# Frontiers in Salvaging the Desert Foot: No Holds Barred

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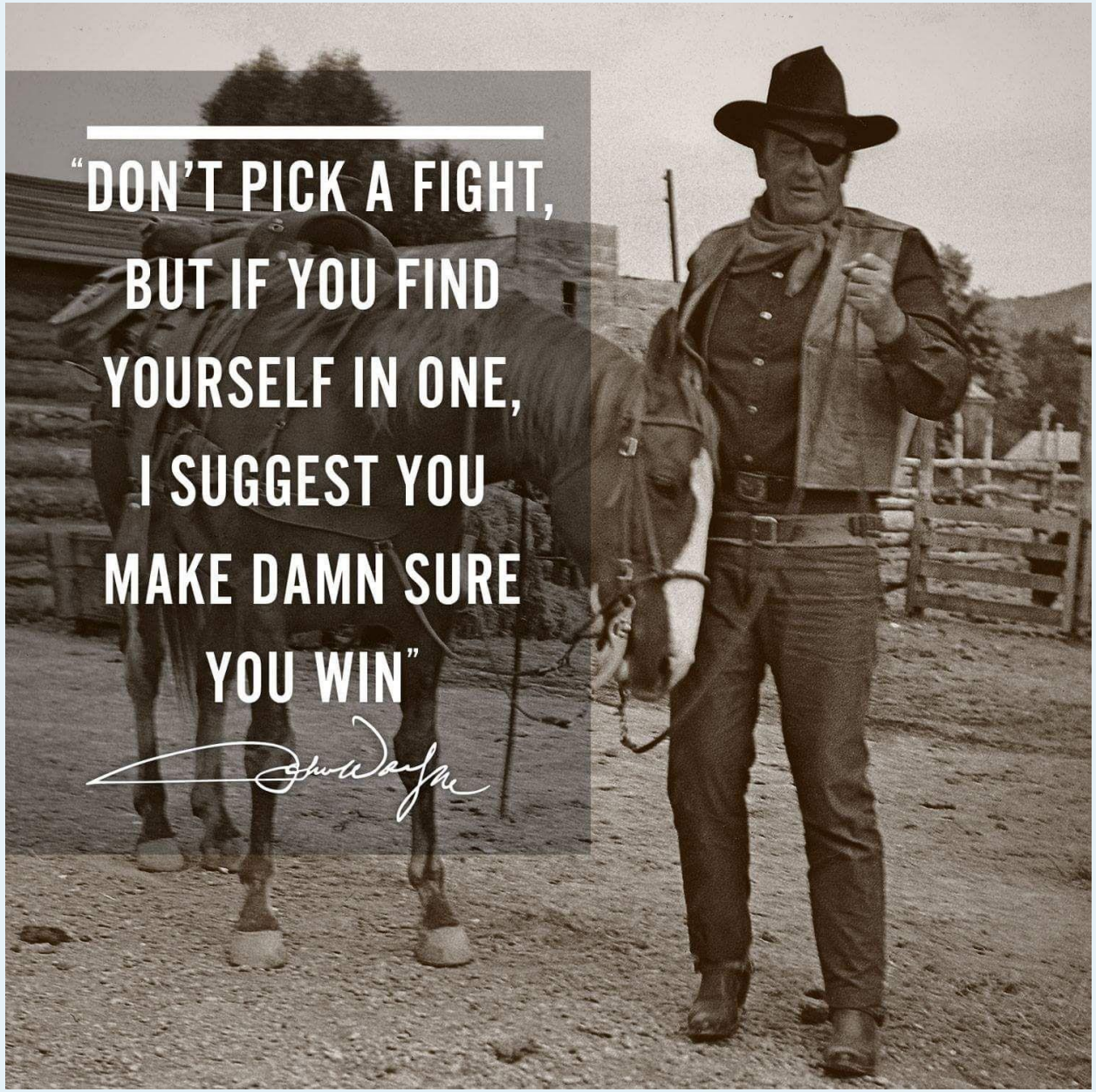
# Disclosure

- Inari – Investigator and Consultant
- Penumbra – Investigator
- Boston Scientific – Consultant
- Mercator – Investigator and Consultant
- WL Gore – Investigator
- BD – Consultant

# My Task

**CONVINCE YOU THAT:**

- New Technology has lead to improved vascular patency rates and lower amputation rates
- Limb Salvage is a Religion
- Fem-Pop, Chop Chop is NOT the right way to think



# My Opponent

**DR. SAMUEL STEERMAN**

- 

# Perspective

- Lower-extremity peripheral artery disease (PAD) 8 to 10 million adults in the US
- Its global prevalence increased by 24% from 2000 to 2010
- Among patients with diagnosed PAD, ≈11% are likely to develop critical limb ischemia
- A quarter of patients with CLI require limb amputations within a year of the diagnosis

# Where Do We Start?

## AMPUTATION RATES FELL

- 150,000 non traumatic Amputations/year in USA
- Amputation rates fell 40% from 2000-2009

## AMPUTATION RATES ROSE

- From 2009 to 2015 the Amputation rate INCREASED by 50%

**Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association**

Mark A. Creager, Kunihiro Matsushita, Shipra Arya, Joshua A. Beckman, Sue Duval, Philip P. Goodney, J. Antonio T. Gutierrez, John A. Kaufman, Karen E. Joynt Maddox, Amy W. Pollak, Aruna D. Pradhan, Laurie P. Whitsel and
On behalf of the American Heart Association Advocacy Coordinating Committee

**Originally published** 25 Mar 2021 | https://doi.org/10.1161/CIR.0000000000000967 | Circulation. 2021;143:e875–e891

# Steven

- 55 y/o AA male presents to his PCP with history of Diabetes.
- Has a warm R foot.
- Palpable distal pulses
- Small ulcer plantar second metatarsal head.
- Is sent home with follow up with podiatry
- Develops fevers to 103 and progressive pain and swelling in foot.
  - Never makes it to appt.


R
JLO

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# Why Couldn’t We Accomplish This?

# Why Do We Amputate?

## INDICATIONS

| Indication for Major Amputation | Percentage of Cases ( *n* = 131) |
|---|---|
| Critical limb ischemia with failed revascularization | 39 |
| Extensive pedal gangrene | 15 |
| Unreconstructable arterial anatomy | 11 |
| Overwhelming pedal sepsis | 9 |
| Excessive surgical risk | 9 |
| Nonviable, acutely ischemic foot | 8 |
| Nonambulatory status | 8 |

## CAN WE DO BETTER?

- 39 failed Revascularization
  - Do It Again
- 11 Unreconstructable
  - New Tech Options?
- 9 Excessive Surgical Risk
  - New Tech Options
- 59% of Amputations were done on ambulatory CHRONIC patients

# Debate

- Ther

Darwin's theory Have We

**Out on a limb? The truth about a career in vascular surgery**

*BMJ* 2006 ; 333 doi: https://doi.org/10.1136/bmj.333.7567.s93-a (Published 09 September 2006)
Cite this as: *BMJ* 2006;333:s93

There is an old joke describing vascular surgery. "Fem stop, fem pop, fem flop, fem chop." The suggestion that vascular surgeons merely delay inevitable amputations or only deal with diabetic foot ulcer debridement detracts from what an incredibly challenging and rewarding specialty vascular surgery can be.

