

# **First Time Data Release: LimFlow pDVA for No-Option CLTI: The Alps Registry Data at 2 Years**

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# Disclosure

Speaker name: Andrej Schmidt

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I have the following potential conflicts of interest to report:

Consulting:

Abbott, Bard/BD, Cook, Cordis, Reflow Medical, Upstream Peripheral

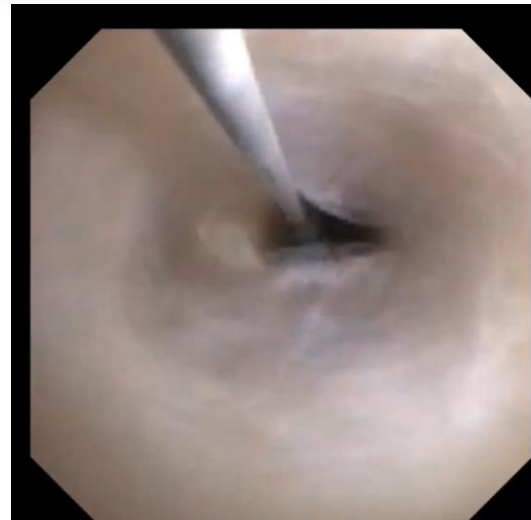
# LimFlow System Purpose-Built for pDVA



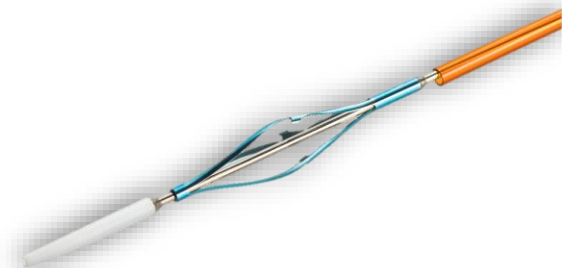
**Straight Stent Grafts**



**Conical Self Expanding Stent Graft**



**Ultrasound AV Positioning Kit**

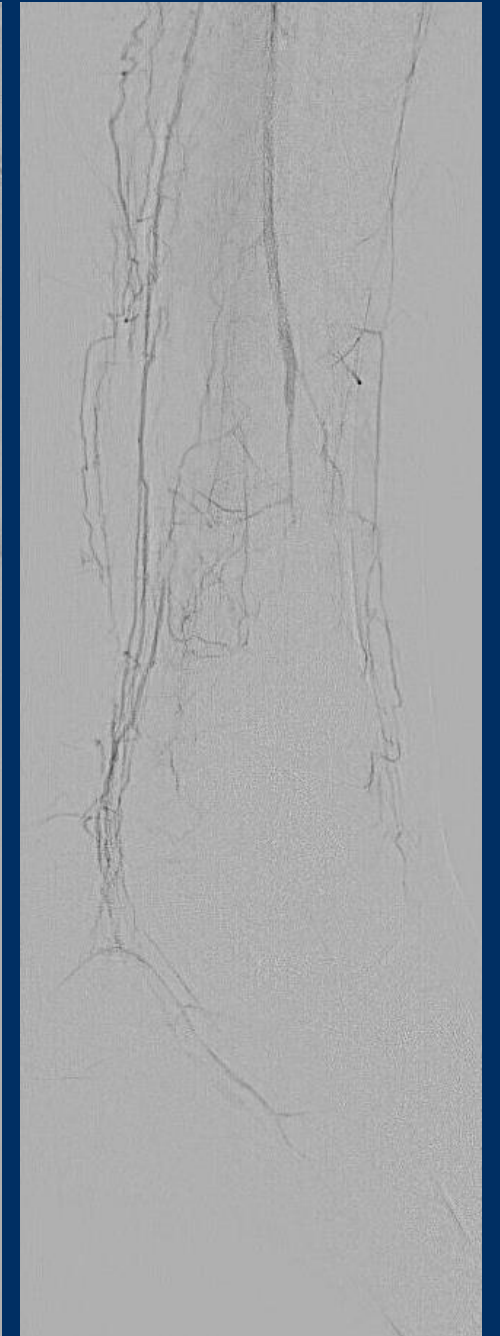
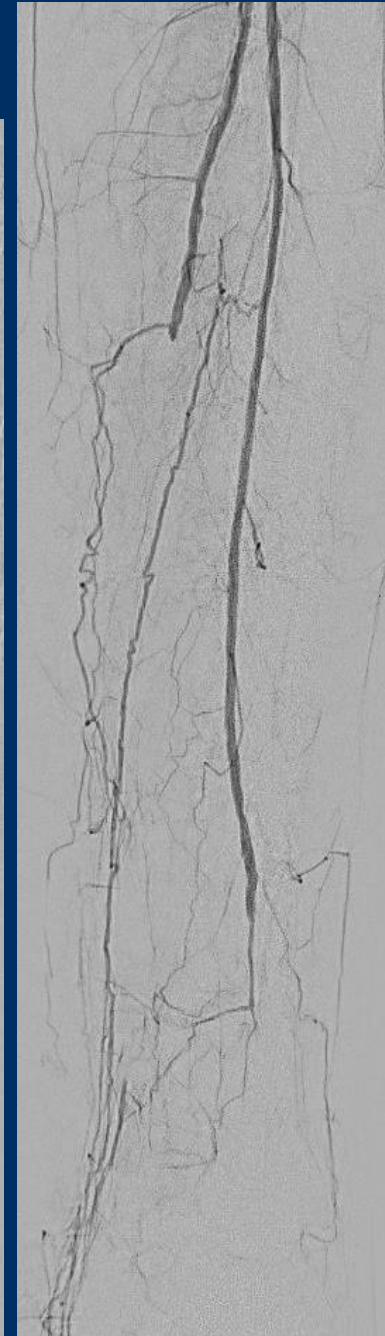


