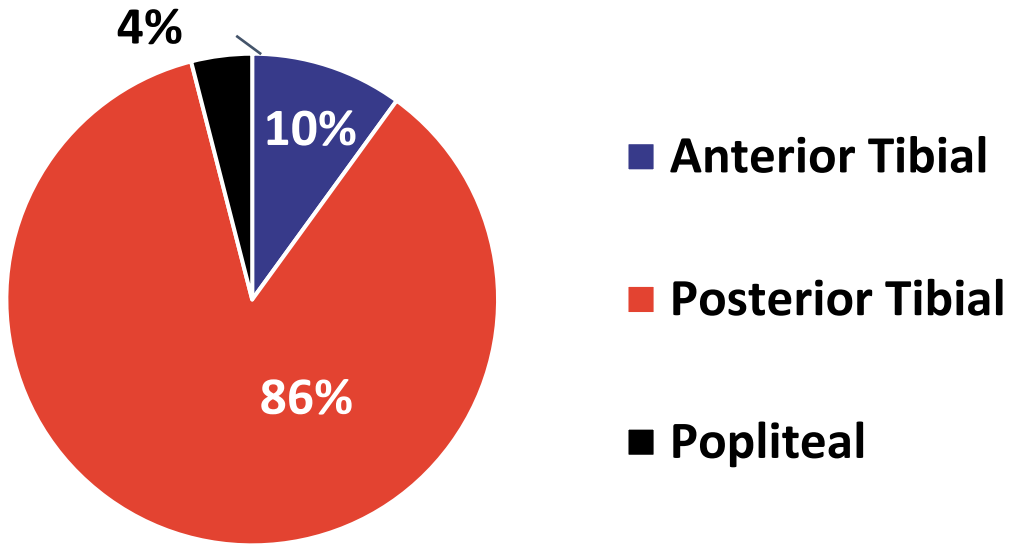
PROMISE I Target Vessels



Procedural Characteristics

Success Rate	97%

ALPS Target Vessels