- We r
- Our MISSION IS LIMB SALVAGE

# What Are the Surgical Options to Prevent Amputation?

## VASCULAR OPTIONS

- Open Bypass
- Traditional Angiography

30 Articles from 1990 to 2006
2,577 Patients
2,653 Limbs
2,693 Procedures

- Creative Operative Solutions
- Creative Endovascular Solutions

| | PTA | Bypass |
|---|---|---|
| **Primary 3 yrs** | **49%** | **72%** |
| Secondary 3 yrs | 63% | 77% |
| **Limb Salvage** | **82%** | **82%** |
| Pt Survival | 68% | --- |

Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

Marcello Romiti, MD,[a] Maximiano Albers, MD,[a] Francisco Cardoso Brochado-Neto, MD,[a] Anai Espinelli S. Durazzo, MD,[b] Carlos Alberto Bragança Pereira, PhD,[c] and Nelson De Luccia, MD,[b]
*Santos and São Paulo, Sao Paulo, Brazil*

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# Amputation Rate Per 10,000 Medicare Patients 2007-2009

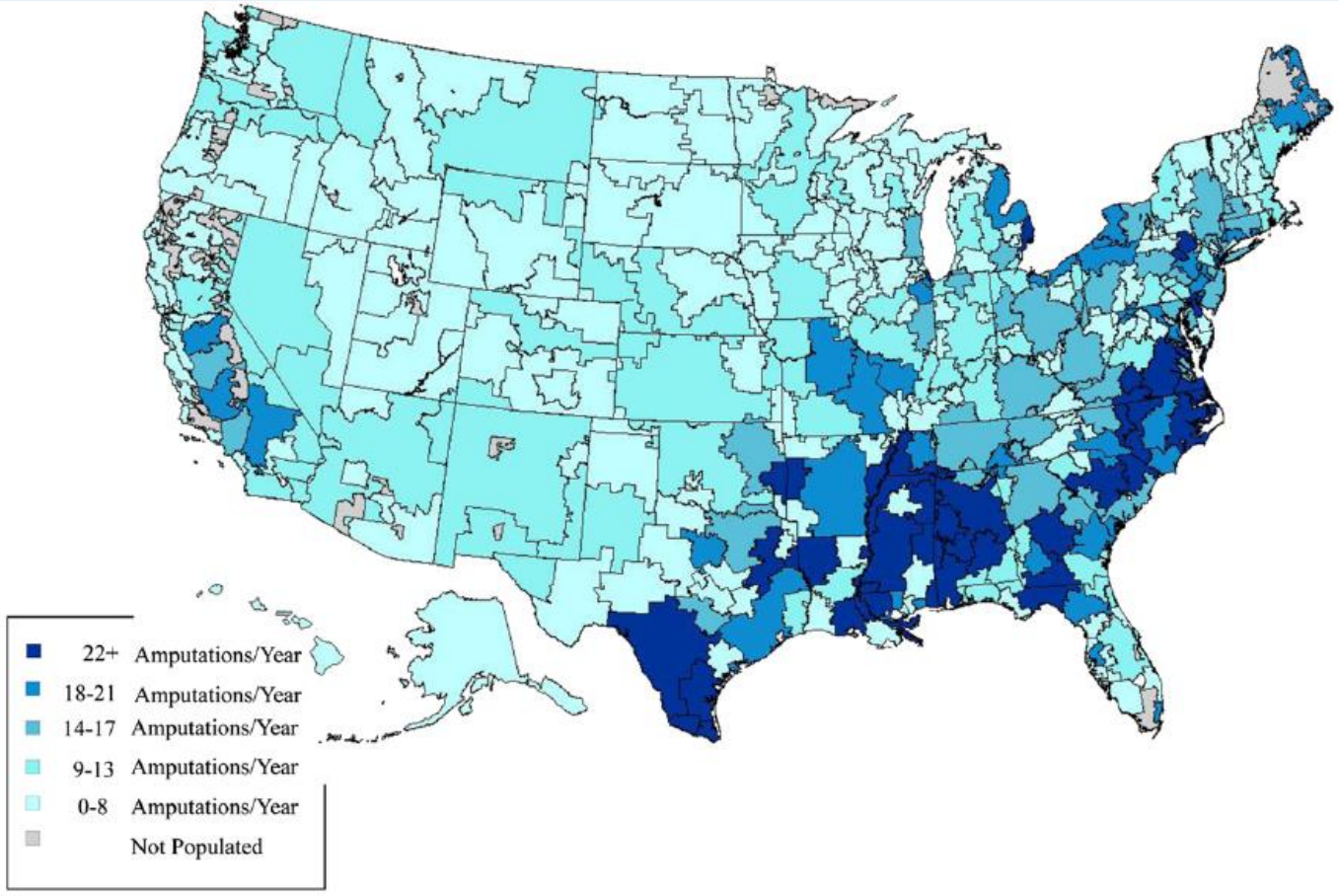
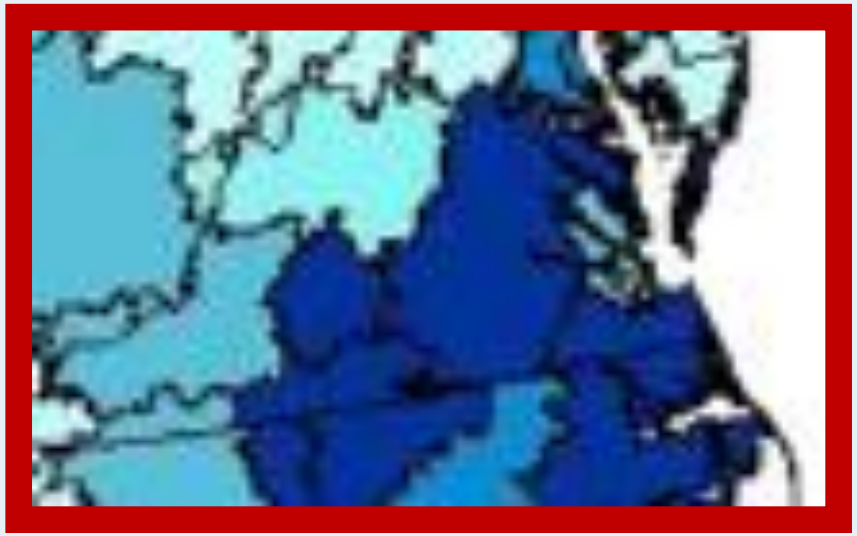
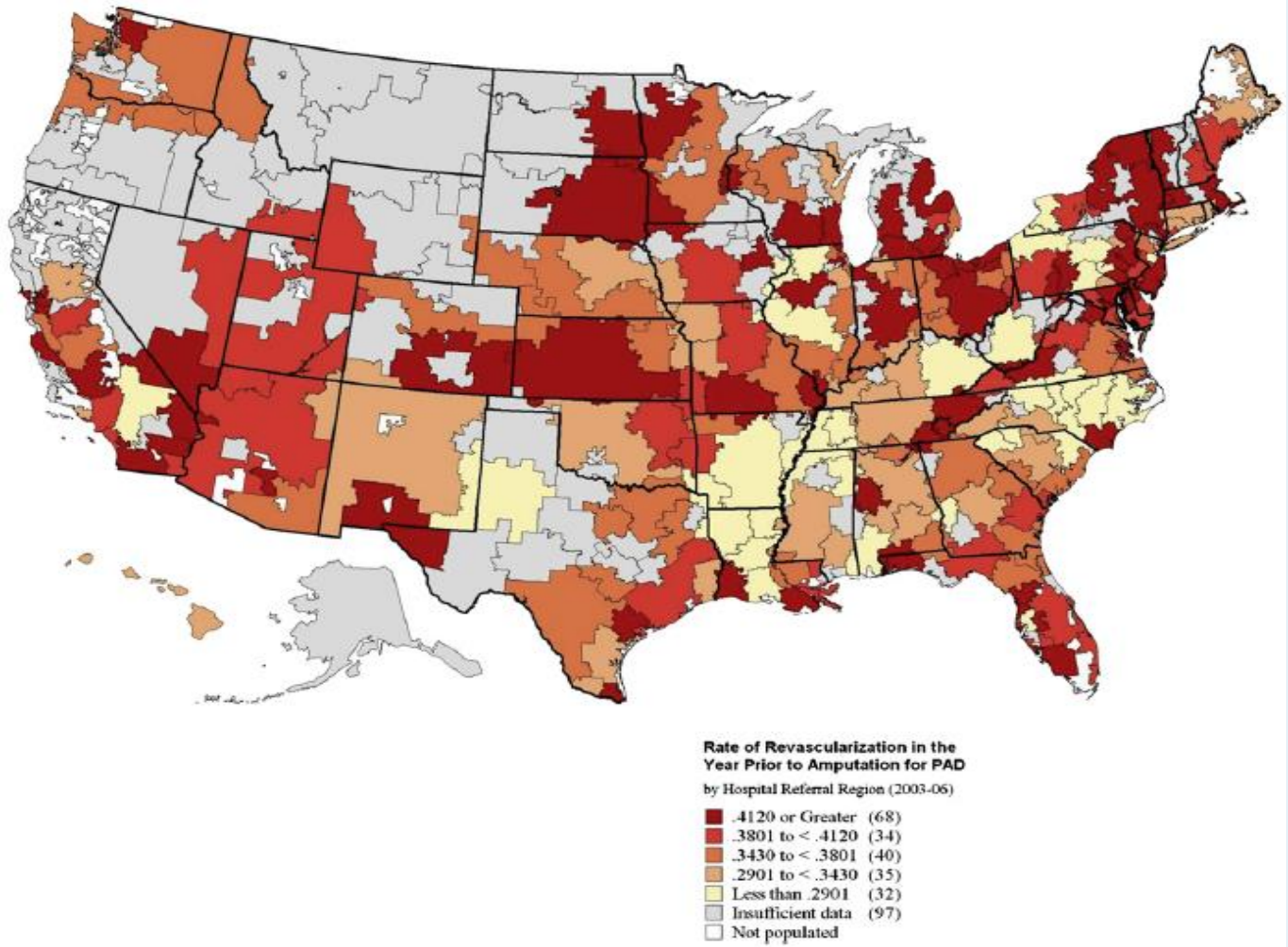