**Push Valvulotome**

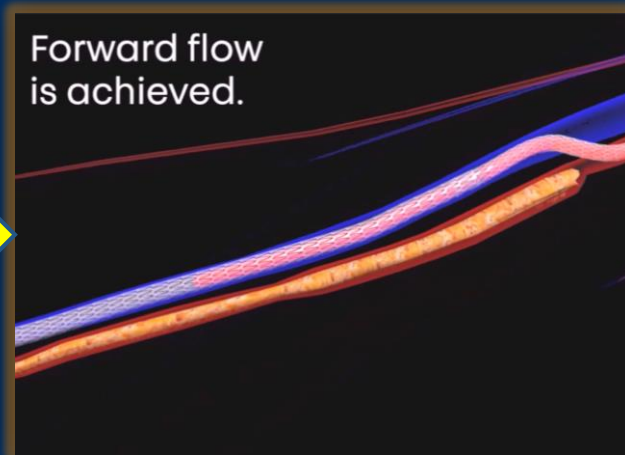
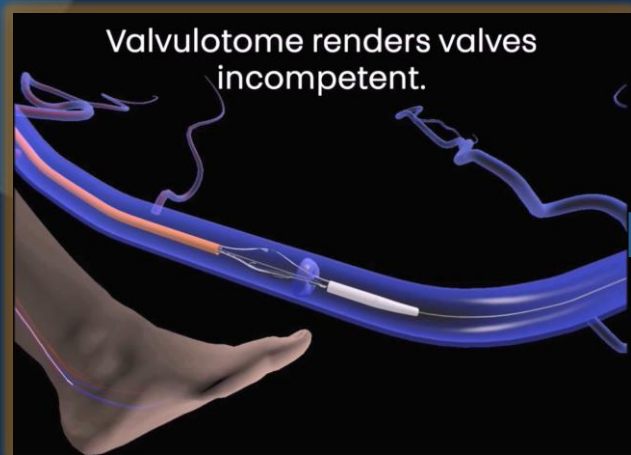
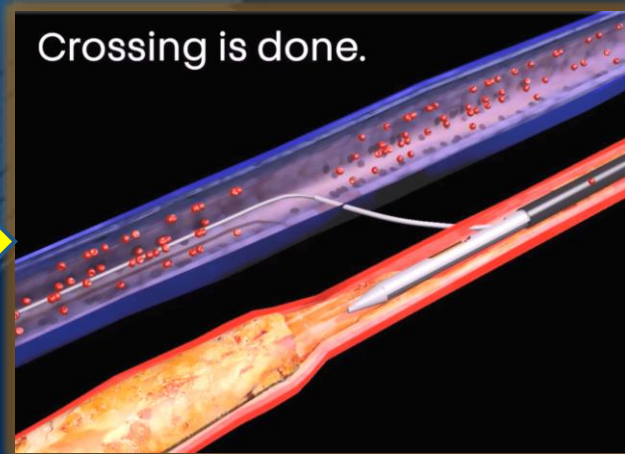
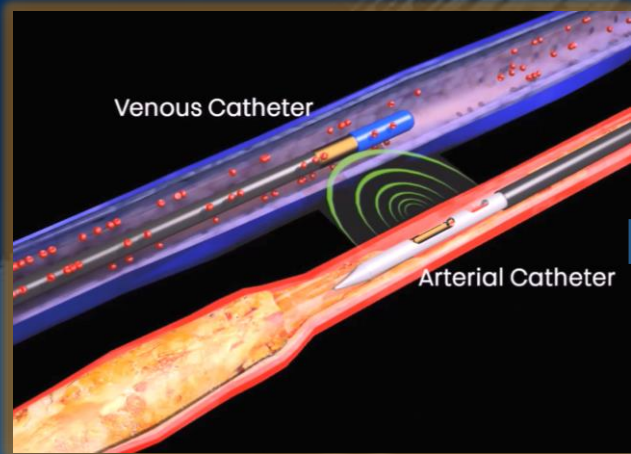
# LimFlow pDVA Procedure Case Example