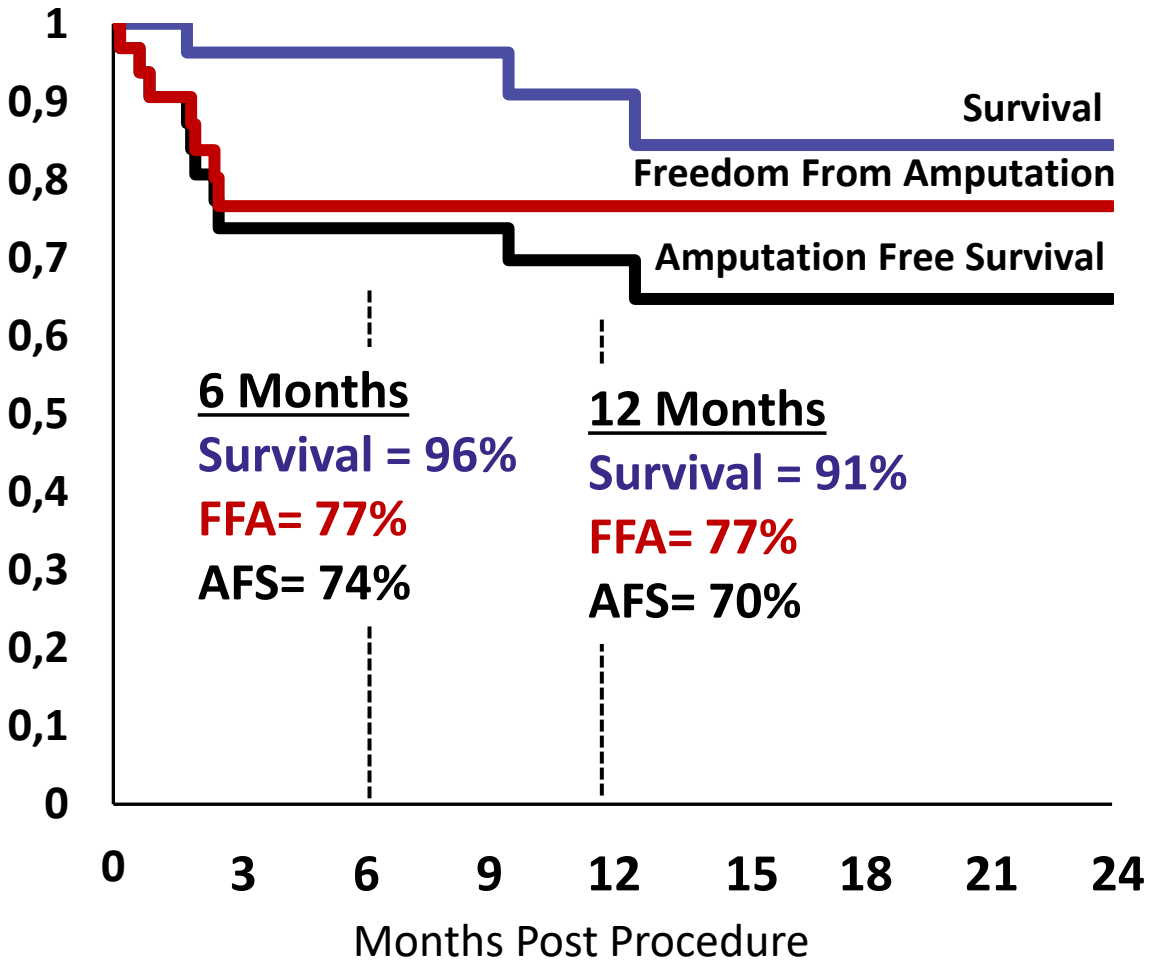
Procedural Characteristics

Success Rate	97%

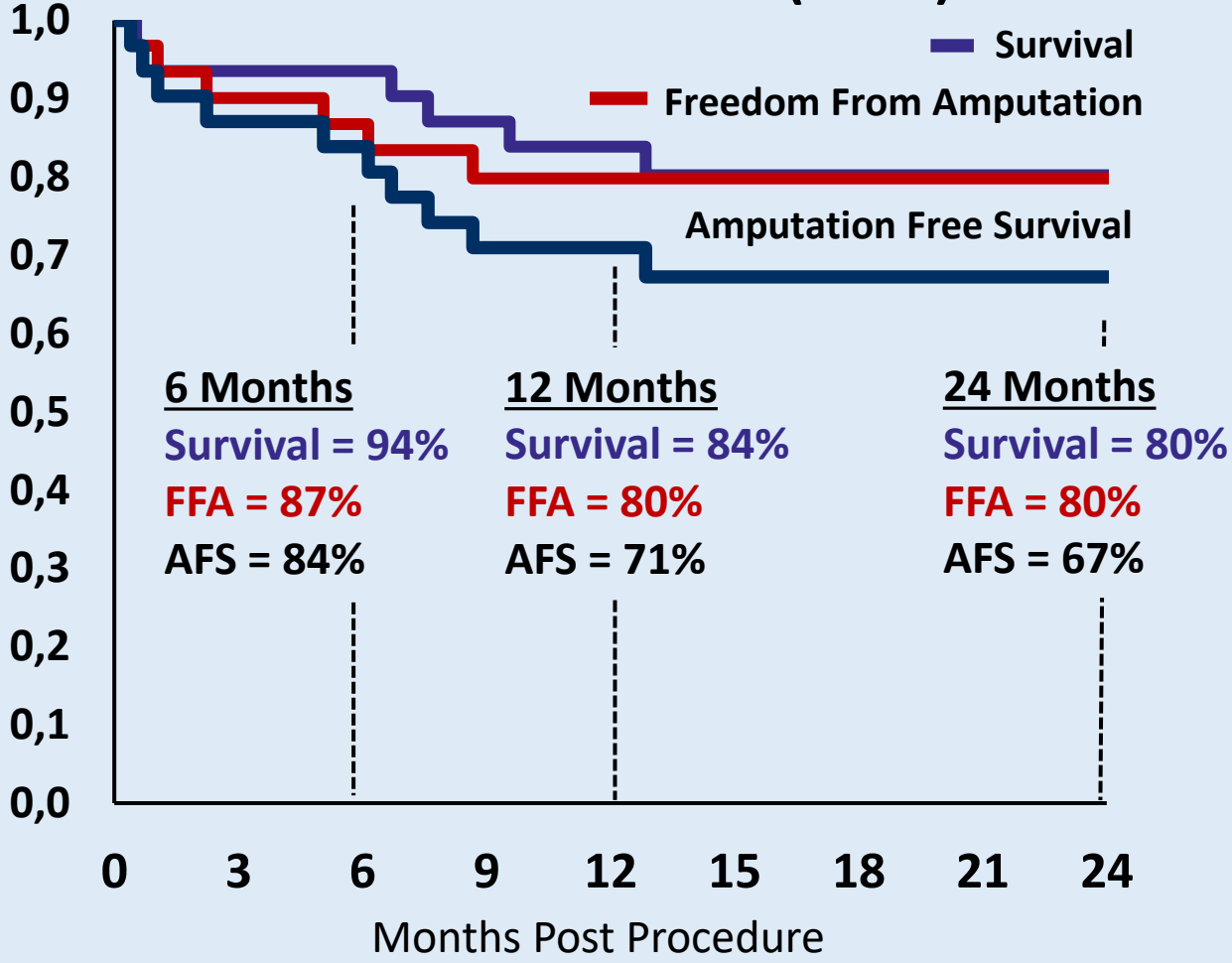