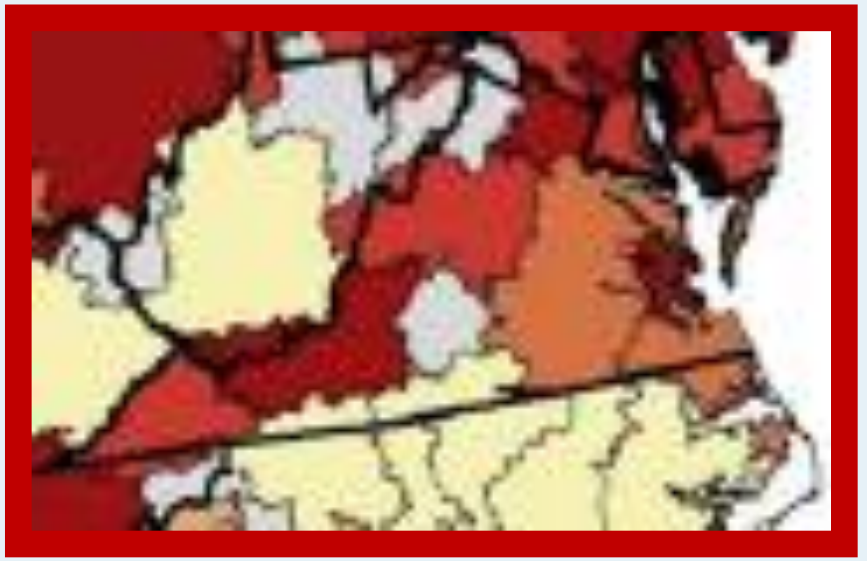

Fig 1. Population-based amputation rates for peripheral arterial disease (PAD) by hospital referral regions are shown on the map.

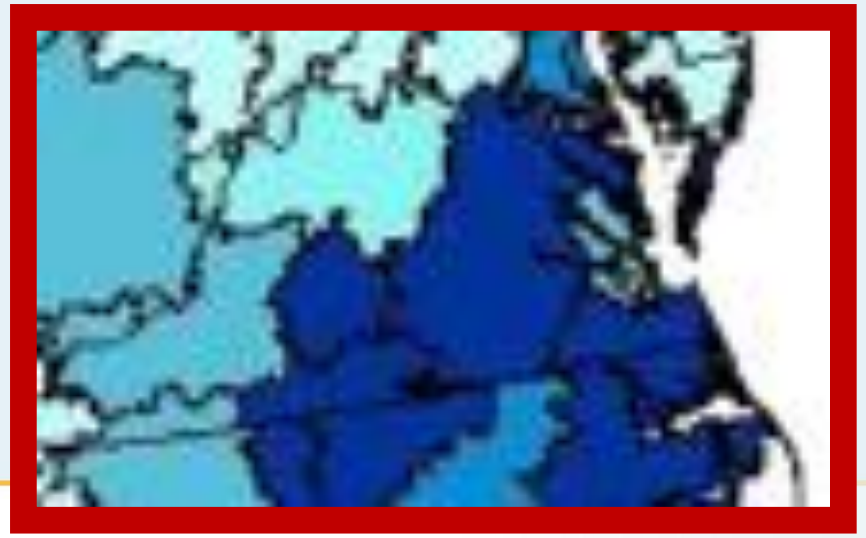


# Vascular Intensity 2003-2006 Open or Endo or Combined (Rate of revasc prior to amputation)

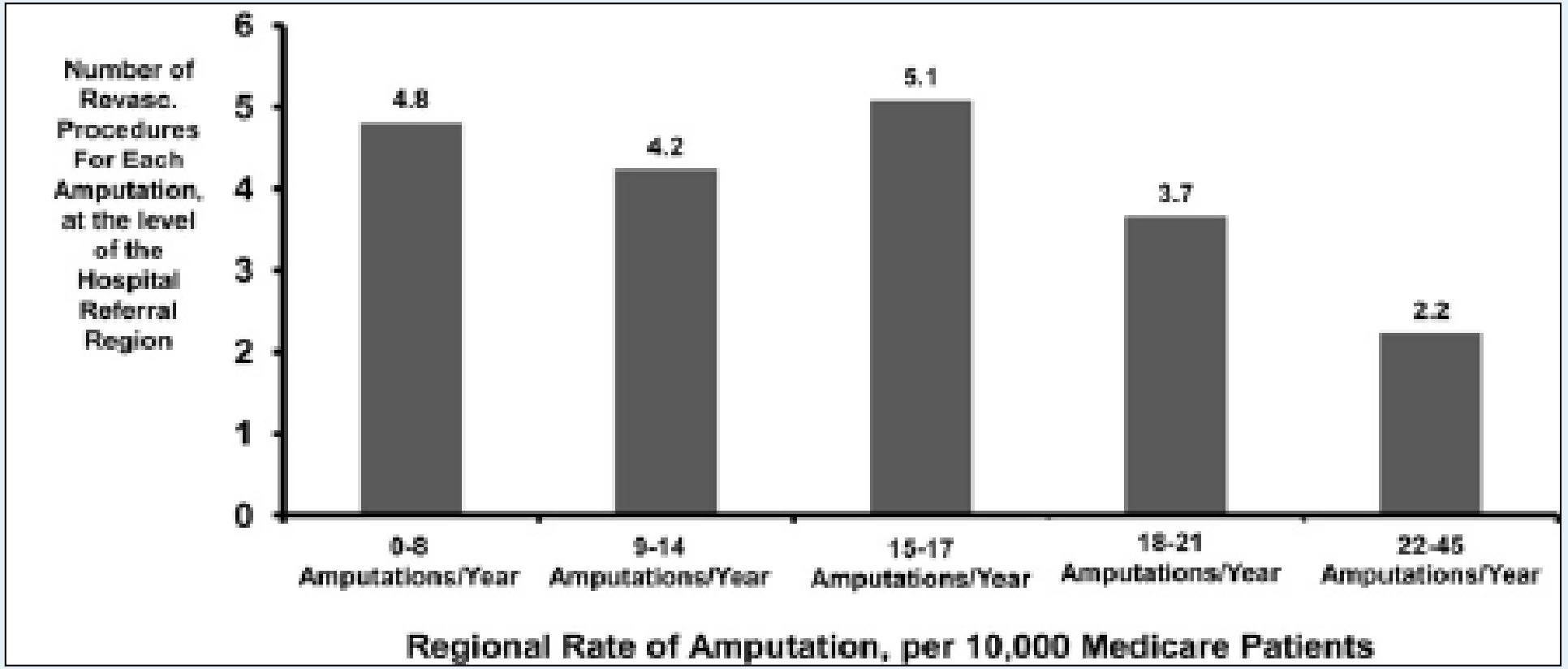



**Supplementary Fig (online only).** Variation in the intensity of vascular care, by hospital referral region, as measured by the proportion of patients in each region undergoing invasive vascular care in the year before amputation, 2003-2006. *PAD*, Peripheral arterial disease.