65 years, male

- Renal failure with chronic dialysis
- Forefoot gangrene
- Several PTA-attempts
- Calcified foot-arteries

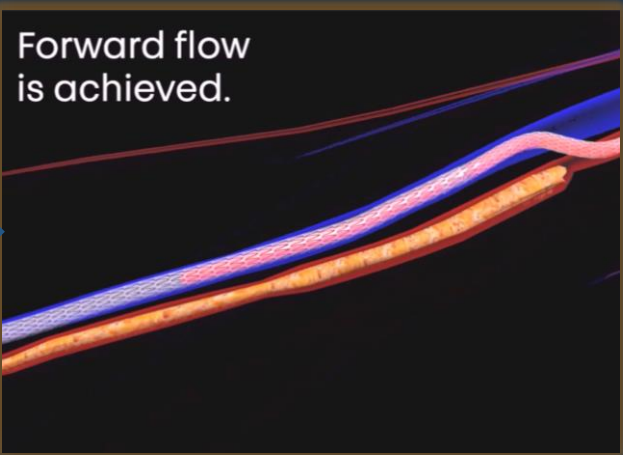
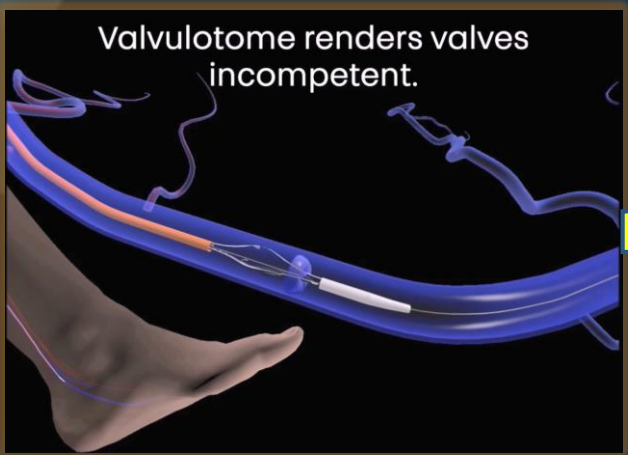
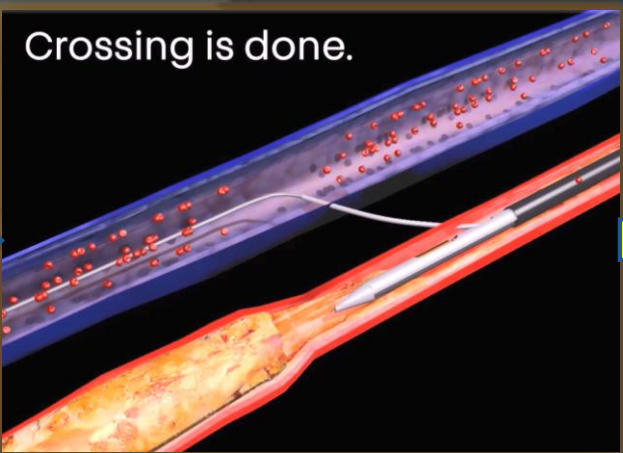
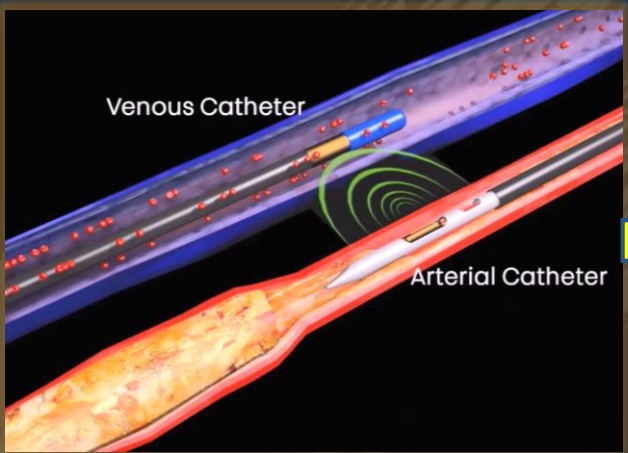