LimFlow Clinical Update

PROMISE I & ALPS AFS Breakout

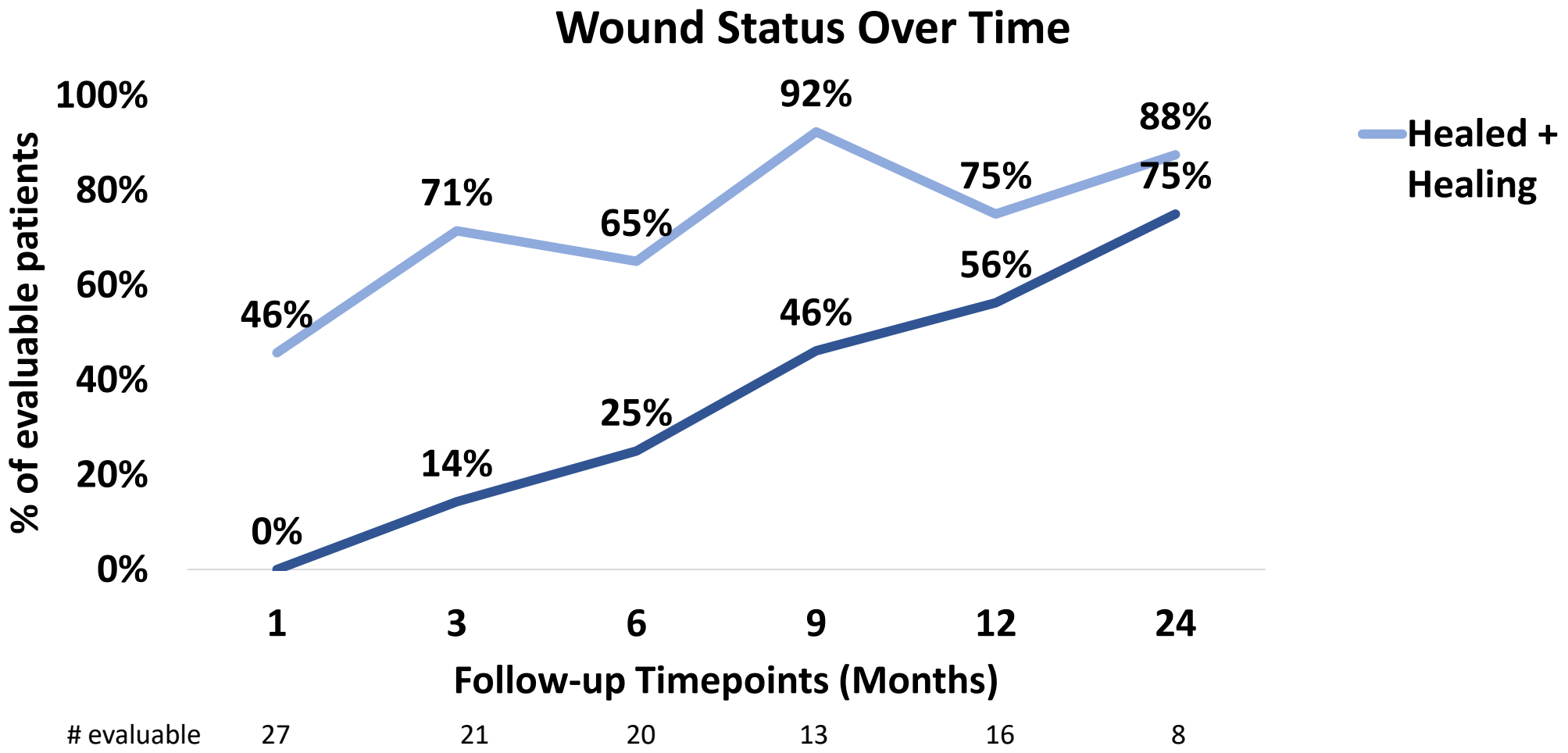
PROMISE I AFS Breakout (n=31)