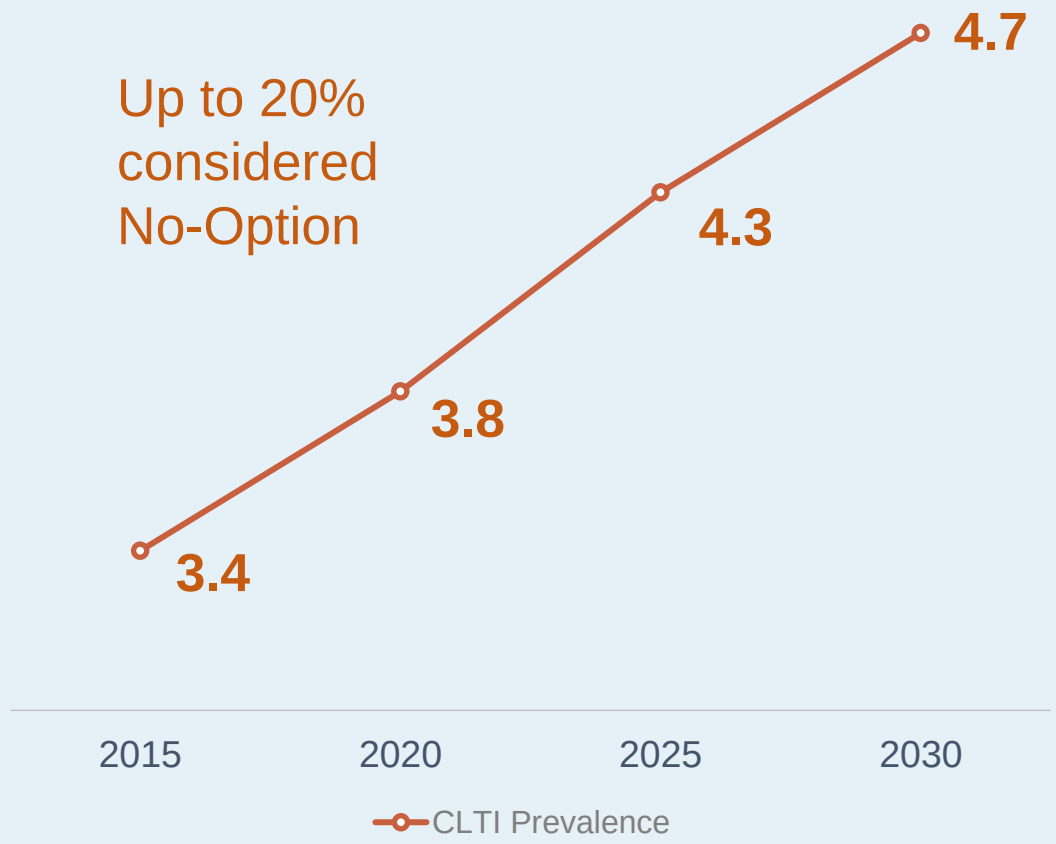


# More Revasc Procedures = Lower Amputation Rates



# US CLTI Prevalence 2015-2030[1]

*Millions*




**No-Option CLTI patients are eligible only for primary amputation or medical therapy**

**Published average No-Option Amputation Free Survival rate of 42% at 6 months[2]**

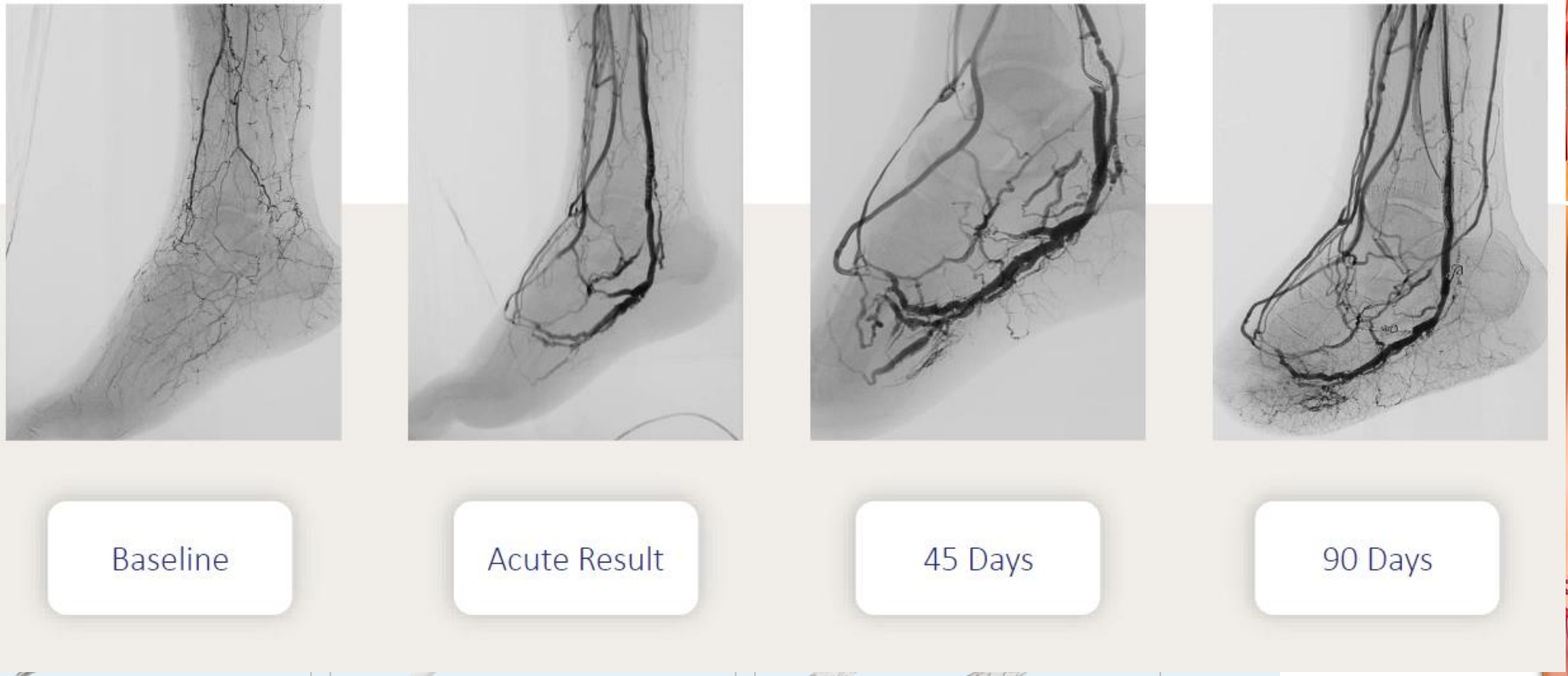
**The number of No Option Patients continues to grow with time**