# LimFlow pDVA Procedure Overview





# LimFlow pDVA Procedure Overview



# The ALPS Multi Centre

## **Purpose**

- Retrospective evaluation of patients with no-option CLTI (NOP-CLTI) treated with the LimFlow procedure

## **Method**

- Multi-centre (Alkmaar, Leipzig, Paris and Singapore)
- Multi-disciplinary centres with integrated wound care
- Consecutive patients treated with LimFlow device
- Performed by a variety of operators (Angiologist, IR, VC)
- 11 July 2014 to 11 June 2018

# Study Design

## Endpoints

### Primary

- AFS @ 6 Months

### Secondary

- Wound Healing
  - Limb Salvage
  - Survival
- } @ 6, 12, 24 Months

## Inclusion/Exclusion Criteria

### Inclusion:

- Rutherford 5/6
- No-Option CLTI (NOP-CLTI)

### Exclusion:

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



# ALPS Patient Characteristics (n=32)



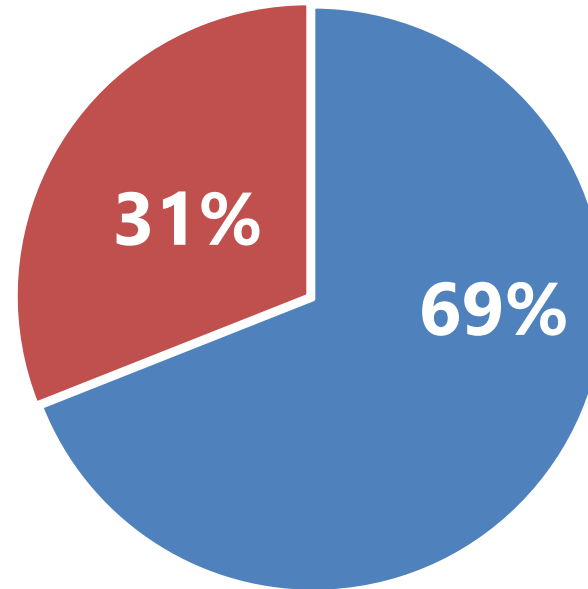
## Baseline Characteristics (n = 32)

Median Age (years)	67 ± 14
Gender (Men)	63%
SVS Wifi (High Risk)	78%

## Comorbidities

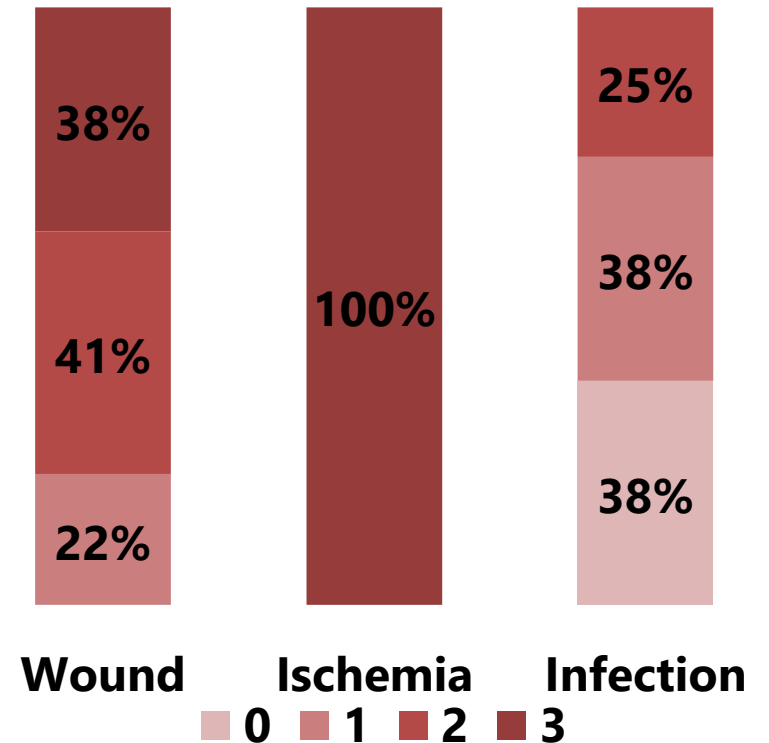
Diabetes (Type II)	66%
Renal Insufficiency	53%
Dialysis Dependent	16%
Immunosuppression	25%