ALPS AFS Breakout (n=31)



PROMISE I Wound Core Lab Results –Healing Status

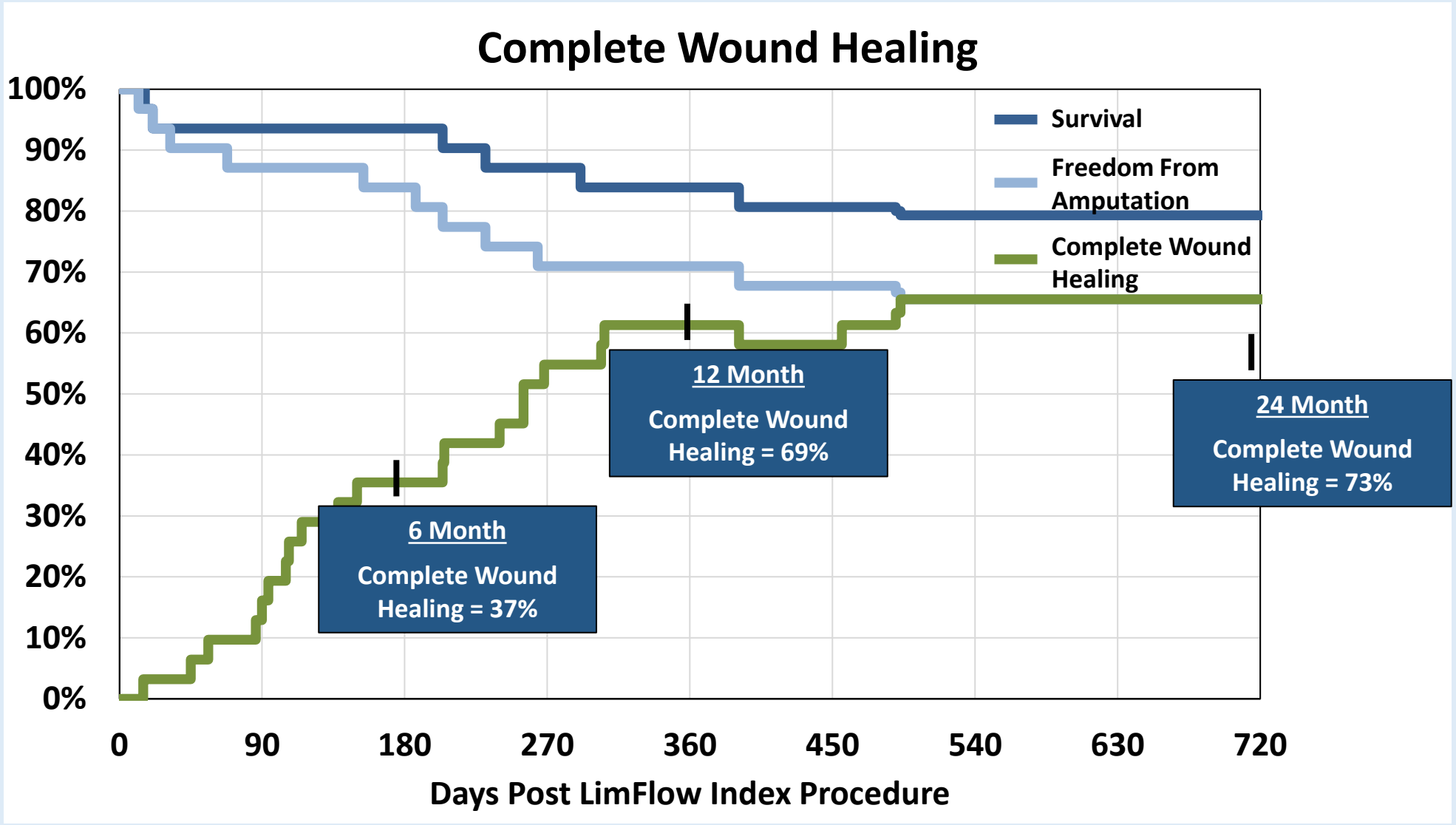


# evaluable	27	21	20	13	16	8

Data on File, LimFlow

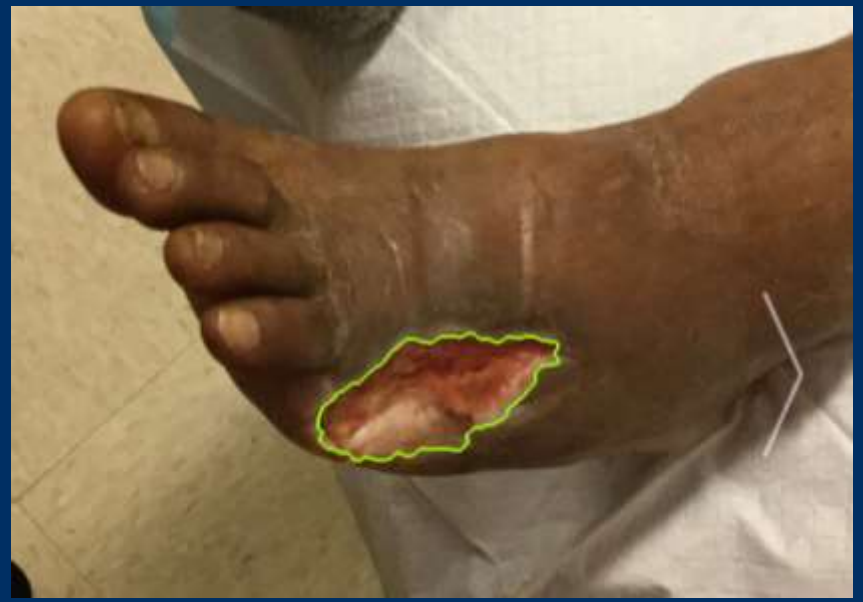
*At 9 months there were 12 patients healed or healing with13 evaluable patients at 12 months there were 12 patients healed or healing with 16 evaluable patients