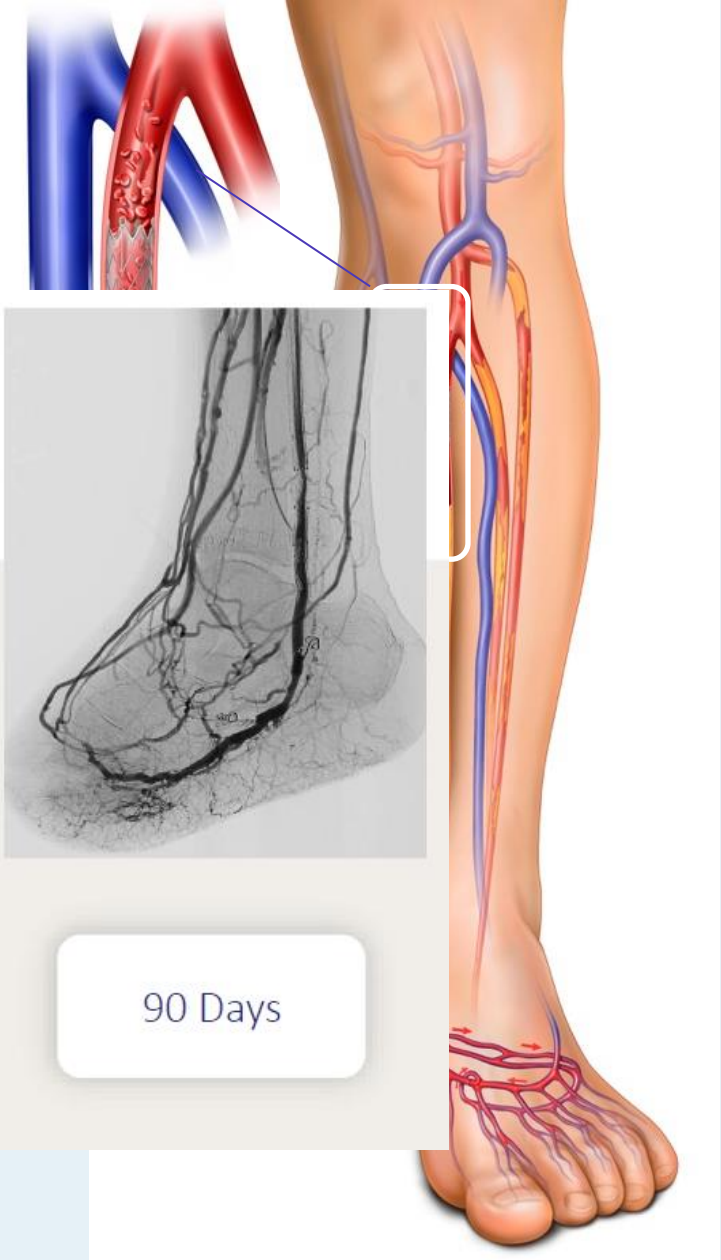
1. Yost ML. CLI US epidemiology supplement 2016. THE SAGE GROUP
2. Ghare 2021
3. Creager 2021

# LimFlow TADV System

Tra

- ►
- ►
- ►



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

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# PROMISE II

# US Pivotal Trial

**Multicenter, prospective pivotal study of the LimFlow System**

**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

**PRIMARY ENDPOINT**
*Bayesian*

**Amputation Free Survival (AFS) at 6M**

*Pre-specified literature-based PG of 54%*

**SECONDARY ENDPOINT**

**Technical Success**

**Wound Healing**

**Rutherford Class**

**Pain**

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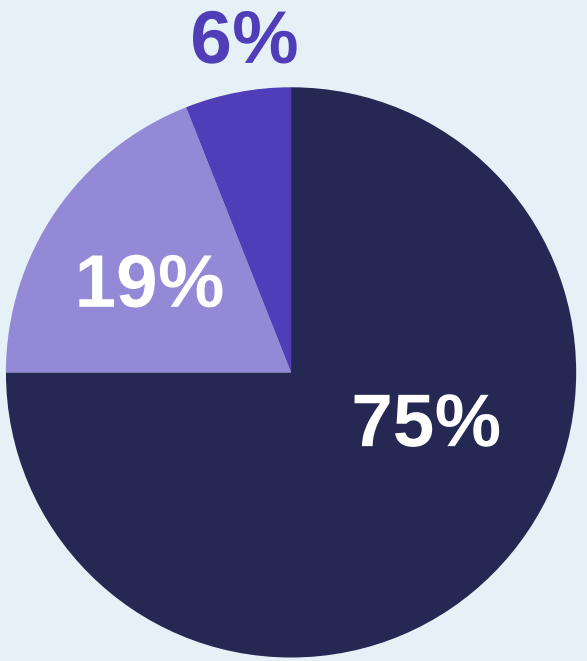
# Patient Demographics

| BASELINE CHARACTERISTICS *(n=105)* | |
|---|---|
| Age (Avg, years) | **69** *(38-89)* |
| Gender (% Male) | **69**% |
| African American | **15**% |
| Hispanic or Latino | **28**% |
| **COMORBIDITIES** | |
| Diabetes | **77%** |
| Hypertension | **91%** |
| Dialysis | **18%** |
| CKD | **39%** |
| Rutherford 5 | **65%** |
| Rutherford 6 | **35%** |