## Rutherford Classification

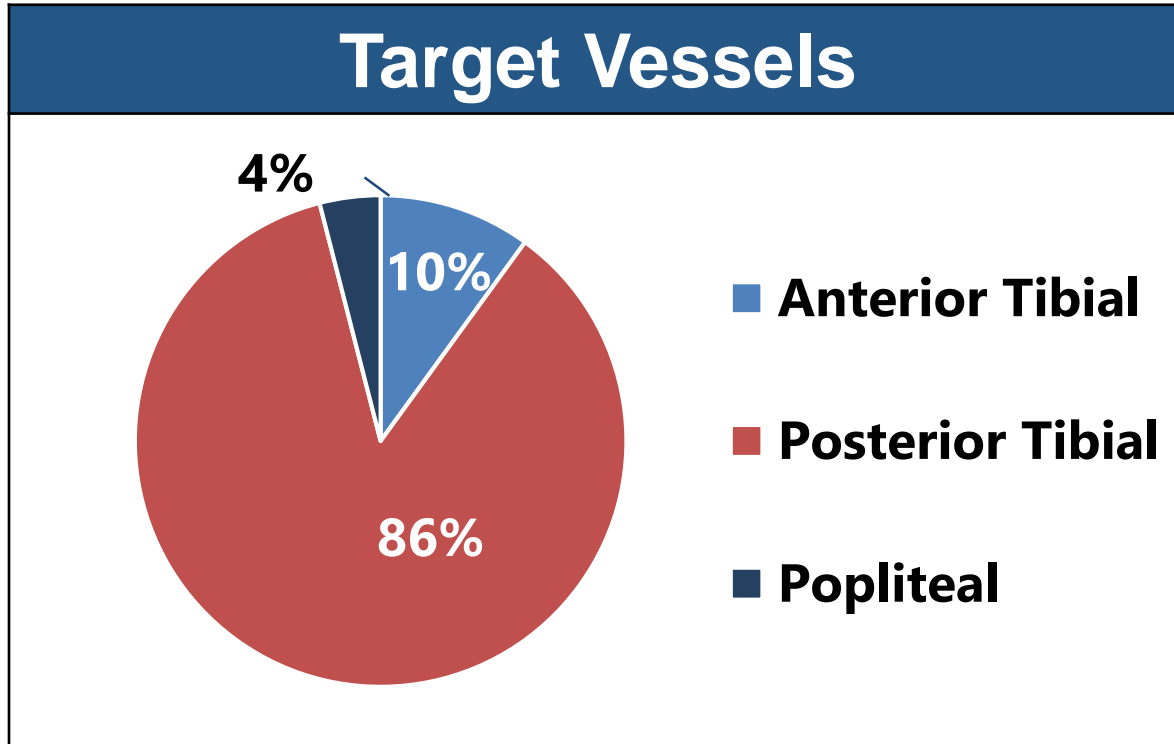


■ Class 5 ■ Class 6

## SVS Wifi Classification



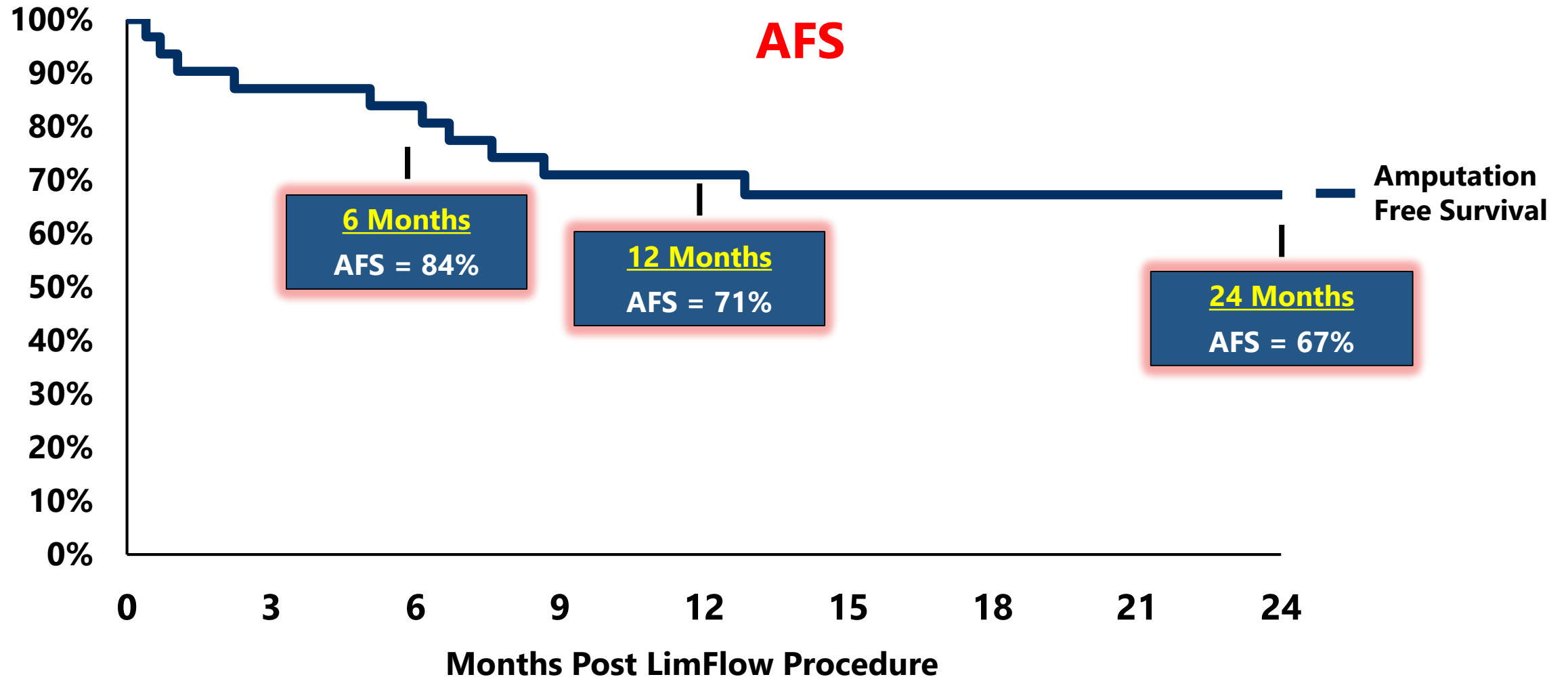
# ALPS Procedural Characteristics