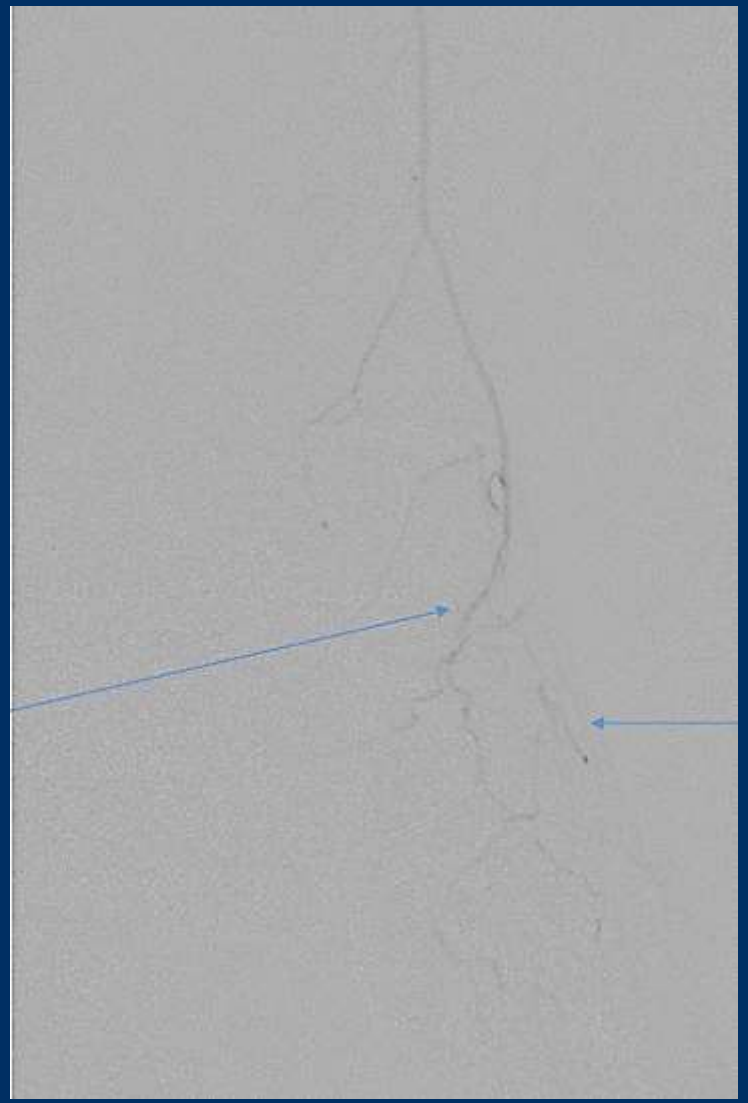
ALPS Complete Wound Healing

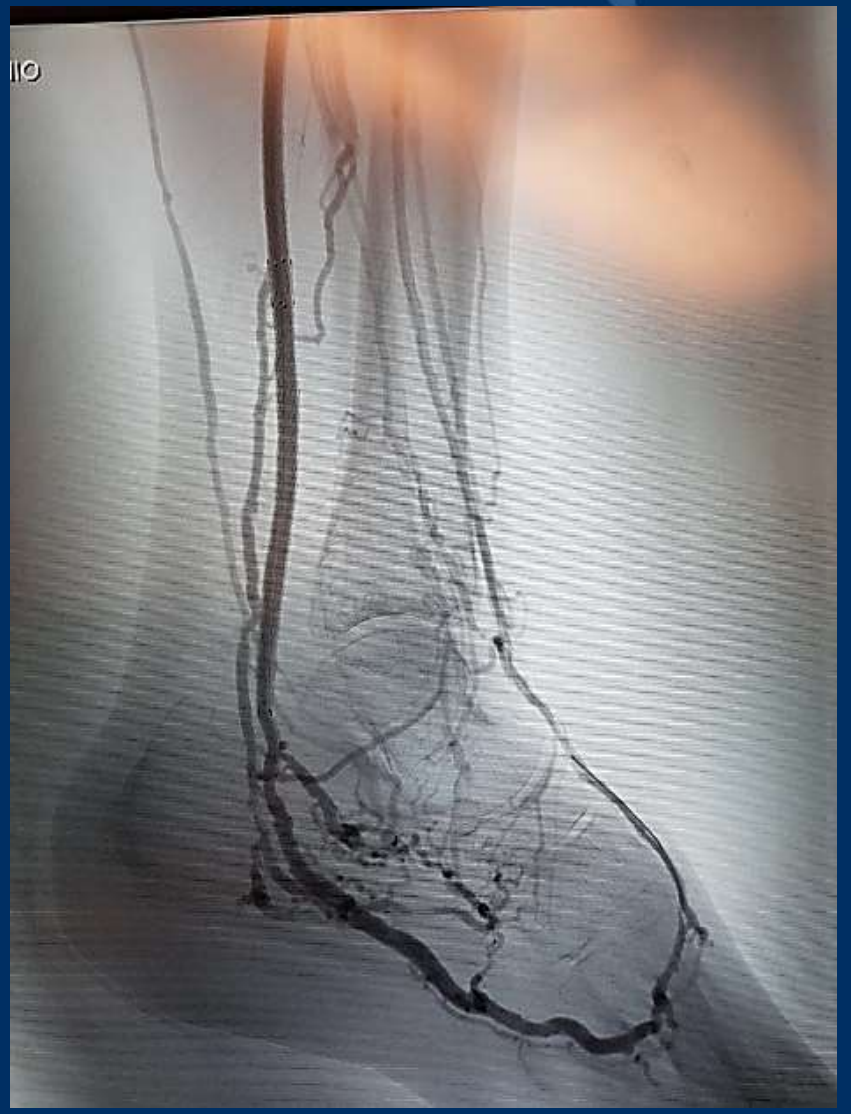


Case Example: Patient Info

- 65 y/o, BL WIfI 213
- Hx of type II diabetes, CKD, smoking, and hyperlipidemia
- Multiple failed prior interventions
- Nonhealing wound at location of 5th toe amputation







Case Example, Wound Progression

No images captured; Site reported wound healed

Data source: LimFlow. Data on file.