**Crossing Artery**

- PTA
- Peroneal
- TPT



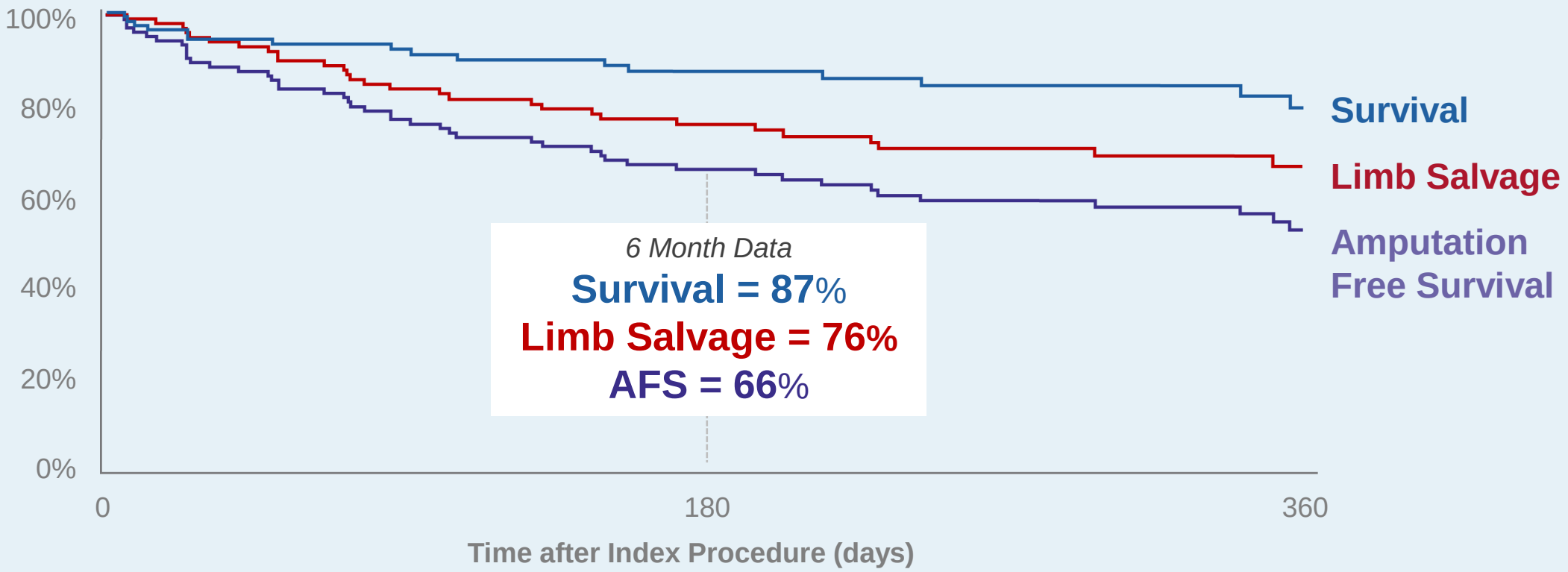

**PROCEDURAL RESULTS**

*Technical Success* **99%**

Data on file LimFlow

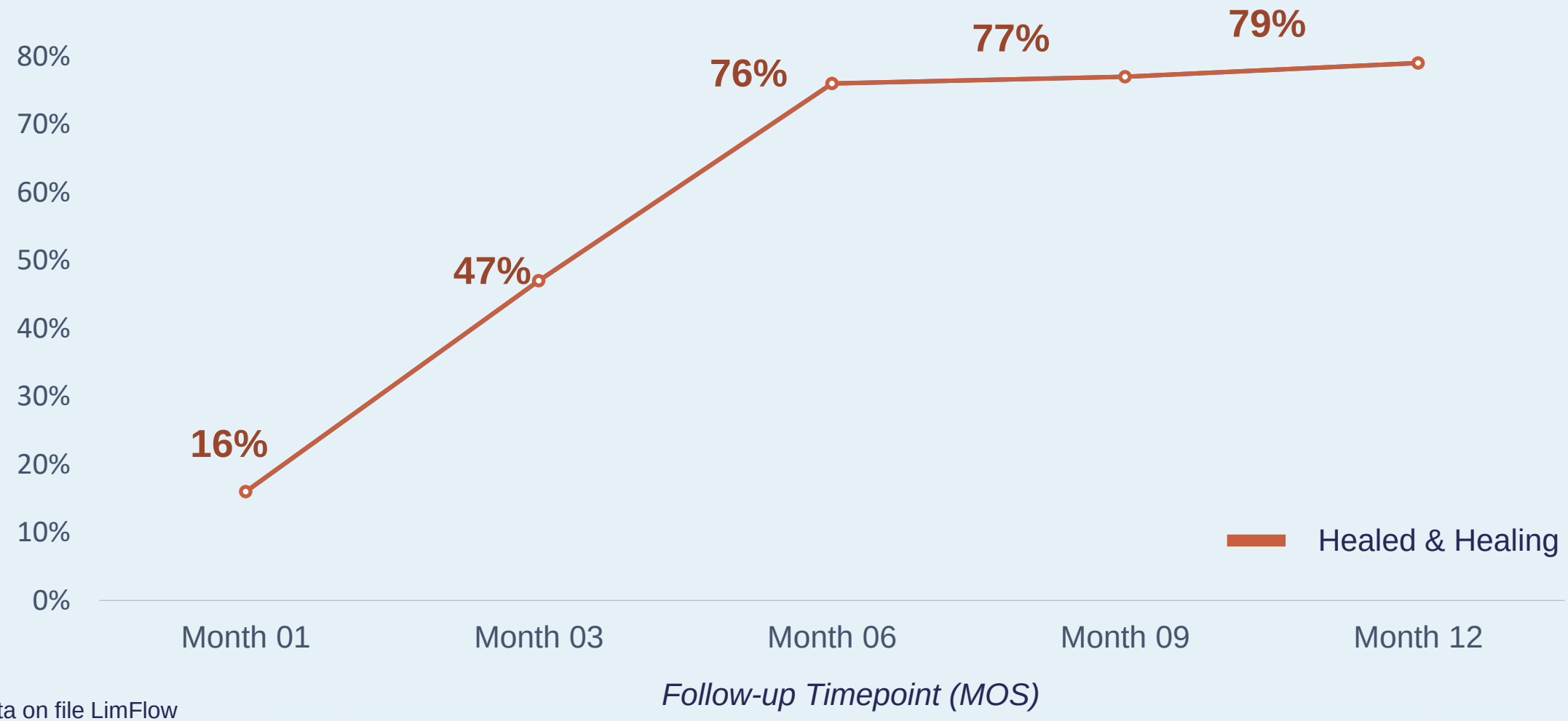
# Primary Endpoint

## 6 Month AFS, Limb Salvage, Survival



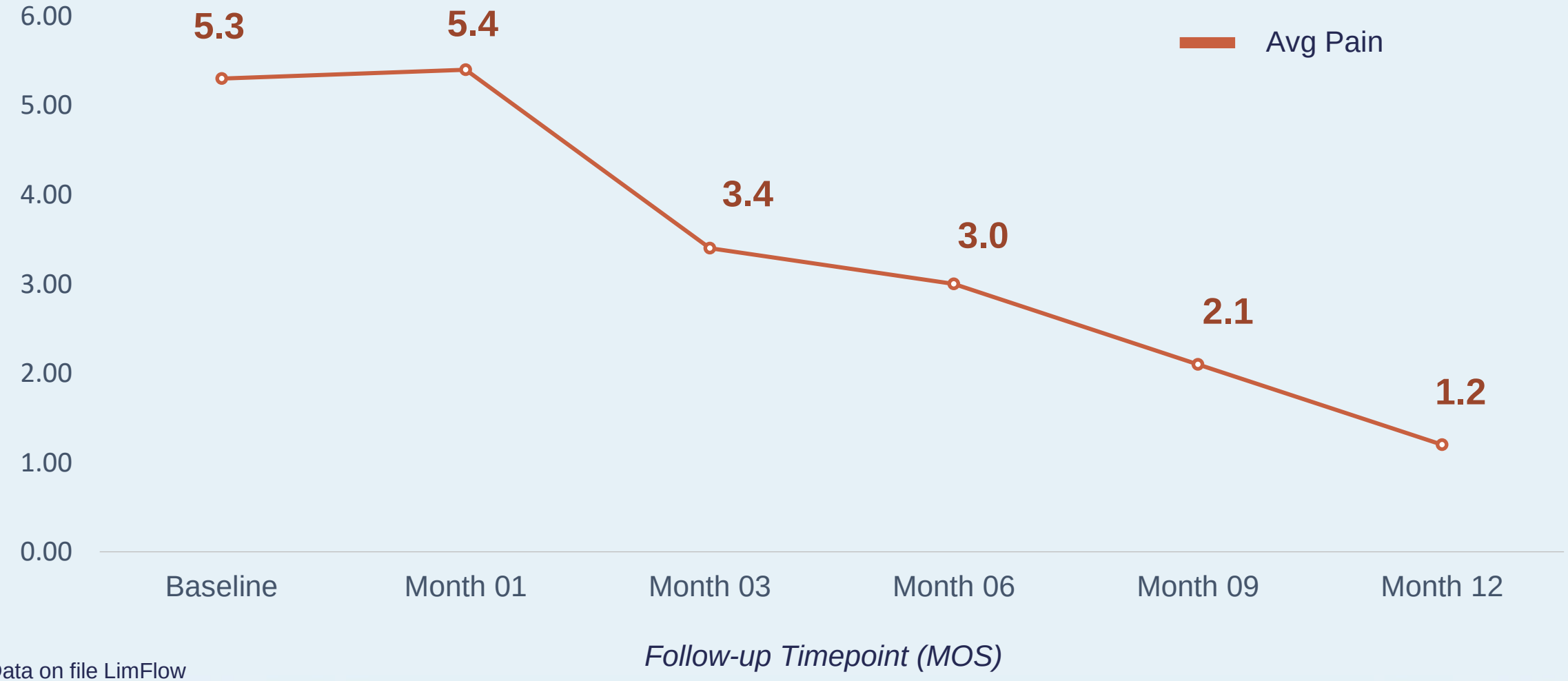

Data on file LimFlow

# Wound Core Lab Results–Healing Status




Data on file LimFlow

# Pain (0-10 Pain Scale)

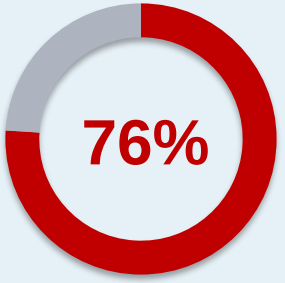



Data on file LimFlow

# Conclusions

- The PROMISE II study met its primary endpoint
- TADV with LimFlow is safe and effective
- Results in-line with PROMISE I outcomes
- “No-Option” needs a new name