### Procedural Characteristics

<b>Success Rate</b>	<b>97%</b>
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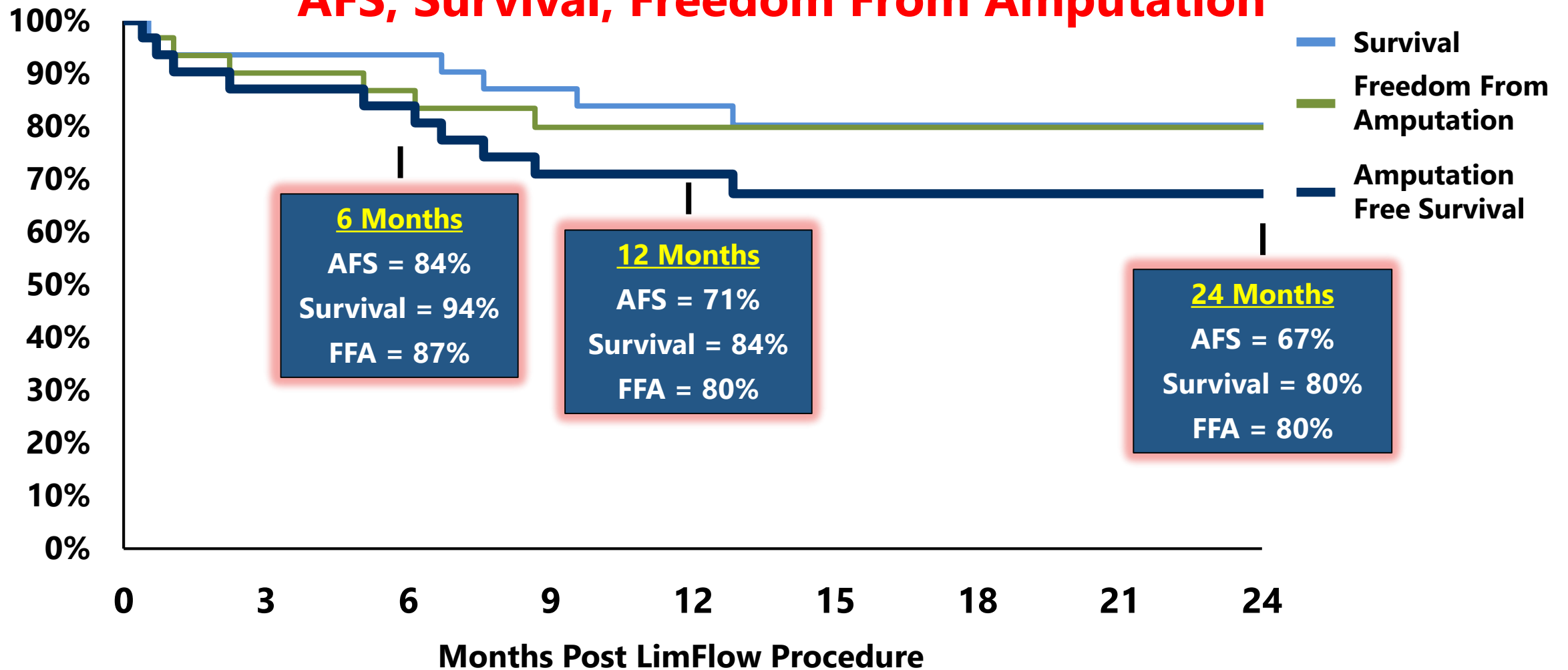
# ALPS Amputation Free Survival (n=31)