Lessons Learned

Patient selection

- Not appropriate for all limbs, requires salvageable tissue
- Anatomical considerations – Appropriate donor vessel

pDVA Maturation and Tissue Perfusion

- DVA requires 4-6 weeks for tissue granulation to start
- Edema can occur in the treated limb after DVA and typically resolves within 3-4weeks
- Preserve native arterial perfusion and manage pedal loop outflow during maturation process
- Monitor changes in foot tissue color (mottling, cyanosis, changes from pre-op)

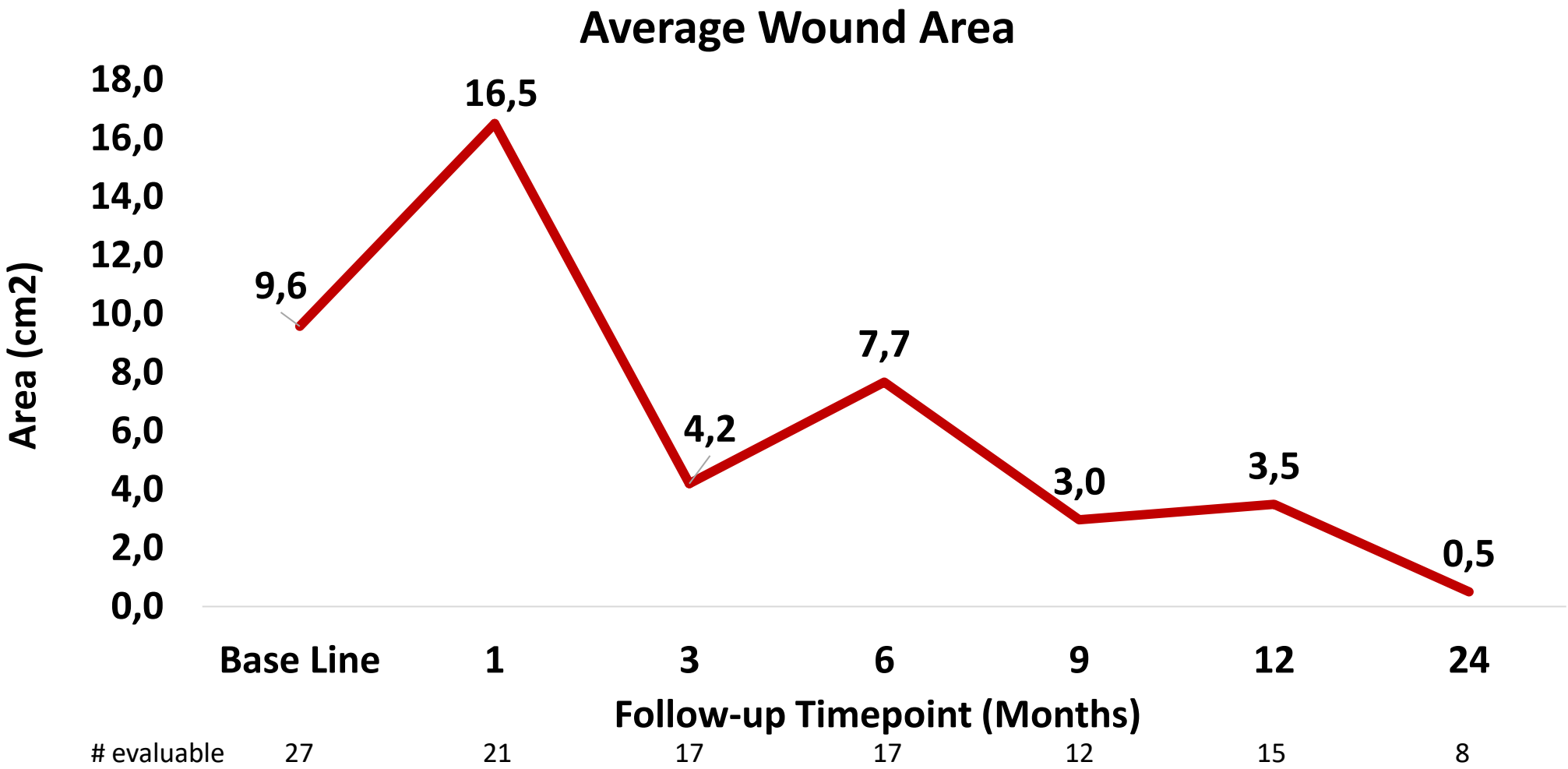
Wound care

- Multidisciplinary collaboration required
- Minor amputation management, debridement, timing

Conclusions

- PROMISE I and ALPS show similar results to 12 months
- Deep vein arterialization is safe and technically feasible
- Limb salvage for patients with “no-option” is achievable in 77% of patients
- Lessons from these initial trials help to guide therapy development

PROMISE I Wound Core Lab Results –Wound Size



Data on File, LimFlow

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