76% limb salvage achievable with LimFlow in No-Option patients




99% technical success rate with purpose-built system


**Why Would I Offer Primary Amputation to These Patients In The Future?**

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# Fake News

- Dr. Steerman will t
  convince you that a
  also evolve.
- Early amputation w
  earlier mobility and
  baseline life


# How do PAD patients do after MINOR amputation?

# What do I propose?

# Let People with SEVERE DISEASE Die with their Legs ON

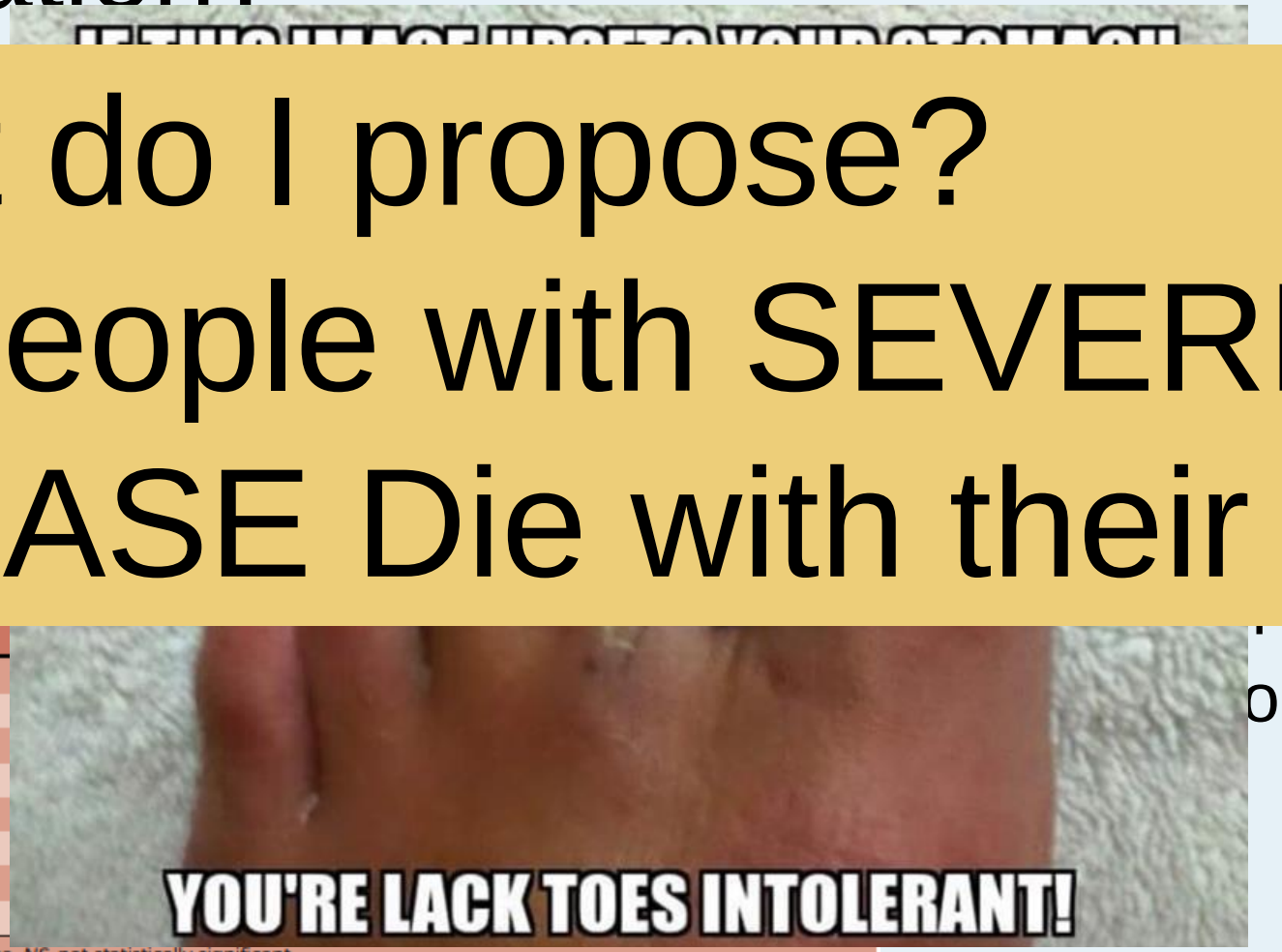


**Table II.**

| | |
|---|---|
| No. of patients | |
| No subsequent amputation | |
| Major amputation rate | |
| Median time to major amputation, months | |
| Minor amputation rate | |
| Median time to minor amputation, months | |
| Mortality | |
| Median time to death, months | |

*DM*, Diabetes mellitus; *PAD*, peripheral artery disease; *NS*, not statistically significant.
Median time to amputation and mortality data by disease group. Values are number (%) or median (interquartile range).

ortality

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Rates and timing of subsequent amputation after initial minor amputation

Jonathan H. Lin, MD,[a] Sun Young Jeon, PhD,[b] Patrick S. Romano, MD,[b] *and* Misty D. Humphries, MD, MAS,[a]
*Sacramento, Calif*

# Amputees DO NOT Return to Normal

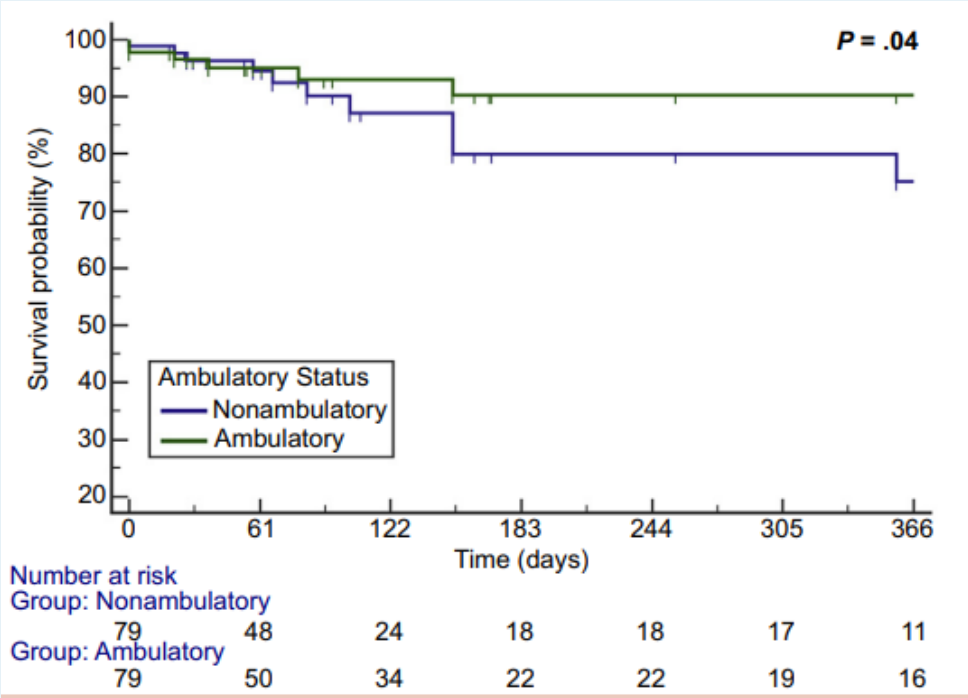
## AKA PATIENTS ARE 4X MORE LIKELY TO BE NON AMBULATORY

**Table IV.** Univariate and multivariable regression analysis of variable effect on a

| Variable | Univariate | |
|---|---|---|
| | Unadjusted OR (95% CI) | *P* value |
| BMI | 0.42 (0.29-0.60) | <.0001 |
| mFI | 0.24 (0.18-0.33) | <.0001 |
| Hemoglobin | 1.36 (1.02-1.91) | .037 |
| Male | 0.65 (0.34-1.22) | .18 |
| Chronic alcoholism | 0.11 (0.01-0.87) | .036 |
| Preoperative functional status | | |
| Partially independent | 2.62 (0.99-6.92) | .052 |
| Dependent | 0.02 (0.00-0.08) | <.001 |
| Family support | 9.03 (4.60-17.74) | <.001 |
| Current marriage | 8.86 (4.48-17.51) | <.001 |
| AKA | 0.24 (0.08-0.66) | .003 |