# ALPS AFS, Survival, Freedom From Amputation (n=31)



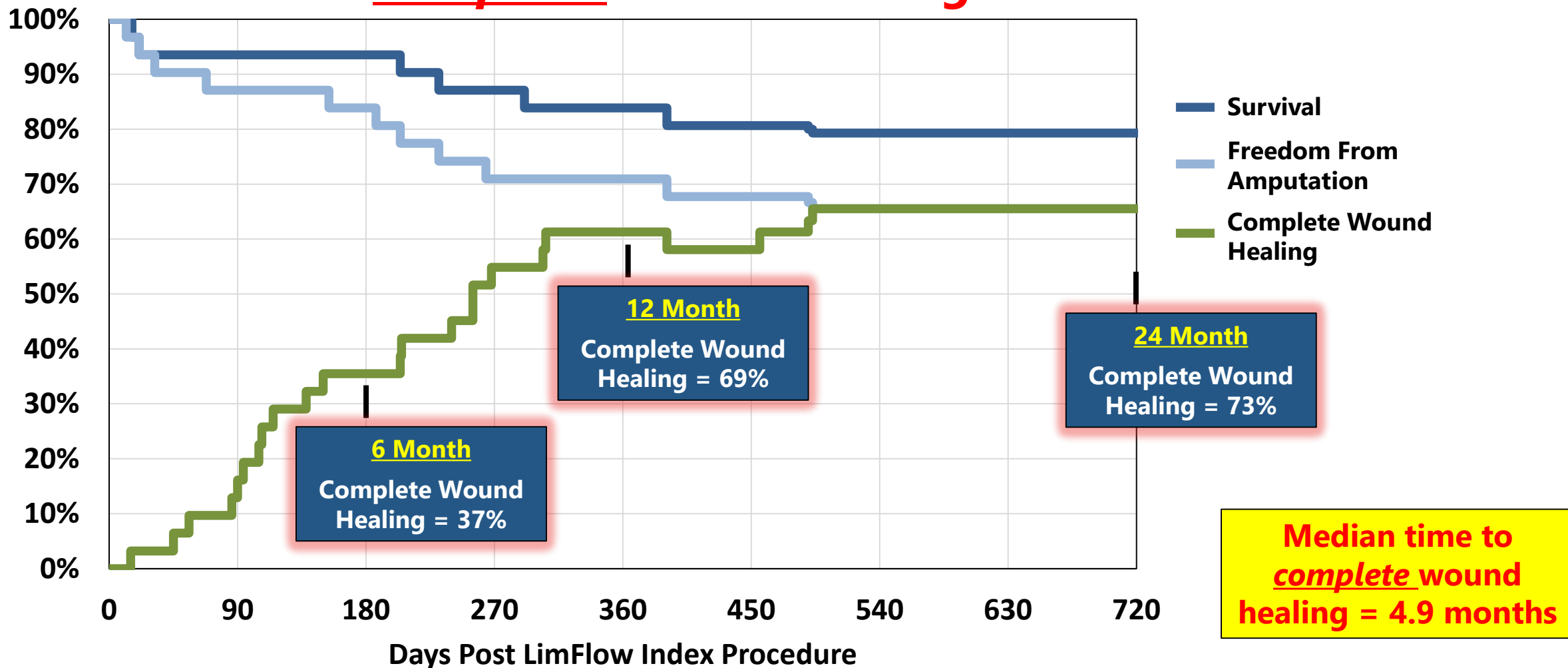
## AFS, Survival, Freedom From Amputation