*AKA*, Above-knee amputation; *BMI*, body mass index; *CI*, confidence interval; *mFI*, modified frailty

## NON AMBULATORY STATUS PATIENTS DO NOT SURVIVE

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Ambulation and functional outcome after major lower extremity amputation

Atish Chopra, MB BCh BAO, Amir F. Azarbal, MD, Enjae Jung, MD, Cherrie Z. Abraham, MD, Timothy K. Liem, MD, Gregory J. Landry, MD, Gregory L. Moneta, MD, *and* Erica L. Mitchell, MD, *Portland, Ore*

# Beyond Just The Cost of Amputation

Amputations carry significant cost outside of the actual surgery
Readmission rates within 30 days are 20%
    Of these, Half are due to wound complications
After amputation, patients average 71 days/year in the hospital over 3 years
Post amputation patients have an average of 3 hospitalizations over a 32 month period

# Amputations are Costly and Unnecessary

# My First Norfolk CTLI Case

- 82 year old DM with large wounds to the Heel and Forefoot
- Has failed 2 percutaneous interventions.
- Recommended for Primary Amputation by the Vascular Fellow

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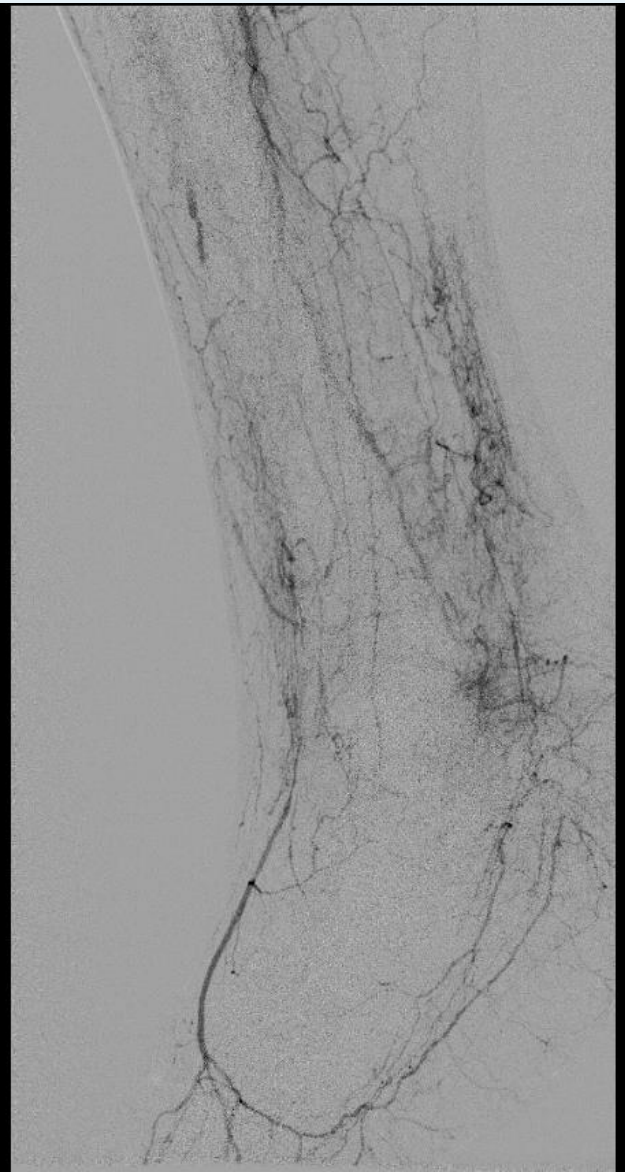

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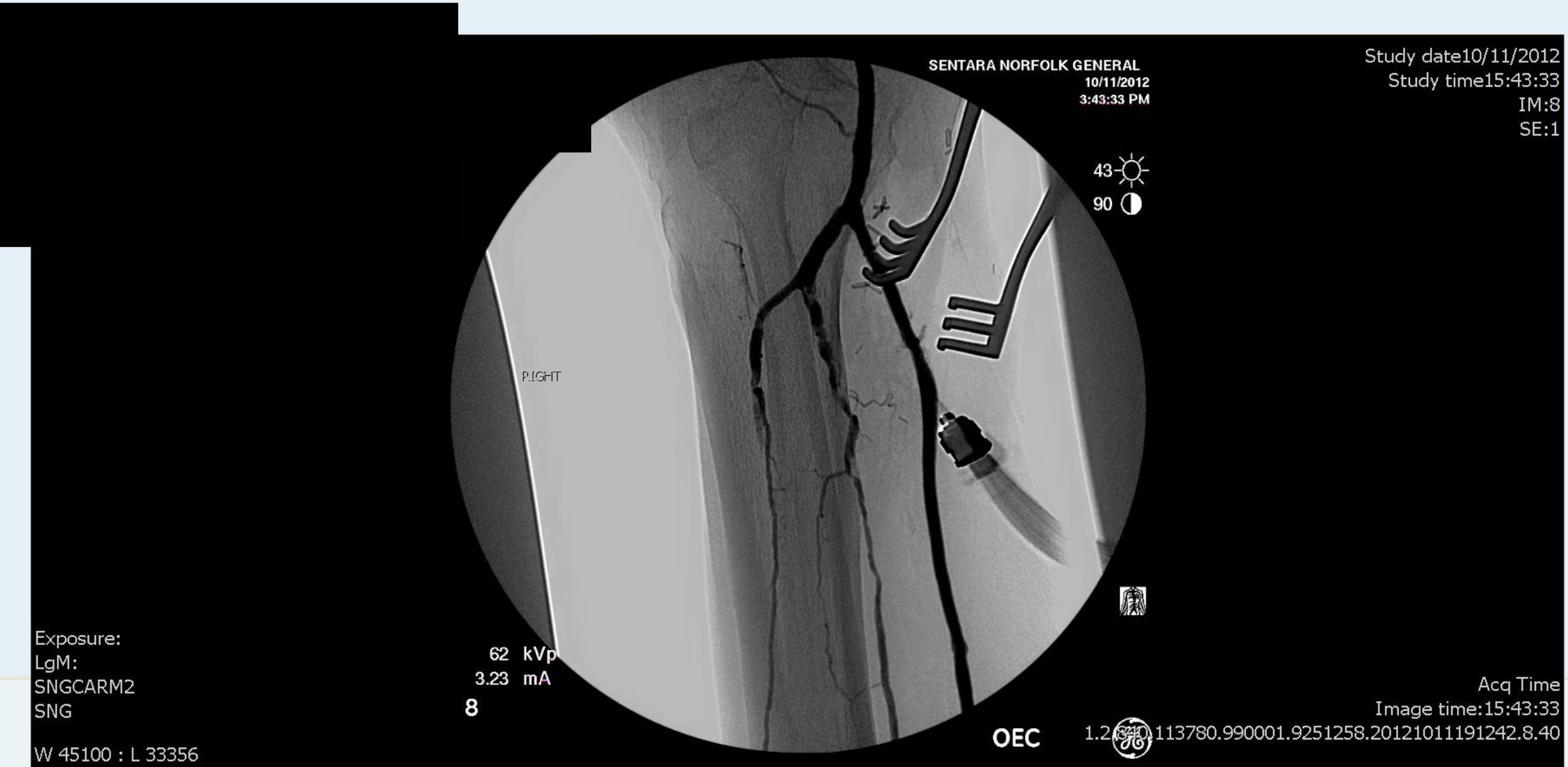
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# Outcome?

- Wounds Healed
- Patient Survived 6 more years

# Remember As You Vote?