# ALPS Complete Wound Healing



## Complete Wound Healing

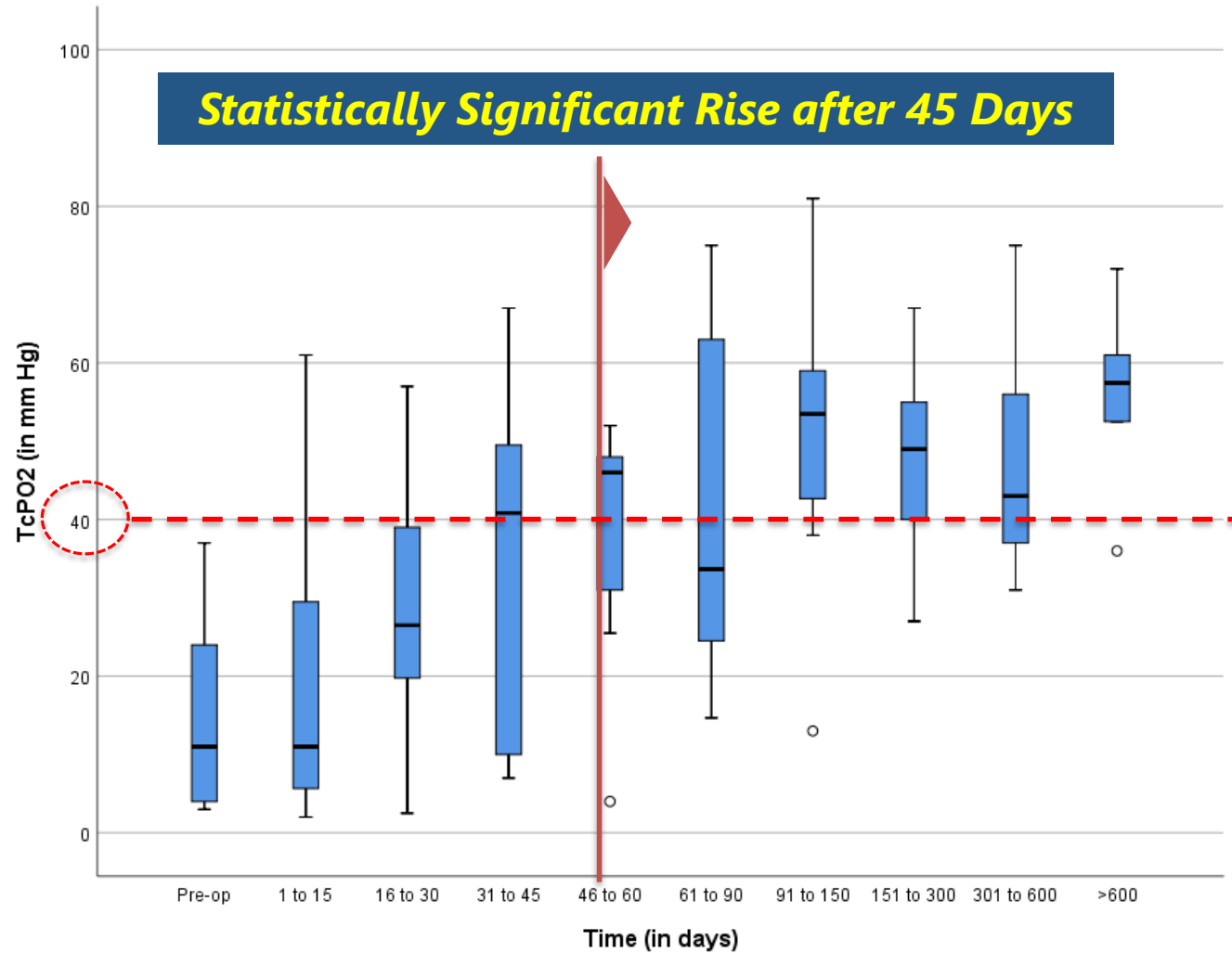




# ALPS Average TcPO<sub>2</sub> Results



142 TCPO2 measurements  
~ 10 measurements/patient



# Conclusion

- This is the ***largest study of NOP-CLTI patients treated with LimFlow*** showing mid and long-term results
- In this complex group of patients, ***high technical success and AFS rates up to 24 months*** are achieved
- Wound healing achieved in majority of patients previously destined for limb loss
- Perfusion indices (TCPO<sub>2</sub>) show significant increases.
- In selected patients with NOP-CLTI, pDVA, when performed in dedicated centres, could be a recommended treatment to prevent amputation and heal wounds

# Participating Centers / Authors

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